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OFFICIAL TRANSCRIPT OF PROCEEDINGS U.S. NUCLEAR REGULATORY COMMISSION

PUBLIC MEETING RE: CHANGES TO RADIATION PROTECTION GUIDELINES

NOVEMBER 4, 2010 LOS ANGELES, CALIFORNIA

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18	Hodgkins, Community Health Network, Vice President,
19	Community Benefit and Economic Redevelopment,
20	facilitating.
21	
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24	Intergovernmental Liaison and Rulemaking
25	

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9	Energy Institute
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11	Angeles Medical Center
12	RICHARD BURKLIN, M.S., health Physicist, EHS&L
13	AREVA
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PROCEEDINGS

Time: 8:30 a.m.

HEARING OFFICER HODGKINS: Good morning, everybody. On the agenda, the first thing that it says is an overview of Day 1, and so as an overview for Day 1, as Don has said several times and probably will say again today, if there is anymore issues, concerns, bring them up. So as far as overview of Day 1, are there any things you thought about as your head hit the pillow that you would like to share?

Well, let me clarify that. As far as activities yesterday content, is there any things you guys were thinking about that you would like to bring up today, and how about we start with Ralph. Anything you want to bring up, discussion? George? Kai is not here. Leonard? Yes, Rob?

MR. GREGER: Robert Greger, State of California. I had given a little more thought last night to the constraint issue that I brought up at the end of the day as an alternate proposal instead of adopting 2 Rem.

I had some additional thoughts, but I guess I would like to hear Lynne's comments, because she had indicated she had some strong feelings on the subject, and maybe can correct my thinking, if I have

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erred some way.

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MS. FAIROBENT: Constraints are Issue 4. So I will bring it up when we get to Issue 4.

MR. GREGER: Okay. That is fine. We can discuss it then.

HEARING OFFICER HODGKINS: Good. Hey, Rob, looking at you because I kind of made fun of asking a question and answering a question, and then also you put on different hats, and you said who you were going to be when you were answering that question.

I do want to say that we are transcribing everything, and to the degree of what hat you are will wearing or your point of view, that So I just want everybody to be aware of transcribed. that, so as you start talking about your issues, and if there is some designation or something that you want to clarify or whatever, I think a couple of people did at the end of the day, because it is going to be transcribed, feel free to do that; or if you want to take off that hat and put on another hat, say It is going to be transcribed that way. So I think, in that sense, it is good.

The other thing is the whole nodding thing and the body language. Seriously, you know, again

can't transcribe that. So probably work a little 2 harder today to verbalize the head nods and the body language. Rob? MR. GREGER: Robert Greger, Conference of Radiation Control Program Directors. The reason I do say this is because the 6 Conference of Radiation Control Program Directors has not taken a position at all, and I would like to make 8 sure that everybody understands that, if I slip up, if 9 I am proposing something that sounds like any kind of 10 11 a position, it is coming from the State of -- my State of California position, not from the Conference 12 position, because the Conference has an open mind. 13 14 are waiting. We will then poll all of our states or as 15 many of our states as are willing to respond to our 16 request before we develop a position. 17 HEARING OFFICER HODGKINS: 18 Okay, 19 good. Chuck? MR. PICKERING: Just that someone has left 20 21 a notepad here, if they are eager to take notes. It is 22 here. HEARING OFFICER HODGKINS: Anybody left 23 24 their notepad? Nobody is going to claim it right yet. 25 Thank you.

Is the Leadership Workshop going to be here again next-door? Do we know? Is it? Okay. So there might be some times where you are going to need to speak up and into your microphone, because that did drown out yesterday. Nothing more? Melissa? Lynne? Donald? Scott? Yes?

MR. SEGALL: Could someone from NRC staff perhaps tell us what the web link is for the transcripts of the D.C. meeting and if it is the same for this meeting, and when they will be available?

HEARING OFFICER HODGKINS: Yes. Don?

MR. COOL: Okay. I don't actually have the specific web address yet. What the staff does, when it finishes each one of these meetings, is prepare a package in our document management system that has a number of documents. It will have a very brief one-page summary saying we met, here are the people that were there, some general themes, but none of the details, not even to the detail of the summary that we have been doing each piece.

All of that is put into our document management system and made public. When the transcript becomes available from the transcription group, that is also made available through the document management system, and at that point I will

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have an actual accession number. So I don't have it yet.

What we will do, I think we can try to make sure that there is a note of that put on the web pages that are all in the Federal Register Notice already, so that you can see where those links are and follow them.

MR. SEGALL: As a convenience would it be possible to just email that link to us when it is available, when the documents are available?

MR. COOL: Sure. I think we can do that.

MR. SEGALL: Thank you.

HEARING OFFICER HODGKINS: Okay, excellent. So now we move into the audience. This is the audience participation part. Anybody want to add or comment on any of the activities from yesterday to clarify, once your head hit the pillow and you thought, oh, great idea, clarification? Anybody? Yes, Donald?

MR. MILLER: Donald Miller, American College of Radiology. I just need to clarify one thing. Yesterday I said that, if you use the overapron badge at the collar as the direct reading from that to estimate effective dose, you would overestimate by 69 times, if you were not using a

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thyroid shield, and by 130 times if you were using a thyroid shield.

Those numbers are correct, but the reference was wrong. It is from a paper by Siskin and published in the British Journal of Radiology in 2007. I apologize.

HEARING OFFICER HODGKINS: Thank you.

Okay. So I think we are ready to go on to

Day 2, and I will turn it over to Don.

MR. COOL: All right. Good morning. I want to add my reminder that this is being transcribed. The transcription will be publicly available. So what you say is going to be available for people to see.

I had someone ask whether that meant it was all going to show up in a Federal Register Notice, were they going to print it all out. No, that is not the case, but I do remind you that it is publicly available and, as an agent of a U.S. Federal regulatory agency, if we actually cross to a point that we really have talked about an allegation, I will have to allow the transcript to be reviewed by our Enforcement folks.

So I do not want to in any way stifle these conversations, but let's be a little b it

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careful of what we describe and talk about, if we can, so that we don't enter into that area. If there are specific issues that you want to raise, of course, please come and talk to us individually, and we will make sure that that gets into the proper channels.

The first thing we are going to be talking about this morning is doses to special populations, and we are actually going to do this in two steps.

I have rearranged the slides just slightly so that we will go through and do the discussion related to protection of the embryo fetus first and complete that discussion and the discussion in the group, and then we will go on to some of the other issues, so that we don't do some jumping back and forth.

I think you will be able to follow pretty easily. It meant I moved one slide of description down in the sequence just a little bit. But let's start with the regulations for the embryo fetus.

First, this limit applies, occupational exposure, when a woman has formally declared her pregnancy. Nothing of that is going to change. That is well ensconced in the U.S. legal system, derives from a number of legal precedents, as way before the radiation issues in terms of an individual's right to

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make choices.

So it is tripped on a formal declaration.

The individual does not have to declare, and it doesn't matter how obvious or otherwise it becomes.

It trips on a formal legal declaration.

The limit in the NRC regs, 500 millirem over the entire gestation period. So if the individual chooses to declare her pregnancy, then as a licensee you have to go back and assess the exposure that has already been received, provide protection for the remainder of the gestation period.

If she is already over that number, you have an additional 50 millirem. So there is some allowance, and you just don't yank her out of the system. So you have that piece that is going on there.

Now internationally, ICRP has over the years said that protection should be generally equivalent to that provided to the member of the public. They have tried to stay away, I think, from some of the legal questions or ethical questions that might go back and forth.

So their recommendation now is 100 millirem after the notification of pregnancy. They actually did that in an attempt to try and provide a

relatively simple to apply recommendation.

These have been adopted in many countries, but not the complete uniformity that you have seen with the occupational dose limits that we were talking about yesterday. Canada, for example, is a lot closer to what the U.S. is doing. They use 400 millirem, and they went through a particular process that got them there that I can't reproduce off the top of my head at the moment. So there are some more variations on that theme.

The International Basic Safety Centers of the IAEA that are currently being updated does use the 100 millirem or the 1 mSV per year value.

So setting that up, I think you can immediately see that there are some differences in the proposal that ICRP has made versus what NRC has, a little bit simpler perhaps but, on the other hand, might or might not be as protective, depending on when the individual might choose to declare the pregnancy.

So the options that we would like you to provide us some feedback on: First, no change. Again, there is nothing that has said, NRC, you do not have adequate protection in this area. So we could leave it just the way it is, half a rem over the entire gestation period; go back and do the

assessment, all of that piece.

Alternatively, change the regulation to align to what ICRP has done and what the IAEA is doing in their Basic Safety Standard to say 100 millirem after the declaration of pregnancy. That, I think, perhaps suggests something a little bit simpler in that you wouldn't have to go back and do the history over the previous periods of time, but that has some other implications; or you could pick something else.

Someone suggested very early on in our discussions, well, since you allow people to have 50 millirem value after the declaration even if they have been over, why don't you just pick 50 millirem and be really, really protective.

So there are that options or there may be some other options. By the way, I will tell you thus far in the discussions, nobody has really liked the idea of doing this, and if you want to just say, no, that's fine. But I will use this as my reminder to you that just voting A, B and C, while it is good to know which direction you would like to have, we need to know the whys.

We need to know, as I specifically asked at one point yesterday, if you were writing some of the text justifying a particular decision, what things

would you include in that description that you feel is important to be considered in making this policy consideration.

We will discuss the options, and then we will use the question slide just to make sure that we have covered the different areas. Thank you.

HEARING OFFICER HODGKINS: Anybody want to start, and then we will just go around the room. I meant to do that -- keep you all awake. Anybody? We will start with Scott then.

MR. CARGILL: Well, I am going to have to say from our side of the industry, we would prefer no change at all. It has been firmly established. Programs have been set up. Everybody is comfortable working in this current set of regulations.

With that said -- and this is speaking strictly me, not the company I work for or anything like that -- we do everything in our power, once the person has declared pregnancy, to ensure they get zero. I mean, that is just a knee jerk reaction maybe. I have no medical background to sit here and tell you that any radiation is bad for that fetus. We take a zero approach. We will find them something else to do during that period.

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Having said that, I say don't make any changes, because once she has declared, if we go to 50 millirem -- pick that number -- what happens when she gets to 49 millirem and decides to undeclare herself? She has that right as well. It is up to the mother to make that distinction. Forty-nine millirem; she undeclares, goes for the next eight months -- It is a moot point.

We can change it. We can not change it. In the end, it is going to be up to that mother and the company she is working for and the situation she is in financially that is going to make a lot of decisions for us.

HEARING OFFICER HODGKINS: Anybody want to respond to Scott?

MR. COOL: Scott, if I could follow up on that, how many declarations do you typically see out of your workforce? How often does it occur for you?

MR. CARGILL: Sadly, not many. I say sadly, mostly because we don't see a lot of women in our industry, and when they are, they typically are not in the radiography side.

We are seeing more. I am actually proud to say that we see a lot more women getting in now than we did 10, 15, 20 years ago. In the last couple

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or three years, off the top of my head I can say I have had two, two employees declare.

One had no contact with radiography directly. She was a support staff. The other was one of our inspectors, and we made -- Like I said, we made every provision to put them in a position where they got zero.

HEARING OFFICER HODGKINS: Yes, Melissa.

MS. MARTIN: One aspect this change would have is we do a lot of shielding design in my company of designing the radiation shielding for vaults, diagnostic facilities, whatever. The limit we shield to is the current pregnancy limit of the .5 rem per year. So that we try not to have an impact on the performance of a staff of a facility when an employee does declare their pregnancy.

This would -- if this change were made, this is definitely a change that, as far as a very standard practice, would have a significant cost implication to construction of facilities, because particularly for medical facilities, we have usually lots of what would be termed potentially pregnant employees in medical staffs.

So if you change -- If this change were made, it would have a significant cost impact.

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HEARING OFFICER HODGKINS: Thank you, Melissa.

MR. COOL: Can we explore that just a little bit more also? i have been told -- and I would love to have some validation -- that the design of the shielding is almost always conservative and that the occupancy factors are usually way over what most people have.

So that the real exposures, if you had designed and constructed it that way, are a small fraction, 10 percent or less, of what the design actually was, which would sort of indicate on its face that it wouldn't matter if you, quote/unquote, "sharpened the pencil." But I see you shaking your head no, and I am asking you to give us a little more understanding of how that impact would show up.

MS. MARTIN: Melissa Martin. You are correct in that we do make conservative assumptions. The challenge would be we are required by state regulation to make those challenging assumptions, because you have to shield for worst case.

You always design with that in mind, that you want your safety surveys for real conditions to be less. That is absolutely correct. What I would say is, for diagnostic facilities, it probably would not

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be as large an impact, but for radiation oncology facilities, for therapy vaults, particularly for the primary barriers, we are very, very accurate in our calculations.

The conservatism comes into the assumptions made of the size of the treatment fields, but the data matches very, very closely with measured data versus calculated data for the therapy facilities.

HEARING OFFICER HODGKINS: Anybody else to add to that conversation? Donald, your turn. Pass for the moment? Lynne.

MS. FAIROBENT: I think the other place where we would see, if we changed this limit on the shielding side, is facilities that would add a PET scanner and are trying to backfit within an existing structure.

Sometimes there is not -- Physically, there is not a lot of extra space and, when you have to backfit and add the shielding for the PET facility, for the PET scanner, it is much more energetic, as everybody knows, with the FA isotope than what might have been in that room before.

So I think that on the diagnostic side, the PET area is probably also where there would be

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significant impacts. Melissa can clarify. 2 MS. MARTIN: Melissa Martin. She is absolutely correct. And just to reiterate, I keep 3 coming back to the radiation oncology and the PET facility. Those are the two that typically get installed into -- as retrofits in many instances, and 6 we have designed construction, which it is literally down to one-quarter inch clearance with the current 8 limits. 9 10 So we would impact the ability to put some of these facilities in at all to serve the patients. 11 12 HEARING OFFICER HODGKINS: Okay. Anybody, reaction? Yes, Ralph? 13 14 MR. MACKINTOSH: I would be interested in terms of shielding, if this was to be implemented, 15 what would be the retroactive effects? 16 Many therapy vaults are designed, obviously, large concrete vaults 17 and such in which you could not go back and retrofit 18 these facilities. 19 20 Would you then have two standards of 21 facilities, some designed to one level and 30 years 22 from now you would finally catch up with whatever, with vaults which met the nuke standard? 23 24 HEARING OFFICER HODGKINS: Anybody else?

Yes, Lynne?

MS. FAIROBENT: Yes. Lynne Fairobent, AAPM, to just follow up on Ralph's comment.

Yesterday Don mentioned when we were talking about backfit analysis and the formal backfit analysis that is in place for reactors and fuel cycle facilities.

This may actually -- If one were to move in this direction, this may actually be an area where NRC would have to consider a more formalistic backfit analysis like was put in place for reactors and fuel cycle facilities. That doesn't necessarily exist today in the materials program, if I heard you correctly yesterday.

MR. COOL: To try a nd clarify a little bit, the NRC requirements do not apply to the byproduct programs. However, in doing our regulatory analysis, in doing an analysis for a rule like this which covers across the board, our expectation is that we will do an analysis, which is equivalent to backfit, across all of the types of issues.

Now it may not be jot and tittle all the way down through all of the details, but that is the expectation that we have for ourselves. I just can't point you to a Part 30 citation like I can point you to a Part 50 reactor citation.

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HEARING OFFICER HODGKINS: Any other comment? Melissa, I think it is your turn.

MS. MARTIN: I seem to be doing well at this this morning, but you happen to hit on something I do for a living.

One other point I would just make is, particularly for PET facilities, many times these centers are going into outpatient buildings, and the seismic requirements for adding additional lead will also sometimes take out the ability to actually build these facilities. The additional weight is a -- and just the impact of adding additional lead production and all the associated hazards that are associated with additional lead.

I would like to see some -- Again, I would come back to the question of: I have not seen the scientific evidence that says we have a problem with our current limit. So, therefore, my position would be to not -- My recommendation would be to go with A and not change it at this point.

I think we all live with ALARA, and we try to design these as conservative as possible, but I haven't been convinced we need to make a change at this point.

HEARING OFFICER HODGKINS: So, Melissa, as

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far as then with Don's request that we not just say vote yes or no, are there any other issues that you think you need to speak to, since you are in the industry, as you say? MS. MARTIN: I will let some of the others that are, obviously, in the industry speak, and then, 6 7 if necessary, I will add something, but there's a lot 8 of people with expertise around this table. HEARING OFFICER HODGKINS: Terrific. People with expertise around the table, any comments, concerns? Yes, Charles? 12 MR. GOMER: Chuck Gomer, Children's Hospital Los Angeles. From an employee point of view, 14 I can say with a lot of understanding that we have not seen at the .5 level any concerns as far as having to 15 have any of our physicians, primarily in this case, 16 to stop procedures because of reaching that 17 limit. However, we go down to the 1, we would have to 18 19 go back, and there may be times where we would have to limit the activities of some of our physicians in 20 areas of cardiology and/or interventional activities. Thank you. 22 HEARING OFFICER HODGKINS: Response? Richard? 24 MR. BURKLIN: Rich Burklin. I am coming 25 from a fuel fabricator's perspective. I would choose

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3(b), which would be the 100 millirem declaration. The reason is simplicity. We don't have -- As for the date of conception, we don't have to go back and reconstruct the dose, and for us we have people who have internal dose. So it can be a little more work to try to determine what the dose is.

Having said that, I have worked for several companies, and we all pretty much do the same thing, as similar to what was mentioned. If a woman were to declare herself pregnant, which is, for Don's question, pretty rare, maybe less than one per year on average, but if she were, we make an immediate assessment of is she okay where she is or may she get that dose.

If she is going to get that dose, then the company will present her almost immediately an offer to work in a different part of the plant with the same or better pay, etcetera. So that we -- It has always been accepted, and I think that is what most companies try to do. They try to avoid any risk of a reasonable dose.

HEARING OFFICER HODGKINS: Point of clarification. When you say less than one a year, is that because the women aren't declaring pregnancy or you don't have women to declare pregnancy?

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BURKLIN: Some women don't declare but I am unaware of anyone who worked, pregnancy, really, in a radiation area that was in that. would be more, for instance, as secretary or administrative assistant that might not declare. although I don't actually know the breakdown of our plant, I would say there are more males than females, and our plant is probably also a little bit -- The average worker may be a little bit older, too.

Hopefully, this nuclear renaissance occurs, we will start getting in a number of young women again.

HEARING OFFICER HODGKINS: Thank you.

Additions, subtractions, comments? Chuck, your turn

again. Nothing? No comment, Chuck?

MR. PICKERING: Chuck Pickering, City of Hope. Yesterday you asked, you know, what is a big change, and Lynne said 10 percent is not a big change. Five hundred to 100 is a big change, in my view.

On the other hand, I can't think of a case where one of our employees has gone over 100. Now our numbers aren't that big in that case, and I can't think of a single case where I have had an interventionalist or a nuclear med tech, at least not in a long time, declare their pregnancy -- I can't

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think of a single case where they have been pregnant and not declared, but I can't think of a single case where we have to deal with that.

Most of them are on our research side. They are working with beta emitters, and it is not a big problem for us, but I just don't have any data to show.

HEARING OFFICER HODGKINS: Thank you. comments? Rob? Oh, I'm sorry, missed you, Melissa.

One thing I would just --MS. MARTIN: Melissa Martin. One thing I would just add. talked about it briefly yesterday, but I think the other thing, for those of us that have had to be involved in malpractice law suits or just law suits in general from employees, if we make this change, this is basically saying, as far as the lawyers are going to be interpreting, we have been working unsafely all these years, and I just think it is something we have to be very mindful of, is we are providing lots of opportunities for law suits, because again I am like Chuck. Rarely do you see an employee even close to the 100, but as soon as we make the change rule, it basically says we have been doing it unsafely all this time.

So if you do have that employee, then we

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have just opened up a lot of opportunity..

HEARING OFFICER HODGKINS: You know, I could add to that, that in the D.C. conversation it was also sort of a marketing issue. It was like, regardless of law suits, just the point is how do you explain and train that it was 500, now it is 100? What does that mean? So that was part of the previous discussion outside of -- Does anybody else want to add to that or echo that? Rob, did you want to? It is your turn.

ROBERT GREGER: Robert Greger, State of California, Department of Public Health.

I have kind of a generic comment to make, which I should have made yesterday. That is that, as a state regulator, I would tend to like to see the dose limits lowered in all situations we have been discussing, as long as doing so is reasonable from the standpoint of overall public benefit, whether it be public health, whether it be expenditure, resources, whatever, with the balance put on there.

Coming out of the starting block as a regulator, I would say I am going to tend to look at the lowering of the dose standpoint initially until someone can make a good argument that it shouldn't be lowered, because I believe that is the safe position

to take for a regulator.

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have a second reason. That is the primary reason. I have a secondary reason also, and that is, from a public perception standpoint, I think there is negative publicity, negative feelings if there are valid recommendations generated by standard setting bodies that have а lower criteria, more conservative criteria, than what have, and we don't adopt it.

I live in a world, in particular, in California, but in other states also where there is a lot of vocal public activists involvement. Now as I say, that is not my primary concern.

My primary concern is health and safety, think that also has to be taken but Ι into consideration, is how the public would react to the situation where we are faced with an international standard setting organization, recommending а organization, and we make a decision not to be as conservative as their recommendations are.

HEARING OFFICER HODGKINS: Okay. George?

MR. SEGALL: I would like to respond to Rob's comments as being inconsistent with our approach yesterday to occupational work limits being lowered from 5 to 2 rem in workers who are not pregnant.

There we said two things.

Number one, there is really no scientific evidence to prove that 5 is unsafe and that, should we consider lowering it, the burden of proof would have to be on agencies to show that a limit at 5 is unsafe. But now you said just the opposite, that we must be consistent with other agencies who are in a bad position, and now the burden of proof must be on the licensee to prove that something is safe above 100.

So it is totally inconsistent with our approach from yesterday in terms of how we believe we should be or don't need to be consistent with other organizations in the absence of scientific evidence and where that burden of proof lies, and I don't think we can be on both sides of the issue at the same time.

HEARING OFFICER HODGKINS: Rob?

MR. GREGER: A couple of thoughts on that.

What I am saying is coming out of the starting block,
that is where I stand as a regulator, is to say that I
am going to bias myself from the beginning to lowering
-- making more conservative regulations, in particular
if those regulations are recommended by authoritative
bodies and if they are adopted and in use in other
countries, other locations.

What I did say was that I would look to

see what the arguments are against it, and weigh that in, obviously, in coming to any kind of a decision on which way we would want to go.

I also did say that -- I should have said this yesterday, because this is my underlying philosophy as a regulator, and it would apply to yesterday's conversations also.

As to whether you have to prove to the regulatory agency that it is not justified to lower the dose or whether the regulatory agency has the burden of proof to justify that it is, I guess I don't know the answer to that necessarily, other than the fact that I would tend to be on the conservative side of it.

Now I don't have that authority personally to change our regulations on my own, but that is my belief, and I believe that is probably the belief of most regulatory personnel.

HEARING OFFICER HODGKINS: Others? Chuck?

MR. PICKERING: I just want to clarify,

Rob, on that. If, for hypothetical discussion, we understood that there was a threshold, for example, at 6 rem, and that was scientifically clear, would you still hold that view?

MR. GREGER: No, I would not.

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HEARING OFFICER HODGKINS: Anyone else?

Not open to the audience yet. Let's go ahead and do it. Ellen?

MS. ANDERSON: Ellen Anderson from the Nuclear Energy Institute.

I guess I am speaking on behalf of the commercial power reactors, the radiation protection managers and, I guess, as a Mom. I have been in this situation. I have to make a determination whether I declare or not and what I think is best for me and for

First of all, Don, I think that the first slide is inaccurate when it says no change, continue the dose limit of .5 millirem. It is not per year. I believe it is per just over the gestation period.

MR. COOL: Correct.

Okay. ANDERSON: MS. So that is inaccurate there. So as you start looking at what is going on, first of all, from the power reactor perspective we do have less women than men, although that is changing. We have increasingly more women in industry than we did when I started industry some 30 years ago. So we do have more concern.

I will tell you that, from a power plant

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my child.

perspective, and I have worked at many power plants, many different companies, we do minimize the exposure once we are aware of the fact that that woman is pregnant, and aware meaning that that woman has declared.

There are some women who do not declare. Very obvious when they are pregnant, but they do not declare, because they have that right. And why don't they declare? The reason why is because they don't want to be taken out of the mainstream work. They want to ensure that they have job assignments as their male counterparts do. So that does happen. Whether it is right or wrong, it is another issue, but that is what happens.

So if you were to look at the three options -- and I think C is out completely, because I don't know what other number there would be, and 50 is so low, but let's just look at the two options.

First of all, there is nothing that says that we have inadequate protection of the embryo fetus at .5 rem over the gestation period. If you look at 3(b), which talks about the 100 millirem after the declaration, it sounds like that is a lower number, but if you really were to look at that and say after the declaration, during the first trimester in some

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My radiation biologist corrected, and it
has been a long time. That tells me that that is
where the embryo fetus is most radiosensitive. So at
that point, prior to declaration, that woman may not
even know she is -- I mean, that is the most sensitive
time, and she may not even know she is pregnant.

So 3(b) is really not the most conservative response to this question, because if a woman didn't know she was pregnant and so, say she picked up 400 -- for whatever reason, picked up 400, 500 prior to even declaring -- she could easily be going over.

So I see no reason to change at this point to go with anything other than leave it the way it is, because I believe that that is, from a U.S. perspective, the direction that we should be going in, obviously leaving it the way it is, and in some cases it may actually be the most conservative approach to take.

HEARING OFFICER HODGKINS: Reaction?

Comment? Eric?

MR. GOLDIN: Eric Golden, Southern California Edison.

I would just like to amplify one thing

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that Ellen said, which is that, if a woman -- The typical way that the power plants are given guidance to distribute that dose throughout the gestation period for 500 millirem, that means roughly 50 millirem per month. Αt 100 millirem for the gestation, then you are down around 10 millirem per month. You are getting into the point where it is hard to measure things.

I could see an untoward reaction where some women might avoid declaring, because they would have the perception that they would lose roughly a year's worth of work experience and seniority to their male counterparts, because they would -- At 100 millirem for the gestation period, they are basically going to be nonradiation workers.

So they are going to work in some clerical position or something basically outside the plant and, therefore, lose. I can imagine that there would be some folks who would just simply say I don't want to do that to my career, and they would avoid declaring for that reason.

MR. COOL: If I could follow up on that just a bit, it sounds like you are saying that using 100 millirem after the declaration would be viewed as a -- Punitive is not the right word, but I can't come

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up with a different word, a word which you are suggesting would actually cause more people to not declare and, therefore, be viewed as sort of discriminatory or otherwise employment-wise, without providing additional protection.

I am adding that little caveat, because you didn't say it, and I wanted to sort of try and clarify what point you were trying to make.

MR. GOLDIN: Yes. That it would be too restrictive and, because the average nuclear plant worker only -- radiation worker with measurable exposure only gets about 180 millirem a year anyway, then the restriction might be perceived as being too restrictive.

MR. BURKLIN: Just one comment, and that is the HR Department has to be involved with this, and if a woman is removed from where she is going and is offered another job, and that job may be off the main thing that she does, the HR Department needs to be very well aware that that could impact her future as far as promotions and things like this, and they need to take steps to make sure that she is not punished.

HEARING OFFICER HODGKINS: Okay. Anybody else? You know, I have a question as a layperson, too, that you haven't really clarified for me, and so

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if I was reading these transcripts. Maybe, Ellen, I am looking at you as far as: When you guys talk about a woman choosing not to declare, part of the clarification I need is because, from an industry standpoint, there is no damage done at the levels that you are talking about. You see what I am saying? So as a layperson, I don't hear that.

I hear you guys talking about radiation. So at those levels, there is no known impact to the fetus.

MR. MILLER: The ICRP in a document about radiation in pregnancy -- I don't remember whether it is 90 or 84 -- says that if a woman is a patient and she is pregnant at the time and the fetus receives a dose less than 100 milli sieverts -- that is milli sieverts, not millirem -- don't worry. No effect that we know about, and it is not a cause for alarm, and you shouldn't have a therapeutic abortion. Just don't worry, it is going to be okay.

We are talking currently about the existing limit of 5 milli sieverts or 1/20th of that and reducing that to 1 milli sievert or 1/100th of that.

HEARING OFFICER HODGKINS: Ellen, you want to add?

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MS. ANDERSON: Well, in addition to that, you are talking about an acute versus a chronic exposure, acute being something where you are going to, therapeutically, give them a great deal of radiation at one time, versus chronic, which would be a small amount over the gestation period, and there is a difference.

HEARING OFFICER HODGKINS: Okay. Thank you. Melissa.

MS. MARTIN: Melissa Martin. Again, I am sure I am not the only one at this table that has participated as an expert witness and being called in.

Dr. Miller's data is exactly the misperception -- or among the public, is the general public, they are trying to apply whatever is used for occupational limits as the doses for their fetus due to medically necessary procedures.

We already have a very significant, quote, "difference" between the data that says there is no documented evidence in a patient, but yet we are trying to lower it for the occupational worker.

HEARING OFFICER HODGKINS: Okay. Any other questions, comments on that? Eric, are you done then or did you finish your comment? Colin?

MR. DIMOCK: Colin Dimock, UCLA.

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So UCLA, we are а large research university with two hospitals and a license. a large number of people. We have -- A very large percentage of those people are women, probably over 500 percent when we look at the hospital. We have a very large percentage of those within the range of pregnancies. We get quite а few pregnancy declarations as a result of that.

We don't really see very high doses with those people, for the most part. We probably stay under 100 millirem. I can't say that for certain, but I am not aware of any cases where a declared pregnant worker has passed the 100 millirem threshold.

That being said, if there is not change compelling reason and, in fact, to the international committee isn't even consistent. are not even gaining consistency with a very large group out there. I am not sure of the value of the change.

There certainly is a lot of cost associated with making these types of changes, just in the paperwork that we issue, all that kind of thing, and re-education of the workers that we have, and in the perceived questions that raises about what was done before versus what is done now, and all that

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business.

So to that extent, I don't yet see the reason for the change. I don't see a compelling reason for that. So I am kind of in the don't change bin.

I will -- I would like to say one thing that hasn't come up yet, which is that I have rarely over the course of my career seen this limit cut both ways. I have seen institutions say, no, you can't change what you are doing, because you are not approaching the limit, which is to say that a declared pregnant worker says I no longer wish to work around this equipment or blah, blah, blah, because I am concerned about the radiation exposure, and the institution also uses that limit to say, well, look, you are not coming up against that limit; therefore, we are not required or in any way compelled to make that change.

I am not sure exactly what effect on that would happen, if you go down toward the 100 millirem limit, but I expect that, as you get more things pushing up against that limit, you are going to see things push in both directions more than we have seen so far.

This kind of brings me up to Bob Greger's

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comment about wanting to lower the limits as a regulator in general. I can very much see from the perspective, also being in California, why you would want that to be consistent, and I can see -- I am very well aware of the special interest groups that use these kind of things as part of their toolkit for making these arguments: Well, the international community says this versus what we are doing, and what not.

I am not entirely convinced that, even if we adopted ICRP across the board, that -- We know they have other tools in their kit that they would go to, that they would use, and that would take away that. I am not sure it would change their opinions of what we are doing very much.

I am a little surprised that I don't see any representatives of some of those groups here today as part of the public representation to discuss this in this forum. I am not sure what message that sends to me right off. But from our perspective within the licensees, we spend a lot more energy.

The amount of energy we spend as you go up against the limits increases tremendously. As we see an individual come up against that, we really start to spend a lot of individual attention on that person and

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what not.

So if we do change limits in general, as we lower these limits in general, me and my staff are going to be spending a lot of time on some particular cases, which is not time that we are spending over other general cases. Something has to give in order for us to spend a lot of time with these, if we start lowering the limits down to where people are frequently coming up against those limits.

I am not sure that protection is achieved in that fashion. I am a little concerned about what that would have.

HEARING OFFICER HODGKINS: Comments? Yes, Rob?

MR. GREGER: In response, Colin, I think that it has been expressed here yesterday at least and today that, for the most part, we are meeting the ICRP 103 numbers. So I don't think we have reached the point that you are referencing of pushing numbers down so far that it is going to cause an extreme amount of effort, other than in some of the specific situations that exist, but it is not an across the board problem, in my perception.

I should have added when I made my statement before that I am not the expert. You guys

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are the expert. I walk into it thinking I would like to -- I am going to listen to your arguments, but my starting point is going to be saying I would like to lower doses, be more conservative within reasonable bounds, and I look to the experts to define that reasonable bound.

HEARING OFFICER HODGKINS: Lynne?

Lynne Fairobent, AAPM. MS. FAIROBENT: Bob, I just want to hang on something that you just I think, yes, we are not seeing perhaps a large number of individuals bucking up to the 5 rem per year limit, but I think that is because all of licensees work with very rigorous ALARA programs and, therefore, their administrative control or their ALARA goal limits, and this will come up a little more an issue for us. So I really don't want to get too far ahead, but felt I needed to bring it up based on your last statement.

If you move the legal limit down from 5 to 2, that also then has the impact of where do the ALARA goals' values have to be set in the administrative controls. And, yes, I do think then you do see a programmatic impact that may be greater than what it - that is simply apparent, because people are not hitting the limit.

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So I think that there is an increasing impact as we lower the regulatory limit with what operational practice and administrative controls are in place.

MR. GREGER: Robert Greger. I hear what you say, Lynne, but I think that is a common misperception of ALARA, because that ignores the "as reasonably achievable" aspect of it, and in my view, and only looks at the "as low as."

You know, ALARA is supposedly monetary value that is used to balance how much effort should go into the lowering of dose. It is not lowering dose for the sake of lowering dose. lowering dose within an overall framework of health and safety and monetary expense or resources, etcetera.

So I don't necessarily see that you would have to have lower ALARA goals than many institutions would have today.

MS. FAIROBENT: Bob, I don't disagree with you. However, it is not my experience that that is necessarily how the inspection and enforcement side of the regulatory agencies view that, once an ALARA goal is set, and that is something, I think, that I want to defer from more extensive discussions until we get to

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the discussion of issue 4 on constraints, because that 2 is really where that belongs. 3 HEARING OFFICER HODGKINS: Thank you, Rob. 4 Colin. MR. DIMOCK: So I can bring up a specific case that I am aware of where we did have one employee 6 who approached the 5 rem limit fairly closely. 8 probably spent about 12 staff hours trying to resolve that situation in the later months of the year, as we 9 saw that developing; whereas, we might spend, say, 10 11 about two hours on people who are right now -- you 12 know, the roughly dozen people right now who may come close to the 2 rem limit. 13 14 If we are now suddenly spending 10-12 hours for those dozen people, that becomes 120 staff 15 hours, and that really starts to bite into what we are 16 able to do. Again, that is time taken away from other 17 18 programs. 19 MR. COOL: So to follow up on that just 20 briefly, I think you were just using an occupational 21 exposure case at the 5 rem, not necessarily the embryo 22 fetus limit here. But taking the more general --23 MR. DIMOCK: That is correct. 24 MR. COOL: -- point and thinking about 25 what you write down in terms of impact, what I think I

hear you suggesting is one of the impacts is additional resources in terms of track, investigate, etcetera, working with an individual as they approach the limit, irrespective of whether it is this one, the occupational dose limit or otherwise, which is something that isn't normally captured when you say I had to change the procedures or I had to change the signs or.

Am I understanding you correctly, and would you like to elaborate on some of those other hidden or not so obvious costs that come into play?

MR. DIMOCK: Well, that is essentially correct, but I was also addressing what Mr. Greger had talked about, conservatively lowering the limits and some of the effect that I see that happening on my program. So it is both in this specific topic and in the earlier topic. It does come into it.

I think that we have kind of covered some of the basics. Is there specific type things you are looking for, for these? I mean, we spend a lot of time as you approach the limits making sure are they accurately approaching that, are we doing adequate dosimetry, are we -- You know, we review the fields by hand.

We spend a lot of hand holding time with

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staff as they -- the closer you get to the limit. If you don't go over our ALARA limits, then e pretty much review the reports, and we are done with you on that. If you do go over the ALARA limits, then we are going to start the interview process and the examination process.

If you are going over ALARA limits and you are significantly higher than some of your other peers, then we are going to look at what you are doing versus what they are doing, and so we see a lot of the comparison to see if you are doing something that we can improve to lower your dose, because your peers are showing lower dose.

If you start applying -- coming up against legal limits, then we need to take a very close look at that so that we don't have to take you out of circulation, particularly again in the case of interventionists, who are the highest dose people that we see at the university.

HEARING OFFICER HODGKINS: David?

MR. APPLEBAUM: Dave Applebaum, UCLA Medical Center. I have a couple of concerns with this issue. One of them is that I agree, I have not seen scientific evidence to indicate --

MR. COOL: Could you get a little bit closer to the microphone?

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MR. APPLEBAUM: Oh, I'm sorry.

MR. COOL: We are competing with our next-door neighbors.

MR. APPLEBAUM; Okay. My apologies.

I have not seen any scientific evidence that suggests that 500 millirem is a hazard. I am concerned that the pregnant personnel will choose not to declare and, therefore, they will not be afforded the additional training, monitoring and surveillance that would be afforded to an individual who did declare, because they are afraid of losing their residency, for example, in radiology, cardiology or nuclear medicine, and even vascular surgery.

I have had people come to me saying I really don't want to declare, because I am afraid I won't get to understand or learn the techniques that are necessary for me to be a good doctor.

The second thing I would like to do is address the point that Dr. Miller had, and I do have ICRP 84 with me, and it says in two bullet points as follows: Number 1: "A fetal dose of 100 milligray has a small individual risk of radiation induced cancer. There is over a 99 percent chance the exposed fetus will not develop childhood cancer or leukemia."

In the following bullet point, it says:

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"Termination of pregnancy at fetal doses of less than 100 milligray is not justified based upon radiation risk." Thank you. HEARING OFFICER HODGKINS: Anybody want to comment? MR. APPLEBAUM: There is one comment that I just want to say. Viewing a fetus as a member of the public after declaration may be consistent with current legal precedent. HEARING OFFICER HODGKINS: Don? MR. MILLER: Please correct me if I am Don Miller. wrong. My understanding of the reasoning that the ICRP used to promulgate this 1 milli sievert limit is philosophical. That is, they consider the embryo fetus a member of the general public, and not because there is scientific evidence newly developed that the risk is greater and, therefore, the limit has to be reduced. Is that correct? MR. COOL: That is my understanding. MR. MILLER: My understanding as well. the United States we don't consider the embryo fetus a member of the general public, because if we did, women would not be allowed to decide whether or not to

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decide their pregnancy. Big Brother would come along

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and say you've got a member of the general public in there; we have to protect that member of the general public.

We are -- As Dr. Cool said earlier, we are specifically not doing that, because there is strong legal precedent that it is not allowable. So we are not dealing with embryo fetuses as members of the general public. We are dealing with embryo fetuses as intimately related with radiation workers who have autonomy and who get to choose.

So our philosophical approach in the U.S. is very different from the ICRP's, and since the distinction of whether to use 5 or 1 is philosophical, I am not sure that it follows we should follow their precedent.

HEARING OFFICER HODGKINS: Anybody?
Leonard.

MR. SMITH: Yes, I would like to make a comment on that, too. If they were considered members of the public, the thing we are going to get into later today is that we have certain members of the public that might be exposed. They may be caregivers, and so we have this — they are allowed to get more exposure, 500 millirem versus 100 millirem.

So from both angles, it seems that one

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could argue that there is an advantage to the fetus that the woman is continued to allow to work. It is better for her wellbeing, and that is probably healthy for the fetus, too.

HEARING OFFICER HODGKINS: Thank you. Any other comment that you want to add, Leonard, as far it is your turn to comment? Okay. Yes, your turn.

MR. SMITH: I have a lot. This business of lowering the limit is a very difficult one for our industry. As you probably understand, we do work internationally, and so we do want to line up with the ICRP recommendations.

There are quite a few practical differences, though, operating at 100 millirem. We heard that just measuring the dose at that level in an occupational setting is difficult. In industry, manufacturing industry, you typically have nonuniform radiation fields, and they can be dynamic, and they can be complex. You can have mixed radiation fields.

We are often dealing with high energy beta radiation, and just the dosimetry is difficult, and it gets much more difficult when you are dealing with low doses of just 100 millirem in a gestation period.

Fortunately, though, there are some advantages in our environment. It turns out that

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mostly people's external exposure is to the upper part of the body. So the abdomen, actually, is fairly well protected, and for most of the radiations we are dealing with, there is an extra effect with dual protection. Just the absorption in the mother's body protects the fetus to some extent.

So it probably turns out that this 100 limit would be doable from the millirem perspective. Now, remember, exposure we interested in the total exposure of the fetus, and one of the problems that we have in industry, we are often with manufacturing, working open sources of radioactive material. Many of those materials are in a radiochemical form that are volatile.

So there is a small risk, a small chance, of a person getting intakes of radioactive material. For most of the radiochemicals, that is not necessarily a problem for the fetus, but we do work with radioiodines, and even working at 500 millirem now, in practice we have to prohibit declared pregnant women from working with radioiodine. It is just too risky. You could get quite a massive dose.

Now there is one thing that is in favor. The concern is actually only the third trimester and, of course, you certainly -- a woman would know that

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she is pregnant by the third trimester. So there isn't a risk of accidental exposure that the woman wouldn't realize. So -- But that is our normal practice in industry, is a woman would not work with radioiodine in the third trimester.

Now the other thing that was not talked about here is that there are other hazards in the work area, and it turns out that there is usually more concern in our industry for the chemical hazards. The women are usually more concerned about that than the radiation hazards, and would elect to avoid working with the radioactive material and the hazardous chemicals because of the hazardous chemical hazard.

So it probably -- This rule and the lower limit probably wouldn't actually affect our current situation, simply because the radiation isn't necessarily the primary concern.

What else? Yes, one problem we do have, we do know that some women do not declare their pregnancy. We have -- In our industry we have people who -- technicians -- do fairly routine dispensing type operations, and they may have -- they may not be very well educated, and they have probably had some insecurity, job insecurity concerns. So that might be an incentive for them not declaring their pregnancy.

They are worried about their careers and not really -They can't afford to not be employed.

Another problem that we have is that we have quite a few researchers. There is quite a lot of research and development work that is done in industry, and they have the opposite view. highly educated, and they usually are not -- They think they are protected. So they don't think the radiation is going to damage them, and therefore, they want to continue working, and they are very concerned They don't want to take a few about their career. months off, because they are doing critical research, and they might miss a breakthrough.

So we do see that. It is small and -- It is a small percentage of people who might not declare pregnancy, but we do have quite a lot of women in the workplace, of course, in our industry.

I think that is all I have for you.

HEARING OFFICER HODGKINS: Thank you.

MR. COOL: If I could follow up on one thing, reflecting on some of the discussions that we have heard up until now. One of the things that was said to us was that an area where this might be particularly an impact was in nuclear pharmacy types of settings.

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At that point, as I recall, what we were told was that a fairly high proportion of females in the population, average doses in the 400-500 millirem per year range, not an issue under the current formulation, but potentially a significant issue under the new formulation.

Can you validate that or provide some additional perspective as to that view which we had seen earlier?

MR. SMITH: Yes. I think what we will need to do here is get some up to date information on exactly how folks are getting exposed. i think the situation is that, if you are using normal dosimetry, that you would have this problem in that industry, but you could potentially customize the dosimetry so that you have a better handle on exactly how the embryo is being exposed.

HEARING OFFICER HODGKINS: Comments?

MR. COOL: I will use this as yet another opportunity. If CORAR or individual members of organizations have some information and you would be willing to share that with us, we would love to have it.

Someone asked me between last night and this morning, if I were to say what would I like to

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have, what would I like to have in terms of the materials; and trying to be generic, what is particularly useful in any one of these settings is knowing the number of individuals that are involved and knowing the number of individuals in each of the series of dose ranges.

For occupational exposure, it is not just two to three, three to four, four to five, but 1.5 to 2 or even 1.8 to 2, and several different denominations in a distribution so that we can see how many people are in different groups.

In this sort of setting, it is number of individuals that are approaching 100, 100 to 200, 200 to 300 -- so that we can get some sort of diagram, not unlike what I think Scott waved, but of course, that transcript, get on the that distribution which helps us understand for particular types of uses, in medical even different modalities or distributions the kinds of to understand the kinds of impacts of different kinds of decisions.

So let take this ;me as а We advertisement. would love to have that information, if you have it available, and that is, generally speaking, the kind of information that would

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help us in trying to prepare the assessments that we 2 will have to going forward. HEARING OFFICER HODGKINS: Any comments? Leonard? MR. SMITH: Yes. I can see that this is definitely an area where we need to get information 6 back to you, and we will look to that. I guess one thing I should say is that the 8 information I got from CORAR in the last few weeks was 9 10 that they would prefer the 100 millirem limit, if we 11 could try to get there. We are not -- It is not clear 12 whether we can offer it that way. What is occurring to me here at this 13 14 meeting is that this might be another one of those situations where you might want to preserve a 500 15 millirem limit, but then have potentially a constraint 16 that folks might use at 100 millirem. 17 HEARING OFFICER HODGKINS: Comments? All 18 19 Thank you, and I am going to ask you to sort of put a little marker on that thought, because we are 20 21 going to come to a discussion of constraints and 22 planning and optimization. You have added yet another fact to that particular puzzle. Thank you. Kai. 23 MR. LEE: Kai Lee of USC. I am in favor 24

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I think the reason why ICRP wants to go

of no change.

with this 100 mrem per year is I think they just blindly or arbitrarily follow a recommendation that the NCRP back in the Sixties recommended.

As I recall, reading the NCRP report -- I am not sure whether NCRP report Number 20 or 39 -- they set the fetal exposure limit to 500 mr, because one sentence I remember very well was they defined a fetus as a member of the unwilling public brought into a radiation environment by their occupational mother.

So, therefore, they said, this unwilling public should not be exposed to occupational dose, but rather should be limited to the public exposure. That is how the 500 mr was defined.

50 years later, we have lots evidence to show that mothers exposed to getting 500 mr did not have abnormal children, and for ICRP to arbitrarily say, hey, we should keep in line with limiting the fetal exposure to general -- that exposure, to 100 mrem per year consistent.

I have another concern, I think, that has been echoed by other people, in that we may be arbitrary to put up a barrier to people who do meet the exposed greater 100 mr. I am seeing more and more female radiologists. They do fluoroscopy, and the

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chance for them to get more than 100 mrem is high.

If we have regulations saying that the fetus exposure should not be more than 100 mr, I will have to step in to tell this young lady, I'm sorry, you can no longer work; you can no longer perform fluoroscopy.

So we are really unfairly -- I'm not sure whether it is discrimination or not, but doing harm to this individual, this young lady allergist, by keeping her from getting her training for no reason. That is the reason why I opposing changing the 5 mrem to 1 mrm.

HEARING OFFICER HODGKINS: Any other comment? George? Ellen?

MS. ANDERSON: I just had one comment. This whole issue of -- and I am not a lawyer. So I don't -- You know, I am not one. But one of the things that is sort of sitting in the back of my mind as we are having this conversation is that we have something in this country that other countries don't have, and that is Roe v. Wade.

If, in fact, the embryo fetus is a member of the public, then it is a moot point. Roe v. Wade doesn't exist. So I don't believe -- and, Don, you may want to talk to OGC about this. I am just

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thinking, if in fact we say -- we go with the 100 millirem because we recognize the embryo fetus as a member of the public -- and this has nothing to do with politics versus religion; I am just looking at the strictly legal perspective -- then we are actually in violation of our own laws, because Roe v. Wade basically says, you know, we allow abortion, which means they are not a member of the public or that would be considered murder. Just something in the back of mind that jumped out, and I just wanted to put that on the table as another spin to this whole conversation. Thank you.

HEARING OFFICER HODGKINS: Thank you. Anybody else? George?

MR. SEGALL: The Society of Nuclear Medicine represents 10,000 nuclear medicine technologists and 4,000 physicians and scientists, and I would say the -- could not underestimate the huge adverse impact lowering the limit from 500 to 100 would have on patient care and clinical nuclear medicine in general.

I brought some statistics from my local facility, Stanford and the VA Hospital in Palo Alto, California, where we badge 20 workers in the nuclear medicine clinic. So this is exclusive of research.

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One hundred percent exceed 100 millirem per year. The lowest recorded dose was, in fact, 145 millirem per year, which means that everybody would exceed the 100 millirem limit per gestational period.

Nuclear medicine departments are small. Many departments are two technologists, and a large size department is four technologists. If the limit is changed from 500 to 100, then it is quite certain that that technologist would not be able to work in PET CT, because a lead apron is not sufficient shielding.

It is almost certain that that technologist also would not be able to administer any kind of diagnostic radiopharmaceutical, even technetium, because even with a lead shield the doses are likely to exceed 100 millirem.

My own badge reading -- and I don't administer radiopharmaceuticals generally, and I don't generally image patients myself, but I am in the nuclear laboratory -- exceeds 100 millirem per year. In other words, there is almost nothing a person could do in a nuclear medicine department.

Unlike the power industry where we have lots of workers in a facility, the majority of whom are male in whom temporary duty reassignment is

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61 logistically feasible, it is absolutely unfeasible for duty reassignment in a small nuclear medicine department. Now even at the 500 millirem limit, at Stanford, VA Palo Alto, 35 people -- 35 percent of the 20 people I mentioned would exceed that 500 millirem per gestation limit, and that is a significant number; and in those workers, we take the appropriate steps to reduce that exposure below the limit of 500 millirem. The way this is accomplished is the work around radiation is shifted to other colleagues. the population risk is the same, and if you believe in

LNT, someone else is assuming a higher risk.

This would have extreme adverse impact on clinical nuclear medicine, has no scientific basis, and we would be happy to provide the data to support those comments.

HEARING OFFICER HODGKINS: Comments? Melissa?

MS. MARTIN: Melissa Martin. Can you just elaborate? At least, I would just question. Μy experience is a large percentage of the staff in a nuclear medicine department is female.

MR. SEGALL: I think it is greater than the majority.

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HEARING OFFICER HODGKINS: Any other clarifying questions, input? Ralph? Oh, Kai.

MR. LEE: Just a comment to my Melissa. In my department, we are more male than female in nuclear med. technologists.

HEARING OFFICER HODGKINS: Ralph?

MR. MACKINTOSH: I currently work in — mostly radiation oncology, but in my career in diagnostic and in nuclear medicine, and I would agree with Melissa that a high percentage at least of the population is of childbearing age, and these are highly trained people. They are not easily replaced. There is no place to put them. They are not going to sit at the front desk and answer the telephones during that time period.

We do take several steps when we know that they are pregnant. We generally double badge. We have them wear a waste level badge during the time of their history of their pregnancy.

I am concerned about the cost. If we had to shield to this level, and certainly in radiation oncology, we are talking about two half-value layers, and two half-value layers on 18 MEB accelerator is not an insignificant space taker upper, if you are dealing with concrete, and certainly we are talking about a

considerable cost. And again, I am concerned about any kind of retrofits, which would be impossible in most cases.

Second, there is the personnel cost. We talked about that, having to bring in additional FTE to cover the tasks, because especially in small departments there is nobody to switch with. You would have to bring in additional personnel to cover that time period.

Finally, just a little anecdote. In my family we faced this issue. We had a fetus with a dose of several rem during the first trimester, but I am happy to say there is a 30-year-old paramedic fireman running around the state of California somewhere.

HEARING OFFICER HODGKINS: You done good, Ralph. Any comments, concerns? This is Carol's favorite part of the program where we open it up to the general public. She puts her knitting down and comes to the microphone.

MS. MARKUS: Carol Markus, UCLA. Thank you very much.

Not only is there nobody of data showing danger to fetuses or embryos at 500 millirem, there is an extraordinary body of data showing absolutely no

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effect, because of the many areas in the United States and in the world where background radiation exceeds 500 millirem or more from the average of 300 millirem natural background that we have in the United States.

Copper City, Colorado, has a background rate of about 890 millirem a year. Millions and millions of babies are born in these areas. Ιf anything, what we find in these areas is a lower cancer death rate. Colorado, with the highest radiation levels in the United States, is tied for the third lowest cancer death rate in America.

If radiation had any significance at these low levels, we might see something, but we don't. So it is not just that the experiments haven't been done and we are not sure that there is no effect. The experiments have been done on millions and millions and millions of babies, and we know there is no effect.

So if you want to drop your limits by a factor of five, this is not conservative, because we know there is no scientific sense to this at all. It is pure discrimination against women, and male chauvinists, and there is absolutely no validity to this "well, we are just being conservative" routine.

To kowtow to anti-nuclear wackos, because

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you don't have the common sense to tell them off suggests to me maybe you are in the wrong business.

HEARING OFFICER HODGKINS: Other comments?

Go ahead.

MR. MITCHELL: Good morning. Chad Mitchell, U.S. Navy baromedicine and surgery. A couple of points here I would like to point out, maybe tying this morning with yesterday.

I think there are three guiding principles that we need to keep in mind: One, scientific basis; two, a reason to change the regulations; and three, just the practicality. Our prime directive is as low as reasonably achievable. We have all agreed upon multiple times. As far as the scientific basis goes, you would be amazed what happens -- you know, when in doubt, actually read the book. So I think sometimes out of respect for the science that is in publication 103, we then take the leap into the policy recommendations of publication 103.

So yesterday I pointed out that on page 244 it says knowledge of these biological effects is growing, but is currently insufficient for radiological protection purposes. It recognizes the limits of its own science within.

On page 57, for those of you who were

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wondering where some of this 100 milligray, 10 rads, fetal dose came from, page 57 and 103 goes through in detail various birth defects that are not seen below those limits.

So in the science of the report we see information that doesn't exactly follow when they put on their regulator hat and make recommendations that are unduly restrictive.

I would also echo the previous speaker in that we are here to use scientific basis and common sense and not try to give in to activists or any fringe of the population.

The reason for the change: I keep hearing this underlying tone of this international peer pressure where all the other countries are doing it. You know, my mother raised me not to give in to those sorts of pressures, and I think, hopefully, we can practice the same.

We should apply the admin controls. A lot of people are saying, well, we are already safely below these limits. That's great, well done. In certain industries, yes, you can assign someone somewhere else. That's great.

You can provide various controls to keep exposures low, but I would point out that last week

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was the Marine Corps Marathon in Washington, D.C. I have never run 26 miles in my life all at one time. I did not participate, but I am sure people my age did.

Does that mean they should pass a law that everyone my age has to run a Marine Corps Marathon, because some people are capable? No.

The laws need to have a common sense limit, and I think we have seen over and over again, as we lower the limits, we are targeting very highly trained, highly educated individuals who have that skill and get those exposures for good reason, which ties in with practicality, my third point.

We saw yesterday, it is mainly interventionalists who have a long training pipeline and understand the risks of what they do. Now we are seeing in the regnancy realm we would be targeting out other interventionalists as well as technicians -- or technologists, excuse me -- that fall into these ranges.

So you know, we are targeting specific groups when we tighten the screws on these things. I would further point out that, you know, the regulations are not written for the benefit of the regulator. The regulations are written to control the doers. So they don't need to be overly prescriptive.

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Then finally, one last parting shot is just on a philosophical point of view. If I could please have a show of hands, how many people have worn a dosimeter? How many people, either now or in the past? Right. You can put your hands down. Thank you.

For myself, it was a badge of pride. This allowed me to go places that other people couldn't go. Those other people were the members of the general population. Correct? You know, a decision was made that I had sufficient skill and training that I would be issued this thing so I could go around and do my job.

So what does that say when you take it away from another trained professional and say now you are relegated back to the status of a member of the general public? So that is my two cents, worth every penny. Thank you.

HEARING OFFICER HODGKINS: Any comments, reaction with that? Any other comments from the audience? No, Eric, go ahead.

MR. GOLDIN: Well, just a couple of comments, and Carol can correct me if I am wrong. My ancient radiation biology training -- and I know that biology is grays and not black and white, but fetal

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effects, if I recall, are deterministic, which means they have a threshold.

So the threshold, as Dr. Miller has mentioned, is about 10 rem for fetal effects. So if you lower from 500 millirem down to 100 millirem, you are going from safe to safe. There is no net benefit to the fetus.

The difference between a public dose limit

-- I'm sorry, an occupational dose limit of 5 rem or

whatever it is and the public dose limit that is

substantially less than that is because, for the

occupational workers, you can measure the dose and be

assured that the person gets less than the limit.

The fetus in a declared pregnant worker has the dose accurately measured. So there is no real benefit to lowering the dose, because it is known. We do know how much the fetus gets. So there is no reason to lower from 500 down to 100.

HEARING OFFICER HODGKINS: Okay.

Comments? Yes.

MR. SMITH: Leonard Smith, CORAR. I am sort of reflecting on what Carol had said earlier about the risk. One thing that seems to be missing in a lot of these discussions about risk is ultimately we are interested in the lifetime risk, and the doses to

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special populations are typically doses that are gotten in just one year in a lifetime. It is not a dose that is likely to be repeated. Obviously, with a fetus, it is not going to be repeated.

Also, when we get to talk about caregivers, members of the public, nuclear medicine patients, it is not likely to be a dose that is repeated for many years, and so the risk is actually very low indeed.

HEARING OFFICER HODGKINS: Okay. Anybody else? So now Don will go through the questions.

MR. COOL: Yep. And I think we have touched on most all of these questions anyway. So each of these are just an opportunity for any of you to see if there are other things that you would like to put onto our transcript and the record.

We have talked quite a bit already about anticipated impacts. I think one of the things that we heard today that we have not previously sort of specifically focused on was the level of effort that is involved in the RP programs as individuals approach some of these values.

There was also something raised about challenging the limits of some of the dosimetry. Are there any other impacts that have not been raised that

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someone would like to make sure that we have on this 2 record? 3 HEARING OFFICER HODGKINS: Panelists, 4 public? Yes? MR. GOMER: I think we do need to include the legal aspects that we heard, absolutely. 6 7 sounds like that is one of the most logical concerns 8 that I heard this morning. HEARING OFFICER Anybody else from the public? 9 HODGKINS: Thank you. 10 Panelists? Moving on. 11 MR. COOL: The second one, which I am not 12 sure we have touched on explicitly, but there may not be much that you wanted to add in terms of 13 14 implementation impacts on recordkeeping. Now majority of you have suggested that you would wish to 15 current approach, although 16 back and 17 require you to go do retrospective 18 assessments. I am assuming that your view of that as an 19 impact does not outweigh the other issues with regard 20 21 to the level of risk and complications and standard of 22 care, legal issues that have been raised. Any other suggestions that people would like to add? 23 HEARING OFFICER HODGKINS: Ellen? 24 25 MS. ANDERSON: Ellen Anderson from NEI.

1 It is already a level of effort. We already do that. 2 There is no added burden at this point in time. COOL: This question was actually 3 4 asked in part because just occasionally something 5 might happen to the regulations which reduces burden. HEARING OFFICER HODGKINS: Chuck? 6 MR. PICKERING: I think that is exactly what would happen. Recordkeeping burden would go 8 down, because more employees would not declare their 9 10 pregnancy. 11 go ahead, Ralph. MR. MACKINTOSH: As we lower the limits, I 12 am a little concerned about recordkeeping and the fact 13 14 that we do retrospective recordkeeping. We badge people, and we find out six weeks later what they got, 15 and as you lower the limits, now do we have people 16 retrospectively suddenly being in violation after we 17 can no longer do anything about it? 18 HEARING OFFICER HODGKINS: 19 MR. SMITH: Yes. One concern that I would 20 21 have is that, if we lower the limits, we would want to 22 preserve the current ability to use a variety of methods for estimating the dose to the fetus. 23

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calculating a dose rather than measuring it.

example, we might increasingly need to be actually

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HEARING OFFICER HODGKINS: Anybody else?
Colin?

MR. DIMOCK: There may also be a one-time recordkeeping increase just because I know for myself I would be likely to have my staff go and take a quick look at who would have been in violation of this, so that I can be prepared in case that is brought up as a legal issue.

HEARING OFFICER HODGKINS: Charles?

MR. GOMER: I would have a concern if there would be an expectation for the many, many clinical centers, large and small, to expect them to do individual dosimetry on their employees. I think that is unrealistic.

HEARING OFFICER HODGKINS: Melissa, do you want to add to that? Just echo?

MS. MARTIN: I would just agree with it.

I think, you are looking at a very top level group of
people at this table at relatively large centers with,
as the comments have been said, staff to support them.

I think, as soon as you get out into a community hospital where many times the radiologist is the radiation safety officer, there is a consultant physicist that is available once a year. To have those people expected to do dosimetry calculations on

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74 1 their staff is not reasonable. 2 HEARING OFFICER HODGKINS: Yes. 3 SMITH: I think our industry 4 would have the same concern for those pharmaceutical 5 dispensing staff. HEARING OFFICER **HODGKINS:** From the panelists to the public, any comment? Let's move on 8 to 3. Which I think we actually just 9 MR. COOL: 10 touched on, because it was a follow-on in terms of the 11 reduction in the assessment and recordkeeping. 12 unless there is someone who suddenly came up with another idea, we are going to go on to the next one. 13 14 I think some of you have touched on it. I give anyone else an additional 15 just wanted to opportunity, because when you get to some of these 16 levels, you then, in fact, press some of the detection 17 technologies. If anyone would like to provide any 18 observations, either validating that or issues that 19 20 you would see in your area? 21 HEARING OFFICER HODGKINS: Scott.

MR. GOLDIN: Just a real quick one, and I would assume that -- and I haven't read this; I apologize -- the ICRP recommendation, if it was 100 millirem for the gestation period, similar to the old

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recommendation is to spread that out over the gestation period and try to be even across the time period. Is that -- I know that is what the current recommendation is.

If it is, that means you are on the order of 10 millirem per month is what you are supposed to assess, and while we can do that, we change our TLDs on a quarterly.

so you would have 30 millirem, up to 30 millirem roughly in a quarter, and that is certainly measurable. But the electronic dosimeters that are read periodically, you know, for every entry are going to add up to a lot of zeros for your typical job, and then you are going to have a mismatch that somebody who is concerned about their dose is going to wonder about, and you are setting yourself up for some difficulties, as well as the fact that, if the legal limit or the regulatory limit is 100, as I have already mentioned, you are going to end up with an administrative level that is considerably lower than that to make sure you don't approach the regulatory limit.

HEARING OFFICER HODGKINS: Scott.

MR. CARGILL: Just to expand on where Eric was going, we also have to bring into consideration

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the accuracy of dosimetry. Plus or minus 20 percent accuracy, depending on the response curve, the energy levels we are seeing — it would be very difficult to see and to measure that 10 millirem in a month's period, above or differentiated from background. So it could become a very difficult task.

HEARING OFFICER HODGKINS: Colin?

MR. DIMOCK: Yes. I would just like to point out that it would -- Currently, we are doing monthly dosimeters for declared pregnancy so that we can monitor to see if there is anything that warrants a very quick response.

It would force us to go to quarterly dosimeters because of the limitations in the detection technology, which naturally would limit our ability to respond.

HEARING OFFICER HODGKINS: Melissa, then Chuck.

MS. MARTIN: I would just follow up with Colin. For those facilities that have converted over to the new OSLs or TLD dosimetry, you might feel a little more comfortable, and you do get readings below 10, but unless -- as far as my memory says, 10 mr per month is the limit that a film badge will actually be reported in.

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So for those facilities that are doing film badges, you are literally at the detection limit if you change them on a monthly basis, which is standard practice in medical centers.

HEARING OFFICER HODGKINS: Chuck?

MR. PICKERING: There are new technologies out there to get more immediate dosimetry, but they are not NAVLAB accredited, and they probably can't be NAVLAB accredited. So from a technological standpoint, I mean, if we could ever get to that, that will be fantastic and give me more comfort if I could daily monitor a person.

Now that -- Colin is not going to like that, because that is a lot of effort, and I agree, but if I could daily monitor somebody, then I really know what is going on, if you could get to that, and I don't think you can, technologically.

HEARING OFFICER HODGKINS: Okay. Anything else from our panelists? Yes, Kai.

MR. LEE: I would like to thank Melissa for answering or saying what I was going to say. We still use film badges, and 10 mr is just at the limit of detection, and I cannot change to quarterly badging cycle, because we have a very mobile group of people, residents, fellows coming in and out all the time,

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students coming in and out all the time, and I cannot 2 change to TLD because the county doesn't have the money to switch to TLD. So for those two reasons, it would be a big problem. HEARING OFFICER HODGKINS: Okay. Any other comments from the audience? Then there is one 8 more? There is one more, which is my 9 MR. COOL: 10 standard tee-up for: If you've got some data -- I 11 described this a little bit earlier, but this is the 12 second time I will say it. To the extent that you have the information that would allow us to 13 14 distributions and number of individuals that would help support our analysis, we would very much like for 15 you to send that to us after the fact. 16 am sure you didn't necessarily come 17 prepared with that today, but if you've got that and 18 19 are willing to share that with us, that certainly 20 would help us as we went forward in developing our 21 analysis and assessment. But, of course, if you would 22 like to add something on the record right now --23 HEARING OFFICER HODGKINS: Ladies 24 gentlemen? Can you go to the microphone, please? 25 MR. TAKAHASHI: Joe Takahashi, Northridge

2 dose that the mother received on that also in comparison to the fetal dose? MR. COOL: If you have that separation, that would be quite interesting, keeping in mind that 5 I do not want personally identifiable information, but 6 to the extent that you could correlate specific ones 8 for Case A, B and C because you may have only had two or three of them, sure, that would be interesting, 9 10 particularly if it involved interventional or some 11 other situation where there was some shielding such 12 that it might have been a substantial difference. Well, we do double badge MR. TAKAHASHI: 13 14 the declared pregnant female. So that we would have that, I think, available. 15 HEARING OFFICER HODGKINS: Other comments? 16 Questions? 17 We will now take a break, and this time 18 coffee is in the back of the room for those who had 19 requested it yesterday. We aim to please. A three-20 21 minute break. That way it will be 15. 22 (Whereupon, the foregoing matter went off the record at 10:36 a.m.) 23 HEARING OFFICER HODGKINS: So for those 24 25 who were hoping to get a chance to review some of

Hospital. On that data point, do you want to have a

those transcripts, look for those to be available, and if they are not, you might want to just give Don or someone a call to say, hey, did you miss my email, because they have every intention of sending them out.

Okay, let me repeat them one more time. The transcripts will be available for the D.C. meeting on November 15th, for the L.A. meeting, this meeting, November 22nd, and the Houston meeting November 29th. So we will be sending every participant here the link, and you can download them from there.

MR. COOL: And that makes a perfect opportunity to remind everyone that the comment period actually remains open until the end of January. So even though it is coming in over the holiday, when you get an opportunity to think about it, because I know that you will think about it over the various holidays, you still have the opportunity to send in all of those great thoughts afterwards.

With that, let's move to the second component of this, which actually was not on some of the initial discussions which the staff had, but which was raised to our attention as a question. So we are asking for inputs and thoughts on this.

As ICRP had said generally protection for the embryo fetus similar to that as a member of the

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public, they have also made some slightly more firm statements with regard to protection for various categories of members of the public, particularly young children, over the course of time.

So ICRP's public dose limits, as NRC's limits are, is 100 millirem or 1 milli sievert with a special circumstance allowance possible for up to 500 millirem, very short duration type of time frame. remains as the ICRP's public dose limit. However, ICRP has also recommended a tentative age group such as children and, therefore, they would suggest apply that to nursing mothers because of the transfer of many radionuclides through the breast milk, that they should not really be allowed to exceed 100 millirem.

exceptional other words, the circumstance situation really wouldn't be applied in those cases. Now NRC has exactly matching provisions in our public dose limit section, including a separate little paragraph that allows a licensee to apply for an alternative dose limit up to 500 millirem specifically for a limited period of time. licensee has to apply for that. That has to be approved before they can use it, with all of caveats and description as part of the license and

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approval.

The regulation does not in any way limit or delimit or constrain or -- I am not sure of what other word to possibly use in there. It doesn't define the kinds of individuals. It could be any individual member of the public.

So the question that was raised to us was whether or not the NRC should be in some way defining the boundaries under which licensees would be allowed to apply for a higher value, and we have immediately a question here for clarification.

MR. DIMOCK: I just want a quick question.

Do the ICRP limits for children specify that this does not apply to medical doses that they receive?

MR. COOL: Yes. Let me say it in a slightly different way. ICRP specifies that dose limits do not apply to medical treatment or medical exposure. So said the reverse way, but you have reached the same conclusion.

MR. DIMOCK: Thank you. I just wanted to clarify that. I wasn't sure.

MR. COOL: No, but one of the corollaries that I am sure that we will probably get into is the ongoing debate associated with the exposures of other individuals from an individual who is being

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administered. Now that is actually not the topic I am raising here.

I am actually raising the Part 20 topic at the moment. Yes?

MR. GOMER: To go a little bit further, medically indicated procedures versus medical research procedures, because in many medical centers there is clinical research going on involving diagnostic procedures where exposures could be higher than 100 in a non-medically indicated situation. So the clarification is -- I am asking what would the clarification be for what this means?

MR. COOL: I believe that ICRP includes research under approved protocols, which I am sure is what is going on there, considers that similar to a medical exposure and does not apply the limits to that. I believe that is the case.

So with that brief а sort of as introduction, and we have actually sort of already started the discussion, we wanted to raise question as to whether or not there should be any change in the current provisions that NRC has in place for the public dose limits, recognizing that what NRC has today matches exactly the current ICRP recommendations for public dose, but does not

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constrain that to be adult members of the public, as in children or anyone else could receive the special circumstance if it were approved upon application by a licensee.

everything alone; to specify in the regulation that that circumstance would only be considered for adult individuals; or to say the rule is good enough as it stands, but perhaps something should occur in guidance that would basically remind licensees that there would be an extra burden of proof, should they be wishing to enter that space for young children or otherwise.

That is, in fact, a connection to what is already in place in the NRC regulations related to patient release where there are additional information that has to be provided and mechanisms to assure that doses are as low as reasonably achievable, if young children re likely to be exposed as a result of an individual administered radioactive materials and released following that administration.

So with that very brief tee-up, let's go to some discussion.

HEARING OFFICER HODGKINS: And how about, Ralph, we will start at this side of the room today for this issue. No comment? George?

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MR. SEGALL: i think my comments will be 2 substantially similar to when we talk about patient 3 release. So I will pass right now. HEARING OFFICER HODGKINS: Okay. Kai? 5 Leonard? MR. SMITH: I just made a comment that was 6 7 voiced earlier that, when we are dealing with these 8 caregiving situations, it is typically a one-time exposure, and there is just really not a risk basis 9 10 for these restrictive limits. 11 HEARING OFFICER HODGKINS: Thank you, Anybody want to comment further? David? 12 Leonard. Pass. Colin? Eric? Ellen? 13 14 MS. ANDERSON: Ellen Anderson from NEI. Don, I have a question. You are asking us 15 So I would like to ask you for some data. 16 How often do you receive these requests from an NRC 17 perspective? 18 MR. COOL: I don't think we have ever 19 20 actually gotten one. 21 MS. ANDERSON; Okay. So it is not --22 MR. COOL: But there has probably been a Okay, let's clarify. My answer is in the 23 24 context of the licensee-specific application under

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Part 20, not related to patient release.

Т	MS. ANDERSON: All right. So do you know
2	how long this regulation has been in the books?
3	MR. COOL: It was implemented in '94.
4	MS. ANDERSON: Okay. So my vote is what
5	are we I mean, if we haven't had a request, then
6	why bother changing the regulation at this point.
7	Just leave it in the books as is.
8	HEARING OFFICER HODGKINS: Comment? Yes,
9	Lynne?
10	MS. FAIROBENT: I guess I would also,
11	though, have to ask Bob, because NRC only has 14
12	percent or roughly 13 percent of the materials
13	licensees: Are the states getting requests?
14	MR. GREGER: Robert Greger, CRCCD. I
15	don't know the answer to that, but I suspect that they
16	are not.
17	HEARING OFFICER HODGKINS: With that, Rob,
18	it is your turn to comment. Any further comment?
19	Chuck? Charles? Richard? Lynne? Donald? Scott?
20	MR. CARGILL: I am always good for at
21	least a one-liner. This is, obviously, more of a
22	medical side issue than anything. Industrial
23	radiography, we don't employ children.
24	My question would be: What would your
25	definition of a child be? That aside, in our world at

my company, our internal rule is anything to do with children. We have been asked to conduct radiographic operations near a school. We will shut it down. We will not make the exposure during school hours. We make every attempt to avoid it.

My personal belief here would be no change at all. Let industry, whether it be medical or power plants or whatever, deal with keeping it internal, make our own little internal rules.

Since you haven't off the top of your head had any of these types of specific requests, and I have to probably go with Mr. Greger, I would suspect that none have been made. if they are made, handle it on a case by case basis.

HEARING OFFICER HODGKINS: Okay.

Comments? Rob and Chuck. Chuck first, then Rob.

MR. PICKERING: i was just going to say, you have the power over denying those applications, of course, as well. If someone did apply and you wanted to be consistent with ICRP, you can make that -- That is your call.

MR. COOL: In fact, that is part of why we put this C version up there, because one of the things, consistent with some of the other things we have done, because it is an application, because we

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can provide some guidance, we have the option to just add to the guidance the fact that these recommendations are out there, and that, therefore, the staff would expect some greater justification if the analysis showed that more sensitive individuals were to be involved.

So there is that possibility, which makes this one a bit more unique than some of the others. But thank you for putting that out.

HEARING OFFICER HODGKINS: Rob?

MR. GREGER: Thank you for saying that, Don, because I was going to come back and say I would like to make a comment, and that comment was that, if there are none, there has been no impact on us. Why would we not want to be more conservative and take option C, which acknowledges that there sensitive populations and that we may want to be more careful in allowing any deviations, any increases in we doses, if talking about sensitive are populations.

HEARING OFFICER HODGKINS: Panelists?

Scott, did you want to --

MR. CARGILL: Yes, I think I will. We have kind of --

HEARING OFFICER HODGKINS: Use your

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MR. CARGILL: Just a little bit?

HEARING OFFICER HODGKINS: Yes, because it is getting noisy over there.

MR. CARGILL: all right. We have kind of circled around this and brushed on it a couple of times already now. It is interesting to me, and I consider myself like the lowest tier guy here when it comes to professional rad safety. Even we, rad safety professionals, are afraid of it, and I don't mean to pick Robert there, but from a regulator's standpoint you are entrusted by the public to ensure public safety. We all understand that and respect that. But to sit here as a group of professional rad safety types, why would we approach this let's be more let's be more scared of conservative, promote more fear?

We are back to show us the data that says this is a bad thing. A child -- Let's take an eight-year-old child. Five hundred millirem, is that a detrimental effect? Five hundred millirem over a year's time? Five hundred millirem over a month's time?

Now, obviously, at a medical side of the issue, if treatment is necessary and this child is

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going to receive 400, 600, 1r, that is up to the doctors and the regulators and everybody to deal with.

I suspect it will be unanimous; if they need that procedure, they are going to get that procedure.

The rest of the world, the rest of the side industries, nuclear power plants, my side, the industrial radiography, we are going to take it upon ourselves. We don't need a regulation to tell us not to nuke a child. We are going to make sure that doesn't happen.

So -- but it does kind of make me curious interesting thought. and Why are the we, knowledgeable individuals, always skirting back let's be more conservative? I think that is pretty much already built into rad safety. Do we need to be if conservative, and we need to conservative, we are back to the argument, what were we being before, unsafe? That would be my question to the group as a whole.

HEARING OFFICER HODGKINS: Group as a whole, do you want to respond? Rob?

MR. GREGER: Robert Greger, CRCCD. Not to pick on you, Scott, at all, but if I take your comments and extend them, what I could come up with as a conclusion is why do we have any regulations at all

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for radiation safety -- for radiographers, I will limit it to, seeing as that is what you are representing -- because your statement is the RSOs will ensure that what they are doing is safe.

I think you would acknowledge that we do need regulations. The question may be as to how precise and at what level those regulations should go to. And that kind of brings me to an issue that I wanted to mention and haven't yet.

That is, there have been a lot of discussion here about what is safe, and the fact that there isn't any demonstration that practices are unsafe currently and, therefore, there is no need to change the regulations.

I guess I have two comments on that. The first is that, while I respect everybody here for their achievements, their positions, their knowledge, their comments, I am not sure this is the appropriate body to come to a conclusion on what is safe and what isn't on a scientific basis. Not that the people couldn't come to that conclusion, but I don't think that this is the forum to be able to do that.

The second comment is that the basic premise of the radiation safety regulations, or one basic premise is that they are based on LNT. Like it

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or not, that is what the NRC regulations are based on, as an assumption.

If that is correct, if the NRC maintains that as a basis, you know, then the arguments of things being safe as demonstrated by experience or by

HEARING OFFICER HODGKINS: Should we open it up to the audience now? Okay.

various studies seems to be moot.

MR. CARGILL: I have to agree wholeheartedly. Regulations -- We need regulations. I approach regulations not as the rules that I have to play by, but partly as guidance on how to perform properly.

We have regulations for the same reason we have unions. There are people who will go too far one way or another. Regulations set the bar for the entire group. We expect -- Like you hit on, maybe we aren't the exact group, but there should be a group out there.

We have an NRCP, IRCP. We have IEA, the NRC. We have a whole pile of groups out there in this world, a lot more knowledgeable than I am on this subject, bringing these pieces together.

In our case, we have hit on it a couple of times, and I just hit on it partly from your comments

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and partly the rest of the body. Is there data showing it? Yes or no. I don't think that, even if there were a preponderance of data showing one way or the other, even we as professionals -- we tend to shy toward the more conservative by nature. That, to me, was an interesting point.

Again, here on this particular question, this particular issue, you haven't had any requests off the top of your head. Rob didn't remember any or think of any. There is not a whole lot of call one way or another to change it or not.

I am always for let the industry regulate itself when and where possible. If industry is not doing it, that is when regulations need to be brought in or tightened up in some way.

HEARING OFFICER HODGKINS: Donald?

MR. MILLER: I am not a regulator, and I am not really a radiation protection professional. I am just a simple interventional radiologist, but I don't think it really is a question of what is safe, because really nothing is safe. There is no safe bathtub. There is no safe swimming pool. There is no safe car, etcetera and so forth.

What we are just, I think, trying to do is to say that, if you are going to increase the

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regulatory burden, it should be done with an end in mind, and the end in mind should be to increase safety or reduce risk; and if there is no scientific evidence that the proposed regulation will increase safety or reduce risk, then it is not reasonable to impose the regulation.

HEARING OFFICER HODGKINS: Ellen?

MS. ANDERSON: I would like to modify my vote just a little bit. I have been listening to people talk. I think the best option is A and C, Alpha and Charlie.

There is reason no to change the regulations as they are today. However, if NRC would like to develop a regulatory guide, and regulatory guides provide acceptable methods for implementing the regulations, they can go ahead and information, exactly what they want in the application, place it in the regulatory guide. So it would be both Alpha and Charlie.

HEARING OFFICER HODGKINS: Thank you, Ellen. Dr. Miller.

MR. MILLER: I would like to second that, and I would do that, because while I cannot conceive at this point any reason why anybody would need to apply for such an exemption, that doesn't mean that no

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such reason exists nor that no such reasonable reason 2 exists, and the guidance is a good way to put it. 3 The guidance should make clear that the bar is very high for exposing sensitive populations to the higher dose, but not necessarily so high that it is completely unreachable, because as I say, there may 6 be some conceivable appropriate reason to do that. HEARING OFFICER HODGKINS: Ralph? We will 8 9 start with you, then George, then Colin. 10 MR. MACKINTOSH: Correct me if I am wrong, 11 but as I read C, it says that sensitive populations may not be included. It doesn't say there is a higher 12 It says they must be excluded. 13 14 certainly rather say there must be greater proof and a higher standard rather than saying they are absolutely 15 excluded. 16 17 MR. SEGALL: That was my comment exactly. I think C reads differently than what you understood 18 19 it to read. HEARING OFFICER HODGKINS: Colin. 20 21 MR. DIMOCK: That was also my comment on it as well, though I was going to add that this seems 22 to be a pretty low important subject. So my opinions 23 24 are very -- not strong on this. 25 HEARING OFFICER HODGKINS: Can we take it

from the public? How about -- to the microphone.

MR. HEDGER: Troy Hedger from Alpha Omega Services. One of the things -- I mean, we have the potential for what we do to expose a lot of people quite a bit, and we take extra precautions to make sure that whatever hospital we are working in or whatever site we are working at that no one is going to be exposed.

So I am wondering why have that exemption at all? Typically, I am the opposite. Typically like, no, don't regulate us more. But I am looking at that from a radiation safety officer perspective. I would never need that specific approval. But also, you know, if that is sort of given carte blanche to somebody. Hey, just in this area, I always want to be able to expose certain people to this particular amount of radiation, as opposed to, hey, there is limit of 100.

You can always call your regulator and get an exemption for a particular time, a particular circumstance, but it just seems a little carte blanche to -- you know, just a comment. So I wouldn't mind if they got rid of it or not.

HEARING OFFICER HODGKINS: Okay. Carol?

MS. MARKUS: The same embryos and fetuses

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that grew up in the high radiation area become young children and older children and adults, and they have been extensively studied without showing any harm at these 500 millirem and even far higher doses.

When you have a theory and then you have data accumulating, and the data don't fit the theory, in science we all learn to throw out the theory and get a better theory that fit the data.

Yes, Bob, the NRC does use LNT, but the data don't fir the LNT, and maybe it is really time that the NRC led the First World and said, no, we won't use the LNT. At these low levels, there is no effect. We may have a linear effect above 20 rem or whatever number you can find harm at, but nothing at these lower doses.

The second thing I want to say is that, when I wrote the petition for the 500 millirem patient discharge rule, it was using that Part 20 section where you petition the NRC for an exemption for members of the general public, and the petition was written exactly as detailed in Part 20.

You expect the NRC to make a decision. It took six years of open warfare, as the physicians and many of the radiation safety people well know. Maybe that is why nobody else has ever tried it since,

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because it is suicide. You know, you are going to spend years of your life arguing with people. But if you get all squishy about young children and decide, well, just to be conservative, even though we know that the data show no harm at all, and let's lower it, what you are basically doing is throwing out the 500 millirem patient discharge rule.

The same thing would happen with the pregnancy situation. A woman of childbearing age in a home could be pregnant, and then all of a sudden, you have thrown this whole thing out.

So all these patients now are back in the hospital at enormous expense for no good reason, and no data showing that there is any relief of risk to anyone? This is a very dangerous thing to do, and I really suggest that you not change dose limits to young children to make them at 100 millirem.

It is just so absurd when you look at what natural background variations are. To muck around at these low levels -- it just doesn't have scientific backing. Thank you.

HEARING OFFICER HODGKINS: Thank you. Any comments from the panelists? How about, Chuck, I think we were at you as far as going around the table. Anything to add?

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MR. PICKERING: Again, I agree with Dr. Markus on that in terms of just the pure science of it. This really is ridiculous, I think, at that point, at that level.

HEARING OFFICER HODGKINS: Charles?
Richard? Lynne? Donald? Scott? All right. Rob?

MR. GREGER: In listening to what Troy had to say and thinking about that for a moment or two, I guess I would just like to throw out some generic experience that we have all had and some personal experience that I have had for just people's consideration.

We have all just gone through an election period when we were bombarded by half-truths, sometimes not even half-truths. That is the generic observation.

My personal observation is that, if someone wants to distort and tell a half-truth about what our regulations -- let's say what the NRC regulations with respect to dose limits for members of the public say, they would say the NRC limits the public dose to 500 millirem a year.

Because that option exists, whether it is ever, has ever or ever will be ever utilized, because the regulation says this, that is in my personal

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experience the half-truth or less that is propagated to members of the public, community members who really have no understanding on their own to be able to determine who is being truthful.

So if indeed we have never -- this provision has never been utilized, maybe it is time that it should be removed. It has been stated, there is still the general provision in Part 20 to get an exemption from any of the Part 20 rules/regulations.

HEARING OFFICER HODGKINS: Comments?

Questions? I think we are done with that. Opening it

up to then the general public as far as comments,

concerns, amplification, modification.

I think we are ready to move on to the questions.

MR. COOL: Yes, and I would like to start with a question that I know isn't on one of the slides, which is the extent to which other individuals around the panel in the room here would take this opportunity to actually say it has never been used, it is not necessary, remove it from the regulations, and what the impact, if anything, would be associated with that.

We have had a viewpoint, and perhaps

Robert Greger would like to elaborate a little bit

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more, because that is another possibility, although we didn't put it on the screen.

MR. GREGER: I just -- I think just a fine correction. I am not sure that I expressed that as my viewpoint as much as asking a question for everyone to consider and decide for themselves.

HEARING OFFICER HODGKINS: Colin?

MR. DIMOCK: So Dr. Markus tells us that this has, in fact, been used once in one -- for the people sitting around this table, one very important situation. Is that correct? Do you want to comment on that from the NRC's perspective?

MR. COOL: It is certainly true that we received a petition for rulemaking. It is true that there was a lot of time in debate, not only in actually promulgating the rule but to this day about the application of the rule, specifically related to the release of patients following administration of radioactive material, 10 CFR Part 35.75. That is certainly true.

MR. DIMOCK: So if we were to vote to -not that we have the power to do that, but if we were
to remove this entirely, what would the mechanism be
for making that change if another situation like that
came up, in your perspective?

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MR. COOL: The same mechanism that was utilized then. There could be a petition for rulemaking. Likewise, any individual licensee could apply for an exemption or a license condition.

I think Bob Greger noted, and I would reinforce, there is right at the very end of Part 20 a provision that says that a licensee may always apply for an exemption from any or all of these requirements, which would be granted if the Commission so chose upon a review of the request. There's always those opportunities.

What happens is that, for places where we think there might be ones and for which there might be some boundaries within which that is much more likely to be acceptable, specific inclusions are placed in the regs, and there's lots of these.

The question that I think Bob was raising was: If no one has ever used it absent this case -- and we are not talking about any change of 35.75 here; that remain on the books as it stands -- whether or not this needs to continue to be present and foster, if I understood you correctly, the uncertainty because people would think, well, it would allow this, or whether all of this is sufficiently low in the noise that we should be moving on to constraints. And

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several people are now nodding their heads up and down. Okay.

HEARING OFFICER HODGKINS: Colin, did you want to add?

MR. DIMOCK: I see that Dr. Markus is standing at a microphone. So maybe I will let her go ahead.

MS. MARKUS: You know, as I recall the last Part 20 redo, the reason the Commission dropped the public dose to 100 from 500 did not have anything to do with harm. It has to do with achievability and a decrease of the overall public dose and, therefore, a theoretical decrease in cancer rates, if you believe in LNT. But it did not consider 500 millirem to be in itself deleterious, and that is why it put the takeout clause in there.

retaining the 500 millirem limit, then let us know what it is, and we will consider it. So I don't recall that NRC ever thought that 500 was a safety limit that was no longer safe, but just that the 100 level was achievable, and less is better. If you believe in LNT, then less is better, and we should wipe out all radiation. I mean if you take it to its logical extreme.

So it wasn't -- Don, you were certainly a part of this. Wasn't that the thinking at the time?

MR. COOL: Yes, in part, and I am going to suggest no in part, and here I will give you my personal opinion. I will take off my NRC hat at the moment.

What you saw there was a reflection of the fact that we knew that the risk levels were changing. We already knew that the revised recommendations moving internationally were bringing the recommended level for members of the public down, and we could build it into the rulemaking process.

We did not have a similar opportunity in the occupational area, although that revision, in fact, was lowering the dose already, because it was up to 12 rem per year occupational under the 3 rem per quarter, 5m minus reg. So in a sense, it certainly was something that could be achieved, but it also was a recognition of the changing risk levels and a determination of what made an adequate protection limit, plus a law.

That determination was made for the public. It was not made for occupational, and we are in a situation now where everyone is saying from an occupational standpoint, you no longer need to make

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any other changes. Yet that was part of the argument that was made for public exposures at the time of the rule.

HEARING OFFICER HODGKINS: Yes?

MR. PEDERSEN: Roger Pedersen, NRC. I, too, have been around for a couple of years, and was around back when we made the major change to Part 20 back in the early Nineties.

My memory is a little different than what was just expressed. I don't think that we changed from 500 millirem to 100 millirem because it was achievable. I think we changed because there was the changing recommendations coming from the ICRP, and it is my memory that the reason we put this clause in is because there was some uncertainty as to whether it was achievable by all our licensees, and this was the out in case there was some unforeseen impact that changing from 500 to 100 created.

So the fact that nobody has ever used it, I guess, goes back to what Bob was talking about.

HEARING OFFICER HODGKINS: Eric?

MR. GOLDIN: Eric Goldin, Southern California Edison. I will take off my Edison hard hat and put on my philosophical hat, and just say that I think we ought to leave the provision in place,

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because just the term exemption is kind of creepy sometimes.

My recollection is 50 or 20 years ago the rumor was that the Chair of the Commission said, because of criticism from Congress, there would be no exemptions to the rules, and I know that I have spoken with a state regulator in the past because of criticism from anti-nuclear folks, that asking for an exemption was not a recommended avenue.

So having a provision is a lot easier -- A provision in regulations is a lot easier for management to swallow than saying I am going to go ask for an exemption from the regulations. It is just creepy.

HEARING OFFICER HODGKINS: Ellen?

MS. ANDERSON: I see a correlation between this provision and occupational exposure, and that is the planned special exposure. I understand that that has never been used as well, unless it has been -- I know it has not been used in the power reactor sector.

So we do have precedence or whatever, and I know we haven't even talked about whether we would remove the planned special exposure from the regulations. I know it is in there. I assume we are going to keep it in there. Why not just keep this as

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MR. COOL: For the record before we go on, there have been at least a couple of instances that I have become aware of, of planned special exposure in the material side of the house associated with capturing and preparing for disposal of rather large sources.

HEARING OFFICER HODGKINS: Okay. Richard, then Donald.

MR. BURKLIN: I was just going to say, Eric, we have a number of exemptions, and they all pretty much sailed through.

HEARING OFFICER HODGKINS: Donald?

MR. MILLER: The argument has been made that, because this particular provision has never been used, we don't need it. I would just remind you that almost certainly when you were a child, at some point your mother said to you never say never.

HEARING OFFICER HODGKINS: Robert?

MR. GREGER: Just to clarify, it is not simply that it has never been used. It is that there is another mechanism within the regulatory framework of 10 CFR Part 20 for doing exactly what this provision would do.

HEARING OFFICER HODGKINS: Okay.

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COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701 Comments, questions? Back to the audience, comments, questions? Move through then the questions, I think.

Yes? I'm sorry, Lynne.

MS. FAIROBENT: Sorry we are dealing with an issue where they again -- and I had to step out while Melissa was on the call, though. We were both supposed to be on.

If you are referring to an exemption request as the alternative, I have been in numerous — and I will follow up with what Eric just said. I have been in numerous NRC meetings over the years where it is clear that the intent is not to regulate by exemption, and unless there has been a recent policy change that I am not aware of, that is the Commission directive that is in place, as far as I know, and maybe — I see our friend from Region III shaking her head back there agreeing with my statement.

I am just not -- You know, regulating by exemption is not a good way to do regulation. We either regulate. There is a basis for the regulation, and there is a basis for a rule, or we shouldn't have to request an exemption to do something, whether pro or against.

So I just don't think that is consistent with Commission policy.

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1	HEARING OFFICER HODGKINS: To the
2	microphone.
3	MR. HEDGER: Yes. I am sorry. I am going
4	to have to disagree with you, because the regulations
5	they try to take everything into consideration, but
6	they can't. I mean, there are times and there are
7	situations that the regulations can't account for.
8	That is why you need exemptions.
9	If the NRC If you're nodding your head,
10	saying you don't want to give exemptions, I would be
11	really disappointed, because there are We need
12	those.
13	MR. COOL: Can we have this on the record
14	on the microphone, please?
15	MS. FAIROBENT: I will follow up, because
16	I think she was saying impersonally what I was going
17	to say.
18	It is not that an exemption should not be
19	granted in a special circumstance, but the general
20	rule of thumb is that we should not be regulating by
21	exemption, that it should have to be a special thing.
22	We already have a provision. Why take it
23	out of the regulation?
24	HEARING OFFICER HODGKINS: Any other
25	comment then, further comment on that? Okay. So
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moving through the questions.

MR. COOL: Moving through the questions, I think, very quickly, because I am not sure that there is any reason to prolong this discussion. I don't think we have identified any particular impacts to limiting the applicability. We have actually had a discussion about whether the whole provision was even necessary.

I think what I heard was that NRC might wish to consider elaborating on the guidance, and that that was clarified as what kind of threshold of demonstration was necessary, not that it simply wouldn't be considered. I am seeing some nodding of heads up and down. So I say that again for the record, since we are not video-transcribing this. We get a thumbs up from the transcriptionist. Thank you.

Any data available -- As I said, I wasn't aware and I don't think anyone else is aware of the criteria, as long as we are staying outside of the patient release.

That finished that particular discussion. We would see if anyone else had anything -- last things they wanted to add. Otherwise, I think we have wrapped up this topic.

HEARING OFFICER HODGKINS: Terrific.

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1	Anything else anybody wants to add to that discussion?
2	With that said, it looks like we are a little bit
3	ahead, and then yesterday there was some difficulty
4	with lunchtime, because there is only one place.
5	So what I would suggest is there are on
6	the back table some restaurants that were recommended,
7	but also the concierge can direct you to some of the
8	fast food restaurants around here if you need to just
9	get out for a moment, but we will then extend lunch
10	for an hour and a half or hour-15. Okay, let's do an
11	hour-15, because there was some constraints.
12	MR. COOL: So you are suggesting that we
13	would come back at like 12:30?
14	HEARING OFFICER HODGKINS: Twelve-thirty.
15	MR. COOL: Or 12:40. I'm asking the
16	question. Okay, 12:45.
17	HEARING OFFICER HODGKINS: Twelve-forty-
18	five. We will see you all at 12:45. Thank you very
19	much.
20	(Whereupon, the foregoing matter went off
21	the record at 11:22 a.m.)
22	
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AFTERNOON SESSION

12:47 p.m.

HEARING OFFICER HODGKINS: Welcome back, everybody. I hope you had a enjoyable lunchtime, and we will be closing shop here, hopefully, promptly, and you will get out of here on time.

We have two more issues -- well, really, one more issue, and then opening up for dialogue in the end, and at this point I think this is the moment we have all been waiting for. At least Lynne has said several times she is saving a whole lot for later.

So with that, I am going to turn it back over to Don, and he will talk about incorporation of dose constraints.

MR. COOL: Okay, thank you very much. Welcome back.

So this is the area that several of you have been mentioning several times through the discussion. What I want to do is spend, actually, a bit more time than I have on some of the others, giving a little bit of the background and discussion.

This is the area which is under active international dialogue now in terms of the concept, exactly what it means, exactly how it might or might not work within a regulatory structure.

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So unlike some of the other places where there is 15 or more years of implementation and everybody else has done it, we are not in that role here in this part. So that changes the scheme just a little bit.

The international recommendations: ICRP103 places an emphasis on optimization in all exposure
situations. That is, in fact, the biggest single
shift, if you will, in the philosophy in publication
103, at least from my personal standpoint, is they
move to a whole situation based approach and a
consistence approach saying in every single exposure
situation, you should be optimizing protection, doing
the best you can in the situation.

Now recognize that the word optimization is what the international community uses for the whole process associated, reducing doses as low as reasonable achievable, taking all the factors into account.

That is what they mean by optimization. Rather than simply saying ALARA, they refer back to optimization or occasionally the process of optimization, and even the difference between those two words has been subject to debate, etcetera, etcetera.

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Now the next piece that went along with placing an emphasis on optimizing protection in each situation was saying that process and the planning needed to be have some boundaries associated with what would be an acceptable range of options that you would consider in that process, and constraints were intended or are intended to be the planning values that get used in that process.

Now typically, and for ICRP, they express protective in different it in terms of dose situations, although theoretically it wouldn't necessarily have to be in those. It could be much more operational quantity translated as you look at your particular activity. But the idea was anytime are trying to improve protection, there certain boundary conditions that should be in place around your optimization process, so you are not too far out of line.

You have good practices from other things.

You want to make sure that you are not exceeding the dose limits, etcetera, and those are boundaries, and that is what constraints were supposed to be.

In the long process of developing the ICP recommendations, there was a lot of dialogue on that, a lot of back and forth, because almost everybody

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initially reacted and said, gee, cracks like a limit, doc. Sounds like a limit. How is it not a limit?

So there was an ongoing dialogue. ICRP's statement was that these are prospective values, planning values, not limits, that an exceedance of the planning value should not, in and of itself, be a regulatory violation. You should be using it prospectively. You should be looking at what you intend to do, plan, set up your protection system, and perhaps use these to help benchmark how well you are doing against your plan, but not serve as a limit in the classic sense of regulatory limits.

As I said, t here has been quite an ongoing dialogue about that, because there's still a lot of people who say, hmm, sure does sound like a limit unless you are really, really careful about how it is described.

The IAEA in their basic safety standards - this is from the draft that is currently under
discussion at IAEA. So don't take this slide back and
think you have final text of the IAEA basic safety
standard. It might still change.

I tried to highlight a few things. One:

It overall said the regulatory body needs to establish requirements for optimization. The United States has

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some of those. To require documentation -- well, all good regulators should require documentation. Okay.

Establish or approve constraints or the process for establishing constraints, as in the regulators should be setting up some system as part of the planning and documentation of the optimization process that guides them. It doesn't say that the regulator has to establish them.

There were some people who said, government, tell me what to do. But rather, they could in certain circumstances, or approve that which a user would propose, or simply approve a process or some other mechanism that a user might use. So this is actually sort of flexible, but sets a framework that says you should be optimizing, you should be doing planning, and there should be some planning values, to use a different set of words.

The European Union/European Commission similarly says that dose constraints should be established. This is referring to users, workers and members of the public. Then a lot of text here which I am not going to attempt to try and read to you, but note that they describe it as an operational tool in cooperation with the employer and the undertaking, under supervision of a competent authority.

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By the way, in the European Union, undertaking means somebody who is doing the work. So if you are a licensee in the European Union, you are an undertaking. That is the terminology that they use in that process; and similarly, for the public that there be some constraints and ensure compliance with the dose limit and the sum of doses from all of the different authorized practices.

Both of those are draft documents. Neither one has been approved. They are in the process, but it gives you an example of some of the directions that are going on internationally right now.

NRC regulations today, in fact, have the word constraint defined, and there is a constraint within the regulations. Now overall, starting at the beginning, licensees are required to develop and document a radiation protection program. You are all familiar with that. That has been in place a long time.

Licensees are required to use procedures and engineering controls to achieve doses that are ALARA. It doesn't actually say planning or anything like that, just says use procedures and engineering controls.

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We do not specifically explicitly require a licensee to establish any planning values in their RP programs or their ALARA analysis, although most all of you do, because it is sort of how you go about things. It is sort of the industry practice these activities.

So many of you do it, but it isn't specifically required by the regulations.

A constraint is simply defined as a value above which a licensee action is required, and the constraint that is in our regs today is for airborne effluents for nonreactor facilities, and it got there as a result of a fairly long set of interactions between the NRC and the Environmental Protection Agency to try and avoid dual regulations of airborne effluents under the Clean Air Act and the Atomic Energy Act.

EPA, when they looked at NRC programs and were looking for something that they could hang their hat on so that they didn't have to issue separate regulations for the Clean Air Act, looked at the reactors and said, okay, there is all this sort of stuff for ALARA, for effluents and Part 50 Appendix I for all the planning and effluents. That is a sufficient regulatory basis.

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On the material side, there is no comparable thing. NRC -- we don't quite see how that would work and assure that things are very, very low. As that process went on, this thing entered into the regulations to avoid that dual regulation.

The actions required by the rule re to report if the value is exceeded, and to take corrective appropriate actions to return your below the constraint level. effluents to That actually goes beyond, or can be said to go beyond, what ICRP was defining as a constraint, because it begins to look and behave a bit like a limit in the sense that it requires you to take actions to get back below it.

It is not simply an analysis, and it is not simply prospective. But on the other hand, it does match up to the extent that having 11 millirem in your airborne effluents is not, in and of itself, a violation. The violation is if you don't tell us, and you don't do something about it.

So it is a mixture of what is now ICRP's view of a constraint, recognizing that this was put in place a number of years ago, long before Publication 103 came out and the more recent discussions of the issues.

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So as we start to look at the options, I would like us to explore what the concept is, how the concept could work in various situations, what might be pieces of the concept, and it doesn't necessarily mean that, just because NRC today has defined a constraint and has used it in a certain way, that that needs to be how the group might see things working under some future model.

So don't assume that there has to be a report. Let's debate that subject. Don't assume that there has to be actions to get back below it. Let's debate that subject. How does the idea of planning values, how does the idea of more explicitly requiring planning fit in with the radiation protection program, and how might that, as a couple of you have already suggested -- does that provide a mechanism for helping increased alignment demonstrate an with international recommendations, perhaps at least in terms of the outcomes achieved?

So, of course, there are always several different options. You could say, well, if it is an industry best practice, there is no reason to make it an explicit requirement of the requirements; don't bother changing the regulatory structure at all.

Don't add constraints or some other

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terminology or requirements to the regulatory some changes to specify or add licensees have to establish a constraint, or some other word, and use that as part of the radiation protection program and implementing the requirements for ALARA; or as was suggested at one point, so open for discussion, you could conceivably not only say you have to establish and use planning values, but those planning values should not, for an individual over the course of an entire year, result in planning for people to be above 2 rem per year or some other number, thereby more explicitly including a numeric value which might demonstrate increasing alignment.

It doesn't necessarily mean you would pick two nor does it necessarily mean that two is the number that you would want to use in all cases, but sort of a magic upper boundary for some demonstration of increased alignment.

With that, Dan, there's lots of room for discussion in this. Let me just reemphasize, don't make an assumption that things have to behave exactly as they currently are written, because this is an opportunity, and this is a dialogue.

HEARING OFFICER HODGKINS: Just before we get to the dialogue, is there any clarifying questions

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1	with what Don just presented? How about that, so
2	everybody seems to understand it, and no clarifying
3	questions from the panel? Colin?
4	MR. DIMOCK: Colin Dimock, UCLA. Would
5	In the case of special groups, would there be an
6	opportunity to set optimization levels above the
7	current 5 rem per year limit?
8	MR. COOL: I am not quite What I
9	thought I heard you say was optimization levels above
10	the limit. Of course, that would violate the limit.
11	I don't think that is what you actually intended to
12	say.
13	So can you try me again?
14	MR. DIMOCK: No, it is exactly what I
15	intended to say.
16	MR. COOL: Oh, all right. I guess I would
17	have to say that I wouldn't expect you to set planning
18	values that would put you in violation with another
19	regulatory requirement.
20	HEARING OFFICER HODGKINS: Okay. Any
21	other clarifying Are you done? I'm sorry, I didn't
22	mean to cut you off.
23	MR. DIMOCK: That answers my question.
24	HEARING OFFICER HODGKINS: Yes? Go ahead,
25	Leonard.

MR. SMITH: Isn't there a possible exception, that you might have a license condition that gave you a waiver from the regulation? So if there was a limit, you might have a wavier.

MR. COOL: If you had a specific license condition that established an alternative set of criteria, then that is your license basis. While I was -- All I was trying to reflect was that I can't quite imagine you deliberately planning in such a way that you would be outside of your license basis, at least as a starting point. But you can discuss a little bit more where you think you were going with that.

HEARING OFFICER HODGKINS: Again, I don't want to get into the discussion as much as just clarifying the presentation. All right? Ralph?

MR. MACKINTOSH: I have great difficulty with the word optimal. Does optimal still have space optimize something as a for reasonable? When I mathematical function, there is no room. If I have optimal efficiency, I regulation may have no if I have optimal protection, I may have whatsoever. no room for any radiation. If it is optimal for me that the Yankees win the World Series, it may be totally not optimal for you.

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It is all -- Depending on what variables 2 you include and your point of view, it is an extremely subjective word. MR. COOL: Very true. In fact, there has 5 been an enormous debate about that in the IAEA as they have been developing their basic safety standard. 6 ICRP's definition of the term, basically, 8 then reads as reducing exposures as low as reasonably achievable, economic and social factors taken into 9 10 account, the classic phraseology that we use, 11 driven to lowest dose or some other single function. Most of the discussion in IAEA has not 12 been that optimize means that you have found 13 14 ultimate solution and it never changes, but for the given set of variables, the best set of operation, and 15 that you then implement it. That is the way those 16 discussions have been held. 17 Now a different question here is whether 18 the NRC decides to use the word optimization, because 19 20 the regulations at the moment do not. So that is yet 21 another piece that we could add to the equation. 22 HEARING OFFICER HODGKINS: Yes, George? MR. SEGALL: A clarification for C: 23 that imply that exceeding your own constraint 24 25 regulatory violation?

MR. COOL: It depends on how you would construct the condition. That is when I am going to hold up the mirror, because one way to describe this - I am not advocating this one way or the other, but one way of describing this is saying, licensee, you have to establish a planning value, and if you exceed the planning value, then you need to go figure out what happened, and otherwise, but the only violation that might be associated with that is if you blew through it and did nothing about it. That is B.

C would simply -- C is simply an option which suggests, in addition to saying that you say that you need to do that, you sort of put a boundary on the numeric value over the course of the year that we would expect people to use. Ιt is one more step, but it doesn't necessarily mean that two or would violation, otherwise be а unless you deliberately decided to plan at some larger number, and that is the way the regulation was written. that is part of the discussion here, pros and cons and implications of different pieces of that. Does that help?

MR. SEGALL: I will summarize what you said by saying it would be a violation.

HEARING OFFICER HODGKINS: Colin?

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MR. DIMOCK: Yes. I am trying to find the space here in the language between "set ALARA limits," which we already do, and make these limits that you have to meet. I am not finding a gap between those two concepts.

What I am hearing is it wouldn't be a violation to exceed these limits, but you have to get back below these limits by doing something or it is a violation. That is sort of what I am hearing. Am I missing something?

MR. COOL: Let me try a little bit first.

The way the current is written for airborne effluents, that is the way it works. But I am suggesting to you that in this discussion, we don't have to assume that is the way it works.

We can simply assume that you have established a value. You use it in planning, and that you need to do some things in evaluating your program, but it doesn't necessarily mean that you have to bring it back below if you have a justified set of reasons to document it, because you have a number of cases in certain situations, this individual is going to be there, and that is the best that can be done.

So that option, I believe, is open as we debate the possibilities here.

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HEARING OFFICER HODGKINS: Rob

MR. GREGER: Yes. Don, I think you were talking about licensee self-imposed optimization at this point. I think the other possibility is a regulation along the lines of the airborne effluent constraint rule where there would actually be a regulation with, in this case, a 2 rem constraint.

Now unlike the airborne effluent rule, which was meant, as you indicated, to get the EPA out of dual regulation of materials licensees -- and because of that, I am guessing that there was a push to have corrective actions being needed to get back down below.

I this particular case, I could see very well that there would be no corrective actions required, but in my mind, there would be a self-evaluation by the licensee as to whether or not this is a justifiable dose in excess of the constraint number, and put the onus on the radiation safety committee, if there is one, or on the RSO if there is not a radiation safety committee, to make that determination themselves.

So many of the things that we talked about yesterday where there is a feeling that doses in some circumstances and for some type of licensed operations

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are just not going to easily be able to be reduced below 2 rem.

So if that is a decision that is made by the licensee, there would be no expectation that they would do anything other than to look at it and say is it credible that this is necessary to have this dose or is it not.

Obviously, if it is not, then the expectation would be that the licensee do something, although I could see that you didn't specify -- have that specificity in the regulation at all.

From a regulator's standpoint, I would like to see those instances reported to the regulatory authority for a couple of reasons. One, it puts a little more pressure on the licensee to do a legitimate evaluation as to whether this was a credible situation that should be allowed to go on, or not.

The second reason is it would -- Well, probably three reasons. A second reason, it would give the regulatory agency an alert to try to look into see if a particular licensee is coming up with a significantly increased number of situations like this compared to another licensee doing the exact same thing, which would allow the regulatory agency to go

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and do an inspection and see whether or not there are improvements that can be made. But I wouldn't see that there would be a citation of violation issued, other than -- depending upon how the wording would be, other than for not having done the internal review or not having reported it.

The third reason for reporting it would be to generate data that could be looked at in the future

The third reason for reporting it would be to generate data that could be looked at in the future as to the number of occurrences and the types of situations to evaluate for potential future regulatory changes.

HEARING OFFICER HODGKINS: Again, we are still just trying to clarify the slides. Chuck, did you want to add something?

MR. PICKERING: No, not for clarifying the slides.

HEARING OFFICER HODGKINS: Clarifying slides? Don.

MR. MILLER: I think I am clarifying what a constraint is. ICRP-103 and, I think, ICRP-105 as well define what a constraint is for medical exposures, and they define that as a reference level, and a reference level, which is an ICRP concept, is not even remotely like what is being discussed here, in that a reference level -- Most people here, I

think, know what it is, but just in case.

You look at an average exposure for a specific kind of procedure, a chest X-ray or a bone scan, and you compare that to the average values, the values of the same procedure done at many other places, many other institutions. You take the 75th percentile of dose level at the many institution database, and you look at that and you look at your average or median. If your median is higher than the 75th percentile of everybody else, you need to investigate to see what is going on.

You need to determine if, in fact, there are extenuating circumstances why your doses are higher, but you also need to consider that, if your dose is substantially lower than everybody else's, that that may not be good either, because you need a certain image quality to be able to make a diagnosis. If your dose is so low that the image quality is not accurate, then that is not good either.

The principle difference between a reference level and a constraint, as given here, is that a reference level is not a fixed value. It is expected to change over time; whereas, the constraint that you are talking about here would appear to be fixed in the regulation, if I am correct.

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MR. COOL: It could be, but it wouldn't have to be, by any stretch of the imagination. In fact, it could -- First of all, I agree with you that ICRP makes a distinction between how it uses reference level in the medical arena, as you have described it, and that is my understanding also, versus how they use constraint in the rest of planned exposure situations. So putting that piece first --

Then secondly, and trying to open this back up for discussion, there is nothing that would say that the numeric number would have to be fixed in the regulation. There is nothing that says at the moment, as we enter this dialogue, that the regulation would have to establish a numeric number at all.

In fact, in the ICRP discussion the real use of this in the hands of a user as a prospective planning tool, you pick the right one for that job, and you might -- as I know Ellen will probably say at some point, you might have hundreds of them for your different things, because you know for this particular circumstances this is where you would plan to be.

So you might even have multiple layers of this idea in the system, which would have different numbers and might change over time as you got smarter or in different parts of the plan or in different

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radiography situations or otherwise. 2 So there are lots of possibilities here, and part of what I am asking us to try and discuss is 3 each of those variables to see what might make sense in the context. MR. MILLER: Thank you. That is what I was trying to bring out. HEARING OFFICER HODGKINS: 8 Back to the 9 microphone. MR. PEDERSEN: Yes. I think I do want to 10 11 make my comment. As was just pointed out, the ICRP 12 uses the term constraint for several different things in 103. 13 14 So what I was going to caution the group: Before you jump into a discussion of whether a 15 16 constraint should or should not be established, you need to define what the purpose of that constraint is, 17 so that you are all talking apples and apples and 18 19 oranges and oranges, as opposed. Last week I noticed that there was a 20 21 little cross-talk where people talking were 22 different purposes, still using the term constraint and not realizing that they were talking 23

In fact, Don is actually -- His slides

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different things.

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actually point out two different reasons for using the term constraint that the ICRP uses. In the public dose area, they use constraint as a means of ensuring that a member of the public who is exposed to several different sources, you would establish a constraint on each of those sources, so that the sum of those doses didn't exceed the dose limit.

That is different than establishing a constraint in the occupational area such as this 2 rem that is up on the board right now, which would be a level below the dose limit for an individual where it might not be ALARA and, therefore, you need to do something to convince the regulator or yourself that, in fact, that exposure is ALARA.

So there's different aspects to -- you know, different purposes for putting a constraint in place, as constructed by the ICRP. So just keep that in mind as you go through the discussion.

HEARING OFFICER HODGKINS: Thank you.

MR. GOMER: Chuck Gomer, Children's

Hospital Los Angeles. Just for clarification, would a

scenario possibly occur at a variety of medical

centers where they could then use this either

politically or for advertising purposes where a center

would say that we have the lowest constraints in town

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and, therefore, we are the safest and best facility for a certain procedure?

HEARING OFFICER HODGKINS: Ellen.

MS. ANDERSON: Ellen Anderson, NEI. So are we talking about an annual constraint rather than a de facto dose limit, something below the limit, or are we talking about a constraint for a job or a procedure?

MR. COOL: It could be either. I am leaving that open at the moment for the discussion. Should you wish to think about putting some overall numeric number, as someone suggested yesterday, that helps sort of having numeric alignment, then at least at that level it would probably be an annual value of planning, but that doesn't necessarily mean that, even at that, that the detailed planning wouldn't be on much shorter time intervals.

Coming into this, I am not suggesting to you that there necessarily needs to be a numeric value. In fact, I will be very up front with you. In last week's meeting in D.C., lots of people liked the idea of saying that there needed to be planning, that there needed to be planning criteria, but please stay away from the numbers.

So that was one set of views. I am ir

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hopes that we can talk about how those ideas and other ideas work back and forth to see what might make sense from a regulatory perspective.

MR. PEDERSEN: Roger Pedersen again from the NRC. To expand a little bit on Don's answer to Ellen's question, I believe the reason why Don threw up the 2 rem number up there is that we have heard up 'til now people floating the idea of using a 2 rem constraint instead of a 2 rem dose limit.

So getting back to my previous comment about make sure you understand why you put a constraint into place. So I think we are looking for a discussion of whether that is a viable option to having a 2 rem dose limit, but I don't think Don wants to constrain the discussion, excuse the pun, but just that topic. He would like to explore the entire topic.

MR. COOL: That is correct, and for a complete and open disclosure, we have had people who have suggested, not unlike what I think Bob Greger was suggesting earlier this morning, leave the limit at 5, require people to have some planning values, and tell them that at the first level of planning, they should not plan to have an occupational worker over the course of a year exceed 2 rem, and then the licensee

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has the flexibility, if they have individuals in that range, to figure out whether that is the best that they can do, and maintain that flexibility, but be able to at least at some level say, see, we have 2 in there.

So that is something that we have heard. So that is part of what we want to explore. It is not something that we are pushing or directing or even necessarily favor or otherwise, because there is lots of bits and pieces to that. But that is something that people have suggested as a combination of things.

HEARING OFFICER HODGKINS: George, then Colin.

MR. SEGALL: So this comment is about clarification of terms. In the first day of our workshop, we all agreed that we should not use the same term for different processes, and we were talking about using effective dose equivalent versus effective dose.

We said, if we have different methodologies we shouldn't confuse things by calling them the same thing. So the first thing we -- I shouldn't say we need to find it immediately -- is the word constraint. That is already defined by ICRP.

If we are moving in that direction, but we

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come up with a different working definition, we should not call it a constraint, because that is going to be very confusing to everybody. Calling a planning limit, an actionable level, whatever you want, but I just wanted to point out that clarification.

It is defined, and if we are going to adopt it, fine. We can call it that. Otherwise, we need to call it something else.

The second thing is the definition of reportable. Reportable to whom? I mean, does reportable include the concept of self-reportable? Does the RSO report to a local control committee, or does reportable mean to a regulatory agency? That is a definition that requires clarification.

action is Even corrective open to interpretation, if not precisely defined. feel very comfortable with actionable values where we do an investigation to look if there is a technical problem or a procedural error or operator educational issue that needs to be addressed versus a situational which there is no correctable exposure for corrected action needed, because it is sort of self-It was an increase in workload or correcting. something not due to error.

So I think it is very important that we

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define the terms, because otherwise we can be talking about the same things but having different meanings.

HEARING OFFICER HODGKINS: Colin?

MR. DIMOCK: Colin Dimock, UCLA. So as I am getting this, we are talking about one possibility -- we don't want to limit it, but one possibility is to have an optimization level at 2r, but then we define certain groups that we -- or we might say, well, we know our PET technologist and PET technologists in other parts of industry really get somewhere between 2 and 3. So we are going to set 3 for that.

Getting back to my first point or my first question, I might make the argument on some of the things we have discussed yesterday that an appropriate optimization level for interventional radiologists might exceed 5 rem; and if you put room there, that might actually improve safety and monitoring and all that and the public benefit in those cases.

Now I am not certain that we really have quite that much flexibility in this particular discussion.

MR. COOL: Well, we could certainly talk about those possibilities. I personally have to say that I am not quite sure how we could arrange a

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flexibility to exceed the current limit, but --2 HEARING OFFICER HODGKINS: Okay, 3 microphone 1, then microphone 2. Are you ready? MR. MITCHELL: Thank you. Chad Mitchell, 5 U.S. Navy Bureau of Medicine and Surgery. Building somewhat upon what Dr. Segall 6 just said, everybody is talking so much about 8 subject of this. I haven't heard much about the predicate other than something should be done or Mr. 9 10 mentioned that this may necessitate 11 inspection coming in based on your compliance with these levels. 12 That needs to be 13 So that concerns me. 14 defined a little bit, because it may be that I just picked the reference level incorrectly. So you know, 15 people are consistently above this level over and over 16 again. So eventually I throw up my hands and say, 17 fine, I will raise the level. 18 Is that going to be adequate? 19 I mean, at some point, you know, this comes down to inspections 20 21 and findings. So it shouldn't be subjective, whether 22 you are following the letter of law in your follow-up. 23 HEARING OFFICER HODGKINS: Okay. Any 24 reaction to that? Questions, comments? Microphone 2. 25 MS. MARKUS: This seems to be a solution

in search of a problem. We have ALARA. We don't need another system of constraints that creates needless paperwork to keep regulators busy. Maybe we should just have fewer regulators, if they don't have enough paper already.

I think the ALARA program with a limit is

I think the ALARA program with a limit is perfectly adequate and all we need. I am against constraints. I don't care whose definition of constraint you use. Once you have an ALARA program and you have a limit, that's enough.

HEARING OFFICER HODGKINS: That was Carol, in case anybody needed to know. Okay, Melissa.

MS. MARTIN: I think I am looking for the reason we need to go to this system. I have just been listening to this, and I kind of have the same question. Is this a solution looking for a problem?

HEARING OFFICER HODGKINS: Comments?

Richard, did you want to comment? No? Microphone 1,

comment?

MR. HEDGER: Troy Hedger from Alpha Omega Services. First of all, I want to thank the regulatory people for patting us on the back, saying we did a really good job with ALARA, because that is basically what this is doing. But then on the other hand, you are saying, well, you did really well on

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ALARA but, hey, we want to slap you around a little bit and just -- you know, we are going to make you have these constraints, that you are going to have to actually have it in writing.

You know, we are already doing -- We are already well below the regulatory limits, and then to have these constraints -- It doesn't make any sense to me. Well, I know what it is, and Bob eloquently said it. Basically, it is for future regulations.

You are going to collect all this data, and you are going to say, okay, if you are doing this procedure, this is what your occupational dose is; if you do this procedure, this is what it is. That's crazy.

I mean, first of all, you know, I know that for -- You know, you go to the EU and things like that. They do everything based on an average person. That is how they start the regulations.

I have people that are here in terms of what I can train. They are here, and they do jobs differently. There is no such thing as an average person, and you are going to be causing a lot more paperwork for the smaller groups like -- or smaller companies like Alpha Omega. It just doesn't make any sense to me.

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HEARING OFFICER HODGKINS: Okay. Ralph?

MR. MACKINTOSH: To get to the "quacks like a duck" analogy, any process which includes the V word anywhere in it, to me is a limit. If you are going to charge me with a violation for failing to report something, that is a limit.

Secondly, I would hope that, if you think about this, that you would not be reporting every incident that occurs of a particular process. Otherwise, every single radiation safety meeting we sit down, the RSO looks at badge records. We will be sending in reports.

You would have to be able to do class solutions and say, this is the limit except for interventional radiologists who are a class solution, and we have been able to show that they regularly — otherwise, we are going to have a burden of reporting that is going to be odious.

HEARING OFFICER HODGKINS: Robert?

MR. GREGER: I guess what I would like to comment on is that -- I toss this out as a possible alternative to adopting the ICRP dose criteria, and I am not attempting -- I have used perhaps a little more detail than I could have at this point.

I think, number one, it is the concept as

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to whether this would be viable in lieu of adopting the regulation, because it appears that there is a great deal of disagreement or apprehension over adopting the lower dose limits as dose limits themselves. So I thought this might be a way of softening that blow and still achieving -- As Melissa said, why would we do this?

I think the reasons we would do this is that the risk per rem has increased by a factor of four since the 5 rem limit was put into regulation. So there is a -- There will be an expectation, and should be an expectation on people's part, whether they are regulators or members of the public or licensees, that the dose limit should be reexamined and, potentially or maybe even probably, lowered to reflect that lower dose limit. I'm sorry -- to reflect the higher risk per rem that is now out there.

The second reason is one that was repudiated yesterday, and that is that what is the perception going to be if the European Community has a lower dose limit than ours?

Those -- In my mind, those are the two reasons, and I understand there is disagreement over them, but it is at least generating lots of good discussion.

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By the way, Troy, you would be in luck, because there is probably nobody for us to compare you against. So you could never be in the top tier.

HEARING OFFICER HODGKINS: Yes, go ahead.

MR. DIMOCK: Colin Dimock, UCLA. So yesterday we talked a lot about, hey, let's get everything consistent. Let's look at consistency, and it seems to me that this -- We are talking about everybody setting their own limits. It appears to me on the surface to be kind of chaos compared to that.

I mean, how would we go -- From institution to institution, at least for a significant period of time, we would have big differences. Then I think this goes directly to what Charles Gomer alluded to, which is the possibility of competitive dose limits, more conservative than thou dose limits at various institutions that could be driven even outside of the radiation safety professional's hands.

You could have a hospital director saying, hey, let's shoot for this so that we can say we are better than them, which could cause us to have to meet those dose limits through some pretty strange practices and creative solutions that could limit peoples work time.

I don't even know what might come out of

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1 that. It is a little hard to say what might come out 2 of that chaos. HEARING OFFICER HODGKINS: Richard? 3 4 MR. BURKLIN: Well, seems like we have 5 moved beyond the clarifying stage. HEARING OFFICER HODGKINS: Well, 6 let's 7 make that official. Let's make that official, okay? 8 We are going to start the discussion with Richard. MR. BURKLIN: Rich Burklin. We have heard 9 once or twice that there have been no known adverse 10 11 health effects for people who were exposed to less than 5 rem per year. But the truth is we don't know 12 what the risks are, and it seems to me it is not 13 14 unreasonable for the NRC to accept advice from the leading authorities that there is some risk below 5 15 16 rem. If there is no risk below 5 rem, then it 17 doesn't make sense to have an ALARA program that is 18 going to reduce your dose from point A to point B, if 19 those are below 5 rem. 20 21 that Option 4 (b) is Seems to me 22 reasonable, that each licensee could establish and use its own planning value, that I would think that the 23 24 NRC would find it acceptable for anyone that has a

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planning value of less than 2 rem per year.

If a group -- for instance, a medical facility -- said they can't live with that, then they could establish their limit at, say, 4 rem per year as long as they gave a justification. It seems to me, if you can say you are going to save lives, that is a reasonable justification.

For somebody like myself, if we establish it at 2 rem per year, I would see two situations. One is something special is happening, and we might need someone to go over the 2 rem. So in that case we will get management approval, and we would plan in advance that here is a special case, we are going to go over 2 rem.

If, however, someone went over 2 rem just because of we weren't following the dose close enough, something along those lines, then at that point we would have to put into place some corrective action so that that would not recur.

MEARING OFFICER HODGKINS: Let's kind of move around the room now. Okay? So let's try that way. melissa, we will just move this way, since you were next.

MS. MARTIN: One point, I think, that affects the medical facilities that may not affect some of the other representatives in the room is many

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1	of the medical centers have unionized staff. I think
2	that is something that, as soon as As someone was
3	alluding to, we can have competitive "my area is safer
4	than your hospital," I think when the unions get into
5	this for negotiations for staff, this could have a
6	significant impact on the operation of medical
7	facilities.
8	HEARING OFFICER HODGKINS: Thank you. Any
9	other comments on A, B or C? Oh, Ellen.
10	MS. ANDERSON: Ellen Anderson, NEI. A
11	number of our power reactors are unionized as well.
12	HEARING OFFICER HODGKINS: Any other
13	comments, though, Melissa, as far as A, B C, your
14	thoughts.
15	MS. MARTIN: Well, my preference would be
16	A. I could probably live with B, given the option
17	that we can set our constraints depending on the
18	occupation. That is because we know there are many
19	areas that are or at least several identified areas
20	have been discussed that will consistently go over 2
21	rem per year.
22	HEARING OFFICER HODGKINS: Thank you.
23	Lynne?
24	MR. COOL: Can we explore a little bit

more now before we sort of lose it, because we have

touched several times on this question of different hospitals deciding that they wanted to advertise themselves in some way, because they were trying to recruit certain workers, that they were safer than the others, and whether this would play into the hand.

I don't think I have ever had that thought brought up before. So that is a really interesting thought, and I thank you for adding that to the

brought up before. So that is a really interesting thought, and I thank you for adding that to the discussion. I can't quite envision how that would work that would be any different from what would be possible today, if the licensee put out, well, our techs only get so much or otherwise.

How does saying that you need to have specific planning values as part of your radiation protection program contribute to that? I just don't quite understand. So help me out a little bit.

HEARING OFFICER HODGKINS: George?

MR. SEGALL: It is a sanction concept given validity by the Nuclear Regulatory organization.

Anybody can claim anything now, but the minute you put the imprimatur of a regulatory agent, it becomes more than just advertising.

HEARING OFFICER HODGKINS: Ellen?

MS. ANDERSON: In the power reactor sector, we have something called Institute for Nuclear

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Power Operations, INPO, and we actually compete as an industry amongst power plants. We always want to be the top quartile, the best plants. The lowest dose plants are in the top quartile.

Now interesting enough, the good news is we continue to share information amongst one another, but there is a great deal of competition from plant to plant, even within one's own company.

What I have seen happen with that, by the way, is I think we have actually -- If you were to look at the graph -- I wish we could, had a presentation. I could show you a graph of where our collective radiation exposure is today compared to 10 years ago, and that is a combination, I think, of working together, but also competing with one another.

Now I am not quite sure whether that would actually work in the hospital setting. It has worked for us, but then again we are different animal than hospitals.

HEARING OFFICER HODGKINS: Yes?

MR. GOMER: Chuck Gomer, Children's Hospital. Well, having an ALARA requirement is one thing, and we all adhere to that and want to do that. But to have a specific number that is -- whether it is officially or unofficially approved by a regulatory

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agency as our constraint, and that that constraint number could vary from institution to institution, while we know that we are all lowering and decreasing the exposure as much as reasonably possible, is the concern I have.

We are all doing that, but we could have a number, a quantitative number, that again whether it is officially approved or not from a regulatory agency, but one that we give to a regulatory agency, and if that number could be different from a neighboring hospital, that is the concern I would have.

MR. COOL: Okay. So Ι think the assumptions that are part of that -- and let ;me just The assumptions that I think I heard are: check. One, that you are reporting to a regulatory agency; and that, two, your number is some sort of advertised number or regulatorily approved number, neither one of which would necessarily have to be part proposal here. But that is part of what we are trying -- what I am trying to flesh out a little bit, because in its simplest form, I think -- I may even be making it too complicated.

In its simplest form, it is saying, licensee, you need to plan your ALARA program, and you

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need to establish some criteria. And everything else is up to you, what you do, how you justify and everything else. From there, you could add increments to it of all sorts of different forms, all of which have various pros and cons, may have no benefit at all, may not have any benefit for anybody in the large institutions but might add some structure that helps the folks in smaller institutions get to a basic standard or level that the rest of us assume, or otherwise.

That is part of what I am trying to explore, is which pieces or components. So I would ask you, as you sort of state these sorts of things, let's check our assumptions of what is underneath it.

HEARING OFFICER HODGKINS: Donald.

MR. MILLER: Correct me if I am wrong, as I often am, but it sounds to me like what you are saying is you don't have all these requirements, is that a constraint is the same thing as an investigation level, which we already have now, and everybody knows how to use, and everybody uses.

So the simplest way to deal with this issue and keep us compliant with the ICRP, should you desire to do so, is to just rename investigation levels as constraints. Problem solved. No? Yes?

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MR. COOL: Perhaps. I am not sure it is quite that simple, but if that is how we chose to define the particular usage of a particular word, then it could be maybe. I am not going to rule it in our out.

HEARING OFFICER HODGKINS: Dr. Segall.

MR. SEGALL: George Segall. I always forget to introduce myself.

So a little history lesson. We are sitting here in Los Angeles. In California, if you want to raise taxes, it takes two-thirds majority to raise taxes. That was very difficult to achieve. So authorities began to levy fees, and these fees essentially became taxes, because they were designed to accomplish the same ends.

You could not distinguish them from a tax, because they were applied generally universally, and the fee was used for the general good. So as Ralph said, it quacks like a duck. This is what we are doing here.

We are trying to accomplish with constraints, which we by consensus turned aside as a regulatory limit for occupational dose exposure, for example. But it is really the same thing, because we are going to apply it uniformly to achieve the same

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ends.

Now to those of you who might argue, well, it is not quite the same thing, because you will be able to establish individual limits. I think you have heard many opinions that says that, due to pressures, nonregulatory pressures, there is going to be uniformity in those limits, and I am not talking about just in different industry, but even within the same hospital, let's say, division of licensees, there is going to be pressure to achieve a certain uniform constraint.

So this is just a fee disguised as a tax which, by the way, California voters wised up to on Tuesday, and they increased the majority required to levy a fee to two-thirds majority. But I am afraid, and I think Bob and Rich were very honest about it.

They said, well, you know, we really feel that for safety reasons, and world opinion is agreeing with us, that we should lower exposures, and maybe -- I think, Bob, you said this -- we have a more palatable way or -- I forgot what you -- to do it. But this is wrong.

If we really felt that was the way to do it, we should do it by a regulatory limit and not by the back door.

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HEARING OFFICER HODGKINS: Ralph, then 2 Chuck. MR. MACKINTOSH: Since we already have investigation levels under ALARA, and we have set those as what is reasonable, then by setting these it sounds to me you are telling me that I am 6 reasonable, that the job I am already doing is not reasonable, and you need to codify somehow a restraint 8 is different than my existing investigation 9 10 level. 11 HEARING OFFICER HODGKINS: Chuck? MR. PICKERING: I think, as Dr. Miller 12 mentioned that just redefine constraint as an ALARA 13 14 program essentially, and I had the same idea. What I think could work, too -- again, I 15 am trying to find some middle ground here in terms of 16 how we kind of implement ICRP -- you could state it 17 as, well, we will keep ALARA, and that is sort of our 18 constraint, with the concept of a goal to achieve less 19 than 2r. 20 21 So it is in there. It doesn't say you 22 can't exceed the goal -- or exceed the limit, but our ALARA programs are designed to try to keep us under 23 the 2r limit. 24 25 HEARING OFFICER HODGKINS: I am going to

open it up to the mikes, because they have been waiting patiently. Name first.

MR. TAKAHASHI: Yes. Joe Takahashi, Northridge Hospital. I got two comments. With respect to what Robert said with constraints, when we are talking about these numbers for cancer induction, fatal cancer inductions, and we see that it went from one to five times 10^{-4} , and we see the number of cancers -- you know, it varies from 20 percent to 40 percent -- and depending upon the medical care that that person receives, it may or may not be fatal.

Therefore, that small percentage increase is not going to affect the total cancer -- not the total cancer, but the numbers of cancer that is going to be fatal for that population.

The other thing is that when you say constraints, it sort of relieves the regulator. In my former life, I was a regulator for the state of California, and the thing that I look at is that, if we have an ALARA program, we should be able to assess that ALARA program, and that is done both at the license review stage and then as we come in as inspectors, we look at that also and see if there is a problem with that.

I think that we don't need a constraint

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for that purpose.

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HEARING OFFICER HODGKINS: Thank you.

Next. Your name first.

MS. MARKUS: Carol Markus, UCLA. When nuclear power plants go to efforts to decrease radiation dose to workers, spend money, do whatever they do, their rate payers pay. In medical care, the insurance companies are not increasing their reimbursements because it costs you more money to operate.

I have worked a small amount in private hospitals. I have worked at the VA and mainly county hospitals, and observed that technologists in nuclear medicine in private hospitals work a lot harder than they do at the VA or in the county hospital. They may two or three times the number of cases a day.

It is necessary for the private hospitals to do this to stay alive. Fifty-one percent of California hospitals lost money last year. The hospital administrators are not interested in keeping doses to nuclear med techs very low. They are interested in getting the highest throughput they can for the smallest number of techs possible.

So you are going to see that certain groups of technologists have higher doses than others,

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and this doesn't mean that they are sloppy or that the institution is sloppy. The institution is just trying to survive.

I used to look at the radiation dose levels of my technologists at the end of the month to see who was working, and as a rough estimate you could tell who was doing most of the work, just looking at the doses.

So thinking generally about classes of workers like nuclear med techs is a very dangerous thing to do. Unless the NRC is going to CMS and insurance companies and demanding that they increase the reimbursement for nuclear medicine procedures so that they can hire more nuclear medicine techs and get their radiation doses down to artificially constrained low levels, then I don't think you have a right to expect us to aim for that, because it is totally irrational.

Would you be happy if 75 percent of hospitals in California went belly up? You can't increase costs when there is no place for the money to come from, and I think that this is a real problem with the NRC and its regulations and nuclear medicine.

HEARING OFFICER HODGKINS: Thank you. Okay, Melissa.

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MS. MARTIN: Number one, I want to reiterate the comment that Dr. Miller read out of the ICRP report. The data that is being used that the risk estimate is changed from one to five times 10^{-4} - that number is still very low.

I would also reiterate exactly what has been said previously. The busier the technologist, the higher their doses when they are in a nuclear medicine department. That is exactly what you see.

You also see the same thing when it is the technologist. The busier surgery technologist that is working in the interventional cases, their doses are the highest.

What I don't think we want to see is a number that is established and required, because hospital three, four and five may not be very busy, but hospital six is very busy, and to have the same constraint required of, say, all technologists by virtue of position -- it has to be a variable.

What I fear is the regulator coming in and reviewing a very busy institution, saying, well, obviously, you don't have an adequate ALARA program - I mean a constraint established, because the little hospital down the road, their technologist doesn't get that much.

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It will severely impact the practice of community hospital medicine, and I am saying community hospital over the whole range, from small to large. There's not a lot of these people out there. They are not replaceable, and particularly with the economic climate of hospitals. We can't go out and just double our staff to decrease the dose.

HEARING OFFICER HODGKINS: Thank you. All right. Colin?

MR. DIMOCK: That being said, what Melissa Martin and Dr. Markus just said -- I also want to, though, get back to what Ellen Anderson said about the industry comparing to itself, which I think is a good practice as a rule, and I would like to say that the UCs already do this; and when we do compare notes with other about what our technicians technologists, I should say, are getting, what cyclotron operators are getting, and how do you get that, what is your situation, oh, well, you working more than I am or whatever, but you've got this lead setup, you've got that -- there is even already a little bit of competitiveness between the UCs that try and one-up each other with having the best technology and the best situations.

That process already exists there, and to

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a lesser extent with the CCRSOs, and I think that that professional part is working pretty well. Perhaps it could be worked better.

I think what they have achieved in the nuclear power realm has been a positive move through that program to a great extent, but there is already a system where some of this is going on, and we could talk about improving that. But I don't think regulatory codification is necessarily the route that you want to go to get there.

HEARING OFFICER HODGKINS: Don.

MR. MILLER: Don Miller, ACR. What you are describing is a simplistic form of a reference level. It is not a nationwide collection of data. It is an anecdotal collection of data from your neighbors, and you are comparing yourself to them and saying, gee, I am higher than you are, I wonder why, or I am lower than you are, I guess I am probably doing a decent job.

If you can use a reference level as a constraint, then you don't need to worry about these numbers, because the community is telling you what is good and what is not, and ALARA is not ALARA. It is as low as reasonably achievable, social and economic factors considered.

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1	So, yes, my techs are three times as busy;
2	their doses are going to be higher.
3	HEARING OFFICER HODGKINS: Okay.
4	Microphone.
5	MR. HEDGER: Troy Hedger from Alpha Omega
6	Services. One thing that I want to caution you on
7	doing this competitive thing is, you know, if it gets
8	really competitive, I can imagine sort of like, hey,
9	you know what, we are almost number one, let's not do
10	this maintenance this month. let's maybe shuffle it
11	over to the next six months or something like that.
12	For certain aspects, and for cardiologists
13	I want my cardiologist to be competing. You know,
14	it's like maybe I can just do half-step on this fluoro
15	every once in a while and, you know, get my dose down.
16	To me, it doesn't make sense. It scares
17	me, actually.
18	HEARING OFFICER HODGKINS: Okay. Yes,
19	Don?
20	MR. MILLER: I cannot conceive of a
21	cardiologist going, yeah, my dose is lower than yours.
22	HEARING OFFICER HODGKINS: Okay. We are
23	sort of moving around the room. Lynne, your turn.
24	MS. FAIROBENT: I was really going to just
25	wait and let the conversation fall out, but okay.

A couple of things. I think we have to keep in mind why ICRP and how ICRP develops their recommendations, and then how the IAEA develops their basic safety standards which, I believe, would go back to Don's original slides. Both are mentioned.

A lot of what is done, especially with the IAEA basic safety standards -- and, Don, correct me if I mis-speak -- are done to put programs and directions in place for all member countries. However, what we have in place in the U.S. is probably -- at least in my mind, it is at the upper end of a very good regulatory regime that we have all operated under for longer than my life, but not much longer than my life.

So I think the fact that we have had, and have implemented, the ALARA concept in the U.S., and to the extent that we have embraced it in this country is not necessarily the same as other countries, and perhaps the need to establish constraints in those regulatory jurisdictions may be different than in the U.S.

At the D.C. meeting, there was an individual from Canada who talked about their system, and they have adopted some of the ICRP recommendations already, and he said that they do not have constraints in their regulatory system to date. However, they do

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have an action level in their regulations, and they have applied it across the board.

It is there to notify the licensee or the regulator if there has been a loss of control, and from the Canadian regulatory authorities' view, they expect it to be exceeded a couple of times a year. Therefore, they expect it to be set low.

They are collecting metrics of licensees' programs that are often tied to how many times they notified the Canadian regulatory body and, therefore, are pushed back to have a higher value, since the reports are considered an event.

They are waiting for the basic safety standards before moving forward to incorporate the constraints concept into their regulatory system. So I think that is interesting to look at.

We talked a little bit about -- I think Bob Greger had brought up reporting stuff. That is a whole different gamut, and I don't really think that that is the subject of the Part 20 revision. There is a whole effort going on right now in the U.S. as a result of the New York Times series of articles this past year as to whether or not we need a national event reporting system, and I think that I would hate to mix this and that up at the moment.

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The other thing I thought was interesting from last week is that Lee Cox on behalf of CRCPD NOAS from his view stated that he was not hearing anything What he was hearing in the discussions last week as we were talking about constraints was really an investigational limit and that he, from his view representing CRCPD, felt that the states would see this as another bureaucratic change for no benefit, and that it is already -- in essence a lot of what we talking here with the concept of constraint, providing it stays out of a regulatory limit for it, really the essence, I think, of what discussing -- and Lee also brought this up -- from the safety culture policy statement standpoint, as NRC wants to expand the safety culture policy into other the reactor industry where it has been the longest, and move it across all licensee categories.

So I think there is a lot of things that we do here in the U.S. that I am not convinced are done elsewhere internationally. When AAPM filed its comments on the draft ICRP report on the concept of dose constraints -- and as far as I know, this is still our position -- we said that, as presented, the concept of dose constraint needs further discussion and justification.

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As defined in the current term, the term constraint appears to have multiple meanings, some of which overlap with the meaning of the U.S. term limit. Specifically, clarification is needed to use the term failure to indicate not meeting a constraint. This may or may not be interpreted in the U.S. to mean a legal or regulatory limit has been exceeded.

We haven't even touched upon, in some concept, the implementation of it or the interpretation of the definition of it. I know from my own background, and if we look at Part 35 -- I know it is a different part of the regulation -- those who write regulations write what they think the words are saying to the best of their ability.

The proof of that is not until we try to implement it, and we see time and time again changes in implementation. I would hate for us to rush forward and put something into place that, in hindsight, is going to be problematic.

On that point, I do commend NRC for taking the time to have all of the public outreach that they have before the publication of an advance Notice of Proposed Rule or a Proposed Rule to solicit the best input from the community at large on this collectively to help them make the best decision in going forward.

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HEARING OFFICER HODGKINS: Any reactions? Support, echo? Donald. 2 Comments? 3 MR. MILLER: i support what Lynne said. 4 In particular, the IAEA's function as they see it is 5 to provide guidance for the many countries in this world that do not have adequate radiation protection 6 authority and programs in place. Quite specifically, 8 that does not apply to the United States, because we have a very robust radiation protection system. 9 So what the IAEA recommends does not 10 11 necessarily apply to the United States nor is 12 necessarily intended to apply to the United States. HEARING OFFICER HODGKINS: Scott? 13 14 MR. CARGILL: Let's go back to A. No Now you have heard me say it before; I will 15 change. I am a firm believer in letting 16 say it again. industry regulate itself. I would rather see no 17 change in the regulations. 18 I will echo what Lynne and Don here said. 19 I would love to see it moved into the safety culture 20 21 side. Industrial radiography -- 30 years ago we were 22 the pirates. We were the muggers in the back alley. We really have a poor reputation when it comes to 23 24 things.

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radiography has grown greatly. Gail Flagor over there at GE, you have been at this a good deal of years longer than I have. You back me up on this, right? Our industry has gotten better.

Our industry has grown. We have gotten more responsible. I am sure the regulators would agree with this, to some degree. Part of that is from regulation. Part of that is just simply from safety culture growing and our industry growing.

I am not opposed to constraints. Label that term how you like. I agree, no new taxes, by the way. But we do it already internally. We have our action limits, our action items or our self-imposed constraints.

I've got one set at 400 MR. Badge comes back 400 MR, I absolutely have to do something about it. I am completely opposed to any idea of having to report it to anybody. I am well below any regulatory limits. I have done something. I have documented it. Regulators want to come in and see what I have done, that's great. But to sit there and report it -- we are starting to look like a lemon. I have to agree.

Who is going to be that judge and jury?

Am I going to get a regulator, an enforcement agent

come in fresh out of college or am I going to get the

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regulator with 20 years of experience who happens to look at my documentation and realize, okay, this guy has just shot 100 wells on a convection box; yeah, he got a little bit more that week.

So we start into the issues with that. I have to really go with George's comment with no new taxes. If you put constraints -- and again, term that however you like or define it as you like -- into regulation, who becomes that authority that will approve them?

I am perfectly happy with ye shall establish your own constraints. My constraints may be different than yours. Obviously, industrial radiography versus medical versus nuclear power plants are all going to have their own pluses and minuses and their own decisions.

I keep coming back to it, and I will again. I much prefer industry to regulate itself when and where possible. I understand that, from the regulator's standpoint, that may not always be possible or you may not allow us that option.

In this case, I see no need to add another regulation or another part to regulation just on the basis that the rest of the world is thinking about it.

That will be it.

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HEARING OFFICER HODGKINS: Ellen?

MS. ANDERSON: The nuclear power industry does not support any change to the current regulations, and there is a couple of reasons why.

We actually establish our own internal constraints on several different levels. First of all, every licensee establishes an administrative dose limit, and that limit is something below the regulatory limit. I don't have that buffer in between.

In order to go over that limit -- and again, we call it an administrative dose limit; I don't know if we call it anything else, but that is the word we have always used.

In order to go over that, we have to have senior management approval, site vice president, plant manager/site vice president, chief nuclear officer, depending on how up the chain you want to go, getting close to that 5 rem limit. So we already self-impose that.

Form a job perspective, we also have another process where we actually -- when a maintenance job is to be worked, we evaluate the job, the dose levels in the area. We establish what we consider to be an estimate for the job, and then

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beyond that, we actually establish a goal for that job, which is always less than the estimate. So we self-impose that as well.

In most companies, if in fact you go over your estimate, you have to enter -- I'm sorry, go over your goal, you have to enter something into the corrective action program to evaluate that.

Beyond that, we have the significance determination process through the NRC. Any job greater than 5 rem is actually reviewed, and if it is 150 percent over the actual -- help me out, Roger -- over the estimate, the plan dose, the estimate for the job, we actually have that entered into -- It could be entered into the significant determination process, which usually it is, and there is actually a regulatory -- Roger is back there, tell you more about it -- regulatory process.

So the bottom lien is we already have constraints. We have them from the actual annual dose limit constraint, be it 2 rem per year, 2.5, whatever the company decides it to be, and then again at the day to day job level as well.

So we don't support any additional constraints into the regulatory framework, because we already do it.

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HEARING OFFICER HODGKINS: Thanks, Ellen.

MR. PEDERSEN: Just a point of clarification. The criteria that Ellen is referring to that is in the significance determination process were not developed as a constraint. I don't see them as a constraint. They are actually a performance criteria as to how well you did your planning.

What I do see in the power plant ALARA processes that could be possibly called a constraint are your planning values at 1 and 5 rem collective dose in which, if that job that Ellen was talking about is projected to exceed one-person rem, then there is a certain level of planning that is required. That is that thing that would be required at that level. Then if that collective dose looks like it is going to exceed five-person rem, then there is an additional amount of approval by management to go ahead with that job as planned.

So just to straighten things out just a little bit. I didn't want people to confuse the SDP.

HEARING OFFICER HODGKINS: Ellen.

MS. ANDERSON: So I just wanted you to understand that in the power plant arena we do have a very rigorous planning process with planning values. Maybe they are not considered constraints, but from a

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plant perspective they sure feel that way. 2 HEARING OFFICER HODGKINS: Yes, Scott? Yes. I would like to echo 3 MR. GOLDIN: what Ellen said, and add to it that I participated in a working group a number of years ago which was called Optimization in Operational Radiological Protection, and it dealt with what was going on in draft form with ICRP recommendations and the international 8 what community believed needed to be done. 9 10 At the time this report was issued, it was 11 clear that the international community -- there was a 12 working group of about 30 of us on it, only four of whom were from the U.S.; the rest were from other 13 14 countries. Two rem per year was not the consensus of where people were. 15 result of this 16 the end recommendation that the ICRP not -- that countries 17 needed the flexibility to go to 5 rem per year, if 18 19 necessary, and those sorts of things. 20 So I put my power plant hat back on, and 21 say don't fix it, if it ain't broke. Okay. 22 HEARING OFFICER HODGKINS: Microphone. 23 24 MR. FLAGOR: Ι am Gale Flagor, 25 Inspection Services. Personally, I don't think we **NEAL R. GROSS**

need to make any changes in the regulation, from what they stand now. We already have ALARA programs set up in industrial radiography business. They are already approved by the NRC or the states in the approval of our operating emergency procedures, which each one of our personnel has to have with them at all times on the job. If there is an emergency, they know who to contact. There's already published numbers and everything to contact people.

So i don't really see a need to make all of these changes that everybody is talking about changing, just to comply with the international.

HEARING OFFICER HODGKINS: Okay. I think we are to Ralph as far as going around the table. Nothing more to say? George?

MR. SEGALL: I am not sure I have anything substantively new to add to the conversation, but since you gave me some face time, I will use the opportunity.

I always think about the practical applications. So constraints sound perhaps more palatable than limits, because they are individually determined, but I am thinking, gosh, you know, maybe I should set my constraints at 4 rem.

Yeah, I could probably come up with

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justification and documentation to support it that would meet the ICRP definition of a constraint. But when I undergo an inspection, an inspector says, well, you are 4 and 99.7 percent of your similar cohorts are at 2 or 3, I just don't think your justification is sound and your documentation is adequate, and that forces me to conform. Well, then it is not determined anymore, because in the regulatory phase

individually there is essentially a limit.

HEARING OFFICER HODGKINS: Reactions, Leonard, your turn. comments?

Well, first of all, I would MR. SMITH: like to comment on the word constraint. Remember, one of the problems that ICRP has is that, when they choose a term, they have to be able to translate it to other countries, and they certainly have a problem around this word.

I partially feel it is the wrong word, because constraint, to me, means it is a limiting function. it has a concept of limiting something, and basically, a limit is doing the same thing. So I just feel they picked the wrong word.

I agree with what Don was saying earlier, that what we really need in our programs are goals to

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administer the radiation protection programs, and these are administrative action levels. We might want to set a stretch goal, if we are trying to deploy continuous improvement in an area. You could call them constraints if you like, but I think that is the wrong word.

It is interesting that -- A little comment

I like to make is that I think we all understand why

we are trying to reduce radiation below the limits.

It is because of this concept that there is some risk

below the limit, and that is the basis, and so we are

challenged to do that. But there is actually another

use.

I mean, if we accept that there may be some risk above a limit, then we do -- there is also a risk of exceeding that limit. So we probably need some -- We do need some administrative practices to reduce the risk of exceeding a limit.

So even though normally we are using constraints or administrative limit, an administrative action to reduce those local limits, there is also functions to reduce the probability of exceeding the limit.

What else do we have? Yes, we had that constraint has been recommended for protecting in a

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multiple exposure situation. Yesterday we did talk about the business of people working for multiple licensees, and a very easy administrative way to deal with that is, if the two licensees would agree, to use an administrative action level which might be lower than they would normally use, so that the two licensees can essentially work independently. They would only talk to one another if one of these persons was exceeding that administrative level.

So these are just practical ways for controlling exposure, basically.

HEARING OFFICER HODGKINS: Thank you,
Leonard. Comments, reactions? David? Colin?

MR. DIMOCK: We don't have too many people that go over 2 rem a year. We already have ALARA limits, action levels. If it is helpful to the state or the NRC to be able to tell the international community that we are all going to have an ALARA limit that we do something with it to rem, then my facility could live with that. But I -- I presume that there is a benefit for being in that sort of alignment with the international community that we are trying -- that you are trying to get to.

HEARING OFFICER HODGKINS: Comments?

Questions? Amplifications? Echoes?

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1	MR. GOMER: My understanding is that that
2	constraint really can vary from institution to
3	institution so that number or whatever that value
4	would be.
5	MR. MILLER: Which wouldn't meet the idea
6	of we are doing this so that we can tell the
7	international community that we are with them. So
8	that is a different concept than this idea of us each
9	setting our own limits. I am not sure how to parse
10	this out.
11	I am not sure why you are asking the
12	questions you are asking, I guess, was what that comes
13	to. But for what it is worth, 2 rem as something that
14	we are going to say, yeah, we are going to look at
15	what is going on over 2 rem and do some evaluating and
16	take action, if appropriate for that person's work,
17	that is something we could live with, if that is
18	helpful.
19	HEARING OFFICER HODGKINS: Lynne?
20	MS. FAIROBENT: Yes. Roger, I just want
21	to pick up on your comment and explanatory from what
22	Ellen had said.
23	If the term constraint had been in the
24	regulatory mix at the time of the significant

determination process was put into place, how would

the preplanning effort that currently goes on under the significant determination process be different than -- When we started this discussion today, we talked about constraint being for preplanning purposes.

So help me understand -- I know, when that process was put in place, constraint wasn't a terminology that we were even envisioning on our regulatory scheme. So help me understand why -- You know, I am with Ellen. I did come out of the nuclear power industry. That is my background. I did work for NEI's predecessor, and I licensed reactors for NRC.

So help me understand why you don't see that that could be in actuality, although not called it right now, their way of meeting constraint, if NRC were to adopt the concept.

MR. PEDERSEN: Roger Pedersen, NRC. The reason I made the comment is because there are two different purposes, and it goes back to my original comment, is make sure you understand what the purpose of the constraint is before you debate whether it is advantageous to put it into place or not.

It is my understanding that a constraint is associated with an ALARA program. It is some level

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that you have predetermined at which you should do something. That something could be planning.

Like I said, the one-person rem is that point at which you do planning, or it could be something higher. The proposal would be 2 rem for an individual, and which you would have to do something more than just plan, but do some sort of an analysis to demonstrate that on an individual level that is ALARA.

referred to in What was being the significance determination process is -- Well, first of all, for those of you that aren't familiar with the significance the determination program, process is a way in which we determine how significant a violation or a performance deficiency, which is a result of our inspection -- how significant that is, how much the NRC should expend additional resources to follow up on that particular issue.

So when we put the SDP in place for ALARA issues, we were trying to establish a very scrutable and clear process that ends up consistently with more significant failures are at a higher level than lower levels.

The thing that we ran into at the time is there is no gold standard on what is or what is not

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ALARA. A hundred millirem can be ALARA or it cannot be ALARA, depending on the circumstances. There is no dose that is ALARA.

What we came to, to solve that problem is that, in the reactor program, we are going to judge an ALARA program against its own planning. So the criteria that Ellen was referring to is criteria we have established as what we consider as more than minor.

If your planning has resulted in -- or excuse me. If you planned a job, and then you have executed that job, if the results of executing that job varied from your planning by that criteria, then we said that your planning isn't good or your job control isn't good. There is something wrong there. That is a more than minor performance deficiency.

That is not the level where you should start planning. That is a criteria that says your planning that you were already supposed to do is deficient. So there are completely two different purposes. That is why I said that that is not a constraint.

HEARING OFFICER HODGKINS: Ellen, did you want to add to that at all?

MS. ANDERSON: No. Roger is right.

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HEARING OFFICER HODGKINS: Okay. Roger is right. Yeah, you are feeling pretty good right now, Roger, aren't you?

Okay, we were at -- I tell you at. You know where we are at? We are five minutes over our break time. Is this a good time to take a break? Fifteen minute break. I think it -- What time does everybody have? -- 2:30, 2:25. We call it 2:30, and at quarter of, we will come back in.

(Whereupon, the foregoing matter went off the record at 2:25 p.m. and went back on the record at 2:45 p.m.)

HEARING OFFICER HODGKINS: Don, did you want to sum up or start anything or do you want to just keep on going around the room?

MR. COOL: Well, I think I would like to check a couple of things as we move forward. I believe that lots of people agree that planning ALARA activities and checking yourself as you go along are the right sorts of things, and that, in fact, most everyone does that to some level in various forms, some of it at multiple and detailed levels, some of it not quite so many levels. So there are lots of variations, and that all of that is a good thing under the control of the individual licensees.

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A lot of people have drawn various analogies to terms that are already in use, planning values, investigation value, action level. Sometimes the word has the word limit associated with it, and otherwise all these different sorts of terms that have been used in various places, which may to some extent fulfill these portions of the idea of what ICRP was talking about. There is certainly some confusion on that or some continued discussion.

There's lots of thoughts that everyone is doing it; so we are all in good shape. So there is no reason to add any additional regulatory requirement. There would be no improvement to risk, and there is probably burdens, because then there is another regulation that somebody might come and check, and that may well be also the case.

It leads me to the same sort of question that I asked yesterday afternoon. Okay, how do we know, and what do you write in the paragraph descriptions that talk about this that help provide confidence to the decision makers that, in fact, the things are behaving throughout the industry, throughout all the different programs do have that higher level of confidence that there is -- that that going and that, therefore, there is on

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additional need for any regulatory requirements?

I am not asking that because I don't believe you, but rather again, sooner or later we have to write down the rationale and an explanation of why this does or doesn't line up and how the U.S. system works.

Made the observation -- I am not sure whether it was Lynne or someone else -- yes, the International Atomic Energy Agency drafting up their basic safety standards is establishing guidelines used by many of the member states of the IAEA, many countries, essentially verbatim. They do not have large programs. They do not have years of experience. They need basic structure in order to try and do the right thing, because they don't have this -- I won't call it state of the art, but the ongoing professional cross-connections that are there.

So some of these ideas are in place there to add structure to enable them to do the right sorts of things. Perhaps in the United States, we are more fully evolved, and it is not necessary to have any of that structure in the regulatory requirements. If that is the case, how do we write that down?

There has been a very good discussion. I would like to see if we can explore some of those

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ideas as we continue to go around the room.

HEARING OFFICER HODGKINS: Anybody want to tackle it first? Okay, how about who wants to be second? Okay, Scott.

MR. CARGILL: I think this statement can be written very simply, that this subject would be more appropriately handled by the safety culture initiative that is being fostered by the NRC right now.

I have said it several times. I will say it again. Let the industries regulate themselves when and where possible here. In this case, whether we want to compare ourselves to Brazil or Uganda or any other country out there is all fine and good.

I have heard stories of other countries literally taking a source, cutting the source off, dropping it in the source changer, sending it back to the manufacturer. That doesn't happen here in the U.S. So, obviously, there are differences between the different countries.

Honestly, I think this subject is much better in the safety culture side of it. So I would start the paragraph off with that. It might even be just the one sentence, and that would be good enough. Somehow I kind of think that in Washington, D.C.,

that probably might not be the case. 2 MR. COOL: Very rarely do one-sentences 3 cut it, but okay. Oh, that it would be so simple. HEARING OFFICER HODGKINS: Colin. MR. DIMOCK: I would say we are already covered under our ALARA program. 6 HEARING OFFICER HODGKINS: Anybody else? Not the nod. Can't write the nod. Donald. 8 9 MILLER: I would say even 10 strongly that the constraint process envisioned by the 11 ICRP is duplicative of the ALARA process that we already use. 12 HEARING OFFICER HODGKINS: Okay. George? 13 14 MR. SEGALL: I might point internally to data on record of violations and enforcement 15 NRC actions that would indicate that the ALARA program is 16 actually working because of the paucity of those type 17 of violations and actions required. 18 HEARING OFFICER HODGKINS: Leonard? 19 20 MR. SMITH: I think that most licensees, industry, would consider 21 certainly in that 22 constraint that is imposed on the licensee by regulator and requires the licensee to carry out 23 24 certain actions, prescribes to them certain actions

like reporting and like reducing below the constraint

-- I would say that that would be regarded as a limit, and we shouldn't be using that term.

The EPA constraint we have for the air

The EPA constraint we have for the air emission standard, the 10 millirem constraint that was bargained with the EPA -- most licensees consider that to be a limit, in all practical purposes.

HEARING OFFICER HODGKINS: Thank you.

Anyone else? Panel? Do we have microphone 2 being ready to be used?

MR. TAKAHASHI: Yes. Joe Takahashi,
Northridge Hospital. I am looking at, with respect to
the ALARA requirement. The NRC has these regulatory
guides. That has been very helpful, especially like
with the pregnancy, the fuel dose, so forth.

I am wondering if they can develop an ALARA guideline which then would give the licensee an example of how the ALARA program should be run, you know, some points that they should look at and, therefore, there is no need to have any regulations, but you have a regulatory guide to assist them.

MR. COOL: Okay. If I can respond to that a little bit and set up some possible discussion. First, there are several regulatory guides that the NRC already has that generally relate to ALARA programs, and there are some discussions in some of

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the guidance documents that relate to various materials activities in the NUREG 15-56 series that generally describe ALARA activities.

I don't think that those get to a description of many of the things that we have talked about today in terms of doing planning and setting levels of investigation or otherwise. That is a little bit more detailed, and it is associated with that.

I would reflect back to yo, because in fact, the same question was raised in D.C., and I am going to say the same things that I said there, which is: In order to be able to write guidance on what are good or acceptable practices, one way to implement it, there has to be some linkage to a regulation. That is part of the rules that I am supposed to play by.

You don't set a bunch of guidance and have subterfuge regulation rather than actually writing it in the regulation. So simply saying, well, wouldn't it be nice, NRC, if you just wrote some additional guidance on how you should do all of this planning and you should set various criteria as part of your planning, and these are the sort of factors that come into play, all of that might be very nice things to write. But what would you point to in the regulation

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1 that would give you a basis that that is one 2 acceptable method of implementing the requirements? I will offer that reflection. And so 3 4 maybe there is, and maybe there isn't. Let's open I see I have gotten some vibrational energy 6 now. HEARING OFFICER HODGKINS: Lynne, then 8 Ellen. 9 MS. FAIROBENT: Well, you could always cite the provision that allows you to regulate by 10 11 extension. MS. COOL: That ties nicely to 12 morning's discussion. Okay. Not quite where I thought 13 14 you were going, but --MS. FAIROBENT: Sorry, Don. I 15 couldn't But in all seriousness, one of the other 16 issues, I do think, that we have to reflect on, at 17 least for the materials licensees, quidance documents 18 19 are not binding on the agreement state programs. NRC might develop some nice 20 although quidance 21 documents of how one could do this, whether it is tied 22 to a policy statement or something else or even a regulation, the agreement states do not have to follow 23 24 the guidance documents.

HEARING OFFICER HODGKINS: Ellen?

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MS. ANDERSON: I was just going to say, you can tie the whole issue of constraint back to the ALARA requirement for the ALARA program, and then within there identify the use of -- use constraint. You can use ALARA planning value, whatever you want to use as a recommended action for an ALARA program.

Obviously, if in fact it is in there in writing, and you don't do that, then you have to justify why you aren't with your own existing program.

But I think we already have that there. I mean, you can call it ALARA planning standard. You can call it a goal. You can call it a investigation level from this side of the house.

There are different ways you can do it, but you can tie it all back to the ALARA program.

MR. COOL: Okay. Let me play devil's advocate for just a second, from a direction you probably wouldn't expect, which is: Okay, that is nice, but the rule says licensees have to reduce exposures using procedures and engineering controls to levels that are low as reasonably achievable, blah, blah, blah.

I don't see the word planning. I don't see the word criteria. How could I write that guide?

HEARING OFFICER HODGKINS: Chuck, you are

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being too tentative.

MR. PICKERING: I think adding then a sentence there -- and I think, so to set it, I am trying to figure out the right wording, which is why I am hesitating maybe, but that we -- And in all that, we strive -- I think that is the right word -- for keeping doses below 2R per year or whatever it is.

So again, it is sort of a goal that we are looking to achieve that gets us sort of what ICRP -- I look at it where we have a two-tier system right now. We have limits, and then we have -- at the upper end, and then at the bottom end we have ALARA, which I think we all agree is an exquisite system unique to our industry.

OSHA doesn't have the concept of ALARA. They have maximum ceiling limits. You are trying to add a third tier to the system in the middle, and maybe even on the upper bounds, that I don't think is necessary.

MR. COOL; Okay, a bit of reflection for clarification. It could be a third tier or it could be a more explicit acknowledgment of what is ALARA planning to begin with, and I would like -- and I am saying that, because I would like to draw a separation between the question of planning and using planning

values from some suggestions that that is a rubric to get you to being able to say 2, because I think those are two entirely different things, and you could do the one without having to do the other at all.

MR. PICKERING: So here is my problem with that, in that we are already doing better than that. If you were to say ALARA is 2, we are way better than that already in general. So I think we are going backwards then.

HEARING OFFICER HODGKINS: Leonard.

MR. SMITH: I think it is fine that we have limits that are established nationally, but the problem in setting constraints is that there are going to be at a lower level than a limit, and they are probably going to be more operational constraints.

So a limit is like something that you are -- It is more like a goal. You know, you can't exceed a limit. That is your goal in your program, and you've got multiple ways of dealing with that.

As soon as you set a constraint at a significantly lower level, you get into this problem of how do you actually administer the program to achieve that constraint. I think the problem is that it is almost impossible to come up with a constraint that would suit all the different practices.

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So what needs to happen is that you need to give the licensees the freedom to choose their own constraints or their own administrative action levels. For that reason, it is not possible to come up with constraints that would suit everybody.

HEARING OFFICER HODGKINS: Ralph?

MR. MACKINTOSH: Anytime we write regulations, I am always leery of setting these hard numbers, not only philosophically, because how they become interpreted in the field. I am old guy. So I like to tell anecdotes.

I spent eight years under the NRC as a chief physicist of a VA hospital, and I came under the NRC. I remember being inspected one time. An inspector came out, and he spent two days going over my records in detail, every page after page, and he found in the daily record of the morning warm-up of a cobalt machine in three years worth of records that someone had written a number but had not placed his initials beside the number, and I got a violation.

To me, when you start putting hard numbers in there and they get interpreted in the field, you end up with needless violations and interpretations that are rigid rather than flexible.

HEARING OFFICER HODGKINS: Lynne?

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MS. FAIROBENT: Yes. Don, just to follow up, you are quoting 20.1101, I believe, with your statement on engineering designs and stuff. But if you go back and look at the definition of ALARA, I think it actually can be used to cover constraints similarly to what Ellen was saying, because if I read the definition from Part 20, from 20.2, it says ALARA, acronym for "as low as is reasonably achievable.

It means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Part as is practical, consistent with purpose for which the licensed activity is undertaken, taking into account the of state technology, the economic improvements in relation to state of technology, the economics of improvement in relation to benefits to public health and safety, and other societal and socioeconomic considerations and in relation to utilization of nuclear energy and licensed materials in the public interest.

I could argue that in that definition of ALARA is the entire concept of planning that, I think, is envisioned under the ICRP rubric of constraint.

Maybe I am reading ICRP 103 incorrectly, but I do think that that really does cover their whole concept.

HEARING OFFICER HODGKINS: Donald.

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MR. MILLER: Don, you asked earlier how you would hang the guidance onto the regulation, and the regulation says "make every reasonable effort," and the guidance is this is what a reasonable effort is.

HEARING OFFICER HODGKINS: Scott.

MR. CARGILL: Actually, I would even take that one step further. I would love to see guidance be guidance. This is not here is how to do it. Here are suggested ways that we see doing it. Much like Ralph said, I hesitate to even approach anything where I set a regulation or a regulator in position to be that judge and jury.

Don, you have been at this a long time. I have no doubt whatsoever that you know what you are doing, but I have had auditors come in who weren't as experienced. I'll use that as a politically correct term.

When an auditor walks up and essentially tells one of my people to move away from my material, that is not safe to stand there, I have to question that auditor's perception of their job and the regulations and what it is we are doing. But to offer guidance, I am all for that.

As I have already pointed out, ALARA

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already pretty much encompasses this entire concept, as low as reasonably achievable. Each of us has our own reasonable expectations. How to regulate that term -- that is nearly impossible. You can't regulate reasonable.

I would love to see guidance in ALARA.

These are ways of doing things, and that way we can pick and choose the pieces that work for our industries.

HEARING OFFICER HODGKINS: Microphone.

MR. TAKAHASHI: Joe Takahashi, Northridge Hospital. In California, we have a medical guide that assists the medical licensees in order to apply a license or to do a renewal, and I believe that that medical guide was taken from the NRC.

In there, there is an ALARA program in which they use the 10 percent of the quarterly limit back when, in the old days, we used to have a quarterly limit, and they used to take 10 percent of that.

So there were some numbers that they had to give guidance to the individuals, and we use that in our hospital. But because of the interventional and cardiac cath, we have increased that, and we just recently increased it to the nuclear medicine techs,

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because they are involved with PET isotopes.

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So I mean, in California they allow minor changes in the radiation safety program without asking for an amendment, because it ties up the license reviewers in order to process those amendments. But I think it is just that type of medical guide that the NRC had way back when that we could then produce out that, for the ALARA side, there is some type of guidance that they have. It should say that there is flexibility in that, but they have to be able to justify that to the license reviewer as well as to the inspector that comes in to look at them.

HEARING OFFICER HODGKINS: Thank you. anybody else from the panel? Comment? So where are Have we discussed -- Has everybody had an we? opportunity to talk about Option 4(a), 4(b), and on the next screen 4(c)? Is there any further comment from the panelists that we want to do, have, behold? audience, any final words, comments, reflections, amplifications? We are good? I think we are ready to move on.

`MR. COOL: Well, I think what that means is we will walk through the questions just to make sure that that doesn't stimulate some other thing that you would wish to say, and perhaps this also gives me

1	a little bit of an opportunity to see how well my
2	brain has or has not processed some of the things that
3	you said, because we wrote several questions. They
4	are in the Federal Register.
5	Significant impacts and benefits
6	associated with imposing use of constraints on
7	licensees' radiation protection program: What I have
8	heard you say is that there are probably impacts to
9	making it more formal. There is probably not a whole
10	lot of benefit, because you already do planning with
11	various sorts of criteria, and that while it would be
12	useful perhaps to have some additional guidance that
13	helps to link these international concepts to that
14	which you are already doing, you didn't see anything
15	that would suggest that there was really any benefit
16	to having text to the regulations.
17	I have seen lots of heads bouncing up and
18	down. Anyone want to add to that verbally?
19	MS. ANDERSON: Ellen Anderson, NEI. I
20	agree.
21	MR. MILLER: Don Miller. Second.
22	MR. DIMOCK: Colin Dimock. Third.
23	MR. COOL: We are not voting, but okay.
24	The second followed onto that, of course:
25	Anticipated implementation impacts on inspection,

compliance, reporting.

I have head everybody say, when you start to do reporting, require reports to be sent someplace, then you are much closer to limit, because then things have to happen, and people start coming, look over your shoulders. So no one seemed to be very happy associated with that.

We have actually had a number of discussions about inspectors coming on site and what they look for or don't look for as part of that program. Anything else you might want to add to that?

MS. ANDERSON: Ellen Anderson, NEI. Once you make a report, it becomes a public document, and I am not necessarily -- especially if you are talking about something like a constraint as a de facto limit, not really a limit, you are now reporting something really make any sense, because it is not even a limit.

HEARING OFFICER HODGKINS: Anybody else? Ralph?

MR. MACKINTOSH: I have a comment on the same concept. IN my area, fortunately not my hospital, but the local newspaper has chosen to make the state and Federal record of a hospital in our area the fodder for their front page, and every incident of

any kind that occurs becomes a front page headline and 2 is usually blown out of proportion. 3 HEARING OFFICER HODGKINS: Anyone else? 4 Yes, Melissa? MS.L MARTIN: Melissa Martin. I think one of the bigger questions in my mind is, again coming 6 7 back to the who are we reporting this to, and what level of expertise does that person have that is going 8 reviewing this to decide whether 9 significant, insignificant? Do they know what 10 11 involved in the type of procedures that these people may be performing in their jobs? 12 I think there is just -- You know, in the 13 14 state of California everybody is crying for money, and we have heard nothing but that there is budget 15 constraints and positions can't be filled, and there's 16 limits on personnel. So again, are we adding a burden 17 to the state Radiologic Health Branch personnel at 18 19 this point when we start reporting these incidents in states that are not NRC? 20 21 HEARING OFFICER HODGKINS: Anybody else? 22 Yes, Colin? 23 If these reports that we are MR. DIMOCK: 24 sending, if these aren't limits that we are sending 25 these reports on, what exactly is the state or the NRC

going to do with this report?

HEARING OFFICER HODGKINS: Okay. I think, rhetorical. How about from the audience? Anybody want to comment from the audience? Next question, please.

MR. COOL: Which was the million dollar question, I suppose. The relationship between a constraint and a limit, if any.

I think this group concluded that it wanted to stay away from numeric numbers and, while it was understood that planning criteria, constraint, whatever sort of term you want to use, certainly have a relationship within your individual programs, as in it is part of your mechanism to make sure that you don't get to a limit, that you would not try to draw anymore formal connection between the two, and I think related to that, the group shied probably very strongly away from the idea of having this be some sort of rubric whereby a numeric value of 2 could show up someplace for a, wave a little flag, see, we did the job sort of thing.

That is expressed a bit satirically perhaps, but as part of that process. Other suggestions?

HEARING OFFICER HODGKINS: Go ahead.

MS. MARKUS: The group of people that tend 2 to have the high dose are just most of the time people 3 that NRC doesn't even regulate. These are people who 4 use radiation introducing machines. Ιf 5 NRC insists on reporting when constraint doses are not met, we don't report to NRC 6 7 that the interventional radiologist went over 8 limit, because NRC has no statutory authority. We 9 then bother our state people or what? How can you 10 regulate something that you have 11 authority over? HEARING OFFICER HODGKINS: Robert? 12 I think the answer is that MR. GREGER: 13 14 most states adopt 10 CFR Part 20 or the suggested state regulations from CRCPD, and those regulations 15 would reflect pretty much what the NRC's regulations 16 17 say, Carol. HEARING OFFICER HODGKINS: 18 Lynne? 19 MR. GREGER: And, yes, the report would go 20 to the state in lieu of the NRC, just as they do for 21 materials events that occur in agreement states. 22 MS. FAIROBENT: Lynne Fairobent, AAPM. Yes, I was going to -- Just to echo what Bob said, I 23 24 would think that, if NRC makes the decision to go in 25 this direction and adopt constraints and to a revision

of Part 20, the compatibility level of this would be fairly high in assignment to the regulatory process.

I think that this falls into the general category that the industry in the past has argued: We want a high compatibility level, so that those from state to state under the materials program, are not having two systems or three systems or, in this case, now 37 systems, 38 counting an NRC nonagreement state, where this type of limit would vary.

So I do think that the states -- It would be fairly consistent, and I can't believe, at least for the 37 agreement states, if they had a high compatibility with the NRC change, that they would not also use this on the X-ray side of the house. IN fact, we would probably argue that it should be consistently applied on both sides of the house.

HEARING OFFICER HODGKINS: Leonard, did you want to add?

MR. SMITH: Yes. Just to state again that I think any constraint that is imposed on a licensee and requires certain actions, it would really be considered as a limit. So it is a limit, and just another limit.

For constraints to be different from limits, I think they have to be voluntary

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administrative levels that the licensees could be encouraged and given guidance on, but not imposed on them.

HEARING OFFICER HODGKINS: Roger.

MR. PEDERSEN: Yes, Roger Pedersen, NRC.

I would like to ask the question a little more pointedly.

The ICRP dose limit in the recommendations is 10 rem over five years with not to exceed 5 rem in any one year. In previous discussions with different parts of the industries, the suggestion was floated that a constraint would be used instead of adopting that limit, leave a 5 rem per year dose limit in 10 CFR 20, and use a constraint as a mechanism for the goal of not exceeding 10 rem in a five-year period.

I guess I would like to restructure the question and ask: Do you think that that proposal has any merit? I think I have heard it doesn't make any difference to you, because a constraint turns out to be a limit. Depends on how you implement it. But again, given a definition of a constraint, that a constraint is the level at which you need to do something, that something is open for debate as well.

So it doesn't necessarily mean you have to report. You have to do something with the goal of not

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exceeding 10 rem in a 5 rem period, whether there is any benefit to that system in lieu of having -- adopting the dose limits that is in the recommendations.

HEARING OFFICER HODGKINS: Len.

MR. SMITH: Yes. Ι think particular case of adopting -- continuing to have a 5 rem occupational limit and establishing a constraint to 2 rem -- I think that would probably be -- That is preferable to some of the other alternatives that we were looking at. But my feeling is that the only requirement of the restraint would be -- of constraint in this case would be that the licensee would periodically review their program and, okay, document that they have done that. But they would have complete flexibility on how they -- what other actions that they might take.

So, really, it is just a -- It is really just an extension of the ALARA program.

HEARING OFFICER HODGKINS: Counterpoint?

MR. PEDERSEN: A follow-up. Roger Pedersen, NRC. Sounds to me like you are saying it depends on what you have to do at that constraint level. If we set a maximum constraint at 2 rem, it depends on what the licensee would have to do at that

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MR. SMITH: Yes. Right. I mean, one thing that -- We already have -- We have different registry limits for astronauts, for example. If we are getting down to a situation where we have lower limits, we may be needing to look at having different limits for different communities.

The simplest thing right now is for the licensee would perhaps select that constraint level.

HEARING OFFICER HODGKINS: Other comments, questions, concerns? Let's move on to question 4.

MR. COOL: Is this discussion something that is an appropriate assertion or perhaps an inappropriate insertion of a regulatory requirement?

It is actually a question raised by one of our Commissioners, and it had to do, as many of you have discussed, as to whether it is appropriate and reasonable to be a little more specific and tell licensees that they have to plan and establish criteria as part of the planning or simply rely on the fact that it is what most people do, but there is nothing that you could put your finger on?

HEARING OFFICER HODGKINS: Lynne?

MS. FAIROBENT: Don, from my personal view and not AAPM's, having sat through all of the safety

culture policy statement meetings and workshops and discussions, I think that this can be -- could be perceived by some as a backdoor way of regulating and moving the safety culture policy into rulemaking.

NRC is on record that the safety culture policy statement at this point in time -- now granted, the final decision has not been made yet -- is not to

policy statement at this point in time -- now granted, the final decision has not been made yet -- is not to move that into rulemaking space. I think this just may fuel, if one looks at the constraints as -- or if what we said was to -- as Scott said, to use the concept of constraints in demonstration of an appropriate safety culture, then establishing a formal requirement under Part 20 for a constraint, whatever that may be, I think, could be perceived as a backdoor way of rulemaking into safety culture policy.

HEARING OFFICER HODGKINS: Scott?

MR. GOLDIN: Eric Goldin, Southern California Edison. I guess the existing -- Oh, I'm sorry. Somebody else?

HEARING OFFICER HODGKINS: No, no. I called you Scott. You are Eric.

MR. GOLDIN: Oh, that's fine. The existing constraint that is in regulations now is the NESHAPS rule, and my recollection, which is probably wrong, is that it was adopted because we already knew

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that every licensee except save one, I think, was going to have difficulty, but everybody else would have no trouble meeting that constraint.

Here, we would be establishing a constraint that we already know some licensees, many licensees perhaps, would have some difficult meeting. So it is a little different level of implementation.

HEARING OFFICER HODGKINS: Okay. Chuck?

MR. PICKERING: So if the regulations are performance based and we have a limit that I think we are comfortable with, we have already implemented things like you have to wear a lead apron and we have to shield things, and by doing all those things we are below the limits. I don't think there is any evidence of major problems in the industry of exceeding those limits. So we are performing.

So just a matter of how much do we want to rachet things down. We have had lots of discussion about the science of that and whether it is necessary or not, but we are performing well, and I think looking at it as a performance based thing, if regulators come in and you are not performing, then they should cite you for that and make you then perform better.

HEARING OFFICER HODGKINS: Anyone else?

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Yes, Leonard?

MR. SMITH: I guess one of the concerns I would have is that a lot of the industry is -- licensees are generally extremely good in controlling the exposure. There is always a few out there that are not so good. I suspect the regulators might feel uncomfortable if they can't get a real handle around these less good performers.

So my question is: Surely, you have other methods for dealing with that situation. If you've got -- and you wouldn't need to apply a constraint. So if you have a licensee who is simply allowing their employees to get unnecessary exposure, the inspection process should be able to pick that up, and you have all the means for changing that. You would even impose conditions on the licensee.

So I don't think you need a constraint system that you impose to the entire regulated community. You are better off just dealing with licensees on a case by case basis, since it is likely to be somewhat rare.

HEARING OFFICER HODGKINS: Agreement?

anybody want to verbalize that? A few head nods.

MR. GREGER: But from a regulator's standpoint, we don't like to regulate on an individual

basis. We like to regulate on a generic basis, so everyone is on the same playing field, and everyone has the same criteria that they have to meet.

If we do find poor performers, then we will work one way or another to get them to improve their program. Hopefully, they will do it themselves when it is pointed out that there are significant problems and, hopefully, they will understand and agree that there are problems. If that doesn't work, is enforcement, depending there organization, you balance the two, and one organization may go a little further.

By organization, one state, one agreement state may go a little further one way than the other, but in general from a regulatory standpoint, we don't like to tailor the programs to specific licensees.

HEARING OFFICER HODGKINS: Okay.

MR. SMITH: Going back to that. I appreciate that, and I think that is all we have. I think we have regulations that apply to all the licensees, and I guess what I am saying is I think it is reasonable that there's only going to be a few licensees that are not following the intent of the regulations, and then the enforcement action would deal with that.

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george?

MR. SEGALL: I appreciate what Bob said, but I would offer an opposite analogy. It is safe to drive on a road at 50 miles an hour. You cite the violators who exceed that safety limit. You don't drop the safety limit to 20 miles an hour for all the people.

MR. COOL: Let ;me ask a slightly different question on this, because I have heard at various times, not lately, that the whole provisions for ALARA are a little bit difficult to inspect and enforce, because each system does have to be unique. There has to be individual attributes.

So at one point, there was a thought, does saying that there has to be some planning and that there has to be some planning values and that there needs to be some documentation of those steps, help there to be a more consistent approach so that you would understand when enforcement was appropriate versus not appropriate, and not quite so subjective a process. Any thoughts on that?

HEARING OFFICER HODGKINS: Chuck?

MR. PICKERING: What I think you are saying is -- or what we would like to see then in the

1	guidance documents would be more best practices of how
2	different institutions apply things. If UCLA is doing
3	a great job with interventional radiology and we all
4	could learn from that, then that is what I would like
5	to know. I think that might help.
6	HEARING OFFICER HODGKINS: Lynne?
7	MS. FAIROBENT: Just to follow up on that,
8	though and I am going to put my association hat on.
9	Is it really that we should be looking for the
10	regulatory agencies to be developing that type of
11	guidance or wouldn't it be better for us to be
12	developing that type of guidance for our own
13	industries?
14	MR. SMITH: Right on.
15	MR. PICKERING; I totally agree with that.
16	Absolutely.
17	HEARING OFFICER HODGKINS: Leonard, is
18	that what you were going to say?
19	MR. SMITH: Exactly. You took the words
20	right out of my mouth. I mean, the power industry is
21	a good example of where they have done that very
22	effectively.
23	HEARING OFFICER HODGKINS: Okay, any other
24	comments, question 4?
25	MR. COOL: So to reflect back on that a

bit, I take it then from your reaction or lack of reaction that you don't see there being enforcement issues or lack of clarity around what would be enforceable in terms of whether or not you had an ALARA program and things that could be helped by saying that there needed to be some planning, there needed to be some planning values, that it is sufficiently covered?

HEARING OFFICER HODGKINS: Leonard.

MR. SMITH: I think that the issue is I don't think imposing conditions on the broad range of licensees will work. I think there is some value in advising and showing -- giving guidance, giving examples of successful programs that licensees can learn from.

In our own community, licensees should try to get together and work out things, help one another. In CORAR, for example, there is quite a lot of peer pressure for a member company that might not have such a good radiation protection program to improve that program, because the whole community wants to have good programs.

So the companies will learn from one another. The manufacturers will learn from one another, and that, I think, is a very effective way of

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getting improvement. It is much more difficult for the regulator to create that.

MR. COOL: And I very much agree that there is a huge amount of value in the peer review, best practices learning and things, which really belongs out there. It cannot come from a regulatory organization.

What I was just trying to probe a little bit was whether, in an effort and desire to have clear scrutable regulations where people know expectation is, so that they know that comfortable with it, whether bit added а of specificity helps or whether the current words are sufficient. And it may well be that you are saying that the current words are sufficient. That is okay. I just want to make sure that that is the view of individuals who would like to suggest anything here.

HEARING OFFICER HODGKINS: Ralph?

MR. MACKINTOSH: Part of the problem we have in discussing this is that the people you have in this room are people in programs which have good ALARA programs and are well established.

I know Melissa and I circulate sometimes among the smaller institutions, at least in this area, where more guidance is needed. The State of

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1 California does a pretty good job, as we submit our 2 ALARA programs, of having investigational levels all 3 set, and we are inspected based on compliance with those. I think having suggested levels and having good guidance is important as you go across the 6 7 country and look at different programs, especially those smaller programs that don't have the expertise 8 or the manpower to have robust implementations. 9 10 HEARING OFFICER HODGKINS: Lynne? 11 MS. FAIROBENT: Don, before I go on with what I first was going to say, which existing words 12 are you asking us are they sufficient? 13 14 MR. COOL: The definition that you cited 15 and --Okay, the current ALARA 16 MS. FAIROBENT: definition. 17 MR. COOL: The current ALARA definition, 18 which isn't explicit about planning and using planning 19 Really, what I am asking is: You have 20 values. 21 intimated -- so I want to do a cross-check on it --22 that smaller groups may not have the same degree of sophistication, may not be doing these same things, 23 24 and whether there is any value, or not, of saying we

expect that programs are going to do planning.

expect they are going to establish some planning criteria, but everything that we would say about what constitutes a good program, good planning and things, would be in guidance, would be in industry best practices.

It just becomes clearer to everybody that that is part of the set of expectations, so that then there is a clear linkage, because one of the conclusions I could draw is that there may be an opportunity here for a small amendment that does not have a number, does not have any dosimetric criteria or other, but lays out that expectation more clearly, because we, dare I say, read between the lines, and we all think it is there, but somebody else might not read it there.

MS. FAIROBENT: Don, I agree. I think that there is always room for improvement in guidance and elaboration in guidance. What I was originally going to say -- and again, it ties back, because I have been so involved with the recent draft safety culture policy statement.

Everyone that had been involved in those workshops, which represented all of the industries, potential industries, to come under the policy statement now.

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concern with establishing а single constraint numerical value across all license categories is reflective of the discussions in the safety culture policy where we all said that was not what should be done under demonstration of safety culture, that there is enough differences various professional categories that NRC licenses that there needs to be room for differences, and that as we move from the level we are at now with the draft safety culture policy statement to what in meetings has been termed Tier 3 Traits and developed Characteristics, that those need to be uniquely focused on the industry being regulated.

I would hate to lose sight of all of those discussions that are going on, say, with the right hand, because the left hand may be doing something else in the Part 20 realm, and we are not crosspollinating the discussions and ensuring consistency.

It also was noted extensively in those discussions that, before NRC could move the draft safety culture policy statement, if they should decide to, into rulemaking space, that there needed to be a clear set of metrics developed so that the licensees would know how that policy statement was then going to be used in an enforcement category.

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So I just bring it up so that those who may not have been involved in that other effort realize that there are similar discussions going on with another focus and another purpose, all under the NRC umbrella and rubric.

HEARING OFFICER HODGKINS: Are we ready to move on to the next topic or the next question?

I think everyone has already MR. COOL; demonstrated they are very familiar with different planning in places, and we have all demonstrated that when we start to try and figure out exactly what ICRP meant when they said constraints, we discover something which is not quite mud but is still fairly viscous, and then that dialogue continues. But if anyone would like to add to that --

HEARING OFFICER HODGKINS: I think we are ready to move on to the last question.

MR. COOL: And I think the answer here is that you do do planning. You do use some planning values. They are unique to the kinds of activities that you are doing, and even different groups of individuals in the circumstances, and that all of this discussion has to reflect and allow for that variability in doing the right thing.

Again, there are heads generally bouncing

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1	up and down, which the transcriber can't put on the
2	record.
3	HEARING OFFICER HODGKINS: Leonard.
4	MR. SMITH: Yes, that is what radiation
5	protection people do. Right?
6	HEARING OFFICER HODGKINS: Scott.
7	MR. CARGILL: I am going to have to say
8	that Leonard's yes was better than my yes.
9	HEARING OFFICER HODGKINS: Chuck?
10	MR. PICKERING: And it is what radiation
11	safety committees do. You know, we discuss these
12	topics and, when we look at ALARA reports and review
13	them and we look for trends and, if we see trends, I
14	get instructed to go do things, which I would do on my
15	own, but the committee is involved in that as well.
16	HEARING OFFICER HODGKINS: Anyone else?
17	From the audience, comments? Questions,
18	amplifications?
19	MR. COOL: Here is your final chance. I
20	was in hopes Carol would give us a last guiding word.
21	MS. MARKUS: Yes, this is what my last
22	guidance suggestion is.
23	I think you ought to tell the
24	Commissioners that it is not a good idea to follow the
25	ICRP guidance, because it only encourages them.

I think that the NRC Commissioners should basically say that, until the ICRP accepts widely recognized science and is ready to reevaluate its basic premises, that it is really not very useful to the United States; and that might make them work harder and get more honest. But if you just accept whatever comes out, they are not going to change.

I think many of us seriously find ourselves divorced from this lower is better down to the last atom mentality in the face of a huge database that says otherwise.

HEARING OFFICER HODGKINS: Okay. Are we ready --

MR. COOL: This then opens it up one notch We raised four major areas. I know you all more. radiation protection requirements, love everybody thinks Part 20 is perfect (not). So this is one very brief opportunity of any other things that would wish to place on the consideration, recognizing that we don't have another three days, but it is still your chance, if there were other issues that you want to at least put on the record.

HEARING OFFICER HODGKINS: Ellen?

MR. COOL: Part 20.

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MS. ANDERSON: Ellen Anderson, NEI. 2 recommend that the Commission put Again, the regulations in the books. However, any guidance, take any table, data tables, whatever guidance out of the regulations, and put them into Regulatory Guides. That means that in the future it will be much easier to -- for rulemaking -- You wouldn't have to go through rulemaking every time we decide to 8 9 change a data table. ICRP comes up with a new value or whatever, we can change that without having to go 10 11 into rulemaking. HEARING OFFICER HODGKINS: Anybody else? 12 Specific issues, questions that you would like this 13 14 committee to discuss? Panelists? BURKLIN: T have 15 MR. one other recommendation. In 10 CFR 20, there is a limit of one 16 curie -- this is completely off the subject, but one 17 curie can go into a sanitary sewer, and that is not a 18 19 risk based number. I would suggest that that one 20 curie be removed, and if you wanted to put in a risk 21 based number, then put that in. 22 HEARING OFFICER HODGKINS: Okav. MR. COOL: May I invite; you to elaborate 23 24 and some comments afterwards.

MR. GREGER: If I could just follow up.

1	Richard, just a quick question. Are you talking about
2	You are talking about the one curie of all nuclides
3	
4	MR. BURKLIN: Yes, one curie of soluble
5	nuclides.
6	MR. GREGER: Tritium has, I think, a 5
7	curie per year.
8	MR. BURKLIN: Well, it may. I'm sorry.
9	There is a limit of one for at least the isotopes that
10	I am interested in.
11	MR. GREGER: Carbon 14.
12	MR. BURKLIN: And it would seem to me like
13	different isotopes carry with them different risks,
14	and it doesn't make sense to put in a one curie limit.
15	HEARING OFFICER HODGKINS: Further?
16	Carol?
17	MS. MARKUS: We do have a problem within
18	the medical community with sanitary landfills. Trace
19	amounts of radioactive material from patient generated
20	waste gets to a garbage dump. The garbage dumps have
21	radiation detectors or the medical waste treatment
22	plants have radiation detectors.
23	The detectors go off. People get
24	hysterical. They bother radiation management people.
25	Radiation management people bother the person or the

institution that sent the trash, and almost invariably 2 these are trivial levels of no health and safety concern whatsoever. Years ago I tried to get the NRC to get 5 active in making standards to prevent this hysteria that goes on, whether it is Congressman Markey or 6 Peter Crane or any other group of people screeching, if you can detect it, it is dangerous, which is 8 9 basically what they are saying. 10 If would really be nice to have a set of 11 reasonable, scientifically valid standards disposal in sanitary landfills. We have standards for 12 air, standards for water. Why not have standards for 13 14 sanitary landfills, so that this trouble can go away? HEARING OFFICER HODGKINS: Comments? Yes, 15 Eric? 16 MR GOLDIN: I think there is international 17 quidance of dose assessed at 1 millirem per year 18 should be below the concern of the public. I think 10 19 micro sieverts is what ICRP says is the lower bound of 20 21 what should be regulated. 22 HEARING OFFICER HODGKINS: Okay. Yes, Lynne? 23 24 MS. FAIROBENT: Yes. I just -- because 25 it was implied yesterday, but I don't think we perhaps

stressed it as much at this workshop as it was certainly stressed at the D.C. workshop, that regardless of what NRC's decision might be, to go forward or not go forward with Part 20, unless there is a unified U.S. policy position for all Federal agencies to follow any changes that are made in a consistent manner and also for the states to follow in that same manner, then any single Federal regulatory authority should not be making any changes.

We continue to operate under a disparate set of regulations, depending on whose we pick up, OSHA's or ICRP dose based. DOE's are different than NRC's. Some of the states are different, but if we are going to make a major change to reflect ICRP 103, then it needs to be a U.S. Federal policy to move in that direction, and I really, really would hate to see NRC make -- and I am not implying that you are moving in that vein, and you are sensitive to that. But I did want to put it on this record that I personally believe that, if it is not a U.S. policy, then we should not be doing or discussing any additional changes to the methodologies.

HEARING OFFICER HODGKINS: You know, Lynne, that just reminds me, too -- and, Ellen, you were there -- from the D.C. perspective, are there

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some issues that you heard there that you didn't hear 2 here? The only two things that 3 MS. FAIROBENT: 4 came up in sidebar discussions -- and, Don, correct me if I am wrong, and it wasn't really stuff that you put up, but because we were ahead of schedule and people 6 raised some questions, we talked about the ICRP's 8 effort to move into non-human populations in regulating, and we talked a little bit more focused on 9 extremity doses, whether there was going to be any 10 11 changes to extremity doses. Those are the two other somewhat related 12 issues that I recall from D.C. that we did not touch 13 14 upon here that I recall. HEARING OFFICER HODGKINS: 15 Okay. Anybody want to touch on those topics? chuck? 16 No. 17 want to say something? 18 MR. PICKERING: I read this in some of the preparatory documents coming here, and I haven't heard 19 20 any discussion. Maybe Ellen can help. And I am not 21 in the nuclear power industry at all, but I am a fan, 22 and I would like to see more of it. 23 There was a discussion that, if we did not

come into alignment with ICRP 103, that was going to

hurt the industry in bringing new plants on board.

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Did I read that right, because I don't get that impression from the industry at all? 2 3 MS. ANDERSON: Where did you read that 4 from? MR. PICKERING: Again, I can probably show it to you here. I will find it. 6 MS. ANDERSON: Yes, we have two plants 8 that are currently under construction now, one 9 South Carolina and one in Georgia. The lack of adopting ICRP 103 is not stopping those plants. 10 11 MS. FAIROBENT: Id ont' know where he may have read it, but there was discussion in D.C. that, 12 if a decision -- It was the timeliness of the decision 13 14 to be made and what timeline we were going to operate and implement under, and we did not talk -- Don, you 15 did not talk about the timeline of what you all are 16 under as far as direction from the Commissioners to 17 the staff. 18 I think that there was that point for the 19 20 new reactors. If we delayed too far, the new reactors 21 were going to be built under the old system, 22 therefore, they would have double cost incurrances and a short time frame. I will let Ellen elaborate on 23 24 that.

The other point that was raised in d.C.

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was that, if a decision is made to go forward, that there be ample opportunity to implement the rule once it was put into an effective date/time frame.

HEARING OFFICER HODGKINS: Roger?

MR PEDERSEN: Another big issue that was discussed in D.C., and in fact a whole third day was dedicated to it, was a conforming change to Part 50, and that might be the genesis of the question here.

The Office of New Reactor Regulation is wrestling a little bit with the problem of having dose based criteria in Part 50 that are ICRP two-based, and 10 CFR 20, which is ICRP 2630 based. That Appendix I to Part 50 has already been identified as an area in which we should make a conforming change.

Even if we don't adopt ICRP 103, they are looking for a conforming change to the current regulation. Actually, that kind of segues right into the comment I wanted to make here.

We haven't talked about conforming changes to other parts of the regulation at all at this meeting. I guess I would like to challenge the panel, if there are other parts of 10 CFR, NRC's regulations, that you see if, we in fact, do adopt something that looks something like 103, do you see where that might be problematic in terms of conflict with other NRC

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227 1 regulations in your area, to the point where maybe we 2 should consider a conforming change at the same time. HEARING OFFICER HODGKINS: MR. DIMOCK: Are you opening up the Part 5 35 Pandora's box of 500 millirem? MR. PEDERSEN: I am not opening up, no. I 6 7 am asking you if you see a reason to open it up maybe. 8 MR. DIMOCK: I recommend no change. HEARING OFFICER HODGKINS: Ellen? 9 10 MS. ANDERSON: The document Chuck was 11 talking about was SECY 080197, where the Commission 12 talked about Appendix I -- the Part 50, Appendix I. That is the public exposure portion of the house, 13 14 which we discussed at length for a full day in Washington last week. 15 I just want to fall up on the comment that 16

I just want to fall up on the comment that Lynne made about new plants, and that was -- This came, actually, form one of the licensees who is building a new plant, and the issue that came up was -- had to do with the actual construction and operation of a new plant in the 2016-2018 time frame, and whether coming in with new regulations at that time -- based on the fact that the plants are actually licensed and constructed to the current regulatory framework in Part 20, and what would happen if, in

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fact, we brought the new plants on line with the new Part 20.

I think, basically, what was said was, they -- From a design perspective, there is not much we can do at that point, because it is already being built, but from an implementation perspective, that should not be an issue.

Both the sides in South Carolina and Georgia both have operating plants. Those utilities do have operating plants now. Their radiation protection programs probably wouldn't be all that different from an implementation perspective. So I really don't think that is an issue.

I think, other than -- I think that that representative from that utility just wanted to make sure that you were aware of the fact that, with the possible implementation of a new Part 20 during that time is also in coordination with the actual bringing a new reactor on line.

HEARING OFFICER HODGKINS: Okay. Anything else? Any other comments then as far as open floor, open mike night here at L.A.? Yes, Roger?

MR. GREGER: I guess we are getting to that kind of last comment point. So I would just like to reiterate that I have made comments representing

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the state of California, and I am also here representing the organization of agreement state and the Conference of Radiation Control Program Directors.

From the standpoint of both of those organizations, they have come to no conclusions whatsoever and, for that matter, we have come to no conclusions with the state of California either.

There are -- Of course, you know there are three workshops like this, and there are representatives from both CRCPD and Organization of Agreement States, although sometimes one person wears both hats, as happened at least one day in D.C. I am not sure what is going to happen in Houston.

We will all get together and, hopefully, confer with each and every one of the states before those organizations will come to any positions. But we will listen very strongly to the comments that have been made by the industry at all of these meetings, and then we will make a recommendation similar to the recommendations that individuals can make or licensees can make or that came out of today's meeting on the various questions that were posed by NRC here today, and provide those as comments to the NRC, and NRC will evaluate them as they would anyone else's comments.

I found it a very enlightening and very

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educational and interesting experience.

HEARING OFFICER HODGKINS: Thank you. With that being said, let's talk about what comes next.

MR. COOL: Yes. I think this might, in fact, be a really good opportunity to sort of review a little bit, and it looks like this laser might or might not die.

What are the next steps, again just to sort of refresh where we are? This was the second of three workshops. We will be doing this again with another group of participants, which will have a much larger representation from various industrial segments, not quite so large participation on the table from the medical segment.

So I expect there will be some additional flavor and additional viewpoints and perspectives that are brought into play there. All of this is part of an ongoing effort to get viewpoints and thoughts that we would start to assemble.

This is a good time for me to remind you that this particular record and the request for comments in the Federal Register is open through the end of January.

A long time ago when I first joined the

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agency, I had the privilege of knowing the group of individuals that were drafting the proposed rule that eventually became Revised Part 20. Their favorite slogan at the time was keep those cards and letters coming.

Now that was before the days of emails and electronic submissions and everything, but the sentiment is still the same. Keep those cards and letters coming.

As you fight your way through the LA freeways or climb on the airplanes or whatever you are going to do, when you have additional thoughts, additional information, sources of information that we have talked about, we very much would like to encourage you to send that in, because all of that will be part of the record that we will make available.

The transcript from this meeting will be made public. The slides from this meeting will be public, as will the ones from the workshop next week in Houston.

The staff will, ongoing and certainly the first few months after the close of this more formal request for information, start to develop information that we are under obligation to provide to our

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Commissioners late next year in terms of issues, in terms of the options considered, in terms of what recommendation and the whys that we want to present to them on key policy directions.

The Commission will, hopefully, provide us some direction on that. It may be thumbs up; it may be thumbs down. It is too soon to tell.

Following that, and for a moment, just so the scenario could play out, presuming that there was some direction to move toward rulemaking on particular policy issues, we would need to complete the technical basis, the regulatory basis that was necessary to formally prepare a proposal.

Some of that, as we have discussed today, includes numeric information on dose coefficients and other things, and part of the timing of that will depend on the availability of that information.

That process inevitably and automatically leads to additional opportunities for public comment during the proposed rule stage, if not before, and additional opportunities before we would even get to that.

The Commission has at times made its policy papers available during its consideration and, in fact, has at times invited additional stakeholders

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to meetings of the Commission to gather additional views. So there may be multiple opportunities for discussion.

That is where we are going over the course of time, which leads me back to the one final time. We do very much want to encourage you to continue to think about and offer us any additional views on the record as we go through this process.

I think this has been an incredibly good discussion, an opportunity over the last couple of days. I very much appreciate everyone's being very well engaged.

Dan, with your permission, I would like to turn briefly to my Director for some additional thoughts.

MS. PICCONE: Don did say this, but just to reemphasize it, because the slide has that second from the end bullet point, that only if the Commission directs will there be an effort to develop a technical basis and proposed rule. That is not where staff is at this point.

I just want to add my thanks to all of you. This, I think, has been a very productive two days. We appreciate your candor, and more importantly, we appreciate the time you have taken

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1 away from your busy schedules to help us with this. So thanks again, and good travels, wherever you are going. MR. COOL: Dan, any final process checks and updates? HEARING OFFICER HODGKINS: You know, the long goodbye. Really, just evaluation. Please fill out 8 your evaluations. The feedback really has, as I think 9 10 Lynne and Ellen could attest to, helped us improve 11 this one. 12 We have one more. We would really like to have your feedback on that. So feel free to fill out 13 14 that evaluation, and it will be used. So with that, I think I will close unless 15 there is, for one last time, anything the panel wants 16 to say? Anything that the audience needs to say or 17 add? 18 With that, this session is closed. 19 20 you very much. 21 (Whereupon, the foregoing matter went off 22 the record at 4:03 p.m.) 23 24 25