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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

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SUBCOMMITTEE ON RADIATION PROTECTION AND

NUCLEAR MATERIALS

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TUESDAY

SEPTEMBER 18, 2012

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ROCKVILLE, MARYLAND

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The Subcommittee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 1:00 p.m., Michael T. Ryan, Chairman, presiding.

COMMITTEE MEMBERS:

MICHAEL T. RYAN, Chairman

J. SAM ARMIJO

DENNIS C. BLEY

HAROLD B. RAY

STEPHEN P. SCHULTZ

WILLIAM J. SHACK

JOHN D. SIEBER

GORDON R. SKILLMAN

JOHN W. STETKAR

NRC STAFF PRESENT:

DEREK WIDMAYER, Designated Federal Official

DONALD COOL

VINCE HOLAHAN

C-O-N-T-E-N-T-S

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Chairman

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P R O C E E D I N G S

1:00 p.m.

CHAIR RYAN: [presiding] The meeting will come to order.

This is a meeting of the Advisory Committee on Reactor Safeguards, Subcommittee on Radiation Protection and Nuclear Materials.

I am Mike Ryan, Chairman of the Subcommittee. ACRS members in attendance are Sam Armijo, Dennis Bley, Gordon Skillman, Jack Seiber, Harold Ray, and Bill Shack. Did I miss anybody? And John Stetkar. Sorry.

The purpose of this meeting is to continue discussions on SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance".

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

The Subcommittee meeting continues discussions we had with the staff on a draft of the SECY paper at our meeting of this Subcommittee held on April 27, 2012.

The Subcommittee will gather information,

analyze relevant issues and facts, and formulate proposed positions and actions as appropriate. The Subcommittee plans on proposing a letter report on this matter for consideration of the full Committee at the upcoming October full Committee meeting.

The meeting this afternoon is open, but we have not had any requests for time to make statements to the Subcommittee. However, we will provide time at the end of the Subcommittee discussion for anyone to make a comment if they desire.

A transcript of the meeting is being kept and will be made available on the web. It is requested that speakers first identify themselves and speak with sufficient clarity and volume, so they can be readily heard.

Derek Widmayer is the Designated Federal Official for this meeting.

Thank you.

We will now proceed with the meeting, and I call upon Dr. Donald Cool, Senior Advisor on Radiation Safety and the International Liaison in FSME, to open the proceedings.

Dr. Cool?

MR. COOL: Thank you, Mike.

Good afternoon, folks.

We shall see how long my voice holds out before the bronchitis disintegrates me into coughing. I have brought along three folks who have told me that they are willing to come in and relief pitch and close the game as necessary. So, we will see how this proceeds.

CHAIR RYAN: Thank you for coming in, despite your illness, to be with us. Thank you.

MR. COOL: And with the Chairman's permission, I am going to suggest that we do something that might be just a little bit different. I will try to walk very quickly through this rather thick set of slides -- it has a lot of data and information -- to try to set the whole stage on the set of issues. And then, we can come back here and slice and pick and choose and go back and forth and work our way through the details. But I think it perhaps would be beneficial to try to walk you through some of the thinking and thoughts rather quickly to set that stage before we start pursuing some of the issues.

Would that be acceptable, Mr. Chairman?

CHAIR RYAN: Certainly asking for that to happen is acceptable.

(Laughter.)

Whether it will or not, I can only speak

for one of the members present. So, I make no promises, but I will try my best.

MR. COOL: So noted. Thank you, sir.

This afternoon, to try to quickly set the stage from the previous discussions and without going over too much of that additional information, I intend to touch on three topics that were the subject of discussion in the Subcommittee meeting and in the full ACRS Commission meeting in early June.

First is to refresh and provide a little more information related to radiation risk. Then, to spend a good bit of time on occupational exposure, what we know and what we don't know about what is actually occurring out there, and the regulatory approaches that we considered and the discussions that the staff had with various stakeholders related to occupational exposure control.

To start with, and while it might seem a bit elementary, you have got two different things which happen. You have got risk assessment, the process of characterizing the radiation risk. It is unique to each individual. Dr. Ryan, at 6-foot-4 or 5 --

CHAIR RYAN: Seven.

(Laughter.)

MR. COOL: -- has a slightly different set of organ shapes and geometries than I do at 5-foot-7. Okay? So, when we talk about risk assessment, when we talk about the uniqueness of each individual, you try to incorporate as much of the specifics as you can. Nobody is the same. We have genetic predispositions and previous dose histories, and otherwise, which make us completely unique.

On the other hand, risk management, generalized at a population level, is trying to set up things that can be done for a prospective regulatory program that does not bias against different individuals or genders, or otherwise, in establishing a uniform basis for adequate protection. And I say that, in part, because, as we talk about these and we talk about the limits and we talk about the risk models, and we talk about the way that the limits were formulated, it is using the linear dose hypothesis as a basis for a regulatory construct.

Me, myself, as an individual, do I think the body is linear? Nope. On the other hand, I know of only two reasonably-effective regulatory control programs, which is either a straight line or a switch that is either on or off, neither one of which exactly fits what is probably actually happening in the

biology.

And so, as we work through this, it is with the presumption that we are not talking about a particular individual and that I actually know what Dr. Ryan's risk is if I gave him 1 rem of whole-body uniform exposure radiation. But I have a generalized idea of what that risk may be within some set of parameters, based upon what we know from large statistical studies and evidence at higher doses and information on population in the United States and other places.

The current Part 20, the risk basis going back to the seventies, assumed risk, 1.25 times 10 to the minus 2 per sievert; 1.25 times 10 to the minus 4 per rem of radiation. That is for mortality and morbidity and risk of heritable disease.

As a result of several updates of the dosimetry, multiple revisions, and considerably longer followup of the Hiroshima/Nagasaki cohort, and a number of other studies, since the late eighties/beginning of 1990, the estimate of risk has been more like five times 10 to the minus 2 per sievert. That is the number which underlies the calculations that the staff does today on a day-to-day basis. It underlies the regulatory approaches of the

ICRP and the NCRP's current recommendations. It is more or less consistent with what EPA's most recent set of estimates from BEIR-VII are, but it is not the basis of the occupational exposure dose limits that are currently in Part 20.

EPA -- and this is their latest estimate placed on the biological ionizing radiation -- the mortality number there at the bottom of the slide, central value of 5.8 times 10 to the minus 2 per sievert, range of 2.8 to 1.0, that should actually be 10 to the minus 1. I didn't get that number corrected -- I apologize -- on that slide.

CHAIR RYAN: It is 1.0 times 10 to the minus 1 at the bottom there?

MR. COOL: Yes.

Now certainly the previous estimate and the existing estimate, when you look at their error bands each, the error bands overlap each other. The central estimates are not inside those error bands.

The selection of the limitation value, 1977, the basis of the occupational dose limits, average accidental work in what were generally-accepted safe industries, roughly, at one times 10 to the minus 4 risk, actually, comported to an exposure of 1 rem. And a limit of 5 rem was recommended as the

legal value to cap what was hoped to be the distribution where most all of the exposures would be considerably less than that because of the application of the ALARA principle. So, the one-times-10-to-the-minus-4 average, which is used for comparison, was for 1 rem, not 5 rem.

Moving on to 1990, it becomes a more risk-informed approach. Multi-attribute, looks at morbidity, mortality, genetic effects, and other things that are more built into it; was based on looking at several possible lifetime accumulations and a judgment which was made both by the ICRP, the International Commission on Radiological Protection, and NCRP, the U.S. National Council on Radiation Protection and Measurements, that an individual really should not receive a cumulative exposure greater than 1 sievert or 100 rem over their working lifetime. That would comport to, roughly, a 5 percent change of induced effect as a result of that cumulative exposure, with all of the generalizations that go along with that.

With that, ICRP recommended one set of things, which was a 2-rem average, 5-rem maximum as a dose limit. NCRP recommended a 5-rem dose limit with the individual limited to a cumulative value of 1 rem

times their age in years. Two different approaches, both based on the assumption that you are continuously tracking the individual's cumulative exposure over their entire lifetime.

To move now into the data that we have on occupational exposures over the last few years, I am going to present data from three publications publicly available:

NCRP's Report 160, which came out several years ago. That information is based on data that they received from a number of the dosimeter processors. As we understand it, that is the data from the badges. It is not a reflection of what then may have been a calculated effective dose or otherwise. So, as you will see when we go through these slides in a moment, there are values over the 50 millisievert value. That does not necessarily mean that there were overexposures because it could be that there was a calculation for effective dose. We don't know. That is information that we do not have.

I will also be providing you information from NUREG-0713,l the Annual Report compiled by contractors with our Office of Research on the data reported under the reporting requirements of 10 CFR 420, and in NUREG-2118, which was a special request to

Agreement States for data which they might have available in similar timeframes.

So, let's start with NCRP's Report 160. This little pie chart simply shows you the different areas of occupational exposures that that committee looked at. We will be focusing on the medical, which constitutes something like 39 percent of the occupational exposures as they tallied it in the United States; the industrial and commerce, which is that purple quadrant down in the righthand side, and the commercial nuclear power, which is about 8 percent, that dark blue quadrant. Aviation, the other biggest contributor, is the dose that pilots and flight crews and others receive as a result of flying at higher altitudes from cosmic radiation every day. And there are smaller quantities in education, government, and otherwise, which I am not going to go into for purposes of today's discussion.

For medical exposure --

MEMBER ARMIJO: Don, in commercial nuclear power, you include fuel cycle facilities, stuff that we regulate?

MR. COOL: Yes.

MEMBER ARMIJO: Okay.

MR. COOL: So, for medical, a category

which the NRC does not have any reporting requirements, here are the values over 2003, 2004, 2005, and 2006. You can see that the vast majority of exposures are non-measurables. You have very small numbers.

The percentage of individuals with exposures greater than 20 millisieverts, less than half a percent, but there is that tail of the distribution. And you will see the far righthand column has numbers that are greater than 50 millisieverts. Again, as I told you, it is not clear whether those are actual overexposures or whether those might be badges on the collar of an interventional radiologist who is wearing a leaded apron and, therefore, the actual effective dose, were you to calculate it, would be something less.

MEMBER BLEY: These are reported doses?

MR. COOL: These are the doses from the dosimeters as provided by the dosimetry processors, the information that is available.

MEMBER ARMIJO: So, okay, these are numbers of people right here in the --

MR. COOL: These are numbers of people in each of those dose categories in millisieverts. Okay?

Moving on to slide 9, a similar

presentation of industry and commerce. This is where you find radiographers, other types of folks and other types of uses in industry and commerce that would be using machine-produced radiation.

Similar sorts of distributions. Again, you have got a small percentage, actually, larger than the medical field, of individuals who receive greater than 20 millisieverts in a year, about 7/10ths of a percent. Again, you have numbers that are reported by the dosimeter processors that are over 50 millisieverts or 5 rem.

CHAIR RYAN: So, this includes things like geologists, down-hole logging, and all that kind of stuff?

MR. COOL: This includes all of those sorts of things. Again, you don't know whether these are actually overexposures or not. These sources tend to be higher-energy-penetrating. So, it is difficult to know, but it is an indication. It is the data that we have.

MEMBER SKILLMAN: Do the individuals that have the exposure of over 50 millisieverts have some form of a report filed for that particular overexposure? In other words, is there a second set of data that is not presented here for the far right

column, 81 individuals in 2003 and 26 in 2006? There is actually, if you will, an exposure report for those individuals?

MR. COOL: There is supposed to be. Under the regulations, the licensee or employer is supposed to have records of occupational exposure which are supposed to be maintained. That is true for NRC licensees. That is true for Agreement State licensees. I believe that is true, rolled over into the regulations that the states use for machine-produced regulation. The employer or the occupational group would be responsible for having those records. If they are an NRC licensee, there is a requirement that they be provided a report of their exposure annually if their exposure is greater than 100 millirem or if they request it at anytime.

MEMBER SKILLMAN: Thank you.

MR. COOL: Only in limited cases are the reports required to be provided to us. And I will go into details of that in a little bit.

MEMBER SKILLMAN: Okay. Thank you.

MR. COOL: Of course, nuclear power, a similar sort of distribution, except that you will note all the zeroes out there in the 40-to-50-millisievert and the greater-than-50-millisievert

category in this distribution.

MEMBER BLEY: Don, just a quick calculation off the top of my head says, if we really had the same distribution, and even with a smaller number of workers, we would be seeing two to five or something, where we are getting zeroes. If we took the same percentage out here where we see 80 and 100 and 200 for the other classes of workers, we have got a much smaller population here, but if we had the whole distribution the same, we would be seeing probable numbers in the twos and threes and fours and fives.

MR. COOL: Probably. We will talk a little bit about how much percentage of what we actually have is available in just a moment also.

MEMBER BLEY: Okay.

MR. COOL: This is NCRP's numbers.

MEMBER BLEY: I understand.

MR. COOL: And so, from the dosimetry processors --

MEMBER BLEY: But just based on those three charts --

MR. COOL: It is a pool of dosimetry records. And so, it is a little bit more difficult to categorize.

MEMBER SKILLMAN: What that tells me is that the radiological protection programs --

MR. COOL: The reactors do a pretty good job.

MEMBER SKILLMAN: -- are doing a pretty good job.

MR. COOL: Yes, sir.

MEMBER SKILLMAN: That is what it says.

MEMBER RAY: Let's get through the whole discussion and come back.

MR. COOL: So, let's talk about what we know more specifically from our reporting. U.S. occupational radiation workers, probably about a million or so in the U.S. Most of those are medicals. We do not get reports for medical. We will talk about that issue again a little bit later. They do not have to require a report.

There are roughly 200,000 that are annually reporting into REIRS. The majority of those are from the power plants. We expect that there is only, roughly, 17 percent of the occupational force that we actually have records for. So, we are giving you a very narrow slice of the pie, but it is what we have.

So, in REIRS, Radiation Exposure

Information Reporting System dose database, here are the reactors, presented in both bar graphs and the table. Unfortunately, the bar graphs are 10, 9, 8, 7 descending, and the table is in reverse order. But you can match up the numbers back and forth.

Again, you will see that the only time somebody was greater than 4 rem, they had one in 2002. You can see very small numbers, trend sort of similar, decreasing.

MEMBER BLEY: These are rem on this chart?

MR. COOL: These are rem on this chart, correct. NCRP produced it in millisieverts, the scientific standard. Our report is still in rems. Actually, there are dual units in the report itself. You can confuse yourself all you want.

For fuel cycle licensees, the fuel fabrications and otherwise, you have another table. You have similar sorts of things, not nearly the number of workers. You see the number of workers has stayed roughly the same. You may have a little bit more. The distribution has continued to come down. There hasn't been anybody over 2 rem since 2003. Again, pretty good controls on the programs.

Industrial radiography, for those few that are NRC licensees, you see the distribution.

CHAIR RYAN: How many NRC licensees are there?

MR. COOL: The total licensees in the United States for materials is 22,000. The NRC has 3,500-or-so licensees. I don't have the actual number of radiography licensees under Part 34 off the top of my head at the moment, but it is not --

CHAIR RYAN: But if it holds, it is like 10-11 percent.

MR. COOL: A pretty small number of folks. Also, given that most all of the places where you have active radiography it is associated with pipelines and other things, it is all in Agreement State areas.

CHAIR RYAN: It is probably true that the bulk of the radiography licensees are not touched by --

MR. COOL: Are not touched by our reporting, not touched by this, correct.

CHAIR RYAN: Okay.

MR. HOLAHAN: Don, 40 to 60.

MR. COOL: Forty to 60? Thank you.

CHAIR RYAN: Forty to 60 what?

MR. COOL: Licensees.

CHAIR RYAN: Licensees?

MR. COOL: Licensees. Okay.

So, again, you will see a distribution of doses. You will see that the number of folks approaching 5 rem has been coming down. You will see one that was really nasty. That was an event. You will see several in the earlier years that were greater than 5. Some of those were events. Some of those were actually cumulative exposures that crossed over the line, as I recall from being the Director of the Licensing Division at that time.

I know that in '11 and '12 there would be numbers, ones, twos, out into 2011 and 2012 because of events. But they are in Agreement States, so they wouldn't be on this table. So, that shows you the trend in industrial radiography.

Because there are also state data, here is the Agreement State dose data from the limited sample that responded to our request for information. You will see that the number of individuals is very small. We didn't get a very big turnout when we asked folks for reports. In fact, while we did not conduct a search of each of the state regulations to determine which ones actually required reports, it is the staff's sort of belief that there are only a few states that actually require reports to be provided. It is not a matter of compatibility. States are not

required to obtain the reports. They do not have the matching value to our reporting department --

CHAIR RYAN: The only way that those Agreement States would get at this data is through inspection.

MR. COOL: Inspection. Because the requirement to maintain the records by the employer or the licensee is always in place.

MEMBER BLEY: And just for calibration, there are many licenses, right, thousands?

MR. COOL: Well, there are thousands and thousands of licenses. This is a very tiny snapshot, and we have no idea if it is representative, non-representative, the relationship to the whole, or otherwise.

We went out and asked them for it. We had a couple of big nuclear pharmacy companies that provided us data directly, that actually exist in multiple jurisdictions. We actually got precious little state data.

MEMBER BLEY: Is that right?

MR. COOL: So, this is to show you what we have got and, also, to sort of categorize for you the fact that there is a lot that we do not know, without going out and doing an incredibly-resource-intensive,

licensee-by-licensee, inspection-gathering process or some messy data request.

So, let's move on. Manufacturing and distribution, the rare state of those licensees that report to NRC. We will again see the distribution. You have some in the small number, ones and twos, in the 4-to-5-rem range. That fact has continued through 2010, though the numbers above two have been steadily declining. That is a consistent theme.

Slide 17 is the similar information for the Agreement States.

MEMBER STETKAR: I hate to interrupt, but it has declined in the last two or three years.

MR. COOL: It has declined in the last two or three years.

MEMBER STETKAR: But it was a lot lower before and then it went up in the middle 2000s, and then it has come down. So, there is some oscillation there.

MR. COOL: There is some oscillation. Again, there is also the unknowns with regard to whether this even represents a sample year-from-year --

MEMBER STETKAR: Sure.

MR. COOL: -- that is the same number of

individuals and numbers reported. They grabbed data they had and fired it at us. So, I can't even tell you that the baseline is the same.

CHAIR RYAN: The quality of the sample really is in the --

MR. COOL: So, I would wish that I could draw more correlation, but I would suggest to you that that is very tenuous.

MEMBER STETKAR: Okay.

MR. COOL: Okay?

I would note for members of the audience, those of you who have the black-and-white copies, the slide is correct on the screen; the slide is correct in the color copies we provided you. This morning, as we were going through it, we discovered a cut-and-paste error. When we were trying to slam lots of data into PowerPoints, we got the wrong table affixed to that particular slide. We corrected it on the table here, but we had already done the black-and-white copies. So, we just made a single-page correction, which was available in the back, which is the one that actually has the table that matches the bar chart above it. All right?

Moving on, nuclear pharmacies, again, you have a small number of individuals, greater than two.

1 You have got a small number of folks playing in this.
2 So, these are the folks that report to us.
3 Slide 19, similarly, provides the
4 information from those data that come from the
5 Agreement States. The Agreement State data was
6 actually fairly significantly influenced by this
7 dataset, as I said, because several of the large
8 national pharmacy organizations, which have pharmacies
9 in multiple places, provided records. So, it wasn't
10 actually Agreement State records, but, rather, records
11 that that particular company had. And they may have
12 15 or 20 pharmacies here, there, and all over the
13 place. So, it is an interesting snapshot, perhaps a
14 bit more representative of what is going on in that
15 particular field.
16 However, I would caution you that this
17 does not pick up, as far as we know, what happens in
18 the little, individual pharmacies that a hospital or
19 small group of hospitals may have or the folks that
20 are routinely pulling all of the PET isotopes off of
21 the targets, quickly eluting it, and getting it
22 upstairs before the five-minute half-life stuff goes
23 away. So, there are other categories which are
24 related to this which are not captured in this data.
25 So, moving to slide 20, I am trying to

stand back just a bit.

Individuals with exposures greater than 2 rem has tended to come down, although it has climbed just a little bit over the last couple of years. We seemed to have bottomed-out on the trend. I think the folks from NEI and the nuclear power industry, were they here, would tell you that some of that has been influenced by needing to do some of the larger maintenances, a couple of steam generator replacements, and otherwise, which have caused some of the exposures during outages to be a little bit higher.

Slide 21 is the similar information related to folks in Agreement States. Again, I would point out that the fact that this goes way up and then comes back down is probably more a fact that we just don't have a denominator than it is an indication of number of individuals that actually exceeded a 2-rem value in those earlier years.

But you have individuals who are exceeding it. What this doesn't tell you, and which we simply do not know, is whether those individuals are doing it each year or one time and it is different folks the next year, or otherwise.

CHAIR RYAN: Don, just from your knowledge

of dose records, would you have any insights at all as to what that might be? I guess I am asking for a bit of a guess or an insight. But, to me, if a person is in the same job year-in and year-out, there are a couple of possibilities there: doing the same work and getting the same dose or they have learned how to do it better and faster and they are getting a little bit less dose. You know, I am trying to understand what to make of that.

MR. COOL: I think there are a number of things going on, I'm sure. One, you have got folks who are in a career for a long period of time. They get smarter; they probably get a little bit better. Countervailing that is you may have a little bit of complacency in other ones. To go along with that, they might move up in management and they might not be doing quite as much of it as they used to when they were one of the young bucks. So, you have got things which may drive that both directions.

You may have things that influence it with improved machines, technology, or otherwise. In addition to that, you may have a number of places where -- I will use the medical term -- caseload, although equally in industry and otherwise, the amount of work needing to be done may have significant

oscillations in it in terms of the demand for work.

You can follow rather dramatically the number of individuals employed in radiography and otherwise, tracking very nicely with the rises and falls in the oil refinery and other industries. You see a lot of people coming in. You see it going down when there is low effort. So, you have a number of factors, all playing into that.

You have education/experience. If you get them in and they are smart for a while, they will probably be doing a little bit better. They have that almost like your grand inverse bathtub curve. They have got a learning curve. They are dumb initially; they get smarter. Hopefully, they don't get dumb at the end.

But, in fact, there have been a number of studies over time that have shown that events are rather nastily correlated with people who are not experienced and who make mistakes early on in the program.

So, there are a bunch of influences that are playing that, may force some up and some down.

What is adequate protection? How do we measure that? We actually do that several ways. You measure against the dose limit. That is the legal

boundary for an acceptable level. That is an individual and a number.

We also do it by examining trends and average exposures and distributions. We look at what is the average exposure in a population. We look at, similarly, some different work groups and all that sort of thing.

When you are in a regulatory analysis, cost/benefit analysis, and those sorts of things, you are most often trying to compare blocks of exposure and you are doing it with person-rem and associating some dollars per person-rem value to try to make some estimate that you can equate to other portions of the curve.

Now that is very nice if you are using a utilitarian type of ethics where the object of the game is to do the best for the maximum number of individuals and keep the total down. It isn't necessarily representative of trying to make sure that you have done the best you could for each individual, as in the limit or respecting the limit. They are two rather different things. And respect to the limit is actually something which a typical reg analysis and a collective-dose dollars-per-person-rem simply cannot measure.

So, what are some of the things that we can perhaps find for this? So, things that are reported to us, almost all the exposures are below the limit. Yes, there have been a few events. Yes, in the older days, there have been some situations where people have crawled over it. It hasn't happened very much lately. Trends have all been in the right direction from a macro-perspective.

At the same time, there are individual exposures every year that are in excess of the ICRP's recommended average value, which is different from the limit that is currently established in the United States. The number of those individuals is pretty small, but not zero.

We simply do not have enough information to really know for sure if those individuals are doing it for multiple years, but we have a suspicion it could be true, in part the answer to your question, and in part the statements that were actually made in our public workshops where representatives of the radiography community, CEOs of their company, talked about how they still do exposures after 30 years and they are still not there and they are still getting exposures above 2 rem. You have to take that at face value. Is that a quantitative number I can plug into

this equation? No. But it is another data point. The person-rem total for those is small, because even though the doses are higher, the number of people are very small.

So, based on a traditional regulatory analysis, if I am going to rack this up on a backfit analysis, a regulatory analysis, it is not going to cut it. It is simply not possible This is, in fact, in the end, a question of do we have a legal definition of what portion of the overall framework of adequate protection we find to be acceptable or not.

And I say that very carefully because adequate protection of the system is clearly functioning. We are protecting most everyone. But the law, as presently constructed, would allow individuals to exceed exposures which are nicely above the now-recommended values based on the current estimates of radiological risk.

CHAIR RYAN: Say that again in numbers, Don. I don't understand exactly what you are saying.

MR. COOL: Okay. For the majority of individuals where you can do dollars proportioned around the averages, cost/benefit, they are well below two. Changing the limit, changing ALARA, or anything else isn't going to change that total person-rem

number to any significant amount. So, regulatory analysis, just pure, hard number, wouldn't get you to a justification.

A change in the distribution for a small number of individuals who are getting two, three, or four every year, because it is only several hundred, even if that is times 5 rems, that is only five or six hundred person-rem. That doesn't equate to a very large number. So, from a standpoint of dollars-per-person-rem justifying a change, it is not likely to be justified.

On the other hand --

CHAIR RYAN: I understand that. That is a very important part of what you said.

MR. COOL: If the question is, the law which says that you can get 5 rem a year and it would be legal, would we be happy? No, because you would basically be not doing ALARA, which is another part of the requirement, and we would be exceedingly unhappy, but it would be legal from the limit standpoint.

CHAIR RYAN: I have done pretty good so far. I am just going to ask a question. Are you going to get to the relationship between ALARA and dose limits?

MR. COOL: In just a moment.

CHAIR RYAN: Okay. Great.

MR. COOL: That is what I am building to.

CHAIR RYAN: Okay. Good.

MR. COOL: Thank you, sir. That is a wonderful segue. Therein lyeth the question.

MEMBER ARMIJO: I am just trying to get it. So, for this small population that is exceeding the 2 rem, and many lifetimes doses exceed some number you want to regulate to, you have to come up with some other interpretation of the regulations to address that problem? What do you have to do?

MR. COOL: Fundamentally, what that means is that, if you are in backfit analysis --

MEMBER ARMIJO: Yes, I understand the backfit analysis, if it will work.

MR. COOL: If you say it is adequate protection, and the limit is the definition of adequate protection, and you say that a change in the limit is a change in that definition by virtue of changing the legal boundary, then you can make the change. You don't have to have a justification on substantial benefit, substantial improvement in public health and safety.

If you wish to do that on a pure quantitative measure, adding up the numbers, you are

not going to get there. You may get there on quantitative and qualitative grounds, which was, in fact, the basis which the Commission used when it did the revision of Part 20 in 1991.

MEMBER ARMIJO: Okay. So, you have to go into some qualitative reasoning?

MR. COOL: There have to be qualitative factors associated with this, that is correct.

Slide 25 gives you a snapshot, a bit limited in what you can do with it perhaps, associated with career length and dose. You have got lots of folks who do short things. You have got people who work longer and longer. You have got folks who have been in the industry more than 35 years. There are a number of folks -- this table only goes out to a greater-than-50 number. In fact, there are individuals that you could mark up in a column greater than 100.

What you would discover instantly, interestingly, is that there are a number of those who are down in the one, two, three, or four years because of nasty events back in earlier times.

CHAIR RYAN: Yes, it is hard. I mean, I understand the data. It is very hard to interpret this, I think, for the question at hand today because

it spans three generations, maybe four, of workers and work practices.

MR. COOL: It spans both generations of worker practices.

CHAIR RYAN: And regulatory --

MR. COOL: And regulatory measures, that is correct.

CHAIR RYAN: But it is interesting --

MR. COOL: So, it is there, but just to provide you a sense of what we know and, conversely, the fact that you can't lay a whole lot of, again, quantitative information out that supports how many folks --

CHAIR RYAN: Interesting, but not terribly helpful to our question at hand.

MEMBER ARMIJO: But what I am trying to get is, is there any kind of a medical information on the health of these people who have worked for a long time and accumulating these higher doses? Do we know anything about them? You know, they are radiation workers. Does anybody track their health or measure cancer rates greater than --

MR. COOL: Let me start, and then I will hand off to Vince Holahan.

As a set, this is not actually a study

cohort --

MEMBER ARMIJO: No, I understand that.

MR. COOL: -- although it includes a number of groups that are, in fact, being followed up.

Vince?

MR. HOLAHAN: Several years ago, the International Agency for Cancer Research, which is located in France, did a 15-nation study of power plant workers and other radiation workers. Geoffrey Howe actually did the study of U.S. workers.

The problem you run into is the group that they were looking at, the average age was about 45 or 46, and most of those workers had cumulative exposures of about 20 millisievert. So, even if there was going to be cancer induced by very low doses, you probably wouldn't even see those expressed into those workers who were in their seventies and eighties.

John Boice is in the process of starting a nuclear power plant worker study. We are going to have a meeting with him in, I believe, the next month or so. The focus is going to be primarily workers in the U.S. that were occupational workers in the fifties, sixties, and seventies, when we had much higher doses.

The advantage of looking at that is those

are exposures that were some decades ago, when the medical contribution was relatively small. We have difficulty doing that type of study today because, as you saw in many of those histograms that Don had, we are talking about average exposures of about 20 millisievert per year. Yet, these same workers, on average, are getting 300 millirem from medical. So, the medical contribution on a year-to-year basis is dwarfing the occupational.

So, to be able to look at workers that get the very low occupational doses and try to sort out some sort of health effect that we can contribute to the occupational work is going to be virtually impossible. So, we have to go back to those historical workers.

MEMBER ARMIJO: Yes, maybe even anecdotal information from radiation workers really dropping like flies or something that would give us a feeling that, clearly, we are on the edge of a problem.

CHAIR RYAN: Vince, could you comment on the DOE worker studies, and so forth?

MR. HOLAHAN: Well, DOE has done a number of studies as well. What you are going to find, whether it be the DOE studies or any of the others, we have a healthy worker effect. We are talking now

workers that are well-paid. They are eating well. They have got good medical care. What we find is that they are actually, quote, "healthier" during their working years than members of the public. Now that tails off as they, again, get into their sixties and seventies, and things come back to normal.

But of the many studies that the Department of Energy has looked at for the various labs, for all intents and purposes, they haven't seen anything. There are some outliers where you see some statistically-significant individuals and certain different cancers. But, at the same point, you have the opposite shown, too, where you have got statistically-significant lower-than-average numbers. So, on average, no.

Y-12 is a good indication. They looked at Y-12, the workers that were there during World War II, and they saw a statistically-significant increase in cancer in those workers.

Now they looked at the workers after World War II. It went back to the background level. And what it was, it was, again, a situation where you had 4-F workers that couldn't deploy overseas, and you had another subgroup of individuals that had other health issues related to it. Because of that, they had an

abnormal increase. It factored out when the whole population was looked at.

MEMBER ARMIJO: Okay. That is what we dealt with --

MR. HOLAHAN: Yes, there are worker studies that have been done in the U.S., the UK, France. The big interest has been what is the impact of low doses and low-dose-rate exposure compared to gross for Nagasaki. The data is just so scattered, we really don't know.

As Don mentioned, there was a BEIR-VII report where, instead of using a dose-rate reduction factor of 2, they reduced it to 1.5. Some of the worker studies might indicate that it could be as low as 1.0. But we can't make a decision, based on the paucity of the information at this point. We are monitoring it.

MEMBER ARMIJO: Okay. I appreciate that.

MR. COOL: So, the problems that we have been facing as we looked at what to do with the regulation, with a framework that overall is functioning very well, do we need to make a modification to ensure that each individual, as an individual, under the law, absent the rest of the framework, perhaps a strange hypothesis, is adequately

protected, in the face of a lack of a lot of real data on what is going on out there?

Furthermore, we have a challenge. What is the efficient and effective method to ensure that each individual is adequately protected? You can do a variety of different things and attack it from a number of different ways. We have to be clear and predictable. We have to be reliable. It has to be something that can work for NRC. It has to be something that can work for Agreement States. It has to be something that can work for reactors and radiographers and doctors.

The framework today has the dose limit, a requirement for ALARA, a requirement that you monitor, that you keep records, and that you report. The limit, the boundary that is unacceptable from the legal standpoint, the Office of Enforcement gets very exercised when you get somebody who gets an exposure over the limit.

Of course, we can talk about the uncertainties in the measurements, and we try to be very careful in the reconstructions and calculations. But numerically exceeding the number is a violation. It applies to all occupational exposure situations. It doesn't matter whether you are at a reactor or

radiography or anything else. It is performance-based. It is a number. You figure out how to make sure you keep your doses for each individual underneath of it.

The second component is ALARA. Do all of the reasonable things under your present set of circumstances to improve protection. It operates within the limit and often within other boundaries, depending on the situation.

ICRP used the term "constraint" to describe some of those other boundaries. Not very many people like that term. Okay.

ALARA is unique for each situation. It is dependent on the kind of sources that you have got, the working environment and other factors. Clearly, it is going to be different when you have got a radiographer trying to do radiography on pipes that are six stories up on the scaffold versus where he is doing radiography on sections of pipe laying out in the pipeyard where he is on the ground. Clearly, it is different when you are in an interventional suite and you have got a messy heart attack and other things, and multiple things going on, than it is more simple procedures, et cetera, et cetera, et cetera.

There is no single number that describes

ALARA. ALARA is, by its very nature, a process and an opportunity to continue to see if you can do better with the situation that you have.

A violation is not missing some particular number. It is more a matter of, did you not work through the process? Did you just blow through it and say, "Who cares? I am just going to go along. It doesn't make any difference. There is no real reason to plan. I am under the limit; all is good."?

That, in fact, is why you see that in violation space. Very rarely, if ever, do you see violation cited against the regulation for ALARA. It will be a violation cited against the licensee's procedures, technical specifications, or otherwise, where they have committed to certain procedures and steps in their process which they may or may have not done, because the regulation does not contain a prescriptive set of things that you must do. Because, in any given situation, that prescriptive set might or might not be applicable in whole or in part. So, that has not written in to date.

MEMBER ARMIJO: Don, if you went to a licensee and you said, "You're meeting your 5-rem limit, but I would like to inspect your ALARA program," and he said, "I don't have one," couldn't

you give him a violation just on that basis?

MR. COOL: Well, that flat statement would result in a violation, yes.

MEMBER ARMIJO: Okay.

MR. COOL: That doesn't --

MEMBER ARMIJO: Nobody would be that dumb, I understand.

MR. COOL: Yes.

MEMBER ARMIJO: But let's say he had one and it was really primitive.

MR. COOL: Okay, very basic and --

MEMBER ARMIJO: You have to find some other way, whether it is a commitment or some other thing, to enforce or find fault with what he doing?

MR. COOL: Depending on the situation, if it was clearly not meeting the basic intent, then you could issue a citation. More often, and certainly in the states, in a process of trying to work with their licensees to get good performance, it would be the things you can do, an improvement plan that they commit to. Come back to see whether or not they are doing it in an ongoing effort to try to improve protection, because that is in the end what you are trying to do.

CHAIR RYAN: Don, I think let's back up a

second, if you don't mind. To me, this is a point of emphasis that is missing which should be there. I share some of Dr. O'Neil's**15045 comments.

But I think ALARA is much more important and much less evaluated than it should be by both the NRC and the Agreement States. Now, having been in an industry segment that dealt with everything from dose rates that were, in fact, sequential up to thousands of r per hour, ALARA is very important, I think.

And I would suppose that the dose numbers that you provided in the tables with most of the ALARA programs could be a whole lot lower. It is not hard to do it. I mean, it is time, motion, and shielding, and a few other odds and ends, and you have got a better program.

Part of it is a matter of practice. I don't mean the practice of the craft. I mean practicing in what you do and getting it right in mock-up, so that when you do it for real, it is a whole lot simpler and easy, and you don't have to say, "Oops, I forgot this" or "I have got to do that now" and start over, for example.

So, I think if that is the only kind of dimension that ALARA is going to continue to have, we are missing an opportunity.

MR. COOL: That is part of the discussion that we wish to continue to pursue.

CHAIR RYAN: Okay.

MEMBER BLEY: I will say, might we come back --

MR. COOL: We will cycle back.

MEMBER BLEY: So, 30, we need to focus on it.

CHAIR RYAN: Say it again?

MEMBER BLEY: I have some more to say on 30, but I will wait until he gets three more slides -- slide 30.

CHAIR RYAN: Oh, slide 30.

MR. COOL: Monitoring. Licensees are required to monitor. They are required to make measurements.

Oh, by the way, there is no meter for effective dose. You have got badges. You have got measures of intake and otherwise. You do calculations and you assess with those.

Programs like to keep it as simple as possible. So, to the extent that you can just take the badge and have the dosimeter process you back a number and plug it in, that is preferred because it is easier, less resource-intensive to do.

Everybody has got to maintain those records. Licensees are required to report. This was your question a bit ago. They are required to provide individuals their records of occupational exposure. It used to be everybody. We made an adjustment to say, if it is a really small exposure, if it is less than 100 millirem, then you don't have to. But if they request it, you always have to.

CHAIR RYAN: "They" being the regulator?

MR. COOL: If they, as an individual, request it, if they as an individual --

CHAIR RYAN: So, the obligation to maintain the record is intact? The obligation to report it to you is 100-plus?

MR. COOL: The obligation to maintain the record is always, the obligation to provide that record each year to each individual --

CHAIR RYAN: Is 100-plus.

MR. COOL: -- is mandatory at 100-plus or if they request it.

The obligation to provide it to us is only if you are one of the seven categories specified in the current regulation. As a matter of compatibility, it is a compatibility deed. The states do not have to do it. And very few states, in fact, get reports, but

it is always available upon inspection.

CHAIR RYAN: So, it is the number of Agreement States --

MR. COOL: There are 37 Agreement States.

CHAIR RYAN: The lion's share of badged individuals are in Agreement States is a fair comment?

MR. COOL: Oh, yes.

CHAIR RYAN: So, you don't even have a 50-percent sample of the national population of workers in what you are saying?

MR. COOL: A very small percent sample.

CHAIR RYAN: Like what would you guess it is?

MR. COOL: Oh, 85 percent of the licensees are in the Agreement States. There is probably easily that much in the population.

And keep in mind that none of these datasets that we are talking about include any of the medical categories for the physicians, because they are not one of the categories currently required to provide reports. They don't provide reports to us. They don't provide reports to the states.

CHAIR RYAN: So, who takes care of their badge dosimetry data, themselves?

MR. COOL: Themselves. It is a matter of

inspection record. It is supposed to be there.

CHAIR RYAN: So, I mean, just to be clear, because it didn't come out the way I thought it was going to come out at the end, physicians are badged. Their badges are read. Now does their employer keep their data?

MR. COOL: Yes.

CHAIR RYAN: Okay.

MR. COOL: Yes.

CHAIR RYAN: That is what I thought.

MR. COOL: Yes, they keep their data.

CHAIR RYAN: But the employer is not required to report it to a regulator?

MR. COOL: Correct.

CHAIR RYAN: Only to keep it on file, so that the physician, if they want it, they can get it?

MR. COOL: Correct. Or should the regulator wish to inspect it.

CHAIR RYAN: Or inspect it, okay. Okay. I just wanted to make sure that was clear.

MEMBER BLEY: Who regulates physicians? When you say the regulator can look at it, what regulator?

MR. COOL: The state regulator.

MEMBER BLEY: Okay.

MR. COOL: Probably not the radiation control program. It is probably going to be the Department of Health or otherwise in terms of credentialing of physicians to practice medicine.

CHAIR RYAN: I am not sure that is --

MR. COOL: See, I am having to play this very carefully because, if they are using radioactive materials, they are occupationally-exposed under our regulations. People in Georgetown, they are in the District of Columbia, which is an NRC licensee. Those physicians have to be badged. They have to be monitored. Those records have to be kept. We can go in and inspect those records.

They have to maintain their exposures below the dose limits. If they exceeded the dose limit, they would have to report. That is a different reporting requirement. They are not required to report their annual occupational exposure to us. So, it is just a matter of record kept.

But they are under our control in terms of their occupational exposure. It is a very different question when you say "regulated doctor". That has all sorts of other connotations associated with it that I would rather not go into.

(Laughter.)

MEMBER ARMIJO: Just for those medical people that you regulate, are they obliged or required to have an ALARA program?

MR. COOL: Yes. All NRC licensees are supposed to have; they are required to have a radiation control program, and they are required under 1101(c) to reduce exposures as low as reasonably achievable using procedures, engineering controls -- I am not going to be able to quote the whole paragraph.

MEMBER ARMIJO: So, now these other people, let's say Agreement States people or these thousands, or maybe large numbers, of other people, they don't have to have ALARA programs?

MR. COOL: No. The requirement to have a radiation protection program, the requirement to have ALARA is a matter of compatibility. You may find some variation on the wording, but that requirement will be there. And they are required to have those limits. That is a matter of absolute compatibility.

MEMBER ARMIJO: Everybody has doses?

MR. COOL: Yes.

CHAIR RYAN: Let me try to say this a different way; it might help. In Agreement States, take South Carolina, which I know fairly well, nuclear medicine licensees who handle radioactive material,

they are in the compatibility space of the Agreement State program, which then is, in turn, in compatibility with the NRC program and is inspectable by both, the state folks and the NRC.

MR. COOL: By the state, not by the NRC.

CHAIR RYAN: By the state, but you can also look at the state's performance with regard to their licensees. So, there is performance there.

MR. COOL: We would look at the state's performance of inspections and otherwise.

CHAIR RYAN: Right. Okay. That is on the material side. Now on the x-ray side, a separate world.

MR. COOL: Yes. If it is a machine-produced radiation, x-ray, CT, accelerators, all the machines, that is not radiation that is subject to the Atomic Energy Act because it is not a material.

CHAIR RYAN: Correct.

MR. COOL: So, that is only regulated by the states. We review each of the 50 states.

CHAIR RYAN: I am just trying to help the Committee understand this. In some states, the people who run the radioactive materials program also are sometimes the same people that run the radiological control program for the machines.

MR. COOL: Correct.

CHAIR RYAN: And in some states, it is not --

MR. COOL: Correct. In some cases, they are the same; in some cases, they are separate; in some cases, it is two branches sitting side-by-side. Sometimes they rob Peter to pay Paul, back and forth, depending on resource needs, all sorts of stuff.

CHAIR RYAN: Yes.

MR. COOL: But what is true is that the underlying set of requirements, because they all work together through the Conference of Radiation Control Program Directors and the suggested state regulations, that framework is all pretty much the same, which is why in the discussions that we are having of possible changes in implications, the implications in those parts of the program, even though it is not NRC jurisdiction, are still relevant in the discussions because the states will not have two different programs. There will be a single program. And so, there are adjustments that need to be made. And so, this is part of the larger dialog and evolution of the process.

So, to move on, as we were talking over the last three years, what are we considering? We

1 started, actually from the standpoint not unlike where
2 I think, Mr. Chairman, you are; we should just add
3 some strength to ALARA and everybody would be happy.
4 Why don't we put some more teeth into the program, add
5 some specificity that you could actually cite against,
6 require them to establish a planning value? We tell
7 them what the maximum value is that they can use that
8 would help maintain that. Require them to take
9 certain actions, perform certain assessments, make
10 certain adjustments to the activity. Require them to
11 make different documentations and increased approval
12 processes.
13 In fact, that is what the federal guidance
14 for occupational exposure, published by EPA,
15 recommends. That is the program used by the
16 Department of Energy. They have limits, and then they
17 have a whole set of things which they call
18 administrative control levels, which are not limits
19 but are part of the contract. Those "quack" just like
20 a limit because nobody is going to get the Deputy
21 Under Secretary to approve somebody going over the
22 administrative control value.
23 What we heard from stakeholders in a
24 discussion to date is that adding teeth to that is a
25 very nice concept. You can sort of philosophically

understand that. But, in the end, as they said, "Dr. Cool, if you tell us we have to have a number, and you tell us we have got to do something to get back underneath that number, then it is a limit. You have just called it some other name." So, all right, the same thing, the same burdens. Might as well be honest about it. Okay. That is part of the view.

A nice set of things. Depending on the circumstance, being able to preplan and set up and do dry runs of doing this and that is a very good thing. Tell me how I am going to do that when your mom gets wheeled in in a severe cardiac arrest and we need to go in and do three stents right now. Maybe not quite so clear how those steps of the process automatically comport.

So, the processes don't always translate in a nice, generic way when you get to the levels of detail. That causes some thoughts.

MEMBER ARMIJO: Don, still, I am hung up. You know, you strengthen ALARA; yet, you have shown data, at least for the nuclear power plant people, that the ALARA program is effective. But it, apparently, is not effective for certain other industries.

MR. COOL: It is not as effective, and I

will give you my personal --

MEMBER ARMIJO: So, why not strengthen that for that population, if it needs it, rather than, "Well, I'll get to it."? You know, just focus on the problem area and the problem technologies or industries that are not performing to the same level as the nuclear industry.

MR. COOL: We will get into that dialog --

MEMBER ARMIJO: Okay.

MR. COOL: -- a little bit as we go along.

So, the second thing we looked at, this was one of the key things that we discussed back and forth. So, okay, what about the ICRP's approach which reduced the dose limit to an average and a maximum value? Well, first of all, of course, everybody said, "No, we don't want you to reduce dose limit. We don't like change. Just say no." Very nice. Okay, well and good.

But with this particular issue, the very strong feedback from stakeholders was "We don't like the idea of the burden necessary to go back and get exposure information on multiple years when somebody comes in," making sure that I have got the last five years of data, and that I know it is right, and how many different places did they work for.

Some of them remember the old days before 1991, where they had to have that data or make their best efforts, and what they had to put on the record if they didn't have it, et cetera. They viewed that as a large burden that they didn't want to go to.

So, that was an approach that, yes, that has some flexibility. There is a lot of burden that is associated with it, which everyone would have to shoulder, if that is the way you wrote the regulation.

Single limit. Again, we don't want to change the limit, but at least from the state perspective and getting to Mr. Armijo's comments, and otherwise, some of the groups were saying, "Well, okay, you can keep it simple. There are other ways to work with individual licensees," because that tends to be an approach preferred by the states on a more one-on-one basis. For somebody who has got a problem, let's work with them and figure out the right things to do and provide them with the right flexibility without imposing the burden of knowing multiple years for everybody in the process.

CHAIR RYAN: I'm sorry, I don't understand what that would give the state.

MR. COOL: So, this was the approach which is actually the approach suggested by the staff that

should be for further exploration, whereby you say a limit --

CHAIR RYAN: Just so I understand on that, this is under the idea that the limit is two?

MR. COOL: The limit is two.

CHAIR RYAN: And the states would be allowed to go above 2 --

MR. COOL: And then, you specifically provide a provision that allows them to apply for a value greater than 2, whatever specific additional information, controls, amendments are necessary, whatever piece of --

CHAIR RYAN: So, whatever they do, all the other radiographers are going to copy the application and get the same four.

MR. COOL: For some period of time, et cetera, et cetera.

CHAIR RYAN: So, we have spun the wheel for what value-added. I don't understand that.

MR. COOL: That is part of the discussion that needs to continue.

CHAIR RYAN: So, if we leave it at 5, we don't have a problem, and everybody can use ALARA to get to 2.

MEMBER SCHULTZ: On the first sub-bullet

where you say, "Do not believe change was necessary," was that universal among the stakeholders or were there particular stakeholders that brought that forward?

MR. COOL: A majority of the licensee stakeholders would, not surprisingly, prefer that you just not change the limit. They are very happy where they are. They know where their margin is and how close or not so close they are to it. Change is bad.

And one of the things that we had to do was get people to go beyond the "just say no" mentality of, no, just don't change it; it is not necessary, to talk about the implications of doing different things, depending on the forcing functions that are necessary to report.

So, I am just trying to re-acknowledge here that most all licensees said, "Don't change it." There were certain other groups, "Well, of course you need to change it," "Of course, you need to reflect the values."

In the occupational exposure area, many of the groups that you are probably more familiar with getting very active in public exposure, environmental exposures, and otherwise, are not active in those areas because they are not public. It is a really

defined set with additional controls, constraints, and otherwise. It is not outside the fence. So, we didn't have as much participation from those groups.

MEMBER SCHULTZ: Was there participation by the Agreement States represented here?

MR. COOL: Yes, there was.

MEMBER SCHULTZ: And what was their feedback regarding the change?

MR. COOL: The states fundamentally would, first, prefer not to change anything. "It is fine; it is simple; we like it. If you are going to change it, keep it simple; don't make us get averages and things. Give us, then, a limit and an automatic provision that lets us work with the specific licensees that we know how to follow. That is what we would prefer."

MEMBER ARMIJO: Don, did they say not only that it was simple and we are used to it, we like to work with it, but didn't anybody ask the question, is it safe? Is it safe enough?

And lowering the limit increases margin, but --

CHAIR RYAN: No, it doesn't. It takes away margin.

MEMBER ARMIJO: Well, margin from some harm from radiation --

CHAIR RYAN: Yes.

MEMBER ARMIJO: -- exposure; that is what I am talking about.

And there are many people who think there is plenty of margin. So, is it safe? What is a safety driver to lower the limit? That is what I am trying to find out.

MR. COOL: There is the fundamental question, sir. You are exactly right, with the majority of people believing that they are safe, and it is just fine and dandy.

MEMBER ARMIJO: Right. So, what is the information that we now have that says we have been regulating to 5 for many, many years and we are now concluding that it is not safe, and we have to lower it down to 2 to make it safe? It is that simple.

MR. COOL: That is what I am looking for.

MEMBER ARMIJO: What do we know that tells us that that is the right thing to do?

MR. COOL: The simplest way I can put this to you is as follows: the framework, limits and ALARA, is safe for almost everybody as long as it is properly applied.

MEMBER ARMIJO: Got it.

MR. COOL: The current limits taken alone

as a legal construct exceed the recommended accumulated lifetime value if you were to get it over multiple years. Now, if ALARA worked, you wouldn't get there. And so, that would not be the issue.

MEMBER ARMIJO: Yes.

MR. COOL: But it is possible and it would be legal.

MEMBER ARMIJO: So, our current framework, 5 rem plus ALARA, when it is applied properly, works just fine? But there is some --

MR. COOL: And that is what they said, that there is adequate protection in the framework today.

MEMBER ARMIJO: Right. But there are some segments of people that should be complying with this that aren't?

MR. COOL: That are not doing what we think --

CHAIR RYAN: As good of a job as you would hope, right?

MR. COOL: As good of a job as we would hope. And then, the question becomes, how are you going to do that? In the paper, based on the discussions to date -- and I cannot emphasize that enough because you get discussions and you get views.

When you write it all down and people see it in a paper, they suddenly go, "Hmmm, I might want to rethink that." Okay?

Changing the limits is a more straightforward approach than trying to add a bunch of things to a process called ALARA.

CHAIR RYAN: It is easier.

MR. COOL: It is easier. It is more straightforward. It is simpler. People understand it. It is the line. Okay, we understand the line.

If you add a bunch of things to a process that sort of looks like you changed the line, well, why didn't you just change the line? That is the feedback we received.

CHAIR RYAN: Well, I appreciate that, but, on balance, you have got to ask the question, well, you know, it really didn't change the line. But you try to emphasize the process of self-evaluation and self-improvement, so licensees can build in the flexibility they want to have by doing a better job of exposure control. And then, if they need margin from a limit, they have got it. I don't understand why that is tough. It may not be tough for you, but I don't know why we ended up with this kind of strange place.

MR. COOL: Well, what I can tell you is the sort of opposite question that has been put to me more than once was, okay, so if you add some of this emphasis or otherwise, do you change the legal environment so that we have confidence, if I look at the regulation, that it is clear to me that individuals would not have the possibility of getting into this range where we don't believe they should be? And the answer to that question is no.

CHAIR RYAN: The answer to what question now? Should you have the legal authority to do something if they --

MR. COOL: In the discussions to date, if you add things to ALARA, unless you make it such that it really is a limit, because you require them to take actions to prevent recurrence, then you do not change the legal outcome for an individual at the maximum dose.

MEMBER RAY: I would like to get involved in all this debate, too, but are we going to finish this first?

MR. COOL: We are almost done.

MEMBER RAY: Okay.

MEMBER ARMIJO: A lot of this is just clarification for guys that are not in this industry.

MR. COOL: Yes.

MEMBER ARMIJO: I am just trying to understand what the problem is.

MR. COOL: So, let me do the last two slides, and we can then go into this in detail.

So, what we concluded was, based on what we knew to date, that we needed to get into the details because the devil is always in the details. What would the language actually look like? How would it work? How might a licensee do it, not do it? What might you add to the different process?

We knew we needed to do additional things with those coefficients and other things which were coming along which no one had disagreed with. We knew that we were going to need more than simply a cost/benefit justification, but we had to develop that which we have, which led us to where we are.

And I think the question before you, Mr. Chairman, the staff has proposed to the Commission a set of things and we have asked the Commission, our recommendation, to give us permission to continue to expend the resources to complete the development of the scientific information, to continue the discussion on the right way to deal with this tail of the distribution that is individual adequate protection of

a small number of individuals, either by a change to the limit or ALARA or otherwise; to continue the discussion on the lens of the eye and embryo/fetus, which are also out there that we haven't talk about today; and to explore the rationale, impacts, and otherwise, for occupational reporting and perhaps venture into that very dangerous zone of compatibility and whether there really is a reason for people to retain these records.

That is the essence of the recommendations that the staff made to the Commission in the paper, and I suspect what the Commissioners would probably be interested in is the ACRS's views on whether they think we, as the staff, should be continuing that dialog and discussion to try to refine these points, and then your views with regard to what directions might be more beneficial in that.

And so, I end up. Let's go at it.

CHAIR RYAN: Thank you, Don.

Dennis, you had a question?

MEMBER BLEY: Well, I had a comment.

CHAIR RYAN: A comment?

MEMBER BLEY: The thing keeps coming back to me, whenever I have heard you talk, and not just this time, but about these problems with the inability

to regulate ALARA. It seems to me very much in a way similar to other programs that the NRC regulates, at least in power plants, such as the QA Program, the Quality Assurance Program, such as something that is coming up more and more now in investigation of events at plants is the corrective action programs at the plants, but, also, just the general practice of operations and training of operators. These are all programmatic things that lead to events, but the agency has found a way to regulate in those areas and push the licensees to strengthen those various kinds of programs. It seems a real parallel to me. I am not sure why it is so difficult.

Now maybe part of the difficulty is the vast numbers of licensees and the problems, the interactions with the state agencies and the others, but it has not been impossible to deal with programmatic regulation in other areas.

MR. COOL: That is true. In the radiation protection area, in the power plants you will find a very refined, robust program that examines in detail each job to see what the best practices are, what they can do, mockups, to minimize the exposure. It is in the procedures. It is part of all the outage planning. They are tied to it by their planning

procedures; obviously, technical specifications. I am not going to use all of the right jargon.

MEMBER BLEY: But part of it is programs they had to write that they then must continue.

MR. COOL: But they are tied to it by the programs and we inspect against the programs with the cornerstones.

MEMBER BLEY: Yes.

MR. COOL: Did they follow those programs? They may not have ended up exactly where they thought they were, but if they went through the steps in the process, okay, that was the point of the process.

A nice, refined program, everybody knows their roles and responsibilities. We know what we are doing in the cornerstone, evaluating their programs, which they are committed to doing and which we have leverage to, because of those commitments in the programs and activities, and otherwise.

It works really great for 104 reactors and some fuel cycle facilities with large programs, with lots of other forcing functions and all of that structure in place. That structure, the degree of sophistication, those resources, those external forcing functions are not present or very limited presence.

MEMBER BLEY: And actually regulators on the site.

MR. COOL: In the materials side of the world, you have 37 state regulators, 50 regulators on the machine side, with limited resources and otherwise. You have activities which are piece-driven. I have got 50 welds to inspect today because this plant wants to go up tomorrow, and they need to know that the pipe isn't going to break when they put the oil back into it under pressure. It is piece-driven. It is time-sensitive. It is number of patients. It is a whole variety of things. It is geometries that change in some cases day-to-day and hour-to-hour in industrial settings, not so much so in some of the medical settings and otherwise.

But the same sort of systematized procedures and process and examination for which the roles and responsibilities are very clear, and it works there, do not work, at least the historical efforts thus far, on that side of the house.

And so, of course, they have ALARA programs. The RSO goes out and works with them. Why are exposures up here, and this and that, and controls them, and sort of feels like the cop going out. "You're over again. You said you were going to do

better. What are we doing here?" Or my favorite cartoon character that is never seen, "Whaa-wha" from the Peanuts cartons.

(Laughter.)

That won't translate on the transcript. I'm sorry.

(Laughter.)

MEMBER BLEY: I mean, I am not fully convinced. You know, take something like the corrective action programs in the plant. Those have been around and people wrote them. They have used them. And then, something happens, and you go in and you look. You inspect and you say it is doing what we all hoped it would do, and you force changes in the program. And you say that the program didn't work.

So, maybe it is the ratio of regulators of things to be regulated that make it impossible to do. But the onus, I think, was always on the licensee to develop these programs and then to succeed them, and you inspected the programs. And some of you guys who have been out in the plants can maybe correct that view, but I think that is true.

MR. COOL: And it works well in those situations. At this juncture of the discussions, with the ideas that were generated for the things that you

might be able to write down, and not having tried to write it down and vet it through 50 different medical groups, and otherwise, the staff's conclusion was that we didn't have an obvious small set of things that you could write into the regulations which would be procedural requirements, or otherwise, that would be universally and consistently effective in accomplishing those purposes across that wide range of different types of activities --

MEMBER BLEY: Okay.

MR. COOL: -- that wouldn't end up being mostly just burdensome paperwork for most of them without accomplishing the endpoint.

MEMBER RAY: I think that is a very understandable and, in fact, logical and good conclusion. The problem I have, and the reason I oppose reduction from 5 to 2, there are other things on the table here than that; let's start with that. And I am afraid we are just going to focus on this one thing and battle about it.

But the reason I do is the converse of what you just said, which is the effect that it has in an area in which -- you know, we are the Advisory Committee on Reactor Safeguards; admittedly, we are concerned about other things. But I would assert,

having done this for a while, that it has a significant negative effect going from 5 to 2 on plant safety because of the unintended consequence that it has in people not doing things that they should do out of concern over a skilled population being burned up doing stuff that I can defer or avoid or not do, even though I would do it otherwise.

I can justify it under an ALARA program, but now I am down to 40 percent of what my limit was before, and I am going to be reluctant to go in and inspect the pressurizer heater connections or leakage on the heater sleeves or maintenance of a low-pressure safety injection pump, or whatever all the things are that we have had to send people out to do because we think it is the prudent thing to do, and inspect the reactor vessel head on a plant that we are going to talk about tomorrow. And so, I am concerned about.

I will say one other thing, though, to my colleagues who are enamored of ALARA. It has a similar effect when it is used in the competitive environment that it is -- the one that you referred to as being so great -- it is a metric, easily measured. Therefore, it goes right into incentive programs and it incents the same thing to happen that the ALARA program can and does.

There was a time when half my total compensation was based on the INPO rating. And the easiest thing to effect on the INPO rating are two things, ALARA and outage duration, both of which in the short-term you can drive way down. And you figure I am going to be out of here before the consequences come on. Truth, right?

(Laughter.)

So, people do that. And the incentive isn't just the CNO. It goes all the way down to the frontline supervisors.

Now that is an understandable thing because we aren't trying to incent people to do the right thing. But I am just saying to you that, even the ALARA program, as flexible as it is in how you can apply it to things that need to be done and justify what you are doing, has the same, tends to have the same effect.

But I am just concerned that the reduction from 5 to 2 is going to have a significant effect on key individuals and their use in performing work in the plant that needs to be done.

MR. COOL: And I would agree with you. That is clearly an issue out there. And I would reflect discussions that I have heard -- these are not

on-the-record discussions, but since we put out whatever -- where in the power industry, sort of like, "Yeah, we fought pretty hard about not wanting to have averages and otherwise because of all of the burden of multiple years and all that, but, gee, now not having any flexibility at all is really a tough thing. Maybe we want to reconsider what is most important in this whole discussion."

And that is, in fact, why, as we go to the Commission and say we need to reflect this, and we need to look at what specific language and how it would be implemented in different groups, to really understand benefits and impact, that is why we made that recommendation. Because, as an individual, set my NRC hat aside, I agree completely with you with both points.

MEMBER RAY: I was just trying to contrast it with a simple application, because I think you are dead right that in the diverse world out there the only way you are going to really have an effect that needs to be had is by a simple change. A complex, sophisticated, programmatic -- you know, I just am skeptical.

But, on the other hand, I am more worried about the unintended consequence of lowering the limit

when it comes to doing things that need to be done. Because it isn't the average 2,000 people at the plant you are concerned about; it is the four or five people who can do this critical thing that needs doing.

I will shut up now, but that is my concerns.

MR. COOL: Dr. Ray, I agree with you, and that is why I think we need to continue a discussion of what -- now let's refine the possibility. Maybe being suddenly inside a box, perceived or otherwise, causes people to think a little bit creatively about what are the ways in which flexibility could be provided that would give you the right outcomes, but yet be a simple and effective approach that would work across the entire --

MEMBER RAY: That is the dilemma.

MR. COOL: That is the dilemma. And I have to reflect to you, also, sort of the grand issue always. If there was a nice, simple solution to this, we would have done it already because it was obvious. It is not obvious.

And the fact that the rest of the world decided to do this, and the fact that a good chunk of the rest of the world is now moving to a single limit because they have concluded that the flexibility

wasn't really needed. It doesn't mean that we should not go through a complete and careful dialog. Because just because they did it doesn't mean that we should follow. Maybe they had the right idea, but we need to convince ourselves of it. I am not suggesting that we do anything just because they did it. We may reach a conclusion that it was the right thing to do or it was close to the right thing to do, but we have got to work through that.

MEMBER ARMIJO: But, Don, you are recommending a change to the 2. It doesn't sound like you are evaluating a change to the 2. Maybe I misunderstood your documents, but --

MR. COOL: We are recommending that the staff continue the development of a technical basis, using that as an option.

MEMBER ARMIJO: The technical basis to --

MR. COOL: Using that as one alternative, but not to the complete exclusion of the others. We are not asking the Commission to decide that 2 is the end of the discussion now.

MEMBER BLEY: If you would go back to your last slide, it is real hard to disagree with you. I mean, the way you phrased that, they are all good things, except maybe they never get to the end is the

one place you end up.

(Laughter.)

MEMBER SHACK: I mean, this slide doesn't quite seem like Option 3, though.

MEMBER BLEY: No, it does not.

(Laughter.)

MEMBER SHACK: This is Option 4.

MEMBER BLEY: Yes, I think that is right.

MR. COOL: This is Option 3.

MEMBER BLEY: This is Option 3. Got it.

MEMBER SHACK: Well, when I read the text of Option 3 and I look at that slide, I don't get to the same place.

CHAIR RYAN: I don't, either.

MEMBER BLEY: But, I mean, it would be hard to disagree with this slide, except for the "is there ever closure" piece of it.

CHAIR RYAN: Well, I mean, I don't take it in a way -- you are doing that all the time, anyway.

(Laughter.)

MR. WIDMAYER: So, you agree with this view then?

CHAIR RYAN: No, I think that is part of the basic job. I mean, the truth in the limits is a whole thing. I am like Bill; I mean, they are on two

different pages of the book. You can't argue with apple pie and motherhood. That is what that is. It is all good stuff.

MEMBER ARMIJO: It is continue to study, but that sounds to me like "Prepare the justification to do the following."

(Laughter.)

MEMBER SHACK: No, the approach to deal with the limit sort of indicates a certain flexibility that I don't see in Option 3. You know, revision of certain provisions of the occupational dose limits sounds like 5 to 2 to me.

MEMBER ARMIJO: Yes, yes.

MEMBER RAY: Don, where in your presentation do you feel the concern that I tried to express is reflected, the concern that it would have an adverse effect on safety long-term? Reactor safety I am talking about.

CHAIR RYAN: Quite frankly, I would extend Harold's comment to non-reactors. I mean, there are other companies that deal with radiation exposure. I concur, service companies that provide service to you are measured in the same way, to the utilities.

MEMBER RAY: But one of the members of Don's staff has been agitating. He doesn't like what

I am saying.

(Laughter.)

MR. HOLAHAN: No, it is not a matter that I don't like what you are saying, but let me throw some numbers out. Maybe we can work with that.

First of all, the recommendation to reduce the occupational dose limit to an average of 20 millisievert a year is 22-years-old. Industry has been anticipating a possible move this way for many years.

In 2010, there were 42 workers that exceeded 20 millisievert in a year. That was out of 89,000 badged workers in the commercial nuclear power plants, some 34,000 of which had measurable doses. So, we are talking about 42 workers.

MEMBER RAY: Okay. Well, all right, but I am not persuaded by that because I had 2,000 people on my site. Okay? And the concern I have just expressed to you would apply to maybe five of them.

Now I am telling you that that kind of data is wrong to use in this argument. It is fine; it is true; it is valid; there is no doubt about it. But it isn't what I am talking about.

MEMBER BLEY: I think the other piece of that, Harold, and I agree with most everything you

said, comes back to what Sam said about, well, you will have better margins. Well, the problem is you have got to keep a margin from that 2, so that you can use those guys if there is a real emergency that you have got to get into.

MEMBER RAY: Yes.

MEMBER BLEY: So, really, it is not 2; it is really 1.

MEMBER RAY: It is 1.

I think those data are fine at one level, but they don't really deal with the concern that I am trying to express, which is quite narrow and not the only issue, but it is my issue.

I don't think it is because I had experience for 25 years. And let me tell you something, this is a serious concern I have.

CHAIR RYAN: You know, I am not too sure -- I don't have the direct experience, but I hear anecdotally from colleagues -- that the nuclear pharmacy area, which is an Agreement State NRC-regulated activity because it is materials, had the same questions, not maybe with whole-body dose, but certainly with extremity dose they do. And they deal with that constantly.

That is only numbers that derive different

ways and all that, but it is the same problem. Those numbers I am assuming would go down, too. We haven't talked about that. The non-whole-body limits, what is the goal there?

MR. COOL: Actually, the extremity number has no proposed changes.

CHAIR RYAN: So, that doesn't make any sense, that it wouldn't be systematic across all the areas.

But, in any case, it kind of looks like we are just poking at something that is not broken, to tell you the truth. That is my view.

MEMBER ARMIJO: I just had a quick question on the ALARA program. It has proven to be very effective, maybe causing some bad behavior in some cases. But have we reached the point of diminishing returns on some things that improve, despite what you do on inspection of a pipe or a steam generator, and you put in new equipment and automation and all of that stuff? But you are there, and you are not going to do much better than where you are now. You can't do more ALARA and reduce the dosage for those operations.

So, if you lower the limit, the only answer is don't do them or hire a bunch of people,

assuming you can hire them --

CHAIR RYAN: Harold may agree with me or he may not, but I think that an ALARA program and the folks that run it come to a third conclusion, which is we have done the best and appropriate things that we need to do for this job evolution to manage occupational exposure as low as reasonably achievable.

Now it may be a slightly different job than the last time we did a particular activity, but we looked at it again. We gave it a thorough scrub. You know, we could do three things and maybe save a little bit of dose, so we really optimized it. So, it is a process to me of self-evaluation on an ongoing basis, rather than ALARA is done now; we don't have to worry about it anymore. It is an ongoing thing. It is not something you just put away at the end of the day and you don't have to worry about it until next year.

MEMBER RAY: Well, my biggest problem was with the effect it had on financial incentives, which are a huge, huge driver.

CHAIR RYAN: Exactly.

MEMBER RAY: And I don't think people here appreciate that enough, how much a simple metric that can drive the wrong behavior that is incorporated in

your annual bonus calculation, as a manager, leader, or whatever, needs to be thought about in terms of unintended consequences.

Because, you know, you match up short-term versus long-term consequences. I can benefit myself in the short-term by not doing a bunch of stuff, and I don't think I am going to be here, and it probably won't happen anyway, five years from now when the results of my not doing what I could be doing today catch up with us.

And those kinds of things are what the real world consists of. I mean, I fought this at INPO, where I was on the Executive Board for a long time, and was able to push back on it some, to try to keep it from being such a -- because it is such an easy metric. It is kind of like what we are talking about here. I mean, what is easier than just taking your dose numbers and feeding that into your standing among all plants for purposes of bringing in the top quartile, the top decile, or whatever the heck you are? And it is just an easy thing to do.

The results of it are unlikely to be -- excuse me, Jack. Go ahead. I am talking too much.

MEMBER SEIBER: Keep going. Keep going.

(Laughter.)

MEMBER RAY: Well, I mean, I am really just trying to make a simple point that you have to think beyond just what we are talking about here to how these things get used. I am not opposing an ALARA program. Don't make that mistake. I am just saying it, too, has its downside and has to be pushed against all the time by people like Jack and me and others who fight against that.

MEMBER SEIBER: I have maybe a misconception, but maybe you can tell me the difference from the standpoint of health effects between having one, two, or three workers close to the 5-rem-per-year limit or having 10 or 15 close to the 2 limit. Because one of the ways of dealing with this problem is to spread the work around, and usually when you do that -- and I have had a lot of experience doing this, not only as a site VP, but a labor negotiator, and so forth -- when you try to figure out a way to lower the peak dose, you end up spreading more dose to more workers.

And so, is there a technical reason why that is a good idea? Because you really don't see any effect at 5 rem per year, and perhaps if there is an effect, I should have seen it by now.

(Laughter.)

And the other thing is, giving more people more dose under the limit, is that a good idea or a bad idea?

MR. HOLAHAN: Why don't we ask this question? What is the definition of adequate protection and safety? What is actual protection --

MEMBER SEIBER: The question is, where do I start doing harm?

MEMBER RAY: Or how can I minimize the harm that is inevitable in the work that I do?

MEMBER SEIBER: Well, it is hard to tell. You know, all you have to do is walk through some valley. Or we tried to set up a contractor body-counting station in a public park, and found out there was a thorium deposit there, and we couldn't get a good background.

(Laughter.)

We ended up using a coal plant as a measuring station. It had higher dose levels than the nuclear plant.

So, you know, it is hard to say. It is all around us. And so, the question is, if I increase the dose to a lot of people a little bit, is it better that I do that than have somebody, one, two, or three, a small population increase by a little greater

amount?

MEMBER SHACK: Of course, we haven't left them a whole lot of flexibility. You know, you can't fix ALARA. That has a bad effect. You can't lower the limits --

MEMBER SEIBER: Well, you can't do anything that you haven't already done.

MEMBER SHACK: Therefore, all those other people outside the nuclear plant are sort of stuck where they are at.

MEMBER ARMIJO: Well, to me, it is some of sort of dose regulations on the guys that aren't doing a good job.

MEMBER RAY: Well, let me answer Bill by saying Don has invited us to think of something that will be more appropriate to the categories of workers that we are dealing with here that will deal with the problem without creating a problem. That is my concern.

MR. COOL: What we have done -- and, yes, this is a different formulation, and I can understand that you don't believe this looks like Option 3. Based on the data that we had in the discussions to date, we concluded, because we have to work in an environment where it has to play to all sources, where

we have 37 Agreement States, that we should explore the implications of the simple change and the right way to provide flexibility. Since the we already had that mechanism built in for other things, let's explore that one. That was not meant to be exclusive of other options, including flexibility or otherwise.

We clearly know that the reactor community is now thinking, well, maybe the burden isn't so bad, maybe we would rather be there. Fine, let's explore that.

But you have to just take the data that you have at hand. You have to look at what the stakeholders have said to you in your discussions and make your decision based on what they provided to you.

What I know for sure is that, when you actually draft up a proposal and float some language, rather than say which of the three options do you like, you will get a different reaction because people will, then, start to think of it in more concrete terms in their specific situation. And that is what we need to explore the details of.

Because, quite bluntly, we have two major models. We have a model which has programmatic approaches and detailed sorts of things, working through things, which works really well in this one

segment of the community, which doesn't work really well at all in all these other things with those other regulators. And we have a model which is much more straightforward. Just move the line and set up a system that gives you the ability to be flexible with the people who need it here, which will work really well with all of these sorts of folks, and the one-on-one doing things, and justifying where you are if you need to be -- which won't play a hoop over here.

MEMBER ARMIJO: Oh, it will, actually. It will penalize the people who are doing a good job --

MR. WIDMAYER: Is that the answer?

MEMBER ARMIJO: -- in order to provide flexibility for the people who aren't doing a good job. And so, you know, I just don't see any merit.

MEMBER RAY: Well, it isn't just the penalizing. I know you are worried about that, Sam. I am worried about the effect that it would have potentially.

And, look, if NEI walks in here and says 2 is fine, what can I say?

(Laughter.)

MEMBER SHACK: Your argument is still valid.

MEMBER RAY: But I still say, what can I

say? But my point is not just it is not fair or it is not necessary; I am afraid it will have an unintended negative effect somewhere sooner or later.

MEMBER BLEY: Let me be the dummy. It is easy.

(Laughter.)

Why couldn't one have an option that says either bring forward an enforceable ALARA program and keep the 5 or, take your choice, go for the simple 2?

MEMBER RAY: Yes, well, I was thinking of it as a certified ALARA program.

MEMBER BLEY: That is what I meant by they would buy off and say --

MEMBER RAY: Yes. I have got a certified program or I adhere to 2. It would have to be industry-certified, just like ASME Code Stamp, Mike, or something like that.

CHAIR RYAN: So, that works for the power plants. How about the other 10,000 ICCs that have to deal with materials?

MEMBER RAY: I don't know.

MEMBER BLEY: They have got to write their own program and bring it.

MR. WIDMAYER: They can write their own program and get it approved or just pick 2.

MEMBER BLEY: It sounds like, up to them, they would pick 2.

MR. COOL: That flexibility -- I am going to try to answer this without getting in trouble; I don't know if I can or not.

(Laughter.)

In one sense, what you have proposed is not that much different from what we have suggested to the Commission that we explore.

Two, or you can write me a specific program and we will do some other things. That is another piece of the puzzle. Maybe it is some other value, and I have got this program, or otherwise.

What I don't know at the moment, because we haven't tried to write it down and see how it works and doesn't work in different categories, is what the guidance or an approvable program would look like in that situation.

Whether it is 2, unless you have specific data, in which case -- I mean, there are maybe other ways to express this. We haven't tried to go to the next level of detail, which is what this, in essence, drives us to now. If, in fact, we reach the policy conclusion that we really should do something because, the way the regulation today is, it would allow at its

maximum legal approach something that we really don't want, even though it is working 99.975 percent of the time, or whatever it is. So, we want to make a change.

So, what is the right way to do that? Do I draw the line and write other flexibilities in the rule? Do I draw a line and write other flexibilities in the guidance? You have got to start someplace.

We chose to suggest to the Commission that it needs to continue to be explored. And based on what the people had told us to date, the logic seemed to be aimed at, at least start with the way other portions of the regulation were already constructed today. Now maybe that won't work, and we will have to explore some other things. I am not closed. This is not a final decision.

CHAIR RYAN: It certainly opened up a dialog, didn't it?

(Laughter.)

MR. COOL: I accomplished what I wanted to.

CHAIR RYAN: Yes, that's right.

MR. COOL: I threw a bb at the iceberg and it went poof.

MEMBER SKILLMAN: In listening to my

colleagues here, I have the same concern that Harold has, but I want to express it differently. The head event at Davis-Besse was driven in large part because the local HPs did not want people on that head because they wanted to be all green on their indicators. If you dig under the surface or if you have been in the program reviews, that is what happened at Davis-Besse. You have kept the B&W people off the head, and B&W finally woke up when third-party inspectors, Section 11, got on that head. The third-party inspectors did not know what they were looking at, and that is when they called B&W. That is when they found the mouse holes, the weep holes, the rust, and the rest. But that was a fully-incentivized site, all the parameters to achieve what Harold is talking about.

In the early days of the corrective action programs, there were not CATIs, Corrective Action Team Inspections. And the corrective action programs kind of looked like traffic tickets, the Keystone Cops, people getting put on report.

In the course of time, those inspectors caused the corrective action programs to achieve a level of sophistication to where now the corrective action programs, in accordance with Criterion 16 of Appendix B, are really high-class programs. And

generally speaking, you can count on those programs to find problems, force root causes, apparent causes, and to get work done.

The radiological control programs have moved in that same direction. And in most cases, you have got a Certified Health Physicist or two at the site. Like a little child in Portland, Maine, who learns baseball, you can go to Southern California and play by the same rules and be successful in that game, we now have, I am going to estimate, two to three thousand people -- I am thinking 104 sites, so I am thinking 20 to 30 people per site -- who really understand 5-rem TEDE and how to protect the workforce under the current 10 CFR 20.

It seems to me that changing that feeds right into the rule of unintended consequences. We have got this force of people that are pretty good at what they do. And changing the limit from 5 to 2 throws a monkeywrench into what is a very successful continuing program.

The one thing that might be of real benefit is keeping track of individual exposure. If that were to be added in and applied to all users of material and all users of electronically-generated exposure, my belief is that in time the industry would

correct itself. Both the medical industry, the x-ray industry, and I believe the nuclear industry would continue to shepherd its resources to be as low as reasonably achievable that would be allowed.

So, I am opposed to dropping the limit from 5 to 2 because I believe it will disrupt what is presently a well-understood body of behavior, procedures, processes, that type of thing, in the nuclear industry.

But what would benefit everybody, I think, is this idea of tracking, as painful as that might be. I have just got to tell you, over the last 45 years, when I left the Savannah program, I knew how much exposure I had received. When I worked at B&W and made visits, I knew how much exposure I had received. So, I have got a pile of papers at home, and I can tell you -- it is simple arithmetic -- how much exposure I have had. It seems to me that that is not particularly difficult.

In any case, I believe reducing the limit from 5-rem TEDE to 2 brings with it some surprises that we may not need to go through. And so, I think there is safety in what we know, and I think there is safety and flexibility to let the local site ALARA team deem when it is appropriate to allow an

individual or individuals to go beyond the current site limits, which are normally 80 percent of the total or one-quarter to do whatever the work is that needs to be done. I have been one of those people that has gotten the special chit to take the hit. I know how carefully it is controlled.

So, I am in favor of staying with the 5 and not going to the 2.

CHAIR RYAN: Okay. We are probably at a good place to take a break. So, I would suggest we break here for --

MEMBER ARMIJO: Mr. Chairman, there were a number of other very specific things related, the cataract issue and several other things --

CHAIR RYAN: Yes, yes.

MEMBER ARMIJO: -- SI units.

CHAIR RYAN: Yes. Right after the break, we will talk about them. Okay?

MEMBER ARMIJO: Okay, yes.

CHAIR RYAN: Yes. Absolutely.

Is that all right, Don, to take about a 15-minute break and then have more discussion?

MR. COOL: Fifteen? Or 10?

CHAIR RYAN: I don't care.

MR. COOL: Whatever you want.

CHAIR RYAN: Let's take the 15 minutes, so everybody can stretch and have coffee, whatever they need to do.

(Whereupon, the foregoing matter went off the record at 2:53 p.m. and went back on the record at 3:13 p.m.)

CHAIR RYAN: The meeting will come to order, please.

I guess at this point I would like to maybe take a first round to go around for additional comments from members, and then open it up to comments for discussion among members, and then, well, certainly the staff, I am sure, will participate where they would like and where it is helpful.

Steve, how about you?

MEMBER SCHULTZ: Thank you, Mike.

I think I would echo, first, the comments that have been made by other members of the Committee.

But I wanted to go back, Don, to really some earlier presentations that you made, information last August on here, but some of the information at least goes back to:

No. 1, what are we trying to achieve? And you have just described that today. You would like better behavior from certain segments of the industry,

the medical community and industrial users of radiographic materials, and so forth.

We know that the process has moved in Europe, for example, as you have described, to lower the limit from 5 to 2 rem. But you also indicated, at least with some comments, that the behavior hasn't necessarily changed for the better. The goals haven't necessarily been met to change the behavior of those segments of the industry. In other words, the medical community is still behaving in the way that they had previously.

So, I think before we would go forward and make a change, it is important to look at the consequences and whether we are going to achieve, by just that one change, simple as it may be, is it really going to change behavior? It certainly would shift behavior. But is it going to achieve the behavior that is wanted?

I think we know that, if we make the change, the effect on the nuclear power industry could certainly have negative consequences. In fact, one could conclude that it is unlikely to make a huge difference in a positive direction because we are already there. That segment of the industry is already there.

But, based on the data you presented today, it could have unintended consequences. That is, the data shows that in the range just below 2 rem there is plenty of the population that is doing nuclear work, and that would have to shift. It would shift in a direction that could provide unintended consequences.

I think that, with respect to the data that we see from the nuclear power industry, that the performance that focuses around 2 rem has a lot to do with ALARA, and I think little to do with what this data could be, the consequences of the industry anticipating that the limit is going to change to 2 rem. That may have been a consequence at one time or a particular plan at one time, but I think the ALARA program really drove that. It is not that the industry is anticipating that the limit is going to change from 5 to 2 rem, but, rather, that the ALARA program is driving it to be what it is, and that 2 rem was used as a particular focus to assure that the ALARA program was meeting its goals for the site communities and the nuclear power program.

So, again, I think more work has to be done to evaluate whether unintended consequences would be the results in any segment of the community, and

then whether the intended consequences in each segment of the industrial community, including medical, would, in fact, be achieved, because I haven't seen the evidence. I have heard at least evidence that would suggest that the behaviors won't change because they have got a set of goals in terms of the program. Now, if you put a focus on identifying in a medical community or in the industrial community what is meant by or intended by as low as reasonably achievable, then I think that would be interesting, an appropriate study.

I also noticed that in the data you presented that, with regard to the Agreement State data, it is sparse. In the medical community, it is sparser.

MR. COOL: It is nonexistent.

MEMBER SCHULTZ: And that is a problem. So, how do we really determine where things are today? Are we suggesting that there is a problem that is -- what size is the problem today? And how do we determine, if we make any change, whether that change will have an intended impact?

And, of course, we have talked about in previous discussions, that in the medical community unintended consequences may be dire for the patients

that are being treated. So, I think that is a very important feature to study before any significant attention is given to whether the limit should be lowered from 5 to 2. But what should each of these communities be setting up as what they would consider to be as low as reasonably achievable, with a focus on, what is reasonable? I believe it is different from each of the segments. I think the data shows that it is different for each of the segments. So, again, it may be simple to lower it from 5 to 2, but I don't think it is the right thing to do.

CHAIR RYAN: Thanks, Steve.

Bill?

MEMBER SHACK: I will take the other route. Regulation is probably most effective when it is kept pretty simple. And it seems to me that lowering from 5 to 2 is probably the only effective way to regulate a good deal of the industry. It is probably unnecessary in the nuclear power industry.

Harold's problem I think is a real problem. I don't know that it is any better at 5 or 2 because you are still going to have the same incentive with the ALARA programs, that the guy wants to be the top dog; he is going to be in the upper decile. And so, I think you have to deal with those

kinds of consequences some other way.

But strictly in terms of the radiation program, keeping it simple probably means keeping it more effective. Trying to write a consistent set of ALARA-type recommendations to apply to everybody just seems to me a very difficult sort of thing. You know, it is not this close relationship we have with the power plants.

So, I am much more sympathetic, although I like slide 38 -- you know, I am researcher; I am willing to think about these things -- but I am, I guess, more sympathetic than most to the notion of just simply lowering the limit.

CHAIR RYAN: Harold?

MEMBER RAY: Nothing more.

MEMBER ARMIJO: Yes, I endorse the prior comments. I just think the problem that I have heard is not in the nuclear industry. That is working well.

So, the fix, whatever the fix you want to do, regulatory or enforcement or something, should be focused more on where the problem is. I haven't seen any safety benefit that will come out of it for the nuclear industry.

And Harold's point, there is a downside. I think the downside is, you know, the lower you get,

the more ALARA may not solve the problem, and cutting corners may be the way people reach new goals. So, I just don't see any upside and I see a lot of downside.

CHAIR RYAN: I think we have raised a lot of interesting questions and had very good discussion with the staff. Now I want to just say at the outset, Don and Vince, and all the other folks who are here from the staff, have done a really good job of preparing for us today. I appreciate their participation here to answer our questions and have a productive dialog. So, first, thank you very much for all of that. I know it is a lot of hard work that goes into preparing. So, thank you.

But with regard to where do we go from here, I come at this from a practitioner who ran an ALARA program for 12 years for somebody that provided services to everybody, to materials licensees, to x-ray licensees, to nuclear power plants, and all that. We have to learn how to tailor to fit into all those client situations.

I share Steve's comments a lot. I mean, I think he hit the nail right on the head with regard to the fact that it is a very complicated role. Once you learn how to get the strings all lined up and pulled in the right way at the right time to achieve

goals and correct goals and the requirements, it is hard to turn it over.

So, my recommendation and thought is that we need to focus on not the dose limit. Quite frankly, I don't think the dose limit is as important as the ALARA program that one has. Whether it is simple or complicated or has many facets to serve many different constituencies, like various customers, and so on, I think that is the challenge.

So, to me, the ALARA program should be a program that is dynamic, flexible, and founded on good radiation protection practice and not expedient, that is designed for one specific thing and to meet a regulatory requirement. It is much more than that. It is how you protect people.

So, I lean on not following the recommendation to change the dose limit for that reason. I think we can accomplish better radiation protection in all areas by improving ALARA. Now I think that is possible for some constituents fairly readily and fairly straightforward. For others, folks that have not been regulated, like the x-ray world, it may take some additional regulatory structure to accomplish bringing that segment of exposure for both workers and members of the public who stand in front

of the machines, and all the rest of it, to maybe get those activities to recognize ALARA as a useful and valuable practice beyond whatever goals they have set and met to this point. So, that the standard of ALARA is kind of uniform, no matter how the regulatory structure comes down.

The bigger question, which is long-range past this letter, I am sure, is, do we have the right structure for how we regulate x-rays, materials, power plants, and all the other sources of ionizing radiation we have to deal with? That is an important question. That is a big one.

So, I am thinking that we are wrestling with the artifacts of something that has evolved from the 19-teens, when x-rays first came along, to nuclear materials, to the Atomic Energy Act, and on down through. And we try to kludge it all in some coherent hole.

So, I just open that as a thought. You know, it impresses me that we don't have harmony because we have a set of disharmonious starting points in all of that.

So, again, my principal idea is that we not support changing the standard, but recommend, instead, that we have a greater emphasis on ALARA and

a greater emphasis on consistency in ALARA practice, not necessarily an application so much as in the principles by which you develop a program or a product.

Thank you.

John Stetkar?

MEMBER STETKAR: I guess I really don't have anything to add at this time.

There are some analogies, and I am not an expert in this area, so I really don't want to battle, but there are analogies to what we have learned regulating the hardware and people side of the nuclear power business, that the entire industry is not uniform, and application of a single goal across BWRs, PWRs, newer and older plants doesn't necessarily make the most sense from regulating real safety.

We have learned that plant-specific analyses are the most important, and we have learned that risk-informed regulation is important, that you look at an individual site and evaluate its risk. And I think there are some analogies here. Like a lot of the things Steve said struck accord --

CHAIR RYAN: I agree.

MEMBER STETKAR: -- where you do have different constituencies and you do have different

pragmatic processes that may apply to a better or less-effective perspective in those constituencies.

And I do agree with the notion that simply lowering the limit for at least the area that I am familiar with, nuclear power generation, does have some downside consequences. I think at least it could have. It will have. And it is not clear that staff has thought about it.

CHAIR RYAN: Thank you.

Dennis?

MEMBER BLEY: Yes, Don, I would like to thank you for really framing this issue out for us from your discussion.

I kind of line up with the things Steve said pretty well. But the reason I like your last slide is because, this way, it gives us some time to -- what I would really like to see us do is somehow be able to do what is needed for the material side while we don't penalize the reactors and create negative effects that really harm our performance five-eight years from now. I don't know if we can do that or not.

It is easier to sit here right now than where you are sitting. So, good luck.

(Laughter.)

CHAIR RYAN: Dick?

MEMBER SKILLMAN: No, nothing to say. Thank you.

CHAIR RYAN: Anybody else, last comment? Jack?

MEMBER SEIBER: Yes, I guess if I were to pick sides, I would pick sides with Dr. Schultz and Dr. Ryan and Harold. But my concern is a broader one, and it has two aspects to it.

No. 1, going from 5 rem per year to 2 rem per year, I don't think that there has been a case made that that is a health benefit, and statistics don't seem to bear that out, at least from what I have seen, ignoring just broad statistical things that an occasional person may come up with to argue about the location of the specific meter at that facility with respect to population figures.

But I do think there is inconsistency. Particularly if you look at the overall dose to the population, you find that the dose due to medical services has doubled in the last 15 years. It bothers me, for example, that that person who goes and gets a scan with technetium-99 is sent home that day or the next day, to irradiate the family and the children who live in the house where this person is, and to

contaminate the bathroom facilities and remainder of the house, and put the residue down into the sewer system, so that it goes into drinking water. That, to me, is not the best practice in the world.

It disturbs me that the person who gets a thallium scan for a stress test and who happens to work in a nuclear power plant can't get through to the guardhouse because he sets all the radiation alarms off the following day, and for maybe two weeks afterwards.

And so, I don't think the case has been made that a certain amount of dose to the typical individual results in these kinds of physical kinds of things that would occur either to that individual or to the population in general.

And the dose of 5 rem per year going down to 2 rem per year, it is certain it is going to have operational aspects to it. For example, more workers being exposed at lower doses to get a certain job done or a certain job that is important to safety doesn't get done. That, to me, is disturbing.

So, my thought is that, even though I like to remove as many hazards from society as I possibly can, they have to be done with reasonable certainty that you are going to accomplish something. To me, I

see inconsistences in all the uses of radiation. I think that needs to be addressed before, and we need to demonstrate that it will have some impact on the health effects of the entire population, or at least a population of radiation workers, if we make this reduction.

And so, my tendency is to hold back, knowing that consequences, safety consequences, production consequences, and so forth, management decisions are going to be affected, and probably adversely, where we don't know where and how much the benefit will be.

So, that is sort of my opinion also.

CHAIR RYAN: Thank you.

Any other comments?

(No response.)

I guess, Don, have we given you some feedback? Anything you and your staff want to add or think about? Or is there any other topic we want to take up?

MEMBER RAY: Sam wanted to --

MEMBER ARMIJO: There were a number of things related to the recommendation about limits for the lens, changes in the limits for embryo and fetus, and SI units, and a number of other things that

interested me. I don't know if anybody else wants to hear about those things or not, but it is up to you, Don. You know, we have got your documents and we can --

CHAIR RYAN: There are pretty straightforward recommendations that you had, Sam. I did read them. I would assume we just put them in the letter, if there is something you think rises to that.

MEMBER ARMIJO: Yes. You know, if you don't have anything to present, I am not going to just take everybody's time just asking my questions.

MR. COOL: I did not bring additional slides down --

MEMBER ARMIJO: Okay.

MR. COOL: -- but I am pleased to answer questions or provide any clarifications that you would --

MEMBER RAY: Just a quick one. Let's hear what you have to say.

MEMBER ARMIJO: Here were my notes on that one. On the lens-to-the-eye proposed change, it was reduce the limits to 5 rem lens-dose-equivalent per year and continue to develop a technical basis.

My question was, does the staff have statistically-significant data that demonstrates that

the current limits are not adequate?

Cataracts are so common, particularly as people get older. Is there any way to say that changing this limit will have a detectable change in the frequency of cataracts among nuclear workers? And if there isn't, again, my question is, why are we doing it then?

MR. COOL: Okay. Let me start, and then I am going to, I think, hand off to Vince here in a second.

This category, like most all of the other categories, suffers from the fundamental problem that the number of folks that you have got doing it is not sufficiently large that you could detect a change signal unless you were really out at the fringe of the exposure. And because the framework of protection is limits in ALARA, and because in this case protection is generally driven by protection to the whole body, there are very few circumstances -- and we can get into the details -- where it would be a driver in the present structure of limits and guidance.

You have very few individuals -- one that I think was somewhere in the data -- that were approaching the lens dose limit as a separate construct from the effective dose limit. When you are

monitoring an individual with a badge on the collar, and you are doing the calculations, and you are making sure that individual has a badge on the collar and the deep-dose equivalent, if you are doing it the simple way, is less than 5, there is no way that the lens dose is ever going to approach the current limit of 15, the application of ALARA. So, the net result is that practice today, again, for the most part, is resulting in less dose exposures that are not close to that guidance.

Now there are certain exposure situations in which lens dose can become more important. Some of the atretic crystallographers and stuff, where you are looking at the beams and stuff, sort of we are giving you quite a lot of dose.

Again, our friends in medical, in interventional radiology and cardiology, where the situation is the tube is underneath the patient and exposure is coming up, you are reading the graph, you are leaning over, your hands are in it, your head may be in, your body is being provided shielding. Lead vapor works pretty well on 70 keV x-rays. If you are wearing the leather glasses, you have got the side shield, so you are avoiding the scatter. You're fine.

Visual acuity is cut way down by those

1 things. And so, my limited understanding -- I haven't
2 traipsed through, yea, any number of surgical suites
3 -- is that a lot of folks don't really like them, have
4 problems with them because of those associated issues.
5 One of the things that we clearly heard
6 was that, if you take the numeric value of that limit
7 down to a numerically-identical number as the
8 effective dose number, so that the only difference is
9 the fact that it is the lens dose at .7 centimeters
10 versus LEAP dose or skin dose, but numerically it is
11 exactly the same, then you would have more cases in
12 which the lens dose would become the limiting
13 quantity. And that could well pose some significant
14 issues to folks.
15 CHAIR RYAN: That equivalency is not well-
16 established, though.
17 MR. COOL: It is not --
18 CHAIR RYAN: So, I mean, you are making an
19 equivalency that has not been proven.
20 MR. COOL: What I am simply referring to
21 is the fact that the ICRP recommendation now, the
22 ICRP's recommendation for the limit for effective
23 dose, is average of 20 and maximum of 50
24 millisieverts, effective dose. The ICRP's
25 recommendation now for lens-dose-equivalent is an

average of 20, a maximum of 50. So, the number is exactly the same.

Now the dose is actually a different calculation because it is a different depth, and it is a single organ versus an effective dose --

CHAIR RYAN: Right.

MR. COOL: -- with all of the averaging. But the numbers are --

CHAIR RYAN: It doesn't matter what the numbers are; it is effective dose.

MR. COOL: Well, right, but the fact that they are numerically the same, no longer here and here, raises issues in certain exposure situations, presents particularly in interventional radiology and cardiology.

I will tell you that in the public comments, because we went out for public comment on this -- this was what was probably more interesting -- there was more of a view that something needed to be done, several people saying it was about time, but that they did not support taking it all the way down to the average of 20 mLs. Several comments saying that 50 millisieverts, maintaining a ratio between between lens-dose-equivalent and effective dose, and keeping that ratio of things was a better approach.

Again, this is the first tier of the comment process, and the devil was always in the detail of how you write it.

MEMBER ARMIJO: And the current number is what? It is --

MR. COOL: A hundred and fifty millisieverts --

MEMBER ARMIJO: A hundred and fifty?

MR. COOL: -- 15 rem.

MEMBER ARMIJO: Okay. So, it is reducing it by a hundred, 150 to 50?

MEMBER SKILLMAN: Sixty-seven percent.

MEMBER ARMIJO: Yes, a big reduction. Okay. But, again, my question was, was there data that showed that would be beneficial? And the answer is you can't tell.

MR. COOL: If I am doing it in an epidemiologic standpoint, the number of folks I got, you ain't got the signal-to-noise ratio to ever show it.

MEMBER ARMIJO: Okay.

MEMBER SHACK: But somehow the ICRP came to that conclusion?

MEMBER ARMIJO: They must have had some --

MR. COOL: Well, what you have is a lot of

data not in the occupational settings, where you have more exposure to lens of the eye from medical treatments that show a significant ramp-up in cataracts when you start to pour more than "X" amount of dose in.

MEMBER SHACK: But you need really expert elicitation for --

MR. COOL: So, then, the question becomes, okay, you have got this evidence here that if you pour "X" amount on more dose, you start to see a substantial increase in cataracts showing up. People are not necessarily arguing with that.

So, what is the appropriate approach to providing protection for this group of folks who are not getting the "bing" but, rather little bits of it over time?

MEMBER ARMIJO: At what dose, lens-dose-equivalent, do you start seeing those things? Is it 500 or is it 1,000? You know, I am trying to see, is there a margin or have we discovered that there isn't a sufficient margin --

MR. COOL: Fifty rem, 500 millisieverts is now the threshold suggested for those cataracts.

MEMBER ARMIJO: Okay, so 50. So, this would be a factor of 10 below observable threshold for

1 something happening --

2 MR. COOL: In a single year.

3 MEMBER ARMIJO: In a single year.

4 MR. COOL: But, again, this is also being

5 laid out as a cumulative impact. So, at the maximum

6 value recommended by ICRP, at 50-millisievert-per-year

7 lens-dose-equivalent, you could get to what they are

8 suggesting is now the threshold for that induction in

9 10 years.

10 MEMBER ARMIJO: Okay. At least I know

11 where something measurable or --

12 MR. COOL: Yes, the underlying threshold

13 -- and this is actually more a threshold effect. That

14 is still one of the debates.

15 MEMBER ARMIJO: Yes, I understand.

16 The other question I had was in your

17 recommendation to change the requirement on the limit

18 for embryo and fetus to 100 millirem over the

19 gestation period remaining after declaration. And the

20 question I had was, is this really -- and this as a

21 rank amateur in this area, so please forgive me -- the

22 most serious risk? Isn't that in the earliest stages

23 of development --

24 MEMBER SEIBER: Yes.

25 MEMBER ARMIJO: -- in a few cells, and

they are getting zapped? But that is the time when, in all probability, the mother has no idea that she is pregnant. Or if she does have an idea and chooses not to declare, how is a change in limits going to help anybody? Is it? It is a nice exercise to say change the number, but how do you really ensure that people have the knowledge to actually benefit from it?

The alternative is -- and I know this is politically-incorrect -- is to say, "Hey, women who are thinking about getting pregnant shouldn't be working in this radiation environment."

But I just don't understand how this would help anybody, to just change the number, unless you do something else that actually makes people -- either give them early warning or provide some regulation that says you can't work in this area if you are going to get pregnant. And I know that is unpopular, but you can't have it both ways. You can't protect a fetus with this rule. I guess that is what I am --

MR. COOL: You have identified the fundamental problem, if you will, with this regulation at all, because this regulation is the only limit which is applicable only upon the voluntary declaration of the exposed individual, the mother. She may choose to declare or not declare. That is a

very-well-established case-law issue outside of the radiation field with regards to an individual's right to choose and anti-discrimination.

Once you make the presumption that it is the individual's right to choose, then the question becomes, if she chooses to request protection, what kind of protection, at what level, should be provided to her? In fact, the debate continues now because of the ICRP's recommendation to apply it after declaration, as yet another variable to the discussion, which in the staff paper you will see we believe needs some more dialog because, in fact, the rule today that is on the NRC books is a 500 number, not 100. So, numerically, it doesn't comport to the protection for equivalent to a member of the public.

But it is applied to the whole gestation period. There is no variable there. It is the gestation period. In fact, the ICRP's recommendation on declaration means that it is applied to a variable, which is, again, completely dependent on the individual's choice.

And so, in fact, in our recommendation we have said that it seems logical and appropriate that, if the individual chooses to declare, then the rules should provide that the protection afforded would be

the numeric value, which is what we provide for limitation for the public. It is an open question because some have put it on the table: you really should apply that to the whole gestation period. Because if you go to the radiobiology -- and that was my doctorate way back when -- the actual most sensitive time period is the organogenesis development, 8 to 15 weeks. Most folks know they are pregnant by that point, although certainly there are cases when they do not.

Whether they have chosen to declare or not probably depends on their desire to provide protection or their desire to make sure that they have completed their residency and internship, or otherwise. And that is completely that the courts have taken my hands off of that.

MEMBER ARMIJO: Okay. Okay, so I understand it. So, it would be 100 millirem down from -- what is the current?

MEMBER BLEY: Five hundred.

MEMBER ARMIJO: Five hundred. Okay. But the other things, the declaration and all of that, that is just the lawyers --

MR. COOL: That, as far as the staff's view and the General Counsel's view, is not a subject

to question. There is well-established case law in the federal courts.

MEMBER ARMIJO: Yes, that's --

MR. COOL: Our current rule and provisions are in accord with that. That piece of it is not open to debate.

MEMBER BLEY: How about the other side, the side of whether you apply from that point forward or the full gestation period?

MR. COOL: That is very open to discussion and the implications that are associated with it, and the pros and cons. In fact, the staff paper said we need more discussion on that because we didn't get to that point.

MEMBER BLEY: Just from where I sit, it just doesn't seem logical to apply it from that point on. It ought to apply to the whole term.

MEMBER ARMIJO: Yes, better protection at the beginning --

MR. COOL: That is quite true.

MEMBER BLEY: Or not from the beginning; two months in.

MEMBER ARMIJO: But, you know, up to -- yes, two months now.

MEMBER BLEY: But the other side of it, I

would think, is, if you do lower it, whether you apply it to the whole time or not -- but, to me, it would make sense to the whole time -- it also is an awareness thing. It kind of says this is really sensitive, and if you might get pregnant, pay attention.

So, I think the idea that it has no impact, well, somebody could make it have no impact, but I think it serves the other side of saying this is an important issue to consider.

MEMBER ARMIJO: I could see where it is very reasonable for the first couple of months now. I just thought it was really early when you were at risk. For the first couple of months, you know, this is the number.

MEMBER BLEY: So, you have got to have something that is pretty well put together before it makes as much difference.

MEMBER ARMIJO: Yes.

MR. COOL: Well, from the radiobiological standpoint, when the cells are rapidly dividing and rapidly differentiating --

MEMBER BLEY: That's right. That is what happens later.

MR. COOL: -- when you are starting to get

to nerve tissue, different kinds of organs and other things, that is the area that is shown to be more sensitive. The more rapidly you are reproducing them, the more sensitive it is. That is statement one.

The differentiation into the different groups, where you are getting a couple of cells here, and they are starting to differentiate, so you, again, have very small numbers, again makes it more sensitive. Once you have had that differentiation and you are growing things, the sensitivity decreases because you are no longer in that rapidly-changing environment with lots of things being turned on and off and differentiation and all of the other biological stuff that goes on in that development process, just from a radiobiologic perspective.

MEMBER ARMIJO: Yes. Thanks, Don. I understand where we are with this.

MR. COOL: Thanks.

CHAIR RYAN: Are you good, Sam?

MEMBER ARMIJO: Yes, yes.

MR. COOL: Vince, you had something you wanted to add?

MR. HOLAHAN: Just with regard to the number. In 1990, when we last changed Part 20, we reduced the public dose limit of 500 millirem to 100

millirem, but we didn't change any of the occupational exposures to include a declared pregnant worker. By going to 100 millirem, we are just affording that fetus the same protection as a developed adult. And that is where the number comes from.

MEMBER ARMIJO: Yes. I understand it.

MR. COOL: And I would also note to you that there is a good deal of difference in the possible impact in different segments of the community on whether you apply it after declaration or the entirety. Since those discussions have not been held at all, those discussions need to be held.

MEMBER ARMIJO: Okay. That is the only questions I had.

CHAIR RYAN: Any other questions from members?

(No response.)

Hearing none, any other comments from, Don, you or your staff?

MR. COOL: No, sir. We came here to try to help elaborate on some of the questions and open issues.

CHAIR RYAN: Well, I, for one, think the discussion both back and forth has been very helpful and useful. It will help us with views that we will

present to the full Committee and on which we will write a letter, I am certain, at the October meeting. So, we will look forward to that. We will be in touch as we move toward that date, again, to form ideas.

So, hearing no other comments, we will adjourn the meeting.

Thank you very much.

(Whereupon, at 3:54 p.m., the meeting was adjourned.)

U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

ACRS Radiation Protection and Nuclear Materials Subcommittee

SECY-12-0064

Donald A. Cool
U.S. Nuclear Regulatory Commission
September 18, 2012

Presentation Outline

- **Risk**
- **Occupational Exposures**
- **Regulatory Approaches**

Risk

- **Risk Assessment**
  - **Characterizing the nature and magnitude of radiation effects**
  - **Unique for each individual**
- **Risk Management**
  - **Manage and reduce risk through education and regulatory means**
  - **Generalized at population level**

Regulation Basis

- **10 CFR Part 20 Occupational Dose limits based on assumed risk of 1.25×10^{-2} per Sv cancer mortality and risk of heritable disease**
- **Current radiation risk ≈ 5×10^{-2} per Sv**
  - **Considered mortality, morbidity and hereditary effects**
  - **Comparable results from UNSCEAR, ICRP, BEIR, NCRP**
  - **EPA "Blue Book" values for U.S. Population**

    Incidence: 1.16×10^{-1} (5.6×10^{-2} to 2.1×10^{-1})

    Mortality: 5.8×10^{-2} (2.8×10^{-2} to 1.0×10^{-3})

Selection of the Limit Value

- **1977 – ICRP 26**
  - **average annual risk of accidental death in industries generally accepted as safe working environment – 1×10^{-4}**
  - **5 rem value based on expectation that most individuals would be unlikely to exceed 1 rem**
- **1990 – ICRP 60**
  - **Multi-attribute approach**
  - **Objective to prevent cumulative exposure to less than 100 rem**
  - **Average and maximum values to provide flexibility for implementation**

Current Occupational Exposures

- **NCRP Report 160 Data**
  - **Based on information obtained from dosimetry processors**
- **NUREG 0713 Vol. 32 2010 Data**
  - **REIRS data as reported to NRC under §20.2206**
- **NUREG 2118 Agreement State Data**
  - **Data from special request to States for information**

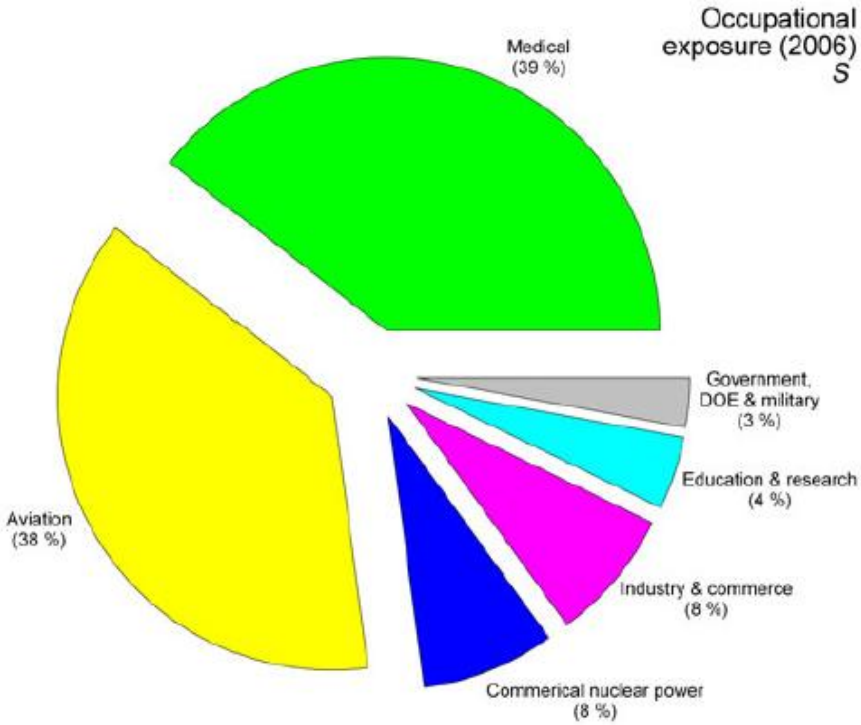
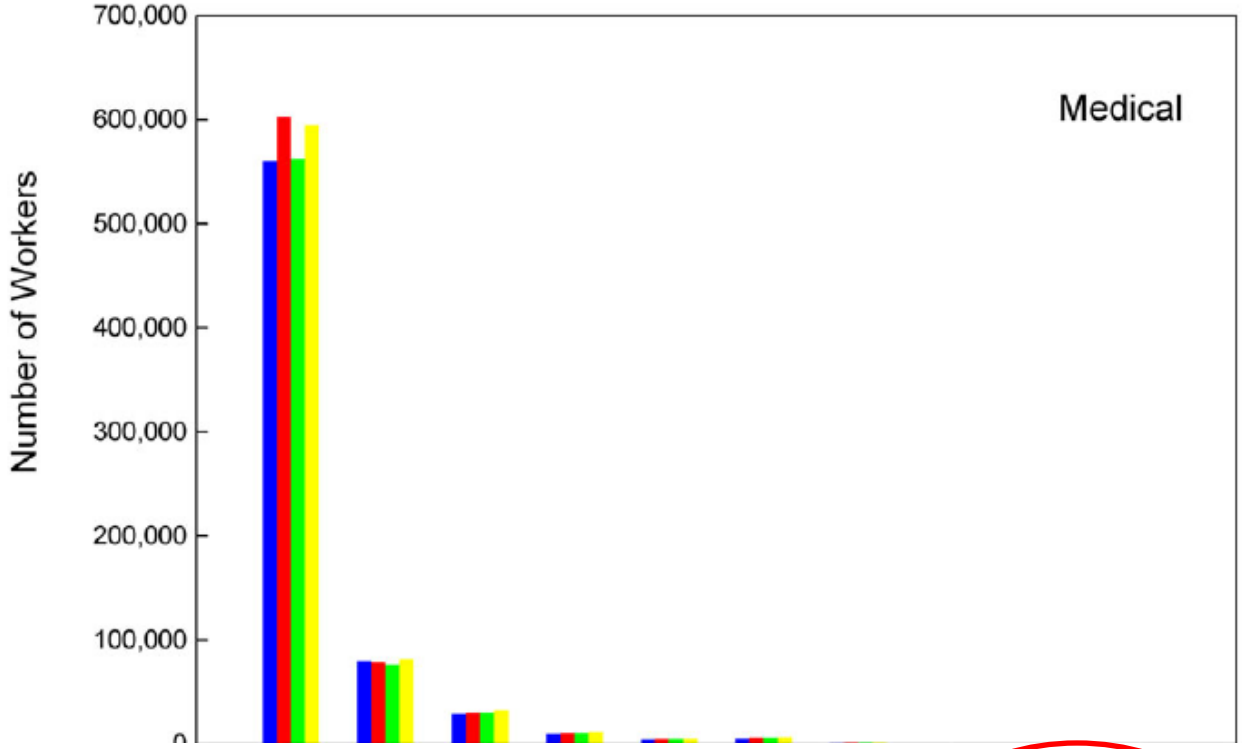


Fig. 7.3. Percent contribution of various sources to S for occupational exposure (1,400 person-Sv) for 2006. Percent values have been rounded to the nearest 1 % [see Table 7.3 for the values of S (person-sievert)].

NCRP Report 160

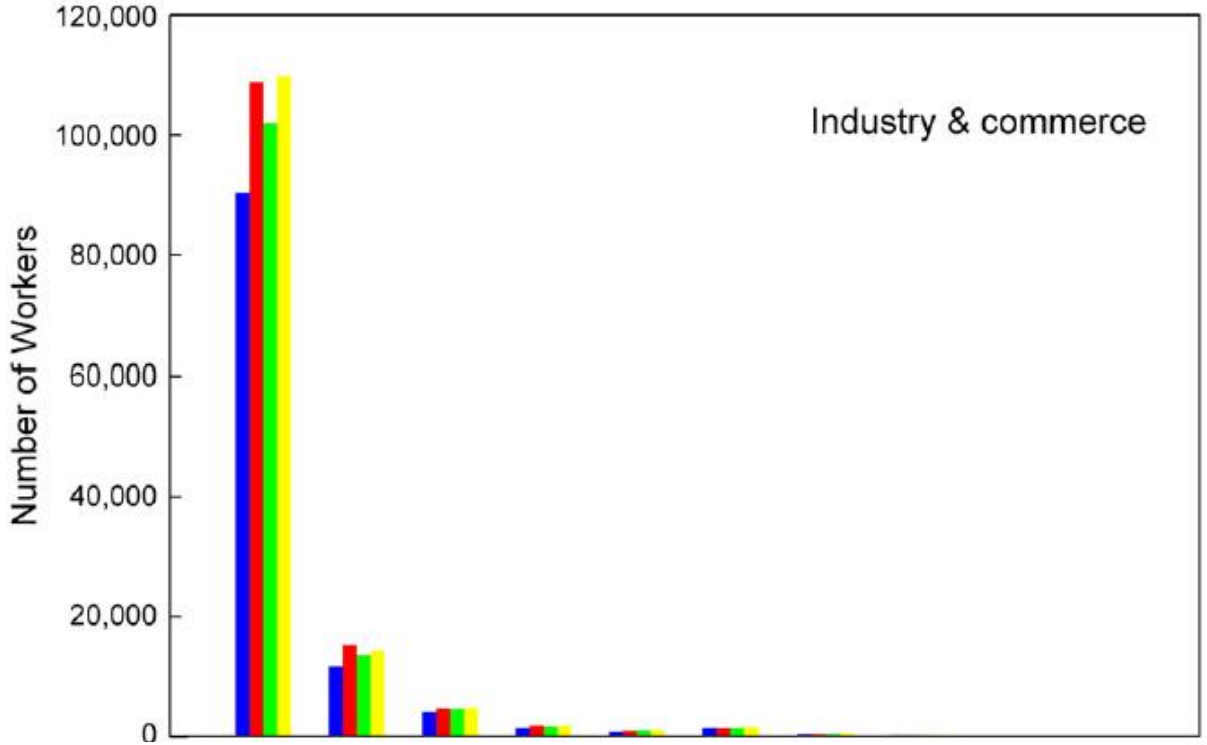


Dose (mSv)		>0 – <1	1 – 2.5	2.5 – 5	5 – 7.5	7.5 – 10	10 – 20	20 – 30	30 – 40	40 – 50	>50
	2003	560,203	79,768	28,889	9,764	4,278	5,245	1,343	527	246	396
	2004	602,153	78,944	30,076	10,495	4,834	6,032	1,504	612	289	461
	2005	562,323	76,247	30,251	10,737	4,970	6,254	1,630	678	320	531
	2006	594,394	81,758	32,782	11,536	5,242	6,506	1,631	646	328	524

< 20 mSv = 99.57%

Fig. 7.5. Dose distribution for workers with recordable dose for the medical category, 2003 to 2006.

NCRP Report 160



Dose (mSv)		>0 – <1	1 – 2.5	2.5 – 5	5 – 7.5	7.5 – 10	10 – 20	20 – 30	30 – 40	40 – 50	>50
	2003	90,337	11,736	4,105	1,470	821	1,443	472	188	73	81
	2004	108,843	15,385	4,756	1,748	905	1,459	477	199	66	88
	2005	101,953	13,648	4,624	1,673	945	1,503	509	220	68	114
	2006	109,849	14,288	4,780	1,723	938	1,597	515	207	80	128

< 20 mSv = 99.31%

Fig. 7.7. Dose distribution for workers with recordable dose for the industry and commerce category, 2003 to 2006.

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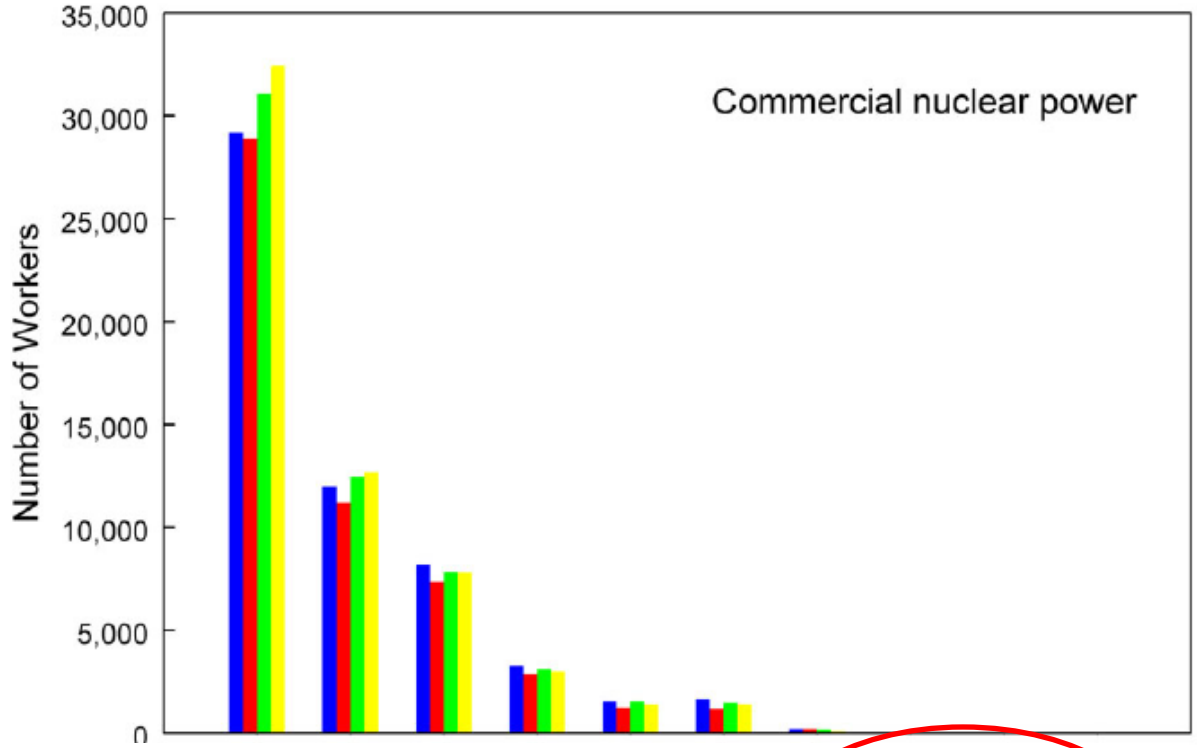


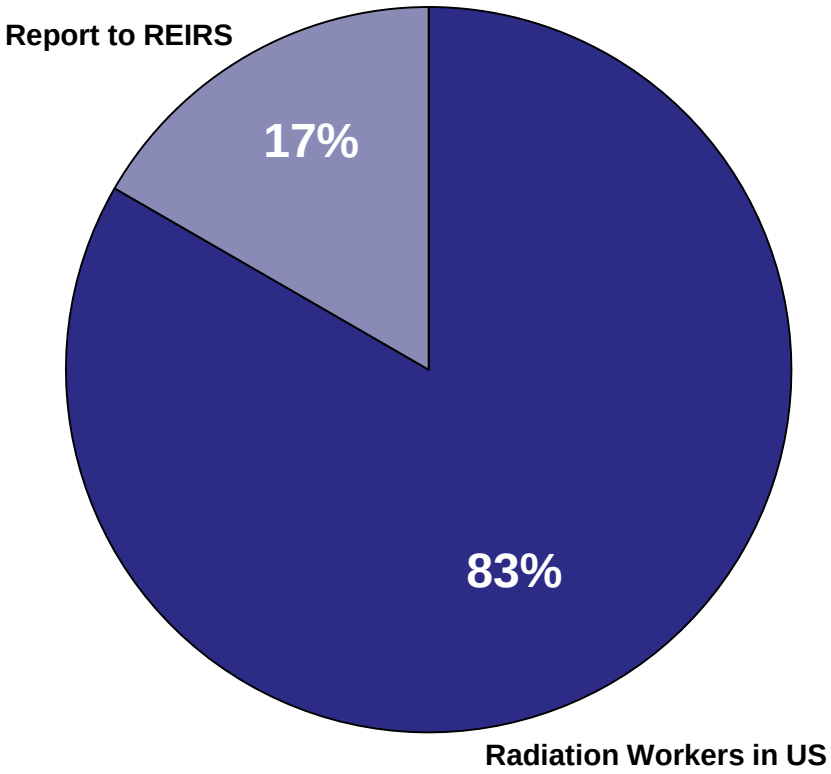
Dose (mSv)	>0 – <1	1 – 2.5	2.5 – 5	5 – 7.5	7.5 – 10	10 – 20	20 – 30	30 – 40	40 – 50	>50
2003	29,164	11,978	8,199	3,249	1,524	1,651	184	18	0	0
2004	28,863	11,179	7,334	2,873	1,233	1,190	188	13	0	0
2005	31,043	12,427	7,815	3,104	1,537	1,490	147	3	0	0
2006	32,426	12,685	7,796	2,975	1,416	1,406	147	2	0	0

< 20 mSv = 99.75%

Fig. 7.9. Dose distribution for workers with recordable dose for the commercial nuclear-power category, 2003 to 2006.

NCRP Report 160

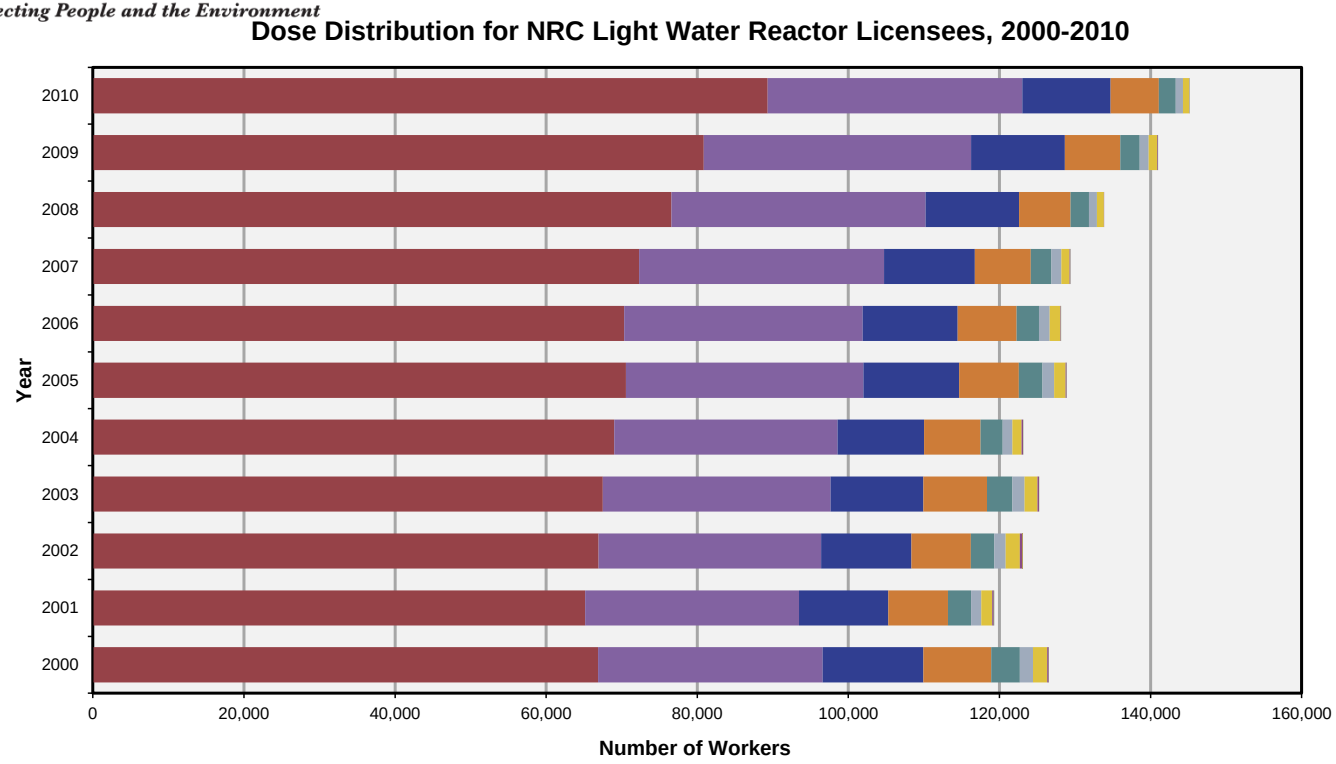
US Occupational Radiation Workers



- ~1,000,000 occupational radiation workers in US**
  - Majority of workers are in the medical industry
  - No medical licensees report to REIRS
- ~200,000 monitored workers annually report to REIRS

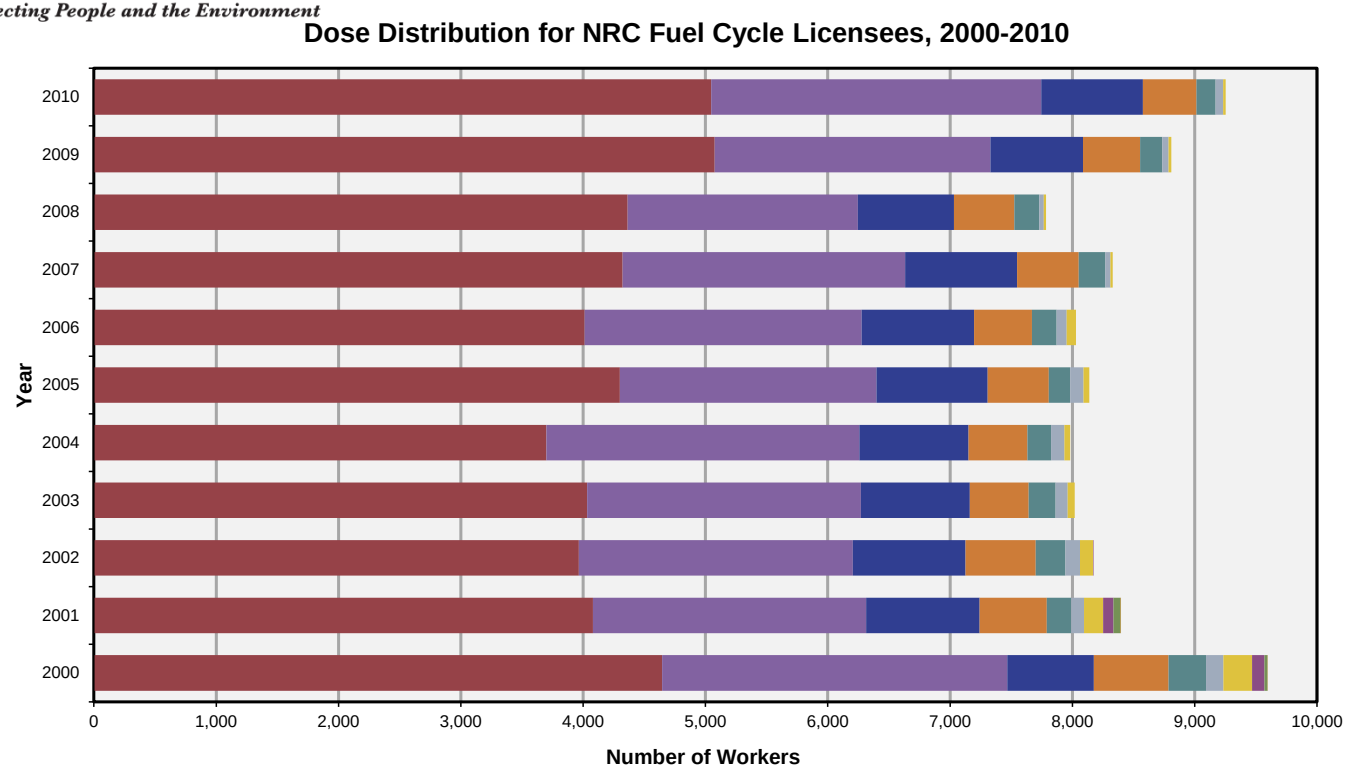
Data compiled from US Dept. of Labor – Bureau of Labor Statistics' O*Net Online Job Statistic Database. Data is primarily for workers who work with radiation sources/materials (i.e., not machine-produced radiation). 2010 employment numbers was latest data provided. http://www.onetonline.org

REIRS Dose Data



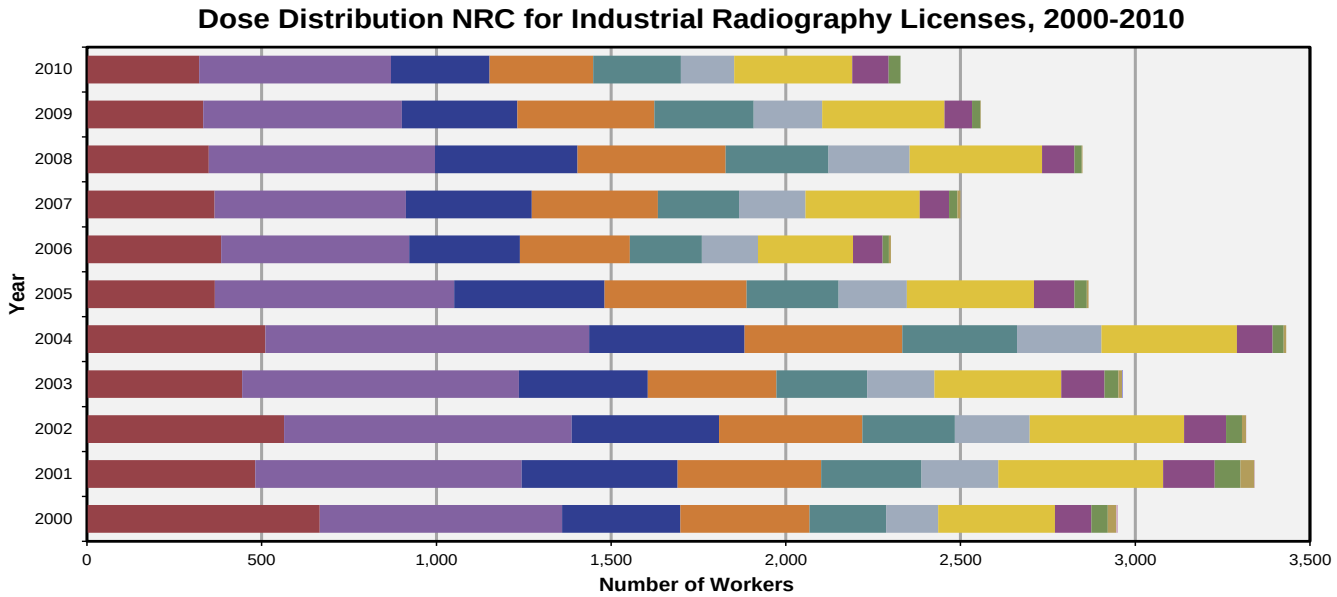
	No Meas.	Meas. <0.1	0.10–0.25	0.25–0.50	0.50-0.75	0.75-1.00	1.00-2.00	2.00-3.00	3.00-4.00	4.00-5.00	5.00-6.00	6.00-12.00	>12
2000	66,884	29,706	13,345	8,973	3,776	1,776	1,853	202	18	-	-	-	-
2001	65,165	28,292	11,830	7,913	3,035	1,372	1,428	221	53	-	-	-	-
2002	66,934	29,475	11,950	7,861	3,100	1,514	1,862	320	35	1	-	-	-
2003	67,489	30,166	12,279	8,404	3,381	1,595	1,729	185	18	-	-	-	-
2004	68,997	29,558	11,473	7,484	2,920	1,272	1,227	188	13	-	-	-	-
2005	70,550	31,429	12,676	7,918	3,134	1,548	1,498	150	3	-	-	-	-
2006	70,331	31,559	12,594	7,781	2,965	1,413	1,415	82	2	-	-	-	-
2007	72,315	32,411	12,016	7,420	2,732	1,289	1,114	99	9	-	-	-	-
2008	76,599	33,641	12,360	6,809	2,436	1,045	927	38	-	-	-	-	-
2009	80,848	35,400	12,423	7,322	2,574	1,174	1,144	68	4	-	-	-	-
2010	89,322	33,697	11,708	6,372	2,234	947	832	42	3	-	-	-	-

REIRS Dose Data



	No Meas.	Meas. <0.1	0.10–0.25	0.25–0.50	0.50-0.75	0.75-1.00	1.00-2.00	2.00-3.00	3.00-4.00	4.00-5.00	5.00-6.00	6.00-12.00	>12
2000	4,645	2,822	708	612	306	141	236	101	24	4	-	-	-
2001	4,081	2,233	928	548	200	105	157	83	55	7	-	-	-
2002	3,964	2,241	921	575	243	119	107	3	-	-	-	-	-
2003	4,033	2,237	891	482	219	99	58	-	-	-	-	-	-
2004	3,699	2,560	893	480	193	110	47	-	-	-	-	-	-
2005	4,300	2,098	910	500	174	110	47	-	-	-	-	-	-
2006	4,013	2,264	920	473	200	84	76	-	-	-	-	-	-
2007	4,323	2,309	917	502	219	42	18	-	-	-	-	-	-
2008	4,363	1,883	785	495	204	37	18	-	-	-	-	-	-
2009	5,075	2,256	756	467	180	53	23	-	-	-	-	-	-
2010	5,047	2,699	831	437	158	61	21	-	-	-	-	-	-

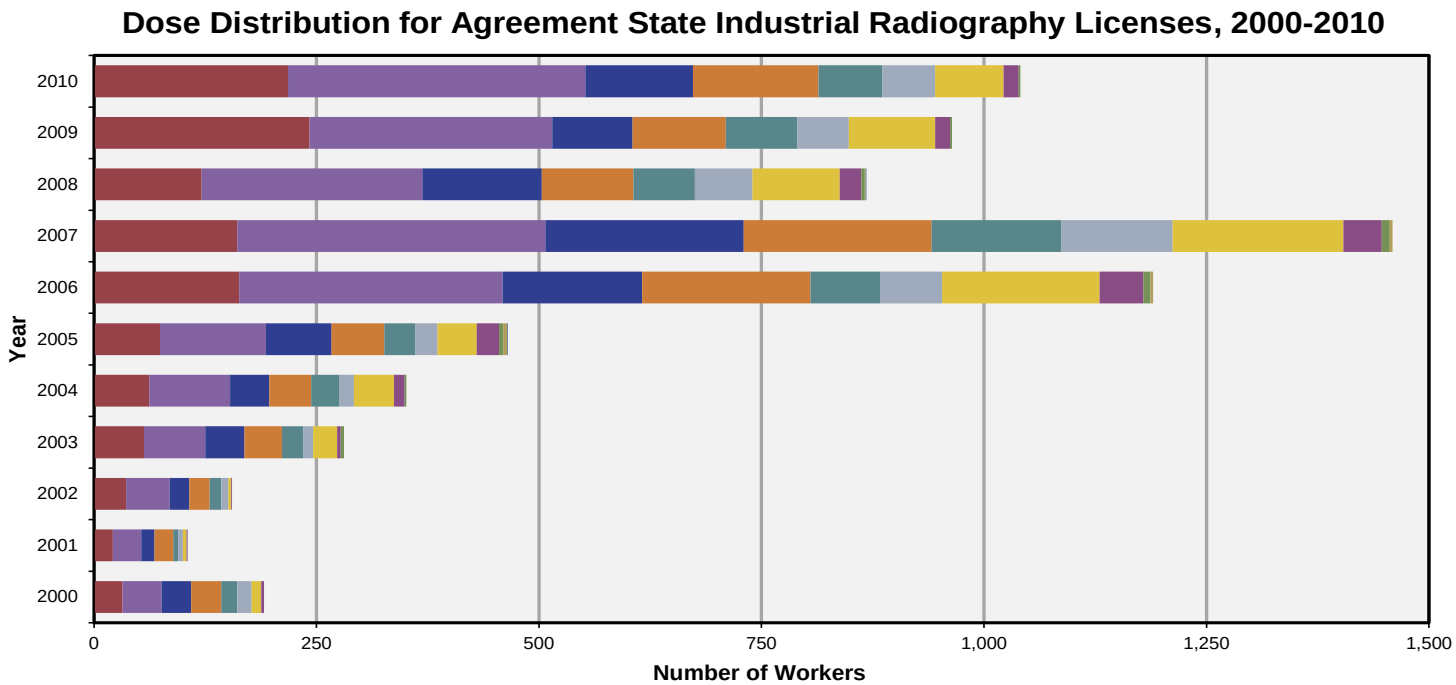
REIRS Dose Data



	No Meas.	Meas. <0.1	0.10–0.25	0.25–0.50	0.50-0.75	0.75-1.00	1.00-2.00	2.00-3.00	3.00-4.00	4.00-5.00	5.00-6.00	6.00-12.00	>12
2000	666	694	338	370	219	149	334	104	47	25	4	-	-
2001	482	762	446	411	287	220	472	147	74	40	1	-	-
2002	564	823	422	410	265	214	442	120	45	12	1	-	-
2003	444	792	369	368	260	192	363	124	40	11	-	-	1
2004	511	926	445	451	329	241	388	102	32	7	-	-	-
2005	366	685	430	407	263	195	364	116	35	5	-	-	-
2006	384	538	317	315	206	160	272	85	18	6	-	-	-
2007	365	548	360	361	232	190	327	84	24	9	-	-	-
2008	349	647	408	424	294	232	379	93	21	2	-	-	-
2009	333	568	331	392	284	196	350	79	24	1	-	-	-
2010	321	549	282	297	251	152	338	104	34	-	-	-	-

**** Data from NUREG-0713, Vol. 32; www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0713/v32/***

Agreement State Dose Data



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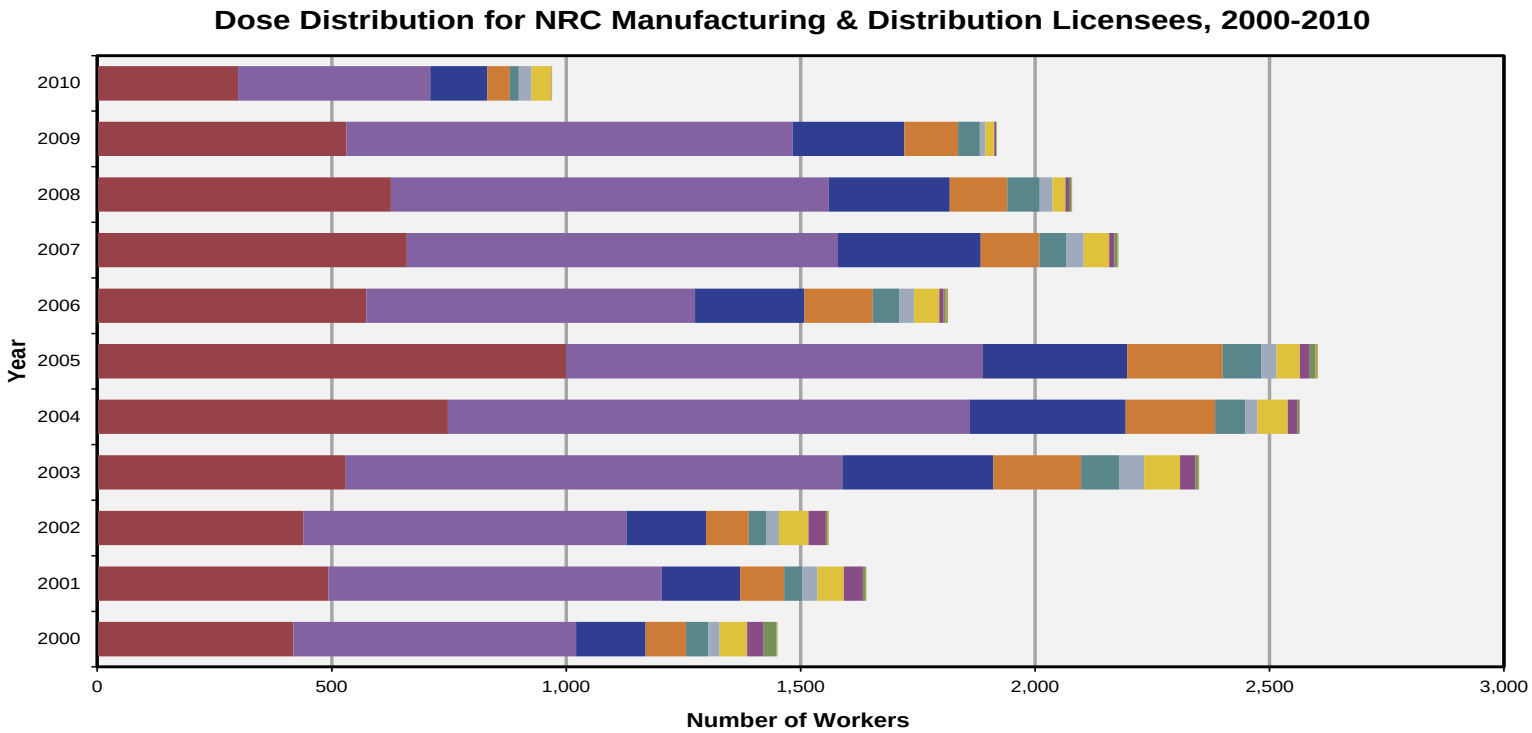
2000	32	44	33	34	18	16	11	3	-	-	-	-	-
2001	21	32	15	21	6	5	4	1	-	-	-	-	-
2002	36	49	22	23	13	8	3	1	-	-	-	-	-
2003	56	69	44	42	24	11	27	4	4	-	-	-	-
2004	62	91	44	47	32	16	45	12	2	-	-	-	-
2005	74	119	74	59	35	25	44	25	5	4	-	1	-
2006	163	296	157	189	78	70	177	49	8	3	-	-	-
2007	161	346	223	211	146	125	192	43	9	3	-	-	-
2008	121	248	134	103	69	65	98	24	4	1	-	1	-
2009	242	273	90	105	80	58	97	17	2	-	-	-	-
2010	218	334	121	141	72	59	77	17	2	-	-	-	-

Data from NUREG-2118, Vol. 1; www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2118/v1/

REIRS Dose Data



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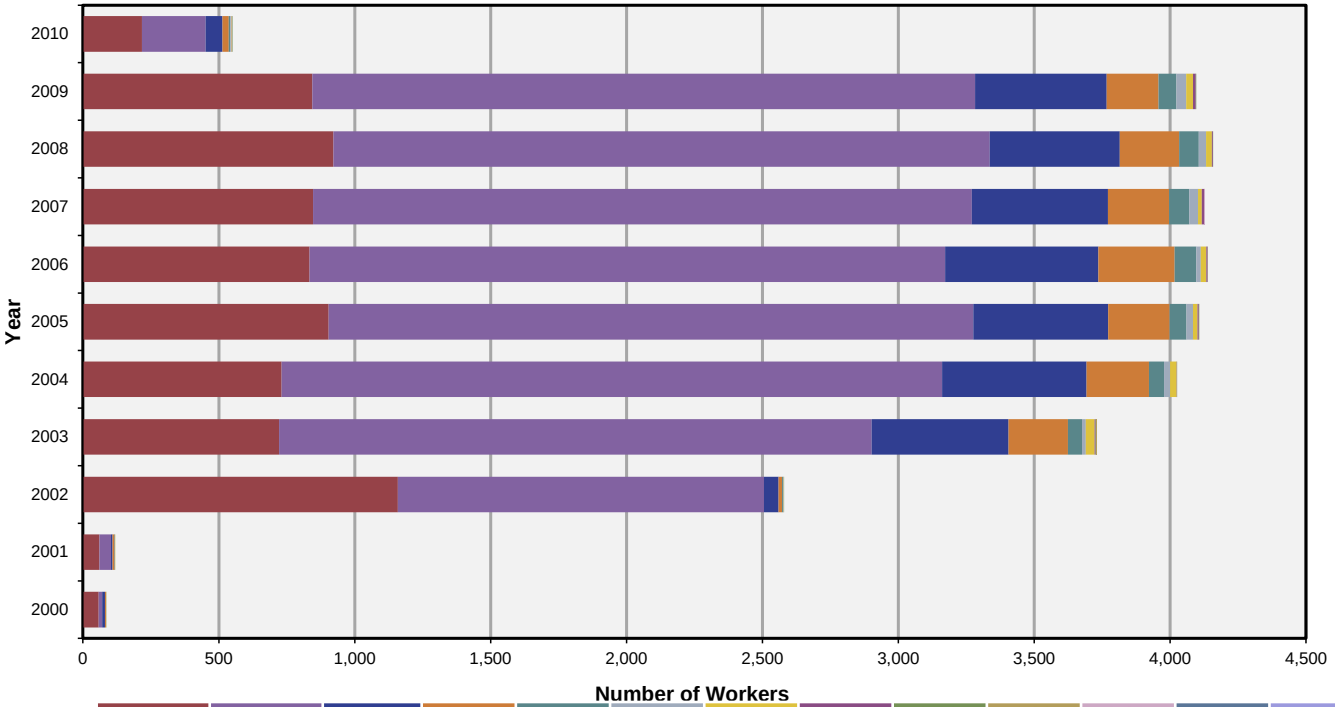
2000	418	603	148	87	47	24	59	35	27	3	-	-	-
2001	493	711	167	94	38	33	56	41	4	3	-	-	-
2002	439	690	169	91	38	27	63	37	3	3	-	-	-
2003	530	1,059	322	187	81	54	76	33	6	2	-	-	-
2004	748	1,113	332	191	65	25	65	21	4	1	-	-	-
2005	1,000	889	307	204	82	33	50	21	12	5	-	-	-
2006	574	701	233	146	56	32	54	9	3	6	-	-	-
2007	660	920	304	125	57	38	54	11	7	2	-	-	-
2008	626	934	258	123	69	27	28	7	6	1	-	-	-
2009	531	952	238	115	46	12	19	4	1	-	-	-	-
2010	300	410	122	48	19	27	42	1	-	1	-	-	-

Agreement State Dose Data

Dose Distribution for Agreement State Manufacturing & Distribution Licensees, 2000-2010



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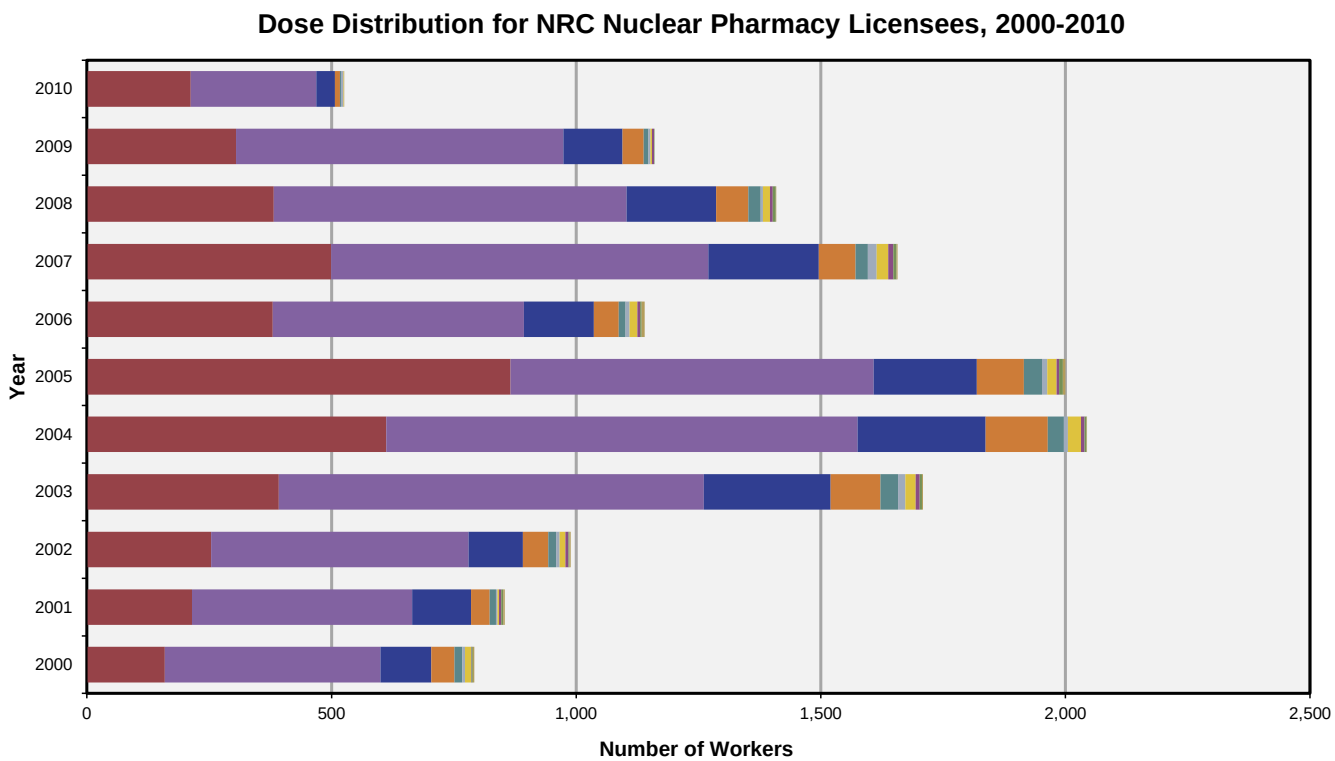
2000	58	13	10	4	1	-	1	-	-	-	-	-	-
2001	61	42	6	7	2	-	1	-	-	-	-	-	-
2002	1159	1347	53	13	4	2	1	-	1	-	-	-	-
2003	722	2180	504	218	52	14	32	4	2	2	-	-	-
2004	731	2430	532	229	56	22	24	1	1	-	-	-	-
2005	904	2372	496	226	62	24	17	4	2	-	-	-	-
2006	834	2338	564	281	79	17	20	5	1	-	-	-	-
2007	847	2423	501	225	74	33	14	8	3	-	1	-	-
2008	922	2414	479	218	72	27	22	3	1	-	-	-	-
2009	844	2438	485	190	66	36	25	10	2	-	-	-	-
2010	217	234	62	24	5	4	2	1	1	-	-	-	-

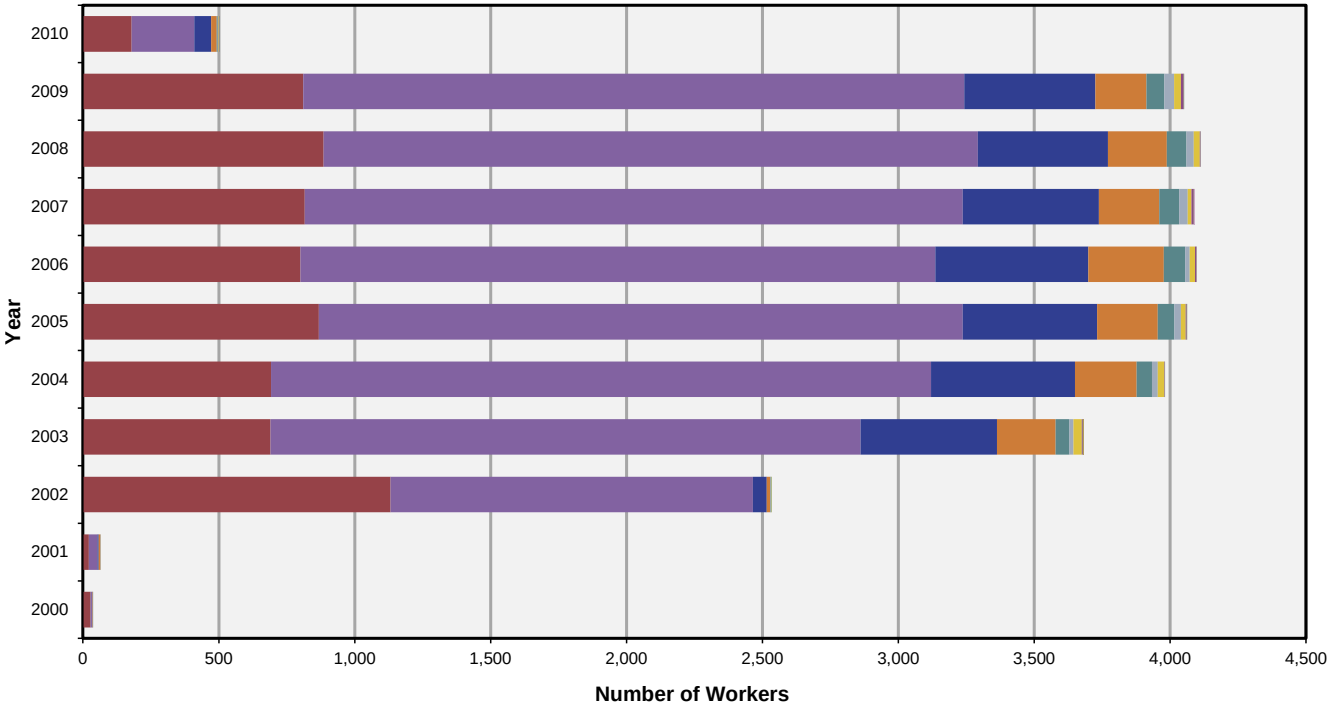
REIRS Dose Data



	No Meas.	Meas. <0.1	0.10–0.25	0.25–0.50	0.50-0.75	0.75-1.00	1.00-2.00	2.00-3.00	3.00-4.00	4.00-5.00	5.00-6.00	6.00-12.00	>12
2000	159	441	104	47	16	6	12	1	3	3	-	-	-
2001	215	450	120	38	13	3	3	5	4	3	-	-	-
2002	254	526	111	52	16	7	12	6	2	3	-	-	-
2003	392	869	259	102	36	15	21	8	5	2	-	-	-
2004	612	963	262	127	33	8	27	7	4	1	-	-	-
2005	866	742	211	96	37	11	19	5	8	5	-	-	-
2006	380	513	143	51	14	8	16	6	3	6	-	-	-
2007	499	771	226	75	25	18	24	10	7	2	-	-	-
2008	382	721	183	66	25	5	14	6	6	1	-	-	-
2009	305	669	121	43	10	4	3	4	1	-	-	-	-
2010	212	257	38	10	2	5	1	-	-	1	-	-	-

Agreement State Dose Data

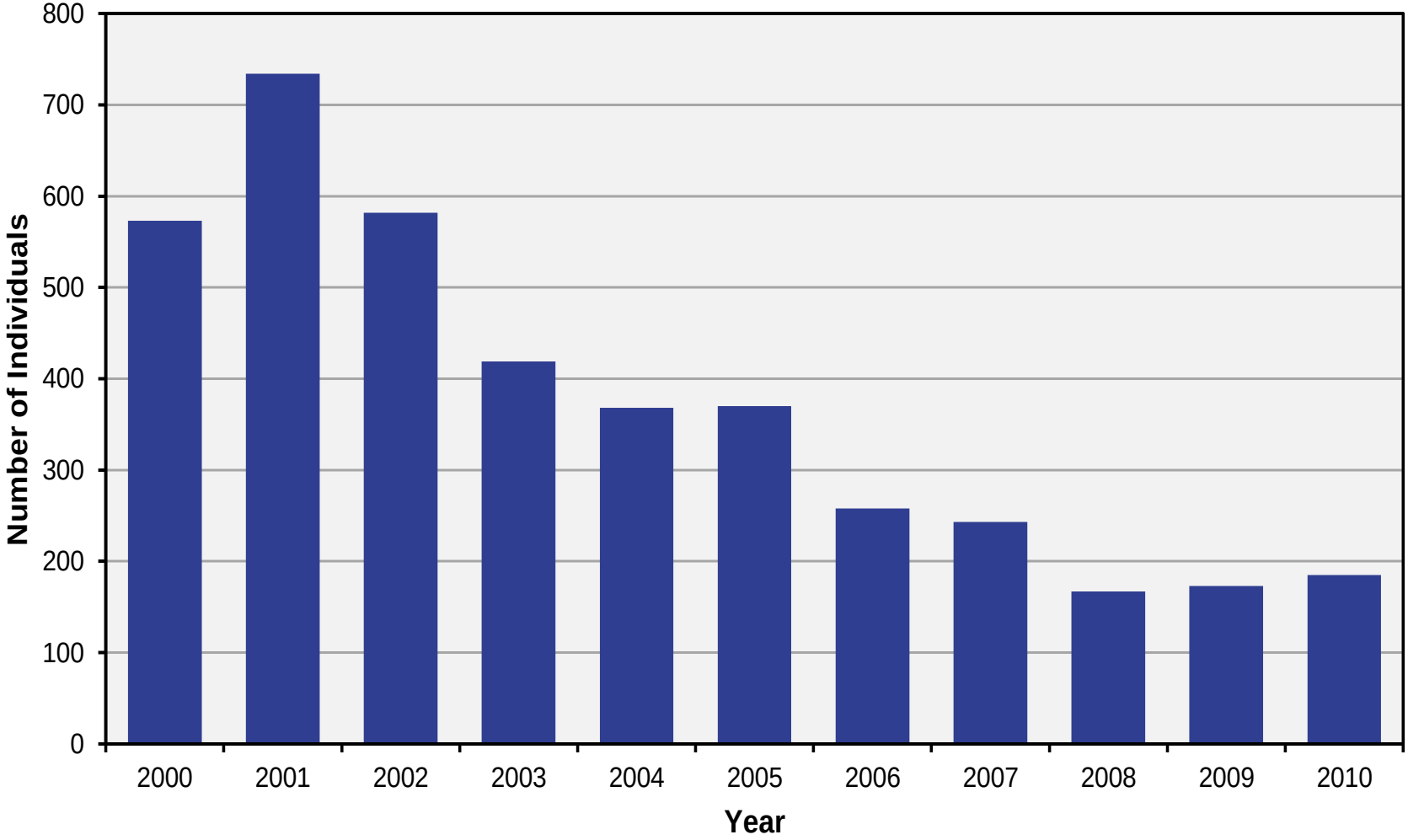
Dose Distribution for Agreement State Nuclear Pharmacy Licensees, 2000-2010



	No Meas.	Meas. <0.1	0.10–0.25	0.25–0.50	0.50-0.75	0.75-1.00	1.00-2.00	2.00-3.00	3.00-4.00	4.00-5.00	5.00-6.00	6.00-12.00	>12
2000	28	5	2	2	1	-	-	-	-	-	-	-	-
2001	22	31	5	6	1	-	-	-	-	-	-	-	-
2002	1,132	1,333	51	13	2	1	1	-	1	-	-	-	-
2003	690	2,171	502	216	51	14	31	4	2	1	-	-	-
2004	692	2,428	530	227	56	22	24	1	1	-	-	-	-
2005	868	2,369	494	224	61	24	17	4	2	-	-	-	-
2006	800	2,336	563	278	78	17	20	5	1	-	-	-	-
2007	816	2,421	501	222	73	32	14	8	3	-	1	-	-
2008	886	2,407	478	217	72	27	22	3	1	-	-	-	-
2009	811	2,432	482	188	66	36	25	10	2	-	-	-	-
2010	179	231	62	20	4	3	1	1	1	-	-	-	-

REIRS Data

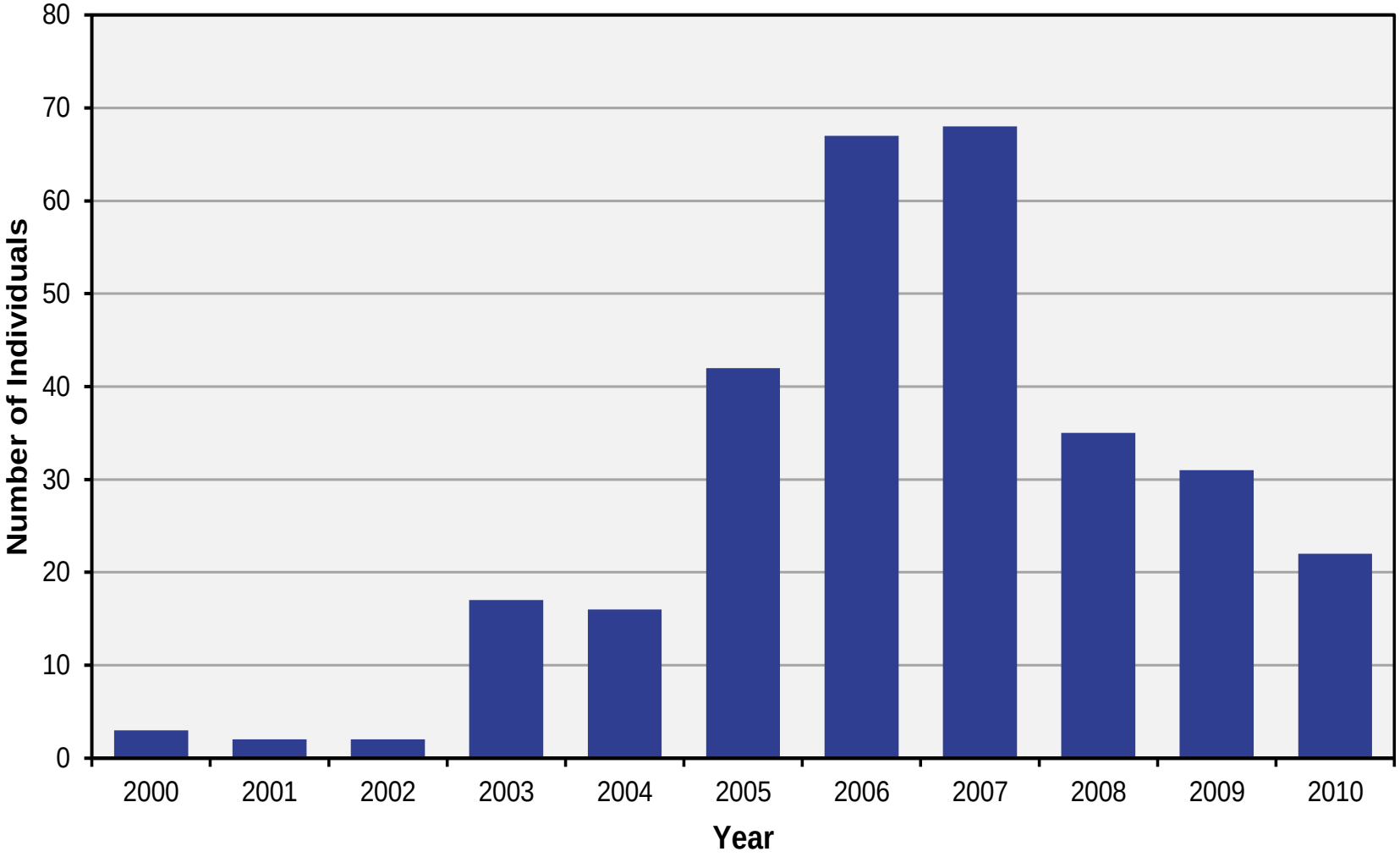
Individuals with Dose Greater than 2 rem



** Data from NUREG-0713, Vol. 32; www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0713/v32/*

Agreement State Data

Individuals with Dose Greater than 2 rem



Data from NUREG-2118, Vol. 1; www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2118/v1/

How is Safety Measured

- Comparison of each individual dose against the dose limit
- Examination of trends in average exposures, distributions
- Regulatory Analysis uses standard dollars per person-rem as one measure

Findings

- For reported exposures, almost all exposures are below limits
- Individual exposures occur each year in excess of ICRP recommended average
- The number of individuals exceeding 2 rem is very small each year

Findings

- For the individuals at the high dose end of the distribution, multiple years of exposure can exceed recommended lifetime value
- The person-rem total of higher dose individuals is small, because of the small number of individuals
- By traditional regulatory analysis, little justification for changes
- The question is one of adequate protection – the Dose Limit. The benefit cannot be measured in terms of dollars per person rem!

REIRS Data: Career Length and Dose

Sum of NumPersons	Dose Range (rems)															
	No Meas.	.001 - .1	.1 - .5	.5 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 10	10 - 15	15 - 20	20 - 25	25 - 30	30 - 50	>50	Grand Total
<=30 days	148840	26388	8777	2544	3004	1051	54	8	3	1	0	0	0	1	0	190671
31 days - 6 mos	84275	45127	27682	9234	7231	2494	1188	302	47	1	1	1	1	1	0	177585
6 mos - 1 yr	39195	22898	12283	4073	3165	1423	740	321	255	6	1	0	1	0	0	84361
1 - 2 yrs	17606	11192	7126	2826	2369	1055	608	344	410	15	2	2	0	0	0	43555
2 - 3 yrs	22037	17593	12320	5091	4373	1999	1083	651	970	71	7	1	0	0	0	66196
3 - 4 yrs	11876	10945	8189	3576	3239	1636	872	591	1057	165	22	1	0	0	0	42169
4 - 5 yrs	8147	7871	6229	3005	2798	1447	856	537	1044	202	47	16	5	1	0	32205
5 - 10 yrs	19494	22278	18994	9829	10126	5684	3513	2346	5008	1378	453	136	47	28	6	99320
10 - 15 yrs	7636	10938	9928	5275	5930	3575	2488	1796	4437	1464	622	284	125	109	11	54618
15 - 20 yrs	3431	6162	6098	3252	3765	2454	1754	1338	3694	1499	644	380	205	220	23	34919
20 - 25 yrs	1507	3518	3739	2030	2337	1596	1113	917	2640	1306	618	372	234	275	49	22251
25 - 30 yrs	549	1673	2016	1113	1260	884	706	541	1709	900	542	300	161	245	54	12653
30 - 35 yrs	209	694	759	452	576	399	282	245	741	400	273	175	124	163	42	5534
> 35 yrs	170	617	401	227	221	178	116	97	288	166	84	72	41	75	21	2774
Grand Total	**364,972**	**187,894**	**124,541**	**52,527**	**50,394**	**25,875**	**15,373**	**10,034**	**22,303**	**7,574**	**3,316**	**1,740**	**944**	**1,118**	**206**	**868,811**

6.02 yrs Average Career Length for Individuals with Measurable Career Exposure
1.46 rem Average Career Dose for Individuals with Measurable Dose

9.19 yrs Average Career Length for Individuals with Measurable Career Exposure and Careers Lengths of at Least One Year
2.06 rem Average Career Dose for Individuals with Measurable Dose with Career Length of at Least One Year

Analysis of the REIRS Database conducted by NRC Contractor (ORAU).

The Problem

- **How to ensure each individual is adequately protected**
- **Lack of real data on occupational exposures**

The Challenge

- **What is the most efficient and effective method to ensure that each individual is adequately protected?**
- **Method must be clear, predictable, and reliable**
- **Method must be applicable to all types of occupational exposures, for all types of uses**

Regulatory Framework

- **Occupational Dose Limit**
- **ALARA**
- **Monitoring**
- **Record Keeping**
- **Reporting**

Limits

- Set the boundary for what is unacceptable from a legal standpoint
- Applies to all situations
- Should not be influenced by the types of activities, or types of sources
- Performance Based – licensees determine what they must do to comply
- Violation is numerical value exceeding limit

ALARA

- Do all the reasonable things to improve protection
- Operates within the limits, and other boundaries specific to the situation
- Is unique to each situation
- Is dependent on types of sources, working environment and other factors
- Violation is not working through the process, rather than meeting some numerical value

Monitoring

- Measurement of the individuals exposure
- Not actually a measurement of the limit
  - Operational quantities vs. protection quantities
  - Uncertainty
- All licensees must maintain records of occupational exposure

Reporting

- **Licensees required to provide report to individual upon request, and if exposure is greater than 100 mrem**

- **Seven categories required to report to NRC**
- **Agreement State Compatibility D**
  - **Some States receive reports, some do not**
  - **No requirement to forward information to NRC**

What did Staff Consider?

- **Strengthen ALARA**
  - **Require licensee to set planning value**
  - **Require licensee to assess dose, and make further evaluations if approaching planning value**
  - **Document need for, and plans, if individual dose would exceed planning value**

- **Stakeholder Feedback**
  - **Planning value is really just another name for a limit**
  - **A whole set of prescriptive details which may, or may not be reasonable for any particular licensee**

What did Staff Consider?

- **ICRP Recommended Average and Maximum Limit**

- **Stakeholder Feedback**
  - **Tracking exposure over multiple years more difficult and resource intensive**
  - **Most individuals would comply with average, but burden would be upon all**

What did Staff Consider?

- **Single Lower Dose Limit**

- **Stakeholder Feedback**
  - **Did not believe change was necessary**
  - **States supported single limit as simpler**
  - **States supported flexibility to work with only licensees who needed it**

Staff Conclusions

- **A change to limits is a more straight forward, performance based approach than additions to ALARA program requirements**
- **Rulemaking would require designation of adequate protection and/or backfit justification on both quantitative and qualitative grounds**

Staff Conclusions

- **Additional efforts will be needed to develop regulatory basis for a proposed rule**
  - **Explore possible draft rule text**
  - **Explore possible guidance for implementation**
  - **Dose coefficients needed before Appendix B values can be revised**
  - **Detailed cost-benefit information needed for specific proposals**

ACRS View

- **Does the ACRS, at this juncture support staff's recommendation to:**
  - **Complete scientific update development**
  - **Continue discussion on best approach to deal with individual protection near the dose limit**
  - **Continue discussion on lens of the eye and embryo/fetal exposure**
  - **Explore rationale and approach to increased reporting of occupational exposure and consistency between NRC and states**

Questions and Discussion