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NUCLEAR REGULATORY COMMISSION

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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A BELOW REGULATORY CONCERN POLICY

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PUBLIC MEETING

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Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Friday, September 16, 1988

The Commission met in open session, pursuant to notice, at 10:00 a.m., the Honorable LANDO W. ZECH, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

LANDO W. ZECH, Chairman of the Commission

THOMAS M. ROBERTS, Member of the Commission

KENNETH M. CARR, Member of the Commission

KENNETH C. ROGERS, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

A. BATES

W. PARLER

V. STELLO, JR.

B. MORRIS

W. LAHS

H. THOMPSON

F. CONGEL

R. ALEXANDER

L. TAYLOR

T. TIPTON

P R O C E E D I N G S

(10:00 a.m.)

CHAIRMAN ZECH: Good morning, ladies and gentlemen. The purpose of this mornings briefing is for the Commission to learn of the NRC staff's progress in formulating a policy in the area of below regulatory concern for practices whose public health effects and safety impacts should be below a threshold level of regulatory concern.

I understand that the staff proposes that the Commission approve for discussion its draft policy statement at an NRC-sponsored international workshop on exemptions from regulatory control for practices where public health and safety impacts are below regulatory concern. This workshop is currently scheduled for October 17th through the 19th.

I would ask today that the NRC staff include for discussion during the workshop any topics that are raised by the Commissioners during this mornings meeting. I believe that the Commission should reach its final decision -- I emphasize final decision -- on the staff's proposal following the conclusion of the staff's evaluation of public comments and the results of the international workshop. In other words, after the public comments and then after the international workshop.

After hearing the staff's briefing this morning, I suggest that the Commission consider the possibility of

agreeing to support the staff's using their draft policy statement or any modifications that we might suggest as a basis for discussion at their forthcoming international workshop.

I also suggest that the Commission consider requesting public comments on the proposed policy including issues raised by the Commission here this morning.

The Commission this morning will also hear from Doctor Lauriston Taylor, Chairman of the Health Physics Society work group on below regulatory concern, presenting the views of the Health Physics Society on this subject. Additionally, the Commission will hear from Mr. Thomas Tipton who will present a brief summary and status on industry efforts on radiation risk which are below regulatory concern. I understand there are copies of the view graphs available at the entrance to the meeting room.

Do any of my fellow Commissioners have any opening comments that they would like to make before we begin?

(No response.)

CHAIRMAN ZECH: If not, Mr. Stello, you may proceed.

MR. STELLO: Thank you, Mr. Chairman. The subject we want to discuss this morning is certainly not an easy one. It is indeed very, very complex for which there are a variety of views of how to proceed. That variety of views exists within the staff as well as -- if you have read much of the

literature -- the debate is considerable within the technical community.

I think there is an element of this approach we are following that deserves a little bit of comment up front in terms of getting a broad picture. That has to do with setting two particular elements to describe an area where we would suggest is an appropriate policy for below regulatory concern. One is to try to establish admittedly a fairly small number in terms of units of millirem -- the ten millirem that is in the paper -- as well as a collective dose. The collective dose is one for which there is in fact considerable controversy and I am sure you will hear more about that this morning -- at least I have heard a great deal about it from some of the scientists who argue that that isn't the way we ought to go -- but one for which there is a considerable precedent within the Agency as a tool that we have used that dates back to the ALARA concept starting back I guess with the very extensive hearings in 1971 I think, and it has been embodied within a great deal of the regulatory approach that we have used over those years.

I think because the precedent is there that we are obligated to still consider it but I think it has two reasons. One is that is where you go when you look at how you do the calculations based on extrapolation of the data collected of the radiation effects from the bombs. You

extrapolate to low exposures and then you integrate under a curve to get the cumulative effects.

But there is another aspect of that and that is we have established a $1,000 a person rem. And, if you look at the bounds of what we have put in the table, it suggests that for a 100-person rem exposure at $1,000 a person rem about $100,000 in almost any kind of analysis that we would undertake and the resources that we would devote. It also suggests that that is another policy call as to whether it is well worth the time and the effort and the energy of spending additional analyses to get further in there because analyses, by itself, cost money and take resources. It also is the precedent.

So, I think there is some history and rationale behind the approach that we take that is going to be one for which considerable thought needs to go into the process but what we really want to do is to start the process, to start the comment, to start the debate, and then come to the Commission after that debate has had a chance to go on, and we can collect that kind of information and then come back to the Commission and say we now think we have got a policy that has the benefit of the input from every word that it ought to have and then can come to the Commission with far more confidence that we have a reasonable approach.

So, we are not here today to tell the Commission

that we think we have the final answer for the Commission. To the contrary, we don't, but we think we have a reasonable approach if the Commission agrees it is a reasonable approach to start this debate, to start this discussion and engage the scientific community to the best of our ability to do so to comment on this kind of policy.

With that background, let me ask Bill Morris to go through the presentation for us this morning. And, we will be mindful of the comments the Commission raises this morning to be sure that as we continue to get into this issue that we have considered all of the issues that will be raised here this morning.

Thank you, Mr. Chairman.

CHAIRMAN ZECH: Thank you very much. Proceed.

MR. MORRIS: Thank you. On the first page of the handout, it provided an outline of the presentation plan for today. It covered the purpose of this presentation, the background, went into the objective of the policy statement and some of the basic considerations that have been in the staff's mind as they developed the policy, covered the key elements of the policy statement and briefly mentioned our plans for an international workshop.

(Slide.)

MR. MORRIS: In addition, if time permits, I will provide a brief discussion of the major issue raised in the

ACNW letter that was issued yesterday.

On page two --

(Slide.)

MR. MORRIS: -- I note that the purpose of the presentation is to discuss this proposed Commission policy statement which would be the basis for decisions on exemptions from regulatory control for those practices with such small health and safety impacts that they may be considered below regulatory concern. As I said, we will go into the workshop very briefly later on.

The next page --

(Slide.)

MR. MORRIS: -- I note that the Commission sent out a staff requirements memorandum on March 30th of 1988 which directed the staff to submit for Commission consideration a policy statement and options which establish a generic number for exposures that are below regulatory concern.

In SECY-88-257 a draft proposed policy statement was provided by the staff. Included among the enclosures are discussions which provide perspective on policy options other than those proposed by the staff but which the Commission may wish to consider in its deliberations. In addition, we included a discussion of the uncertainties in the risk dose data base that was of interest to the

Commission.

As Mr. Stello said, once we get the Commission's guidance regarding your views on this subject of a proposed policy statement, issues you are interested in, we will proceed to discuss this at an international workshop and prepare to issue the policy for public comment.

On page four of the handout --

(Slide.)

MR. MORRIS: -- we note that the objective of the policy statement is to establish a basis for development of regulations and for making licensing decisions. These would define conditions for exemption of certain practices from regulatory control. Specific rulemaking applications that are currently planned or envisioned include disposal of low level reactor waste streams, radiological criteria for decommissioning of lands and structures, radiological criteria for release of materials and equipment.

It is also expected there may be other applications if new consumer product exemptions are proposed. These could also be granted based on the elements of the policy. Once the new regulations are in place, individual licensees would only have to demonstrate compliance with the conditions of the exemption. That is something, for instance, say a volume concentration level of various isotopes would be the condition on which some material could be released in our

reactor waste stream.

Having done that, they would be taking advantage and we would be taking advantage of the policy and the ease with which we would be able to then go forward and release this material.

On page five --

(Slide.)

MR. MORRIS: -- I wanted to go over some of those basic considerations that the staff has been attentive to as it has developed this policy. There are three fundamental principles of radiation protection that we have based the policy on. The principle of justification of practice is essentially the concept that there should be no deliberate exposure to radiation or release of radioactive materials from licensed or exempt activities which does not provide some benefit to society.

The reason the staff recommends that this principle of justification be incorporated into the policy statement is to clarify the Commission's intention to make such judgments in implementing these exemption decisions.

We have also used the concept of radiation dose limits which, by the way, are included as the basic radiation protection standards in 10 CFR Part 20. In the proposed revision of Part 20,which is moving through the concurrence process within the staff now, the maximum allowed

annual dose to a member of the public is 100 millirem. In granting exemptions under the proposed policy, our basic objective is that by no means should an individual receive a cumulative dose greater than this value when all the licensed or exempt practices -- that is multiple exposures -- are taken into account.

In fact, the goal that the staff would have in mind would be that such doses would be well below 100 millirem. Let me clarify that for each licensee the licensee is expected to monitor and take measures to provide that assurance but when you exempt the practice and there is some reduction of control or essentially a loss of control of the material, then there is no monitoring. It is only up to the judgment of the Commission in developing a policy like this that you would be assuring that those doses or multiple practices remain below 100 millirem.

As Mr. Stello pointed out, a longstanding element of radiation protection is the concept that in addition to the basic radiation protection standard, such as the 100 millirem limit on annual dose, the concept of ALARA is applied. That means that you want enhanced protection beyond the limit. In applying ALARA, it has been traditional that we do cost benefit tradeoff analyses to determine when doses have been achieved which are as low as reasonably achievable which is ALARA. And, the reasonable part pertains to those

analyses and judgments that one makes to determine how far one should go in reducing doses.

In addition to the concept of cost benefit tradeoffs in order to attain an ALARA level, the concept also exists and one that has been developed further in this policy that you can decide that doses and risks are ALARA just because they are sufficiently small that they don't warrant further attention.

To go on to page six --

(Slide.)

MR. MORRIS: -- another basic consideration that we had to take into account as we developed this policy was the relationship between radiation dose and risk. The risk estimates in the policy are based on the linear non-threshold relationship between dose and risk. In enclosure five of SECY-88-257, the staff provided a discussion of the uncertainties associated with the linear non-threshold model. This discussion that we provided is primarily based on the BEER-3 report. It highlights the unavailability of epidemiological data in the low dose range and uncertainties in the data base from the atomic bomb explosions in Japan.

Specifically with regard to the latter, I should point out that there is a re-evaluation of the dosimetry from the bomb data that is expected to result in an increase in the numerical coefficient associated with the linear

relation between risk and dose. BEER-5, which is expected to be released early next year, will include this revision. Preliminary estimates based on our staff's understanding of what the new data is telling people is that that increase would not be of an order of magnitude increase but perhaps of an order factor of two.

CHAIRMAN ZECH: Before you go in on that slide, I know there has been discussion for many years on this linear relationship issue. In the extrapolation, as I understand it that you are discussing here and in your paper, it would imply some effect at low doses. I guess my question would be what is a technical basis for associating the likelihood of an individual getting cancer at these low radiation doses? Has there been any change in the thinking in the scientific community in this regard?

MR. MORRIS: I am not aware of changes. I have discussed the issue of what technical principle is at play here. The way I understand it is that the basic effect that may cause the cancer to occur is the impact of radiation on a DNA molecule. If the dose rates are very low, there is the possibility that repair can take place in the molecule but the repair process is not thought to be 100 percent in the sense that all molecules will not be expected to be repaired. In other words, there is a re-combination of the bonds that were broken by the radiation and that process is not complete.

So, from that basis, it has been theorized that even at very low doses you might not be able to exclude the possibility that cancer could occur. I think, you know, this is a very technical subject and there are others who could describe it to you far better than I but that is my understanding of the basis today for thinking that the linear non-threshold hypothesis is --

MR. STELLO: Well, let me add I think a couple of points to it because I have been asking that very question of scientists and I think the impression I got from them is that they don't believe that these low doses are in fact harmful. But the data that you have to get, the scientific data, was one of the reasons I think in the BEER-3 report they concluded that they did not have the evidence to show it was harmful or not harmful because of the amount of information.

But some of the studies provide some insight to that. I remember reading of one -- I believe it was in China -- where they had about 150,000 people in a controlled population, 70,000 at one dose level, the natural background, and about some number on the order of 70,000 at another. There were, as I recall, about one and a half or two times greater background in one population versus the other and they saw no health effects. You see some of the same things in the United States when you go out in the west at the higher

elevations where the background doses are 100 millirem or greater and you look at the health effects. In fact, I think in those cases the incidence of cancer is even lower but then there are arguments that there could be other factors which would in fact have contributed to this.

The point is when you try to go to the actual data to be able to glean from data to conclude that these low levels, prove they are not harmful, you have the problem of statistical data. But based on what we have seen from science and what I understand the scientists have been telling me, there is a growing concensus that they are not. But it is subject to so much debate that we have just decided in fact to avoid it. There seems to be concensus that, to the extent you want to use the word conservative, it is conservative then just to use the extrapolation of the linear hypothesis that we have been using.

That does not mean, in my view, that that is conservative necessarily from a society point of view because you are definitely adding a burden, a cost, that if society did it some other way, you could spend that money for some other purpose. This is one of the big, major issues of debate; are these low doses really harmful? Here is where we hope we will be able to get some of the scientists around the world to speak to this point.

CHAIRMAN ZECH: All right. Well, maybe the

following speakers this morning can also talk to this a little bit. I am sure you will be discussing it at the international workshop too.

MR. STELLO: Yes.

CHAIRMAN ZECH: But it has, as we all know, been a subject of long debate and there are two schools of thought on the subject. But if there is any new thinking or any new concensus or anything like that, I think it would be important to the Commission to become aware of that.

MR. STELLO: Yes.

CHAIRMAN ZECH: Because we do know and we do have scientific data for the higher levels, as we know, and we have reasonably good analysis of the higher levels of doses but we do not, as far as I know, have at the very low levels and that is why we talk about extrapolation and scientific analysis and so forth.

So, if there is any more definitive conclusion in that area, I think the Commission would be very interested in learning about that in your forthcoming discussions with the international community and other experts.

Now, let's proceed.

MR. MORRIS: Going on to page seven of the handout --

(Slide.)

MR. MORRIS: -- I just wanted to come back to this

issue that the Commission raised in its staff requirements memorandum. That is the Commission directed the staff to discuss in the policy statement an approach for implementing the proposed below regulatory concern dose levels where multiple sources or licensed activities might be involved. This has been one of the major issues that we grappled with as I mentioned before. There is a range of views on this issue within the staff. I just wanted to highlight it again. I will be coming back to it later when we talk about these dose limits and explain how we have gained confidence that we can deal with this issue.

On page eight of the handout --

(Slide.)

MR. MORRIS: -- I mention one of the two ways that the staff envisions that an exemption decision can be made. That is the decision would be made on the basis of costs benefit analysis where the costs and technical feasibility of measures which could be taken to reduce doses are weighed against the risk reduction that would be achieved. That's where the use of this $1,000 per person rem dose aversion factor comes into play in the Commission's decision making as used in the application of the backlook (phonetic) rule and other decisions like that. The ALARA principle traditionally has been based on this kind of thinking.

We also have provided another way to get at ALARA

and that is indicated on the next page.

(Slide.)

MR. MORRIS: The second basis for decisions on exemptions is that when the risk from the practice or source is sufficiently small that there would be no need to require risk to be reduced further, then an exemption should be granted. In other words, without cost benefit analyses of feasible dose reduction measures. In other words, it would be a declaration that you had reached a point of sufficiently low risk that it is below regulatory concern.

The staff identified two risk parameters which can be used to define the conditions for which this below regulatory concern condition can be met and for which cost benefit analysis can be waived. These are the annual individual dose and the annual collective dose.

(Slide.)

MR. MORRIS: So, if you look on page ten of the handout, we identify that we propose in the policy statement that these values, these criteria, are ten millirem for an individual and 100-person rem for the societal risk level. We believe that to many these levels would be considered ALARA and below regulatory concern.

So, if a practice is judged to be justified -- that is it has a societal benefit -- and can be demonstrated to meet these criteria, then the granting of an exemption under

the policy would be highly likely. However, it is emphasized in the policy statement that failure to meet these criteria would not result in the exemption being rejected. In such a case, ALARA could be demonstrated through cost benefit analysis.

If we back up and look at slide number one that is in the handout --

(Slide.)

MR. MORRIS: That is on the screen there now. It is about four slides from the back of the package that we handed you. I have indicated the risk methods of some of the doses that could be envisioned. In particular, the ten millirem level for an individual dose is indicated here as representing an increase -- this is an incremental dose -- received from a practice exempted under this policy. That would involve an increase in risk of two times ten to the minus six per year of dying of cancer. This is one-tenth of a percent of the cancer risk from all of the causes.

I think you will recognize that this is the same as the quantitative risk objective for reactor operation adopted in the NRC's safety goal policy.

Using this same table maybe you can see, if you look in this table -- I didn't put it down here but it is in the Commission paper that the risk conversion factor is two times ten to the minus four. You can use that number and remember

that the other criterion we are using, the 100-person rem collective dose which is the summation of all the individual doses incurred because of the practice, that really amounts to a very small annual risk to all individuals summed together per year of the practice that would be exempted under this policy automatically without cost benefit analysis.

Another way to look at this 100-person rem number would be that if the practice persisted for 50 years, that that would amount to one additional cancer fatality in 50 years of the practice. That just gives me a perspective on what kind of risk that we are talking about. But, remember, that is merely a criterion such that it tells you when you must or must not do further cost benefit analysis.

Let's go back to page ten of the handout.

(Slide.)

MR. MORRIS: I just want to mention that these criteria pertain to a single practice. They do not pertain to a collection of practices. It is the notion that you may have individuals exposed to more than one exempted or licensed practice that raises the question of whether or not you might be approaching that 100-millirem limit.

CHAIRMAN ZECH: Before you go on, I was trying to do some arithmetic on what you are telling us when you say one in 50 years at the 100-person rem annual dose. If I calculated correctly, assuming that there are 250,000 deaths

per year due to cancer in the United States -- and I think that is a low number, that it could be higher than that.

MR. MORRIS: I think it is 500,000.

CHAIRMAN ZECH: Okay. Well, just say it's 250,000. That's what I used. But say it's 500,000 or 250,000, somewhere in that ballpark, one in 50 years then comes out to be between 12,000,000, 12.5 million, and 25,000,000, depending on whether you use 250,000 or 500,000, between 12.5 and 25,000,000 deaths then due to cancer that we would expect in a total of 50 years.

MR. MORRIS: Yes, that's what it calculates.

CHAIRMAN ZECH: So, what you are saying is that we would have one additional or one in addition --

MR. MORRIS: That's what this number amounts to.

CHAIRMAN ZECH: -- to the 12.5 to 25,000,000 that might be expected; is that right?

MR. MORRIS: Well, that's --

CHAIRMAN ZECH: So, it is a pretty small number. That's what I was trying to figure. Would you agree with that? That is what you are saying.

MR. MORRIS: Yes.

MR. STELLO: That's why it's so difficult to get the data to show what happens for these very small numbers because these numbers are well within the variation you have in background doses.

CHAIRMAN ZECH: But what I was trying to figure out, frankly, you know, is something that the general public can understand is important I think, and when you tell me ten millirem, I have got an understanding what that means but lots of people really don't. Ten millirem, it's just a number. It's an absolute number. But what does it relate to? So, I was trying to say, well, why do this collective thing? The collective dose, at least in my judgment, would tell me that over a 50-year period when we would expect 12 to 25,000,000 deaths due to cancer in the United States, that this below regulatory concern would mean perhaps one more than that number.

So, it's a very small number; is that correct?

MR. MORRIS: Yes.

MR. STELLO: Yes.

CHAIRMAN ZECH: Were my mathmatics correct?

MR. MORRIS: That's close, yes.

CHAIRMAN ZECH: All right.

COMMISSIONER CARR: I saw a quote from the Cancer Society this morning. Their estimate was 494,000 people this year will die of cancer in the United States. If you look to put that in a one-year perspective, if we went to say the 10,000-person rem, on top of that 494,000, you would see two more people in this year.

CHAIRMAN ZECH: That's if you used what, the

10,000 --

COMMISSIONER CARR: Well, just put it in the one year. The 10,000 number says two in one year.

CHAIRMAN ZECH: Right.

COMMISSIONER CARR: So, you would try to find those two guys in those 494,000 others.

CHAIRMAN ZECH: Well, that's what they are saying. They are not using 10,000. They are using 100.

MR. MORRIS: Yes.

COMMISSIONER CARR: Well, but I was just trying to make the point to do it in an annual year.

CHAIRMAN ZECH: An annual year, fine.

COMMISSIONER CARR: You would see two more people.

CHAIRMAN ZECH: Sure, I see. Okay, fine, I understand. Anyway, it's a small number and that's what you are saying too.

COMMISSIONER CARR: Yes, it's the same thing you are saying.

CHAIRMAN ZECH: I think I'm trying to say the same thing. I just used it for 50 years and you used it for one year.

COMMISSIONER CARR: Yes.

CHAIRMAN ZECH: The point is, to me, the value of it is not so much the number itself but the point I think you are trying to make is it's a very, very small number.

COMMISSIONER CARR: Yes.

CHAIRMAN ZECH: That's what we are interested in, making sure that it is a very small number; is that correct?

MR. STELLO: It is indeed. Perhaps in terms of getting a perspective, it might be easier for the public to understand the recent article that talked about radon exposures, naturally occurring radioactivity in homes. The radiation levels that they are talking about are in fact one to two orders of magnitude beyond what we are talking about here.

Do you remember -- someone help me -- I think it was a couple of years ago when the average background exposure for individuals was in fact raised about 150 to 200 millirem.

MR. LAHS: From 100 up to 300.

MR. STELLO: So, it's a 200 millirem increase average in naturally occurring background radiation. There are levels in the country where the radon levels have been measured and I think they have exceeded 1,000 millirem in background levels in the home. So, you can get a fairly reasonable feel for the relative insignificance of this number compared to something that there has been a great deal of interest recently in terms of radon levels.

CHAIRMAN ZECH: Now, these numbers we are talking about this morning do not include radon.

MR. STELLO: They do not include radon. Radon is not a radioactive substance for which this agency is responsible for regulation.

CHAIRMAN ZECH: But what you are saying I guess in essence is that the deaths from radon as far as we know now would be considerably higher than the deaths that we are talking about from radiation products.

MR. STELLO: If someone would help me, I think as I recall the number in the newspaper was --

MR. LAHS: 20,000.

MR. STELLO: -- 20,000.

CHAIRMAN ZECH: 20,000 per year --

MR. STELLO: Yes, per year.

CHAIRMAN ZECH: -- annual deaths in the United States.

MR. STELLO: Yes.

CHAIRMAN ZECH: And, what you are talking about --

MR. STELLO: Using the same techniques we used which, I might add, there are many who questioned whether those numbers are or are not correct too.

CHAIRMAN ZECH: All right. Let's proceed.

MR. MORRIS: One point to remember there is that that is the increment per practice, the definition that might be involved in granting multiple exemptions under this. So, I just wanted to remind you of that.

CHAIRMAN ZECH: All right.

MR. MORRIS: And, maybe at this time, I think since we are at this point, it would be a good idea to look at backup slide two for a minute. Again, that's in the backup part of the handout.

(Slide.)

MR. MORRIS: I just might make a point now that in the ACNW letter that we received yesterday, there were several points that they made. We think we can accommodate most of those. They talked about the use of international units, the definition of effective dose equivalent, clarification of this concept of justification and clarification of the linear non-threshold hypothesis that we are using. But the major point the letter makes and one that we are not yet ready to accept -- I wanted to call it to your attention for that reason -- is that they believe the ten millirem and 100-person rem criteria should be treated as limits for each exempted practice and, in fact, that exemptions should not be granted, as I understand their letter, should not be granted under the policy if either one of these criteria has been exceeded.

And, if you just look at this figure, we have drawn the region of risk below ten millirem and below 100-person rem as the region where we believe it is simply appropriate to not do cost benefit analysis but that does not preclude in our minds that the Commission would not grant exemptions

for other cases outside that region of BRC risks. You could make the decision on other bases. It is an issue that you will see, you know, if you peruse that letter and I just wanted to call it to your attention now.

Let's see if there is any other point that would be made by this. We have indicated on here the regulatory dose limit. So, in this figure, you could envision that you might be looking at more than one exemption granted, and it is the issue of how far up towards 100-person rem that you might get from multiple exemptions that we will turn to in just one more minute now.

Let's go back to page 11 of the handout.

(Slide.)

MR. MORRIS: The staff has recommended that the proposed policy state clearly that certain practices would be excluded as candidates for exemptions. These would involve practices in which radioactivity has been introduced into toys or where radioactivity would be applied to or ingested or inhaled by human beings. These practices have not been considered to be justified in the past.

However, there was heretofore not a clear statement from the Commission on these issues. We believe at this time that the Commission should make a clear statement of its policy regarding this.

Again, on page 12 of the handout --

(Slide.)

MR. MORRIS: -- this is another way of saying what we mean by justification. We believe that the release of radioactivity where there are clear economical alternatives or where there are no unique benefits from the use of radioactivity should not be considered to be exempt under this policy.

Let's go on to page 13 now.

(Slide.)

MR. MORRIS: I want to summarize some of the provisions that are in the policy that limit the potential that there might be individuals who could be exposed to multiple sources of radiation exempted under the policy or licensed by the NRC which could approach 100-person rem.

COMMISSIONER ROGERS: Excuse me a minute.

MR. MORRIS: Yes.

COMMISSIONER ROGERS: I want to just ask a question on this to see what your thinking is on these items on page 12.

(Slide.)

COMMISSIONER ROGERS: You are talking about excluding from the exemption category items which there are clear economical alternatives or no unique benefits but does that mean in your thinking that you would exclude them from any consideration? In other words, that even though they

would be excluded from exemption, could they be permitted in some way? Now, not falling under the exempted category but still be --

MR. MORRIS: Under some --

COMMISSIONER ROGERS: -- permitted in some way. Have you thought about that?

MR. MORRIS: I have not thought about that. I am not aware of cases where we have done such a thing.

MR. LAHS: I don't know of any.

MR. MORRIS: The members of the group that worked on this do not recollect any case where we have allowed that to happen. We principally were looking at an exemption policy. So, I really have not got a firm answer as to what we would --

COMMISSIONER ROGERS: Well, these things sometimes do turn up.

CHAIRMAN ZECH: Well, why don't you look into that.

MR. MORRIS: Yes.

CHAIRMAN ZECH: See if you see the appearance of anything that didn't follow through there.

MR. MORRIS: Okay.

MR. STELLO: I think that maybe -- I don't understand the question well enough -- but there are clearly cases where there have been applications to use radioactive material where we have rejected the application, period,

without this policy in place. We have just said in our judgment that is not a correct use of the application and we rejected it. Now, any licensee is entitled pursuant to our regulations to follow the process of appeal and go through the agency to have his, if you will, day in court.

But we would not only pursuant to this policy but continue to follow the past practice if we felt there was something that just ought not to be an area where radioactive material ought to be used and that was our judgement. We would continue to make the judgment that that application ought not be allowed and permitted.

COMMISSIONER ROGERS: Well, I don't think we should prolong this discussion on this particular point but my concern ultimately will come back to this question of justification and not that the justification is not an important consideration but who is going to make that decision. It could overlap into this area. So, I would like to return to that at some point when it is appropriate. I don't want to derail the presentation to attack that but I think at some point I want to hear more about how one envisions this question of justification being decided.

MR. STELLO: Okay. Well, let me comment then I think that would be an interesting subject the next time we have an application we are going to reject, that we will come to the Commission and explain what we do, for example, and

why.

COMMISSIONER ROGERS: Well, it's something that we had to grapple with when we considered the gemstone issue.

MR. MORRIS: The gemstone issue, that is correct.

COMMISSIONER ROGERS: I am not sure that we really settled all questions with respect to how this would be decided.

MR. STELLO: No.

COMMISSIONER ROGERS: So, I think it is a very important issue for us to approach but I think we can set it aside for the moment. But I would want it on the list of things which are under active consideration for explanation to the Commission as to how that justification question is going to be decided.

MR. STELLO: Okay. And, I am suggesting that the next time we have an application we are rejecting, we will bring it to the Commission and explain that particular case and then have a more generic discussion of how we do that because I think it is outside this policy.

COMMISSIONER ROGERS: Well, just as a general comment, I always like to make decisions in the absence of a particular case that has to be decided.

MR. STELLO: Okay.

COMMISSIONER CARR: Is the justification issue going to be discussed at the workshop coming up?

MR. MORRIS: Yes.

MR. LAHS: Yes.

CHAIRMAN ZECH: All right. Let's proceed.

MR. MORRIS: Going on to page 13 of the handout now --

(Slide.)

MR. MORRIS: -- and talking about now those provisions that we believe limit the potential to impact people through multiple exposure. First, there are the ten millirem and 100-person rem dose criteria we proposed. With regard to the ten millirem individual dose, it should be emphasized that this is the maximum dose reasonably expected to be received by an individual due to the given practice. So, only under unusual circumstances would the majority of the people exposed to that practice be up near the ten millirem limit.

However, if one were to hypothesize such a situation, the 100-person rem population dose criterion limits the number of individuals who could be exposed at the ten millirem level or near to it to no more than 10,000 people. So, what we are doing is we are saying that if you are looking at potential for people in the population at large to be exposed to multiple sources, these two criteria reduce that potential somewhat.

Also, the policy makes clear -- we have just

discussed this issue of justification -- that only justified practices will be allowed. This principle would assure that we are not facing a situation where unnecessary exposures are being encountered. Therefore, that is going to also give assurance that you won't have many people that would possibly be near the 100-millirem level.

Going on to page 14 and continuing this thought --

(Slide.)

MR. MORRIS: -- there is a key point in the policy that as the policy is being implemented there would be an assessment of this potential for cumulative doses to various key members of the exposed population, that there would be a potential that they would get unacceptably high doses, those approaching 100-millirem. Each time we make an exemption decision, we will look at that population, choosing the key members who would be limiting in that regard that they might be receiving doses from other practices. And, if we find that we believe there is a potential that that could happen, then we are going to require that further analysis be necessary before an exemption could be granted.

Going on now to page 15 of the handout --

(Slide.)

MR. MORRIS: -- we would point out also that in the policy statement, in the very first paragraph I believe, we talk about the concept of practice and the concept of

fractionation of practice. The policy says that fractionation of practice will not be allowed. That is where there are similar activities, similar kinds of releases that could occur. They wouldn't be treated in an integrated way so that you won't have a proliferation of practices that should be actually integrated together in our thinking process. And, by that, we believe that we will have artificial situations that will break these practices up and allow ten millirem and 100-person rem for each exempted practice when that wouldn't be reasonable to do.

Finally, we believe that as experience is gained in this issue as policy is implemented, we will learn more about what this potential is like. If there were a number of new applications for consumer products to be exempted, for instance, that would make us take a close look at whether this policy was giving the kind of protection that we thought was necessary. So, we will just use common sense and good judgment as we go forth to implement the policy. If something is determined to warrant a re-look, then we would take that initiative and do that.

Now, one other point that we wanted to make was in the course of performing collective dose calculations which would be done say for cost benefit analysis, the staff has identified several methods that we would find reasonable in order to truncate these doses.

(Slide.)

MR. MORRIS: We included truncations in space -- that is at some large distance from the source so that the doses clearly are going to be small and negligible -- and truncations in time so that after radioactive products have decayed to a very low level, then the doses would be negligible. We have also open in the policy the issue of cutting off these collective dose calculations at low individual doses which we believe might be considered negligible by most people such as one-tenth of a millirem.

All of these provisions would simplify and reduce the burden on those who are trying to do these sometimes sophisticated cost benefit analyses. We don't think they should necessarily be so sophisticated when they are making these simple judgments. So, this is moving in that direction to send a clear signal that you do not have to go to infinite lengths to determine what the collective dose is.

Finally, we open the possibility too of weighting collective dose with different factors depending on what range of individual dose the collective dose was received in. So far the Commission in Appendix I has indicated that $1,000 per person rem is an acceptable weighting factor to convert dose to cost so that you can compare those with the cost of reducing the dose. Now, this opens up the possibility that other ways to do that could be entertained. In fact, in this

body of ways to treat collective dose that I have just been discussing, the staff would recommend that a variety of these concepts -- you know, that you could combine these concepts to do what makes sense when you are calculating collective dose.

I think just to end this up, I just wanted to mention that we do have the plan to go to the international workshop to discuss the diversity of international regulatory views with other regulators.

(Slide.)

MR. MORRIS: There are commitments from regulators from ten countries who would be joining us.

(Slide.)

MR. MORRIS: We would have the International Commission on Radiation Protection, the Nuclear Energy Agency, and the --

MR. LAHS: Community of European --

MR. MORRIS: -- Community of European --

MR. LAHS: What did we say before? We just looked that up.

CHAIRMAN ZECH: Excuse me. Just one of you talk at a time so the reporter can keep track of what --

MR. MORRIS: I'm sorry. We will also have EPA, DOE, National Council on Radiation Protection, and the Advisory Committee on Nuclear Waste attending. The workshop

will be held, as I mentioned, in October, and it will be held in Washington.

(Slide.)

MR. MORRIS: So, what we would be awaiting is the Commission's guidance on what we would focus on in that workshop.

MR. STELLO: Mr. Chairman, we are about finished. In the paper we had suggested that perhaps the policy statement subsequently would be changed and then issued for public comment. I have been thinking more and more about it and I cannot see any reason for delaying it. I think I am satisfied it is in a form now where we could in fact issue it for public comment.

CHAIRMAN ZECH: Do you mean before the international meeting? Is that what you are saying?

MR. STELLO: Yes.

CHAIRMAN ZECH: All right.

MR. STELLO: So that we would have a generous opportunity for public comment. I don't see any reason to hold up doing that. The only risk is that we might want to have public comment twice but that wouldn't concern me either. I think it is important to try to generate to the extent we can further comment and debate in this area. So, I would urge to move out whatever the Commission feels that we addressed all of the questions that need to be addressed and

if we have to ask specific questions in a comment period, why we could easily just add those to it and move on rather crisply with getting the comments.

CHAIRMAN ZECH: Well, let me make sure I understand. I thought the purpose of this meeting was to get the Commission authority to go to the international conference with at least the proposed strawman policy.

MR. STELLO: Yes.

CHAIRMAN ZECH: And, then after the conference, you would come back to us with your views and then we would go out officially. Now you are saying that we would go out ahead of time for public comment; is that right?

MR. STELLO: And, then come back to the Commission after that public comment but then putting it out one more time.

CHAIRMAN ZECH: There would be a public comment period twice.

MR. STELLO: Yes. I think in this case it might be worth it.

CHAIRMAN ZECH: All right. Then are you making a different proposal than we had before the meeting?

MR. STELLO: I am suggesting that the Commission might want to consider that because of the interest in this issue, that instead of trying to publish it once, do it twice. Put it out right now and have the benefit of that comment

process perhaps twice. I don't see any problem with that in going in that direction. The Commission may want to consider that.

CHAIRMAN ZECH: Does the General Counsel have any comment?

MR. PARLER: There is no legal requirement, Mr. Chairman, for policy statements to be put out for public comment in any event, although that is in my judgment a good practice to follow. The agency has followed it on a number of occasions. I am at a loss myself from my perspective to see how putting the thing out for public comment prior to the international workshop would be overall beneficial. It might give the participants in the international workshop the idea that some minds have been made up prior to the exchange of information and the exchange of views.

Also, it is my understanding that the workshop perhaps may be limited to the participants from the various organizations and countries. To put the policy statement out for comment in advance of the workshop under those conditions might unnecessarily complicate the thing. Those are my thoughts but there are no legal problems.

CHAIRMAN ZECH: Right. Thank you very much. Do you have any other comment on that, Mr. Stello?

MR. STELLO: No, sir.

CHAIRMAN ZECH: All right. I know we have two other

speakers but perhaps before we ask them to come forward, I will ask my fellow Commissioners if they have any comments or questions that they would like to address to the staff. Commissioner Roberts.

COMMISSIONER ROBERTS: No.

CHAIRMAN ZECH: Commissioner Carr.

COMMISSIONER CARR: No.

CHAIRMAN ZECH: Commissioner Rogers.

COMMISSIONER ROGERS: Well, just on this justification. I don't expect an answer now but I think that is something that I really would like the staff to dig into.

MR. STELLO: We will arrange to brief the Commission separately on that issue.

COMMISSIONER ROGERS: All right. Thank you.

CHAIRMAN ZECH: All right. Thank you very much. I guess the next speaker is either Doctor Taylor or Mr. Lahs. What order do we have them? Mr. Lahs.

MR. LAHS: No, I'm here with the staff.

CHAIRMAN ZECH: All right. Doctor Taylor and Mr. Tipton; is that correct?

MR. STELLO: Yes.

CHAIRMAN ZECH: All right.

(Pause.)

MR. ALEXANDER: I would like to introduce the doctor, please.

CHAIRMAN ZECH: All right, fine. Please do.

MR. ALEXANDER: Good morning. I am R. E. Alexander, President of the Health Physics Society. This society has 6,400 members and is believed to encompass and represent concensus scientific opinion in the field of radiation protection and health effects. We believe that concensus scientific opinion should have a more prominent role in public health policy development and today we are making our initial attempt in that direction.

The society is grateful to the Commission for providing this opportunity. We have prepared a list of criteria that we believe should be met by the BRC level selected and this list is available for your consideration. With regard to the collective dose question, the NCRP has stated,"There are no direct data that confirm that a few random ionizations in tissue cause fatal cancers. Irrespective of such scientific opinion, there has for many years been concern over extremely small radiation doses if they are received by extremely large numbers of people.

Considering current radiobiological and epidemiological information, it is our position that public health policy derived from such concerns is not scientifically sound. Risk estimates made in this manner must be described as speculative or inadmissible. Even if such risks actually exist, they are imperceptible and too

small to be of regulatory concern.

For these reasons, it is the position of the society that the Commission's generic BRC level should not be accompanied by a collective dose restriction. Such a restriction could defeat the Commission's purpose with respect to effluent control, low level radioactive waste management, de-commissioning, and other practices involving the exposure of large numbers of people.

Whether an agent carcinogenic at high exposures is also dangerous at low levels may be unknown. If the risks could be substantial, regulation or even prohibition may be necessary. If the hypothesized risk is known to be small, costly regulations can be imprudent. Such is the case with radiation doses as low as ten millirems per year. If doses this low create a substantive public risk, we would have evidence from high natural radiation areas where people received doses on the order of 1,000 millirems per year. No adverse effects have been found among these people.

However, if the Commission should find it necessary to establish a collective dose criterion, we recommend acceptance of the NCRP advice to exclude from the dose calculation those people who receive less than one millirem per year.

The society spokesman today will be Doctor Lauriston S. Taylor who was our President in 1958. Doctor Taylor was a

co-founder of the ICRP and founder of the NCRP. He was the first Chairman of the NCRP, a position in which he served with distinction from 1929 until 1977. He has also served on the ICRP and is now an emeritus member of both the ICRP and NCRP. He has essentially devoted a long and distinguished career to the development of radiation protection recommendations for public policy makers such as this Commission.

It is my honor and pleasure to introduce Doctor Taylor at this time.

CHAIRMAN ZECH: Thank you very much. Doctor Taylor, you are very welcome. Please proceed.

DOCTOR TAYLOR: Thank you. Speaking for the Health Physics Society, I was asked to express two appreciations to the Commission. The first of these was for the opportunity of appearing before you to present evidence of our society's concern and interest in what you are doing and in support for what you are doing.

The second expression of appreciation would be for the Commission's support of one of its staff to become President of the worlds largest radiation protection organization, the Health Physics Society. We realize that this makes a considerable drain from time to time on the parent organization of these individuals but also we believe that it not only helps the society and the country in general

but we think it also helps the parent body.

Since the meeting of the Nuclear Regulatory Commission today is attended by the public, I want to make it very clear what the term "health physics" means. It is a word not well understood by the general public. At the outset of the weapons program under the Manhattan District Operations in 1943, it was recognized that radiation safety and the protection of people would require one of the major efforts in their program. At the same time, they were afraid that if the word radiation were to appear in any way in connection with that program, it might give away the secret of what they were working on which of course was the first atomic bomb. To preserve the secrecy, they called the radiation protection activities "health physics". It was a decoy name meaning nothing that might be associated with radiation.

Unfortunately that same name has hung on and the public most of the time does not know what the word "health physics" means. What it means is radiation protection and health physicists are radiation protectionists. That's what it's all about.

Now, in the radiation protection community, we have been increasingly concerned about the complexity of our radiation control measures, the drain from our professional manpower and the heavy financial burdens that are restraining important applications of ionizing radiation in science,

medicine and industry.

For example, we are facing a continuing shortage of trained radiation protectionists in this country. The costs of protection are no longer commensurate with the degree of protection that is being provided with these high costs in the low level region. The cost per unit improvement in radiation protection increases enormously when we get down into the very low dose range, especially the range which is only a small fraction of the natural background at which we are exposed all the time.

I'm sure the NRC can develop some specific information on this question and I have heard it discussed already this morning their plans to do so and they sound sound. As an example, we have heard something of the order of 90 percent of the costs of the overall effort that is expended on radiation protection is expended in the very low dose range where the effects of radiation cannot be found specifically by any means that we know of today. Why? Why all this?

Well, the statistical methods that we have today and probably will always have are simply inadequate to deal with the small size samples that we have to work with. Also, direct observation may come some time in the future but there is nothing in sight. There are some but extremely limited data in the range of five to ten-rem acute exposure and five-

rem per year exposures extending over many years. We use what data there are available but we are still left with huge gaps in our knowledge with little likelihood in sight for solving some of these openings or closing some of these openings.

Now, the lack of information and data in the low dose range -- I call anything below ten rems a low dose -- but anything lower than that has forced our main scientific body such as the --

CHAIRMAN ZECH: Anything below ten rems.

DOCTOR TAYLOR: Ten rems.

CHAIRMAN ZECH: Anything below ten rems you call a low dose.

DOCTOR TAYLOR: I call a low dose.

CHAIRMAN ZECH: Ten rems, what, per hour or per year?

DOCTOR TAYLOR: Well, ten rems in a single shot, in an acute exposure.

CHAIRMAN ZECH: Over what period of time?

DOCTOR TAYLOR: Ten rems in one minute or one day or a week.

CHAIRMAN ZECH: A total of ten rems you are talking about.

DOCTOR TAYLOR: A total of ten rems.

CHAIRMAN ZECH: Not in an hour or a year but just

a total absolute number, ten rems.

DOCTOR TAYLOR: Well, a total in a short time. If it is delivered in a long time, it can be a lot more than that.

CHAIRMAN ZECH: Well, that's my point.

DOCTOR TAYLOR: Oh, yes. Well, this is a ten-rem single acute dose.

CHAIRMAN ZECH: All right.

DOCTOR TAYLOR: The reason that I name that figure, which I won't support too heavily, is because we simply don't have any decent data to work with below that level. Everything from there on down involves a certain degree of speculation and assumptions.

CHAIRMAN ZECH: I understand. Thank you.

DOCTOR TAYLOR: That's the reason for it.

CHAIRMAN ZECH: You may proceed.

DOCTOR TAYLOR: This situation I was starting to say has forced the main scientific bodies such as the NCRP and ICRP to extrapolate the occurrence of effects from the high dose region where we do know a lot about radiation effects in terms of dose to the low dose region where we have no information. This is an extrapolation and a number of assumptions. Simultaneously, we have to use compounded assumptions, one assumption after another. Invariably, when assumptions are made and you are thinking about a problem that

covers maybe a range, it is almost always the case that the people who are making these assumptions veer in the direction of conservatism and this is the way it should be but it also makes for a very severe and perhaps over-protection requirements.

Big expenditures are made to ensure low doses in the region where we can't find anything except in theory or by involving assumptions. This big effort is known to the public and it creates the impression that if it is designed to meet some strange situation, it must be very dangerous. Otherwise, all of this effort wouldn't be devoted to it. They can't understand it. They don't know that the scientists don't understand it. So, they think it is something about which they should be alarmed.

Any action taken by the government in any trivial matter or a matter of relatively low importance excites undue perceptions on the part of the media and of the general public. That's one of the problems we have to face in this particular question.

Now, from the health physics side, we don't want to pretend that we are trying to tell the Nuclear Regulatory Commission very much or maybe anything that it doesn't already know. I listened to the presentation this morning. I agree with just about every word that was said. Obviously you are understanding these things.

We are aware of your preoccupation with the BRC concept and that you are grappling with the problem. What we do want you to know is that the Health Physics Society of radiation protectionists shares your concern and shares your concern and shares your positive and promising efforts to control it.

I will mention a few further points as I go along but these will be primarily for emphasis and to indicate that our two organizations are thinking alike, yourselves and ourselves. I will assume that you have had the opportunity to read at least the first couple of pages of our letter of September 8th. I hope that's a better assumption than we can make about many of our technical matters.

We will not offer you any specific proposals for a level of radiation exposure that should be below regulatory concern. We do, however, offer you our help and cooperation in solving this problem if you were to request it. The final answer on the BRC problem can come only from you. By you, I mean this organization. But because it is not primarily a scientific or technical problem, however much it may be based on scientific and technical data. Your kind of organization is the only kind that is properly constituted to deal with the question. The question is politic and can be solved only by actions that are, and I quote, "prudent and sagacious in devising and pursuing measures adopted to promote public

welfare", the kindness of Mr. Webster.

Personally, I find it compelling when considering such a problem as below regulatory concern to examine the common sense of the situation, together with the technology. We know that radiation, among hundreds of other agents, cause cancer. We know that one-third of us sitting in this room today will have cancer at some point in our lives and that half of those will die from cancer. But we have no direct statistical evidence of cancer having been induced by radiation exposures below maybe five rem in a single exposure -- I mentioned ten rems before but five rem is a more common figure -- or one rem per year spread over many years continually.

Now, it has been conservatively proposed that the upper limit of exposure of individuals in the public not exceed one-tenth rem or 100-millirem in a year. To ensure that this level of exposure is not exceeded, the protection bodies are suggested a goal of one millirem per year as an average dose to the whole population. This is a dose which they describe as being of negligible risk or at a negligible risk level. One millirem a year. Now, why are we doing this to ourselves? We cannot find any effect, so we theorize them. We cannot measure the exposure, so we calculate them. But each and every step in each process, there is a large number of assumptions and choices of range and, as already noted,

they are almost always drawn in the direction of conservatism.

In the general goals, the Regulatory Commission has an overall safety goal of 25-millirem for its general coverage. I won't go into detail as to how that is distributed. To achieve this at the present time, the NRC must regulate every radiation matter coming within their jurisdiction all the way down to zero exposure but, fortunately, the law does not require the NRC to regulate the exposures from natural background radiation which as a matter of fact outweigh the ones that man is making.

In establishing a radiation control system, there are two factors. One is the matter of individual doses and the second is the matter of collective doses for the whole population. That is the average dose to individuals multiplied by the number of individuals. This can be applied where you can measure doses and you can measure the number of people that are exposed. These objectives can be accomplished with a modest effort in the upper dose region but in the low dose region it becomes increasingly difficult, increasingly costly and decreasingly important in the regions that are less than the 25-millirem level that you regarded as your overall goal.

Now, a perceived stumbling block in instituting a BRC plan has been the incorporation of the collective dose requirement. However, the NCRP recommends that the requirement

for a collective dose evaluation be explicitly eliminated from any need or consideration in the region that is described below regulatory concern. They happen to have suggested what might be used as a BRC as one millirem a year as I mentioned.

Thus, if the Regulatory Commission were to choose a number higher than one millirem per year as their level, that could be below regulatory concern and the same exclusion of the requirement for collective dose consideration would apply.

I might state parenthetically when I said that the NCRP made this recommendation about a BRC, actually their terminology was negligible individual risk level but that is the same as BRL. I'm getting mixed up in my acronyms.

CHAIRMAN ZECH: BRC.

DOCTOR TAYLOR: BRC. The NCRP's suggestion would apply to the whole population for all sources of radiation, whereas the BRC would apply to those sources of radiation subject to regulation by the Commission. To be sure of that last statement, which I think is very critical, I checked them both with the members of the NCRP and ICRP, a member of the ICRP and Chairman of the Committee I of the NCRP, and they have verified those statements that I just made as being in accordance with their understanding.

The ICRP does not like the whole restriction

question about collective annual effective dose equivalent and so far has not mentioned it at all. It is a question that has been under some discussion by them but apparently it is not coming to any visible conclusion at the moment.

Thus, I do not see any restriction on the NRC in choosing a BRC level that will cause conflict with either of the above radiation protection bodies. Thank you, sir.

CHAIRMAN ZECH: Thank you very much, Doctor Taylor. Why don't we hear from Mr. Tipton next and then we will entertain questions from my colleagues.

MR. TIPTON: Good morning.

CHAIRMAN ZECH: Mr. Tipton, you may proceed.

MR. TIPTON: Good morning. I am Tom Tipton, Director of the Operations, Management and Support Services Division of the Nuclear Management and Resources Council, NUMARC. Byron Lee and Joe Colvin are on travel and send their regrets that they could not be here today. I would like to thank the Commission for the opportunity to appear before you at this meeting to present a statement on behalf of MUMARC with input from representatives of Edison Electric Institute, the Electric Power Research Institute, Utility Nuclear Waste Management Group and the U. S. Council for Energy Awareness.

With me today are the following industry representatives and they are to your right: Mary Birch,

Technical Systems Manager, Radwaste Engineering, from Duke Power Company, and Chair of EPRI's BRC Owners Group Technical Advisory Committee; Lynne Fairobent, NUMARC Project Manager; Pat Robinson, Director of EPRI's Below Regulatory Concern Owners Group; Steve Kraft, Director of UNWMG; and Dixon Hoyle, Project Manager, Nuclear Fuel Cycle of the USCEA. These individuals are directly responsible for the projects I will be discussing here this morning.

The nuclear industry has supported and continues to support the NRC's efforts to designate levels of radiation that are below regulatory concern. Since the generic BRC issue involves several industry organizations and addresses a generic issue, NUMARC is responsible for coordinating these industry activities. To accomplish that, we established a BRC Ad Hoc Advisory Committee, which has representation from all industry groups addressing different aspects of the issue. A draft industry program plan is being prepared and will be distributed in the near future. It describes the range and scope of industry activities relating to the BRC issue and the key milestone dates. We plan to make it available to your staff so that you will be fully aware of the industry's programs.

However, we think it is important to briefly highlight today some of the industry activities already completed and those in progress that address this issue and

then mention some important points for your future consideration. Again, we appreciate you allowing us this opportunity.

There have been several detailed industry studies addressing the issue of BRC dating back to the late 1970's. Some examples are identified in Attachment A to my presentation. I want to emphasize that these are not all of the studies but only a representative sample of what the industry has done.

In July of 1984, EEI and UNWMG filed a petition for rulemaking with the NRC regarding the disposal of radioactively contaminated waste oil from nuclear power plants with levels of radiation that should be classified as being below regulatory concern. We are pleased that NRC has published for comment in the August 29, 1988 Federal Register a proposed amendment to its regulations to permit the on-site incineration of slightly contaminated waste oils generated at nuclear power plants. The nuclear industry will be submitting comments on the proposed rulemaking.

The industry has also been involved in related activities. Extensive comments on the proposed revisions to 10 CFR Part 20 were provided in October of 1986 by the former Atomic Industrial Forum and EEI. Detailed comments on the NRC's BRC recommendations were included. The industry also commented extensively on the NRC's advance notice of proposed

rulemaking on radioactive waste below regulatory concern published in the December 2nd, 1986 Federal Register. These comments included a strong endorsement of the Commission's proposal to develop BRC regulations.

NRC published in the August 29th, 1986 Federal Register a policy statement and staff implementation plan regarding expeditious handling of petitions for rulemaking to exempt specific radioactive waste streams from disposal in a licensed low level waste disposal facility. This policy statement provided the long sought opportunity for the nuclear industry to pursue the exemption of wastes with very low activity levels from NRC regulations.

In response to the August 1986 policy statement, EPRI and UNWMG initiated a joint program in early 1987 to develop a petition for rulemaking to exempt very low level waste produced at nuclear power plants. EPRI is providing the research and the technical data to support the petition, and UNWMG is providing program support, including legal support and drafting the petition. The EPRI research effort is nearly complete. It alone represents an expenditure of approximately 2.2 million dollars. The present target is to submit the petition by the end of this calendar year.

The petition will propose that the regulations allow the disposal of slightly contaminated wastes in on-site landfills, off-site sanitary landfills, and on-site and off-

site incinerators. It will fully comply with the detailed criteria set forth in the Commission's August 1986 policy statement and the staff's implementation plan, and will therefore qualify for expedited processing.

Now, I would like to briefly summarize some important points for your consideration during future discussions on the issue.

First, it is important that any NRC action identifying a level of radiation risk or dose below which government regulation would be limited or unwarranted be consistent with, and not negate in any way, the August 1986 policy statement. We need to preserve the options it provides as well as the investment the industry has made in preparing the petition.

Second, we feel that a process should be established to determine appropriate BRC levels and I want to emphasize from the industry's point of view, we feel that the BRC program is a process, including the performance of a cost/benefit analysis for higher BRC exempted dose levels. Less rigorous analyses would be required for lower dose values. We generally support an approach similar to that presented by the staff at the September 13th, 1988 meeting of the Advisory Committee on Nuclear Waste. I want to interject with a very preliminary review of the ACNW's letter of September the 15th. We don't support it because it appears

to eliminate the process that we think BRC represents and it just creates limits. Prior industry comments on the issue support individual doses in the range of ten to 20-millirem per year as the generic BRC.

Third, since protection of the individual assures adequate protection of the overall population, the establishment of an annual collective dose person-rem standard for BRC is not appropriate.

Finally, it is our understanding that the staff currently intends to make BRC standards a matter of compatibility for agreement state regulatory programs. In order to realize the full benefits from the Commission's BRC initiatives, it is crucial that BRC standards be adopted by agreement states identical with federal requirements, in a manner similar to the Commission's other radiation protection standards.

In conclusion, the industry strongly supports initiatives to address the BRC issue, as reflected in the work that has been initiated over the past decade. Further, the industry believes that the development of BRC is important to the conduct of good radiation protection programs while at the same time making it possible to minimize the expenditure of resources on matters that pose trivial levels of risk.

We support the need to address the generic BRC issue in a timely manner and encourage the continued exchange

of information as it becomes available.

Establishing regulatory cut-off values would assure that our limited resources are being used most effectively in protecting public health.

In addition, we also support Vic Stello's recommendation that the draft policy statement be issued for public comment as soon as possible. Thank you very much.

CHAIRMAN ZECH: Thank you very much. Any questions from my fellow Commissioners? Commissioner Roberts.

COMMISSIONER ROBERTS: No.

CHAIRMAN ZECH: Commissioner Carr.

COMMISSIONER CARR: No.

CHAIRMAN ZECH: Commissioner Rogers.

COMMISSIONER ROGERS: Well, I think just really the collective dose question which is the one that is most troublesome, and I wonder if either of you two gentlemen who are positioned to the inclusion of a specific collective dose in the policy statement could say anything about how the concerns that are obviously in back of introducing this into the policy statement could be addressed without setting a collective dose limit in the policy statement?

What is your opinion as to the validity in a sense of these concerns and how they could be addressed without putting them in as a specific limit? You suggested that you are in opposition to that but there clearly is an issue out

there that is troublesome, and how would you suggest that we address that issue?

DOCTOR TAYLOR: Well, as I understand the problem there, if you were to set a particular number as a BRC level, you would have to do that after a determination had been made that individuals were not going to be exposed above whatever level it may be that you have set. At the same time -- well, if you do that, you can stop. You do not need to be concerned any further with the collective dose that applies to the people below that level.

Now, am I saying something that seems to be in conflict there? I think it's that simple.

COMMISSIONER ROGERS: Well, it's clear that everybody doesn't agree that that's the case because our advisory committee on waste seems to feel that there should be a collective dose limit and has some ideas about the size of it and so on. So, there must be an issue here that reasonable people see in a different way, and I wonder if there is some way of approaching that issue which is a little different from we need it or we don't need it and we just thrash it out on that basis.

Can that issue be illuminated a little bit and dealt with in another way?

DOCTOR TAYLOR: I don't know how you treat an issue like that. That is made up of a collection of opinions. This

committee you mentioned, I am not familiar with the name.

MR. ALEXANDER: Dave Mohler's.

DOCTOR TAYLOR: Huh.

MR. ALEXANDER: Dave Mohler's committee.

DOCTOR TAYLOR: All right, Dave Mohler's committee.

CHAIRMAN ZECH: Advisory Committee on Waste.

DOCTOR TAYLOR: Okay, right. Well, I know Dave Mohler very well and I also know very well his attitude on this question and Dave, quite honestly, probably believes that a large number of people exposed below one millirem can add up to some kind of an undesirable cumulative dose. I don't think so and the NCRP doesn't think so. They say so specifically in their report, if I understand what is attributed to the advisory committee. I am not familiar with -- I know of that report but I am not familiar with the details of it.

MR. TIPTON: Excuse me. In our discussions and as I said in my statement, we feel at these low levels if you set the limit at the individual you are protecting the population. Now, in the briefing of the staff, saying that you can use the collective dose to assure that no more than 100,000 people get this ten-millirem, in preparing the petition that we are preparing, we found that the maximum exposed individual for this ten-millirem was actually the truck driver in getting the material from the plant to the

landfill itself. And, looking at the overall issue of who would be exposed, clearly you have to look at the most exposed individual and we feel that that is the driver himself.

We don't see how you use the 100-person rem at these lower levels in terms of the protection of the public.

DOCTOR TAYLOR: If you were to --

COMMISSIONER ROGERS: Well, is it --

DOCTOR TAYLOR: Excuse me. Go ahead.

COMMISSIONER ROGERS: I was just going to say is it really just another way of stating the linear hypothesis really?

DOCTOR TAYLOR: No.

COMMISSIONER ROGERS: Well, because it is taking a small number and multiplying it by a big number and getting something that is measurable and that small number is really one that comes out of the linear hypothesis.

MR. TIPTON: The other problem you have sometimes with levels like this, if you were to multiply the potential exposed individuals, et cetera, and you say that you have a 100,000-person rem of exposure, we are talking ten to 20-millirem, and you divide that by a factor of 10,000-person rem per cancer, you could say that you have a statistical cancer, statistical fatality due to these types of exposures when in fact, as the staff has presented, you are looking at

the safety goal numbers in terms of the incremental additional risk to the public from these types of levels. So, one of the problems you have is public perception of this running the code and running out the numbers and then dividing by a factor, and statistically you have a fatality when in fact you sit here and say how is that possible? That's part of the problem.

DOCTOR TAYLOR: That question of public perception is one of the key issues here. When you think about it in a simple way, if you were to set a level of ten-millirems a year as below regulatory concern, you are saying that nobody who is exposed to those lower levels is going to stand an appreciable likelihood of being harmed. That's what you are saying. Now, I don't care whether that happens to one person or ten persons or 10,000 persons, it still isn't going to produce an appreciable harm unless you get down to the point of speculating how many appreciables make one harm. It gets you into almost ridiculous numbers in my opinion.

MR. ALEXANDER: Commissioner, in answer to your question about alternatives, the position of our society, as I mentioned when I introduced Doctor Taylor, is that if you do find it necessary to establish a collective dose criteria, that we recommend that you accept the NCRP advice to exclude from the dose calculation anyone who receives less than one millirem per year. That seems to be a viable alternative.

DOCTOR TAYLOR: But one thing, Bob; if the NRC were to set a level of ten instead of one, which the NCRP uses, this exclusion of the requirement for the cumulative dose would still apply.

MR. ALEXANDER: Yes.

COMMISSIONER ROGERS: All right. Thank you very much on that.

CHAIRMAN ZECH: Well, it seems to me that as far as the collective dose is concerned, if there is no other reason, it may have some value in order to help us to put in as plain language as we possibly can what is the potential harm to the public. It is very difficult when we talk millirem and micro-curies and all kinds of other -- echo-curies and different measurements of radiation. The general public, I have come to appreciate, has a very difficult time understanding what these numbers are and what is the potential harm. And, if we can say it has one in 10,000,000 or one in 50,000,000 or something like that in as simple of terms that people can understand, I think it is, frankly, an obligation that we all have to try to come up with something that says very truthfully, very honestly, the best scientific knowledge we have and put it in as plain language as we can and perhaps even if the collective dosage isn't all that valuable from a certain standpoint, it seems to me that it could be valuable if it will help us to explain to the general public exactly

what we are talking about.

COMMISSIONER ROBERTS: I tend to think it would obfuscate the whole matter more.

CHAIRMAN ZECH: Well, that's possible. We should think about it. It seems to me that it would have merit to try to come up with some way to explain what numbers we are talking about and what harm, if any, in these low numbers there would be. I'm sure there are different views on this as Commissioner Roberts just pointed out. But to me it is a challenge and it's an obligation and responsibility we have to try to be as truthful and honest as we can and say what we mean, rather than talk about it in these very scientific terms. This is something that I think is very important.

DOCTOR TAYLOR: Well, I think --

CHAIRMAN ZECH: Doctor Taylor.

DOCTOR TAYLOR: Yes. Well, I think in your process of arriving at a suitable number for BRC, you certainly indeed do have to go through just what you are talking about just to show publicly what it is you have done. But once you have done that to demonstrate the number that you have set, when you reach the point of exercising your BRC concept, you don't have to keep track of anything that happens in the region below that level.

Now, as I understood, you are suggesting that you might have to continue to do that.

CHAIRMAN ZECH: No, I don't mean to do that at all. I am thinking about two things. One is, first of all, what is the right number, conservative number, that we as a regulatory body using all the expertise and advice we can gather, what is the proper number that we should place on it for below regulatory concern? That is a very real responsibility we have --

DOCTOR TAYLOR: That's right.

CHAIRMAN ZECH: -- we are trying to exercise. But in addition to that and aside from that really, after we have made that judgment or while we are making that judgment, what is the best way we can explain and say in layman's language what we have done and be very honest and truthful about it and have a clear conscience? That's what we have done and here is why we have done it and here is what we have done. It's very difficult to explain these health physics terms and I think it's important we try to do so.

DOCTOR TAYLOR: I think it is crucially important that you provide an explanation that the public can understand. I have been trying to do this in my own small way for 15 or 20 years since this situation has been getting somewhat out of control in my opinion. But the whole question will hinge upon public conception of what the Commission is doing. You have to put every fact out but, in addition, you have to explain those facts so that people will understand

them in a language that they can understand.

CHAIRMAN ZECH: That's exactly what I'm trying to do too. I think we need your help to do that. That's the only reason I am saying that perhaps this collective dosage has some merit.

COMMISSIONER CARR: Mr. Chairman, I spent two days trying to understand collective dose and I consider myself an average member of the public and I cannot yet see any rational explanation for a collective dose as to what it adds to the problem. I have tried it all. I have discussed it with the proponents and the opponents and I cannot come up -- it just doesn't make sense to me to use it for anything.

CHAIRMAN ZECH: The only thing that makes sense to me is if you say below regulatory concern is ten millirem or whatever it is, what does that mean? What does that mean? And, to me, by itself it may not mean much but if you can say it means that in a 50-year period you can expect to have 12 to 25,000,000 deaths and what this below regulatory concern means is that you would have one more.

COMMISSIONER CARR: Well, that's not the number that we are talking about.

CHAIRMAN ZECH: Well, whatever, what I'm saying is -- the numbers aren't important -- but what I'm saying is that some way of saying in as plain language as we can what we are doing. To me, that is perhaps the greatest value of

using a collective dose, or call it some other name but I am just trying to say that I think my personal feeling is the general public is pretty smart and they deserve to know the answer and I want to put it in as plain language as I can. I think if we do that, they will understand it and we will have done a service. I have great confidence in the public when they know the facts. I do believe that this collective dose -- call it what you want -- is a method at least to try to explain what we are doing, and I think it is important we try to do that.

MR. LAHS: Our society can help in that regard.

CHAIRMAN ZECH: What's that?

MR. LAHS: Our society can help in that regard. I'm sure it can.

CHAIRMAN ZECH: We need help. We are asking for help. At least I am anyway.

MR. LAHS: We can develop that to get it before the public.

CHAIRMAN ZECH: Commissioner Carr.

COMMISSIONER CARR: Let me add one more thing. In trying to explain it to me, they tried to convince me that if you had a lot of these sources that could expose people up to ten MR, then you ought to worry about all of these sources and where they come from, and finally you are going to have to worry about a collective dose of the population. I said

why don't we in lieu of that worry about the individual source that is causing the radiation and measure it and control it at that level, instead of trying to control it across a public that you can't really define? And, I would like them to discuss that in the workshop, whether instead of the collective dose we can look at the particular product that is causing the dose and see if there is not some limit we can set on that and say you can't put this out in the general public.

CHAIRMAN ZECH: Well, I think I would agree, that is a fundamental concern that certainly should be discussed and that we should be aware of.

COMMISSIONER CARR: I tried to find out what the 100-person rem per year, what would be the limiting product that would cause you to get to that. When would this come into effect and what would it mean to the people if we set it or what is the difference between setting it at 100-person rem and 10,000-person rem except in the numbers here? I was unable to come up with a satisfactory answer that I could understand.

CHAIRMAN ZECH: Well, that's what we are trying to find out. We are asking is there one and is there a way that the number we could put out is sensible, is honest, is meaningful? That's what we are trying to find out. We are asking for help from the experts. That's what we are here for.

DOCTOR TAYLOR: I am sure it can be done and the biggest part of the problem, however, is going to be again to find a way of presenting that to meet the public idea of what is being talked about. You mentioned complex terms using just collective dose as a simplification of the real term. Just for your amusement, I will read you the sentence now on that. It is further recommended that assessments of increments of collective annual effective dose equivalents -- that's the right word to use. That's been reduced to collective dose.

Now, there is a problem that we have of reducing that fine scientific idea down to something that the public can understand.

MR. TIPTON: And, I think also the public understands comparisons of risks. I think when you had your briefing with the staff before, they indicated that a round trip flight to the west coast was around five-millirem exposure. The public understands this risk relative to other risks. So, you may even look at it from that standpoint. It is easy to understand. I think they would have difficulty with person-rem. I mean what is a person-rem and what is the affected population we are talking about? Is it within ten miles of the landfill? Why just ten miles? Why isn't it 100 miles, et cetera? And, you play that off and, you know, it's according to who you are talking to. But when you talk

relative to other risks that they understand, it's easier for them to understand what we are saying at these levels of radiation.

CHAIRMAN ZECH: Well, let me emphasize just one final point. There are two issues again. One is our responsibilities for the public health and safety. We don't want to harm the public. That's very real and that is what we have got to decide. That's our responsibility. We are using the scientific community to help us make that determination.

The second thing is how do we explain it and make it understandable to the public. There are two different issues very separate in my judgment. The one is our responsibilities for public health and safety are very real. That is our responsibilities. They expect us to do and that is what we are trying to do. But in addition to doing that, when we have done that, it seems to me we ought to be able to try to say in layman's language exactly what we have done.

MR. TIPTON: And, we support those.

CHAIRMAN ZECH: Well, are there any other questions or comments?

COMMISSIONER CARR: I have got one.

CHAIRMAN ZECH: Yes.

COMMISSIONER CARR: As I say, the whole thing boils down, and I hope we can work it out in that workshop, but the

justification of the practice, this so-called net benefit, I don't know who is going to decide what is net in the benefit or how net is going to be determined. On the issue of collective dose then, I think, before we leave, we ought to clear up this comment in the paper that says that NEPA, the National Environmental Policy Act, requires that the collective dose be figured.

Can the counsel provide any information on that?

MR. PARLER: Well, in addition to the radiological health and safety responsibilities, this agency is subject to the National Environmental Policy Act. The National Environmental Policy Act certainly does not, in my judgment, require that a particular collective dose be set. But in either deciding whether an environmental assessment is required or doing an environmental assessment, certainly the societal impact would have to be considered.

Therefore, it would seem to me that in order to do that, a range of alternatives could be considered or a ban without setting any particular dose level. But after you go through the analysis, you should be left with some certainty as to what the societal impact would be. So, you have to do something but you don't have to set a precise number.

CHAIRMAN ZECH: All right. Any other questions or comments?

(No response.)

CHAIRMAN ZECH: All right. Well, let me then on behalf of the Commission thank you Doctor Taylor very much and Mr. Tipton and the staff for this presentation this morning. It is a very important issue. It has been around for a long time. We have a responsibility to attempt to resolve it. I think the international conference certainly should be very helpful.

I would ask my fellow Commissioners, I believe we have before us SECY-88-257 that asks for -- the staff was asking for our authorization to go to this international conference and present these policy views. Mr. Stello has also suggested perhaps that we go to the public first and then go again after the meeting.

I would prefer, frankly, to go to the international conference I think and then see what they have to say and then go out with public comments later but since Mr. Stello has made the proposal that we go either one way or the other, I would ask you add that to SECY-88-257 and perhaps act on that as soon as we can so that the staff will have our guidance before they go to the international conference.

If there are no other questions or comments from my fellow Commissioners --

(No response.)

CHAIRMAN ZECH: -- thank you very much. We stand adjourned.

(Whereupon, at 11:50 a.m., the Commission meeting was adjourned.)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the U.S. Nuclear Regulatory Commission entitled: BRIEFING ON STATUS OF EFFORTS TO DEVELOP A BELOW REGULATORY CONCERN POLICY

TITLE OF MEETING: Public Meeting

PLACE OF MEETING: Washington, D.C.

DATE OF MEETING: September 16, 1988

were transcribed by me. I further certify that said transcription is accurate and complete, to the best of my ability, and that the transcript is a true and accurate record of the foregoing events.

JOHN TROWBRIDGE, CVR

Ann Riley & Associates, Ltd.

PROPOSED POLICY STATEMENT ON EXEMPTION OF PRACTICES WHICH ARE BELOW REGULATORY CONCERN

STAFF PRESENTATION TO COMMISSION

SEPTEMBER 16, 1988

OUTLINE OF PRESENTATION

- PURPOSE OF PRESENTATION
- BACKGROUND
- OBJECTIVE OF POLICY STATEMENT
- CONSIDERATIONS UPON WHICH POLICY STATEMENT IS BASED
- KEY ELEMENTS OF POLICY STATEMENT
- PLANS FOR INTERNATIONAL WORKSHOP

- Purpose of Presentation:
  - To discuss the proposed Commission Policy on Exemption from Regulatory Control for Practices Whose Health and Safety Impacts are Below Regulatory Concern
  - To discuss plans for the International Workshop

BACKGROUND

STAFF REQUIREMENTS MEMORANDUM OF 3/30/88 DIRECTS STAFF TO "SUBMIT FOR COMMISSION CONSIDERATION OPTIONS FOR A POLICY STATEMENT WHICH ESTABLISHES A GENERIC NUMBER FOR EXPOSURES THAT ARE BELOW REGULATORY CONCERN."

OBJECTIVE OF POLICY STATEMENT

TO ESTABLISH BASIS FOR DEVELOPMENT OF REGULATIONS OR LICENSING DECISIONS DEFINING CONDITIONS FOR EXEMPTION FROM REGULATORY CONTROL.

CONSIDERATIONS UPON WHICH-POLICY IS BASED

- FUNDAMENTAL PRINCIPLES OF RADIATION PROTECTION
  - JUSTIFICATION OF PRACTICE
  - DOSE LIMITS TO DEFINE MAXIMUM ALLOWED RADIATION LEVELS
  - ENHANCED PROTECTION BASED ON ALARA PRINCIPLES

CONSIDERATIONS UPON WHICH-POLICY IS BASED

- LINEAR NON-THRESHOLD RELATIONSHIP BETWEEN LOW RADIATION DOSE AND STOCHASTIC CANCER RISK

CONSIDERATIONS UPON WHICH-POLICY IS BASED

- RECOGNITION THAT INDIVIDUALS MAY BE EXPOSED TO RADIATION FROM MORE THAN ONE LICENSED OR EXEMPTED SOURCE

ELEMENTS OF POLICY STATEMENT

° GENERAL CONDITIONS FOR EXEMPTION

- COSTS OF ADDITIONAL REGULATORY CONTROLS TO REDUCE INDIVIDUAL OR COLLECTIVE DOSE ARE NOT BALANCED BY THE REDUCTION IN RISK.

ELEMENTS OF POLICY STATEMENT

- ALTERNATELY, APPLICATION OF REGULATORY CONTROLS DOES NOT RESULT IN A SIGNIFICANT REDUCTION IN RISK.

KEY ELEMENTS OF POLICY

- PROPOSES 10 MREM AND 100 PERSON-REM AS THE INDIVIDUAL AND COLLECTIVE ANNUAL DOSE LEVELS BELOW WHICH RISKS ARE SUFFICIENTLY SMALL THAT ALARA CAN BE CONSIDERED TO HAVE BEEN ACHIEVED WITHOUT PERFORMING COST BENEFIT ANALYSES.

KEY ELEMENTS OF POLICY

° EXCLUDES FROM CONSIDERATION FOR EXEMPTION PRACTICES WHICH INVOLVE

- INTRODUCTION OF RADIOACTIVITY INTO TOYS OR PRODUCTS INTENDED FOR INGESTION, INHALATION, OR DIRECT APPLICATION TO THE SKIN.

KEY ELEMENTS OF POLICY

° ALSO EXCLUDES

- RELEASE OF RADIOACTIVITY WHERE THERE ARE CLEAR ECONOMICAL ALTERNATIVES OR THERE ARE NO UNIQUE BENEFITS FROM THE USE OF RADIOACTIVITY.

KEY ELEMENTS OF POLICY

- PROVISIONS TO LIMIT POTENTIAL IMPACT OF MULTIPLE EXPOSURES
  - SELECTION OF DOSE CRITERIA FOR WAIVER OF COST BENEFIT ANALYSES
  - EXEMPTIONS INVOLVING UNJUSTIFIED RELEASE OF RADIOACTIVITY WOULD BE EXCLUDED

KEY ELEMENTS OF POLICY

- FOR EACH EXEMPTION DECISION ANALYZE COMPONENTS OF EXPOSED POPULATION TO IDENTIFY THOSE WHO MIGHT RECEIVE DOSES NEAR 100 MREM WHEN OTHER PRACTICES ARE TAKEN INTO ACCOUNT.

KEY ELEMENTS OF POLICY

- REEVALUATE POLICY AND ITS IMPLEMENTATION AS EXPERIENCE IS GAINED

- DELIBERATE FRACTIONATION OF PRACTICE NOT ALLOWED

KEY ELEMENTS OF POLICY

- ALLOWS APPLICATION OF TRUNCATION OR WEIGHTING FACTORS WHEN CALCULATING COLLECTIVE DOSE

  - TRUNCATIONS IN SPACE OR TIME.
  - CUT OFF AT LOW DOSE (E.G., 0.1 MREM).

KEY ELEMENTS OF POLICY

- WEIGHTING FACTORS FOR COLLECTIVE DOSE IN VARIOUS RANGES OF INDIVIDUAL DOSE (E.G., $1000 PER PERSON REM ABOVE 1 MREM AND $100 BELOW).

INTERNATIONAL WORKSHOP

PURPOSE:

- TO DISCUSS DIVERSITY OF INTERNATIONAL REGULATORY VIEWS

INTERNATIONAL WORKSHOP

CURRENT COMMITMENTS:

- REGULATORS FROM 10 COUNTRIES

- INTERNATIONAL ORGANIZATIONS (ICRP, NEA, CEC)

- EPA, DOE, NCRP, ACNW

INTERNATIONAL WORKSHOP

- WORKSHOP SCHEDULED FOR OCTOBER 17-19 IN WASHINGTON, D.C.
- STAFF NEEDS GUIDANCE FROM COMMISSION REGARDING
  - DISCUSSION OF PROPOSED POLICY AT WORKSHOP
  - ISSUANCE OF POLICY FOR PUBLIC COMMENT

BACKUP SLIDES

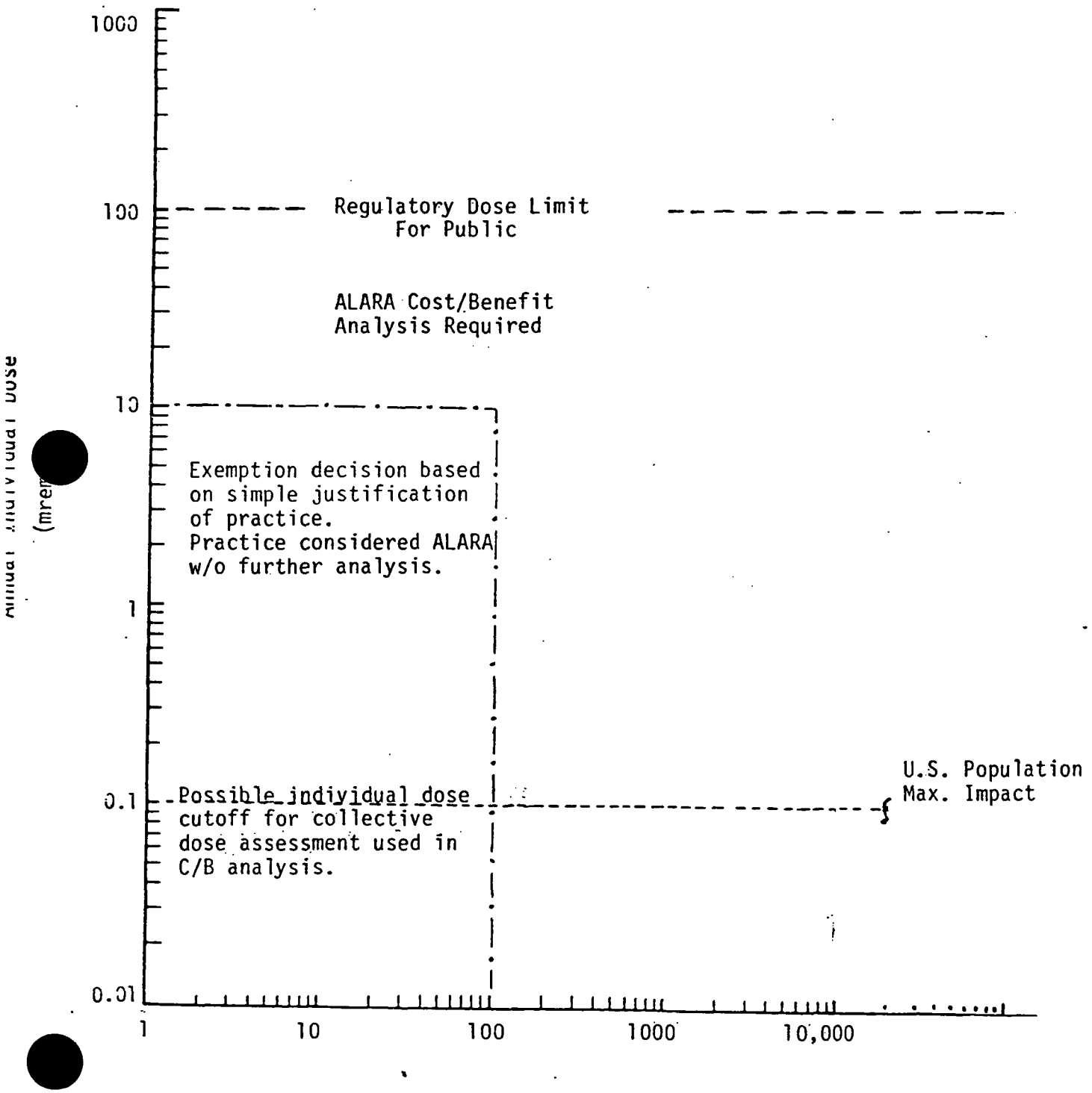
STAFF PRESENTATION
ON PROPOSED BRC POLICY
STATEMENT

SEPTEMBER 16, 1988

INDIVIDUAL RISK AS A FUNCTION OF DOSE

Incremental Annual Dose	Incremental Annual Risk	Lifetime Risk from Continuing Annual Dose
100 MREM	2×10^{-5}	1×10^{-3}
10 MREM	2×10^{-6}	1×10^{-4}
1 MREM	2×10^{-7}	1×10^{-5}
0.1 MREM	2×10^{-8}	1×10^{-6}

PROPOSED EXEMPTION POLICY SCHEMATIC



UNCERTAINTIES IN DOSE-RISK RELATIONSHIP

- UNCERTAINTIES IN DOSES RECEIVED BY POPULATION INCLUDED IN EPIDEMIOLOGIC STUDIES

- EPIDEMIOLOGIC DATA ONLY AVAILABLE AT HIGHER DOSES

UNCERTAINTIES IN DOSE-RISK RELATIONSHIP

- VARIOUS HYPOTHESIS FOR EXTRAPOLATION TO LOW DOSES

- VARIOUS HYPOTHESES FOR PROJECTING FATALITY RATES INTO FUTURE

Commission Briefing on Generic BRC

Friday, September 16, 1988

Good morning. I am Tom Tipton, Director of the Operations, Management and Support Services Division of the Nuclear Management and Resources Council (NUMARC). Byron Lee and Joe Colvin are on travel and send their regrets for not being able to be here today. I'd like to thank the Commission for the opportunity to appear before you at this meeting to present a statement on behalf of NUMARC with input from representatives of Edison Electric Institute (EEI), Electric Power Research Institute (EPRI), Utility Nuclear Waste Management Group (UNWMG) and U.S. Council for Energy Awareness (USCEA).

With me today are the following industry representatives; Mary Birch, Technical System Manager, Radwaste Engineering, Duke Power Company, and Chair of EPRI's BRC Owners Group Technical Advisory Committee; Lynne Fairobent, NUMARC Project Manager; Pat Robinson, Director of EPRI's Below Regulatory Concern (BRC) Owner's Group; Steve Kraft, Director of UNWMG; and Dixon Hoyle, Project Manager, Nuclear Fuel Cycle, USCEA.

The nuclear industry has supported and continues to support NRC's efforts to designate levels of radiation that are Below Regulatory Concern. Since the generic BRC issue involves several industry organizations and addresses a generic issue, NUMARC is responsible for coordinating these industry activities. To accomplish that, we established a BRC Ad Hoc Advisory Committee, which has representation from all industry groups addressing different aspects of the issue. A draft industry program plan is being

prepared and will be distributed in the near future. It describes the range and scope of industry activities relating to the BRC issue and the key milestone dates. We plan to make it available to your staff so that you will be fully aware of industry's programs.

However, we think it is important to briefly highlight today some of the industry activities already completed and those in progress that address this issue and then mention some important points for your future consideration. Again, we appreciate you allowing us this opportunity.

There have been several detailed industry studies addressing the issue of BRC dating back to the late 1970s. Some examples are identified in Attachment A to my presentation.

In July 1984, EEI and UNWMG filed a petition for rulemaking with the NRC regarding the disposal of radioactively contaminated waste oil from nuclear power plants with levels of radiation that should be classified as being below regulatory concern. We are pleased that NRC published for comment in the August 29, 1988 Federal Register a proposed amendment to its regulations to permit the on-site incineration of slightly contaminated waste oils generated at nuclear power plants. The nuclear industry will be submitting comments on the proposed rulemaking.

The industry has also been involved in related activities. Extensive comments on the proposed revisions to 10 CFR Part 20 were provided in October 1986 by the former Atomic Industrial Forum and EEI: Detailed comments on

NRC's BRC recommendations were included. The industry also commented extensively on NRC's Advance Notice of Proposed Rulemaking on Radioactive Waste Below Regulatory Concern published in the December 2, 1986 Federal Register. These comments included a strong endorsement of the Commission's proposal to develop BRC regulations.

NRC published in the August 29, 1986 Federal Register a policy statement and staff implementation plan regarding, "expeditious handling of petitions for rulemaking to exempt specific radioactive waste streams from disposal in a licensed low-level waste disposal facility." This policy statement provided the long-sought opportunity for the nuclear industry to pursue the exemption of wastes with very low activity levels from NRC regulations.

In response to the August 1986 Policy Statement, EPRI and UNWMG initiated a joint program in early 1987 to develop a petition for rulemaking to exempt very low-level waste produced at nuclear power plants. EPRI is providing the research and technical data to support the petition, and UNWMG is providing program support, including legal support and drafting a petition. The EPRI research effort is nearly complete. It alone represents an expenditure of approximately 2.2 million dollars. The present target is to submit the petition by the end of this calendar year.

The petition will propose that the regulations allow the disposal of slightly contaminated wastes in on-site landfills, off-site sanitary landfills, and on-site and off-site incinerators. It will fully comply with the detailed criteria set forth in the Commission's August 1986 Policy Statement and the

staff's implementation plan, and will therefore qualify for expedited processing.

Now, I would like to briefly summarize some important points for your consideration during future discussions on the issue.

First, it is important that any NRC action identifying a level of radiation risk or dose below which government regulation would be limited or unwarranted be consistent with, and not negate in any way, the August 1986 policy statement. We need to preserve the options it provides as well as the investment the industry has made in preparing the petition.

Second, we feel that a process should be established to determine appropriate BRC levels, including the performance of a cost/benefit analysis for higher BRC exempted dose levels. Less rigorous analyses would be required for lower dose values. We generally support an approach similar to that presented by the staff at the September 13, 1988 meeting of the Advisory Committee on Nuclear Waste. Prior industry comments on the issue support individual doses in the range of 10-20 mrem per year as the generic BRC.

Third, since protection of the individual assures adequate protection of the overall population, the establishment of an annual collective dose (person-rem) standard for BRC is not appropriate.

Finally, it is our understanding that the staff currently intends to make BRC standards a "matter of compatibility" for Agreement State Regulatory

Programs. In order to realize the full benefits from the Commission's BRC initiatives, it is crucial that BRC standards be adopted by Agreement States identical with federal requirements, in a manner similar to the Commission's other radiation protection standards.

In conclusion, the industry strongly supports initiatives to address the BRC issue, as reflected in the work that has been initiated over the past decade. Further, the industry believes that the development of BRC is important to the conduct of good radiation protection programs while at the same time making it possible to minimize the expenditure of resources on matters that pose trivial levels of risk.

We support the need to address the generic BRC issue in a timely manner and encourage the continued exchange of information as it becomes available.

Establishing regulatory cut-off values would assure that our limited resources are being used most effectively in protecting public health.

Thank You.

Attachment A

EXAMPLES OF INDUSTRY STUDIES COMPLETED

ATOMIC INDUSTRIAL FORUM

- AIF/NESP-016 (1978): "De Minimus (sic) Concentrations of Radionuclides in Solid Wastes"
- AIF/NESP-035 (1986): "Evaluation of the Potential for De-regulated Disposal of very Low-Level Wastes from Nuclear Power Plants"
- AIF/NESP-037 (1986): "A Guide for Obtaining Regulatory Approval to Dispose of Very Low-Level Wastes by Alternative Means"

EDISON ELECTRIC INSTITUTE

- GP-33040 (1981): "The Feasibility of Establishing a 'De-Minimis' Level of Radiation Dose and a Regulatory Cut-off Policy for Nuclear Regulation"
- GP-R-72005 (1982): "Summary of Potential Benefits of Proposed Regulatory Cut-Off Policy Based on De-Minimis Radiation Dose Criteria - Results of a Survey of Nuclear Utility Personnel"

ELECTRIC POWER RESEARCH INSTITUTE

- EPRI NP-3299 (1983): "Segregation of Uncontaminated Dry Active Waste"
- EPRI NP-3370 (1984): "Identification of Radwaste Sources and Reduction Techniques"
- EPRI NP-5099 (1988): "Update Characterization of Radwaste Sources, Vol. 1 and Vol. 2
- EPRI NP-5670 (1988): "Below Regulatory Concern Owners Group: Evaluation of Candidate Waste Streams"
- EPRI NP-5671 (1988): "Below Regulatory Concern Owners Group: Radionuclide Prioritization Study"
- EPRI NP-5672 (1988): "Below Regulatory Concern Owners Group: Selection of Plants for Sampling Program"

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, D.C. 20555

September 15, 1988

The Honorable Lando W. Zech, Jr.
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Zech:

SUBJECT: PROPOSED POLICY STATEMENT ON BELOW REGULATORY CONCERN

During the fourth meeting of the Advisory Committee on Nuclear Waste, September 13-14, 1988, we held additional discussions with the NRC staff relative to the development of a Proposed Commission Policy Statement on Exemptions from Regulatory Control for Practices Whose Public Health and Safety Impacts are Below Regulatory Concern (BRC). This topic was previously discussed with the NRC staff during a meeting of the ACRS Subcommittee on Waste Management on May 4, 1988. The ACNW also discussed this topic with the NRC staff during our second meeting, July 21-22, 1988, and reported to you on this subject on August 9, 1988. We also had the benefit of the document referenced.

As a result of these discussions, we offer the following comments:

1. The proposed exemption system is based on the risks associated with the exposures involved, and the system, if modified as suggested here, will be compatible with most relevant regulations and policies of the NRC and other federal agencies, as well as those of international organizations.

2. We urge the adoption of dose rates up to 10 mrem (0.1 mSv) per year to individuals and annual collective doses up to 100 person-rem (1 person-Sv) as acceptable limits arising from a single exempted practice. Please note that this is a different use of the dose limits than is proposed in the draft Policy Statement. Provisions should be made to ensure that individuals within any population group are not exposed to any combination of exempted practices that results in dose rates greater than one to two times the dose rate limit. Experience indicates that such occurrences should be rare.

3. The current draft of the proposed Policy Statement is in need of extensive revision, partly to comply with the recommendations made under item 2, above. Additional items that need to be addressed include:

a. The draft of the proposed Policy Statement should clearly specify 10 mrem (0.1 mSv) per year and 100 person-rem (1 person-Sv) per year as the limits for individual and collective dose rates, respectively. The ancillary use of a 100 person-rem (1 person-Sv) per year limit as a guide to the necessity for ALARA analysis should be removed (see item b, below).

b. There is a need for a much clearer statement relative to the role and application of the principle of "justification" in assessing practices being considered for exemption.

c. Instead of discussing dose rates at which collective dose calculations should be truncated, it would be better to do a complete calculation, and include within the data a tabulation of the number of people within each of several dose rate ranges.

d. The section pertaining to the linear nonthreshold hypothesis needs to be clarified. One approach would be simply to include a brief statement that risk (cancer) estimates should be based on the assumption that the linear nonthreshold hypothesis applies and that this approach will result in conservatism in the resulting estimates.

e. Since its use represents a change in NRC policy, the concept of the Effective Dose Equivalent should be defined within the Policy Statement. In a similar manner, since SI units are in common usage throughout the world, all dose rates and collective doses should be expressed in these units as well as in the conventional units.

4. As the proposed Policy Statement correctly points out, the Agreement States will play an important role in the implementation of the proposed exemptions. For this reason, it is important that the Statement be formally submitted to the Conference of State Radiation Control Program Directors for review and comment.

The resulting document, when properly revised, will represent a pioneering effort in nuclear safety regulation, will help conserve those of our resources that are available for the control of environmental and public health problems, and should receive strong support from the professional radiation protection community. We believe that the proposed Policy Statement, if revised as suggested above, will serve

well as a starting point for the position to be stated at the upcoming international meeting on this subject.

Sincerely,

Dade W. Moeller

Dade W. Moeller
Chairman

Reference:
Memorandum dated September 8, 1988 from Bill M. Morris, Office of Nuclear Regulatory Research, NRC, to R. F. Fraley, Executive Director, ACNW, transmitting Proposed Commission Policy Statement (undated)

HEALTH PHYSICS SOCIETY

September 8, 1988

Commissioners Lando W. Zech, Jr.
Thomas M. Roberts
Kenneth M. Carr
Kenneth C. Rogers

U.S. Nuclear Regulatory Commission
Washington, DC 20555

It has come to the attention of the Health Physics Society that, because of concern over the unwise use of available trained manpower and resources associated with the regulation of radiation exposures at very low doses, the Nuclear Regulatory Commission is considering the adoption of a policy to define a meaningful generic level of exposure below which it would have no regulatory concern. Although the unnecessary regulation of very low-level radiation creates employment opportunities for our members, we would like to inform you that this Society shares your concern and is prepared to provide consensus scientific assistance and support for your position. In particular, it is the position of the Society that the efforts mentioned above are in many cases not commensurate with the risks, if any, that are averted.

The Health Physics Society, founded in 1956, has a membership of more than 6,400 health physicists and other scientists who specialize in the protection of people from ionizing radiation, including physicists, chemists, radiobiologists, epidemiologists, physicians, engineers and mathematicians drawn from industry, academia, research and medical institutions, national laboratories and governmental agencies. The Society is believed to fully encompass and represent consensus technical opinion in the field of radiation protection and health effects.

Today a considerable fraction of the regulatory effort is concerned with radiation exposures that are much smaller than those received from variations in natural radiation due to altitude changes and other causes. We currently suffer from what appears to be an irrational public fear of low levels of radiation exposure; this has been fostered, in part, by associated governmental pressures to further reduce them below risk levels found and accepted in nearly all other factors of life. This, in turn, has resulted in the incurrence of inordinate pressures on all phases of the radiation industry, the cost of which is ultimately passed on to the public. We believe a real, and much greater saving of life could be accomplished by the alternative expenditure of our resources on safety operations where the risks are clearly demonstrated, as compared with the low-level radiation risks which are so miniscule that they may never be unambiguously established.

It has never seemed logical to try to regulate radiation exposures that are miniscule relative to those we receive from nature. We believe that the Commission's objectives can be accomplished within the framework of the existing standards of radiation protection as recommended by the International Commission on Radiological Protection (ICRP), and the National Council on Radiation Protection and Measurements (NCRP). These bodies have recommended dose limits for the public that are far below the level where specific health effects have been observed for humans. It is not known whether any health effects in the general range of those recommended dose limits do or do not occur. If they do occur, they occur so infrequently that present scientific methods are incapable of detecting them using the best laboratory and epidemiological methods.

The system of dose limitation recommended by standards bodies does more than provide dose limits which are not to be exceeded without regard to cost-benefit considerations. In addition all radiation users are admonished that doses should be "kept as low as reasonably achievable (ALARA), social and economic considerations being taken into account", and that unnecessary exposures should be avoided. This is not a standard in the sense of a dose limit but is an essential advisory to be applied on a case-by-case basis. The dose limit, when coupled with the ALARA concept, provides an <u>average</u> individual (or collective) dose that is associated with an acceptable risk. A BRC level, would, in effect, truncate governmental involvement in the implementation of the ALARA concept, placing further implementation on an entirely voluntary basis. Thus we believe that the BRC level should, at least in theory, be near the threshold of a public risk of sufficient magnitude to warrant governmental intervention in the lives of its citizens. The current NRC safety goal for operation of a nuclear-power plant is theoretically associated with doses of some 10 to 20 millirems in a year for an entire lifetime, which would seem an appropriate range in which to start considering a BRC level.

Pertinent technical issues are addressed in more detail in the enclosed attachments No. I and II.

Respectfully submitted by the Health Physics Society,

Lauriston S Taylor

Lauriston S. Taylor
Past President
Health Physics Society

ATTACHMENT NO. I

1. **Conservatism of current radiation protection standards.** The recommendations of the ICRP and the NCRP are put forward with extreme caution and in expectation that the responsible bodies (e.g. NRC) will apply the necessary politic adjustment of practical limits to meet the technological and social needs of the nation. Because of the absence of observed health effects in the low dose region (below the order of 5 rem in a year), both the ICRP and NCRP make the conservative assumption that the frequency of occurrence of health effects, per unit of dose at the low dose levels in the range of the dose limits, is the same as at high doses where health effects have been quantitatively observed and extensively studied in both humans and animals. This process allows the theoretical establishment of upper limits on the number of effects--if any--that might occur in the low-dose range. There has been remarkable agreement among the ICRP, NCRP, NAS, and UNSCEAR on all of the quantitative methods by which the effects should be estimated. At the same time there has been agreement that, if used for projecting <u>real</u> effects that will occur following low-level exposures of the public, the assumption of proportionality is inappropriate and misleading, and should not be so used.

2. **Balancing costs and dose reduction.** The taking of social and economic considerations into account is the nemesis of the radiation regulator and is the least understood by the public. Standards bodies have emphasized that in the commitment of resources to reduce doses below the dose limits, there should be an appropriate balance between resources committed to reduction of dose and the real benefits derived in the subsequent reduction of health effects. It is recognized that a point is reached where the effort (cost) required to further reduce dose exceeds the benefit from the small incremental reduction of health effects that is theoretically achieved. In such cases the further expenditure of resources to reduce dose is not justified. While several regulatory limits have been determined using this approach, it appears that a generic BRC level would more appropriately be based on other considerations such as an increase in the theoretical risk as was used in the development of the Commission's safety goals.

3. **The public perception of safety.** Failure to clearly explain the ALARA concept has, in some instances, resulted in public perceptions of health effects from very low-level radiation which are irrational and without factual basis. This, in turn, has led to the needless expenditure of substantial resources by individual members of the public, and by public agencies, because of an unreasonable concern with exposure to low-level radiation. This is all done in the name of reducing health effects which, if they exist at all, are so small as to be meaningless in comparison with the general health effects suffered by the public and as caused by ordinary substances to which people are exposed in everyday living. This type of unwarranted concern with possible health effects from low-level radiation exposure can also lead to a failure to take advantage of the use of radiation-related technologies, even though in many cases a radiation technology may be the method of first choice.

4. **The Public Perception of Risk.** Perhaps the most difficult phase of the BRC problem is that of dealing with the public's perception of radiation risks and its concept of safety of any kind. The average person in the general public does not realize that there is no such thing as absolute safety. They see that if a given condition is not safe, it must be unsafe--that there is a sharp dividing line between the two. Webster defines safe as, "free from or not liable to danger of any kind; free from or having escaped hurt, injury or damage...." Obviously, absolute safety is not obtainable for most human activities. Therefore the question is not "What is a safe level of exposure?", but "How safe is safe enough?". We know that safety is a relative term, but most of the public and the news media do not understand that. A major national effort is probably needed to educate the public as to what safety means and what they are to expect of it.

5. **Contaminated material.** Our discussions at this juncture relate only to health effects in the population. A separate, but related, problem concerns levels of contamination of material that may be returned to industrial use. Under many circumstances such material may not pose any health problem but can introduce difficulties if, by chance, it should be incorporated into devices or instruments where extremely small amounts of radioactivity could interfere with their proper operation. Thus, contamination levels far below any conceivable risk to humans may still be a costly nuisance to the very few manufacturers of radiation instruments or certain shielding materials. Strict regulation of the many thousands of facilities at levels lower than those designed primarily for human risks would be costly out of all proportion to the value of such contamination-free materials. When there is need, let it be a part of the manufacturing costs to find and test the required materials.

6. **Science and technology in radiation protection.** There is another role of the Commission that must be undertaken, and recognized not only by the general public but the scientific community generally, and especially those in radiation science as distinguished from radiation protection practitioners (e.g., health physicists). With his normal background and training, the scientist speaks on the basis of facts or theories (or assumptions or models). For example in discussing possible low-level radiation health effects, he accepts the existence of meaningful data in the range above, say, 10 rem. Below 10 rem, his data are of questionable value, if existing at all, but it appears as though the higher range data might (more or less) logically extend straight down to zero dose. When pressed, he speculates that if we could find some data in that unexplored low-dose range, it would almost certainly not be far out of proportion with the high-dose data. However, he can't say for certain that there are no effects in the low region since it has not been possible to obtain any data there at all. The best he can do is to point out that in such case there is a possibility that for any dose, no matter how small, there must also be the possibility of some health effect. As far as the public is concerned, the associated low probabilities go unrecognized and Pandora's box has been opened. They believe that any radiation exposure whatever will lead to cancer.

7. **The role of the Nuclear Regulatory Commission.** What is the point of all this? The point is that our scientifically derived radiation protection standards, by themselves, are inadequate for some radiation exposure situations, specifically for defining acceptable conditions of "safety" in the low-dose range. The only solution for this is a politic decision by a properly authoritative governmental organization, such as the Nuclear Regulatory Commission. (By politic, Webster means, "prudent and sagacious in devising and pursuing measures to promote the public welfare.") The obvious step is that the NRC must establish, and make clear, its role in the radiation protection standards arena, that 1) it is making the necessary politic utilization and adjustment of the scientifically derived radiation protection data, as far as they go, 2) it is accepting the responsibility for clarifying the concept of nuclear safety, or relative safety, and 3) it is setting a level of radiation that is below regulatory concern.

ATTACHMENT II

In its more than 30 years of direct experience with the public and radiation protection, many points have come to the attention of the Health Physics Society that we believe should at least be thought about in considering the adoption of a BRC concept. Many of them are based on questions that are asked of our members, individually, or statements--and misstatements--that appear in the various news media. We are reasonably certain that you are already aware of most, if not all, of the items to follow but offer them, largely in outline, by way of emphasis. Some additional items are in amplification of statements in the preceding pages.

A. Examples. There is about a 70 mrem/year difference in the dose from external radiation one receives from natural sources, depending on whether one lives on the coastal plane or in the hilly areas in the West. (NCRP Report 93.) The higher exposure to radiation of people who live in the hills and mountains does not seem to make them less desirable to those who want to live there.

Average natural-background radiation levels vary by 100 millirem in a year. Studies have shown a generally lower cancer incidence rate at the higher background locations, thus indicating that a BRC below 100 mrem could be scientifically defensible.

The upper limits of risk that result from levels of exposure comparable to the variations in the natural background are well below the risks from commercial activities that are generally accepted as good neighbors in the communities in which they exist.

Normal living habits such as working on the 10th floor as compared with the 1st floor of a building, or living in Bethesda as compared with downtown Washington, add a few millirems per year to one's dose. So also does commercial flying, medical procedures and so on--none of which are normally considered in individual radiation exposure concerns.

Something is considered acceptably safe when extensive study and experiment demonstrate that one's individual chances of injury or accident are exceedingly small. It should be noted that nothing is absolutely safe, but that all activities and natural events have varying degrees of risk.

B. Data Limitations. In establishing personnel protection standards it is considered by some as scientifically and morally defensive to use the "linear-nonthreshold" approach into the low dose regions as a practical expedient, because it overestimates the dose effect. However, it was never intended that risk evaluation be made using this approach.

To postulate a large number of deaths from very low exposures (less than a single dose of 10 rems, or an annual dose of 1 rem in a year) to a very large population is fundamentally indefensible; it communicates a misconception in the minds of the laypublic and legislators/administrators.

One possible reason for the lack of low-dose-effect data for humans is that such effects may not exist. Another reason is the fact that very large exposed populations (millions of subjects) are required for statistically defensible studies that must extend over 25 to 50 years. Equally large unexposed, but otherwise control populations, are also required.

Estimated Population Size to Provide Statistically Meaningful Effects Values

DOSE	POPULATION SIZE
10 rad	50 thousand
1 rad	5 million
100 mrad	500 million
10 mrad	50 billion

C. Judgment in the absence of facts. Because the general public is not equipped by education and experience to evaluate complex technical matters, the government or some type of public body with suitable expertise must, 1) develop guidelines, excluding conditions outside the area of knowledge, 2) base any guides on facts as far as they exist, 3) clearly define conditions where they do not exist and, 4) apply professional judgment in lieu of facts when necessary, but make the action clear. In the application of judgment, the reasons and need for any action that is not amenable to quantitative evaluation must be explained.

D. Possible objections. It is quite possible that some individuals or groups will bring charges of vested interests on the part of the Health Physics Society because of this submission. Such a claim is the opposite of common sense since the personal interests of health physicists would appear to be better served by more severe rather than apparently less stringent radiation protection regulations.

It can be foreseen that objections may be raised to the implementation of the BRC concept because of the frequently stated misconception that we "know nothing about the effects of low levels of exposure." Objections may also be raised on grounds that "there is no such thing as a safe dose of radiation." Both points are discussed in Attachment I.