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NUCLEAR REGULATORY COMMISSION

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BRIEFING ON POLICY STATEMENT ON RULES FOR EXEMPTION FROM REGULATORY CONTROL

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Tuesday, July 11, 1989

The Commission met in open session, pursuant to notice, at 1:30 p.m., Kenneth M. Carr, Chairman, presiding.

COMMISSIONERS PRESENT:

KENNETH M. CARR, Chairman of the Commission
THOMAS M. ROBERTS, Commissioner
KENNETH C. ROGERS, Commissioner
JAMES R. CURTISS, Commissioner

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

FRANK CONGEL, NRR

ROBERT BERNERO, NMSS

JAMES TAYLOR, Deputy Executive Director for Operations

THEMIS SPEIS, RES

WILLIAM MORRIS, RES

BILL LAHS, RES

P-R-O-C-E-E-D-I-N-G-S

1:33 p.m.

CHAIRMAN CARR: Good afternoon, ladies and gentlemen.

The purpose of today's meeting is for the NRC staff to brief the Commission on the revised policy statement on exemptions from regulatory control, which is the subject of SECY-89-184.

The staff has revised the policy statement based on information gained from an international workshop on exemption for regulatory control held in October 1988. Public comments on an advanced notice of the proposed policy statement issued in December '88 and a public meeting held in January 1989.

Copies of the presentation slides should be available at the entrance to the meeting room.

Do my fellow Commissioners have any opening comment? If not, you may proceed, Mr. Taylor.

MR. TAYLOR: Good afternoon, Mr. Chairman.

The policy statement discussed today can have a significant and positive impact on the way the resources of both licensees and the agency are used. Specifically the staff believes that the policy establishes a basis for assuring that these limited resources are not directed toward elimination of small

risks from low levels of radioactivity when they could be better spent in reducing risks for larger quantities of material, of radioactive material, or in otherwise enhancing public health and safety.

There's been significant public interest in the proposed policy and a range of views on what the policy should say in its specific elements. This is demonstrated by the large number of comments you will hear about today and the diversity of views expressed by the commentors. There have been numbers of letters from state and county officials and from Congressmen relaying questions or concerns from constituents.

With that introduction, I'll now turn it over to Dr. Speis to commence the detailed briefing.

DR. SPEIS: Thank you, Mr. Chairman, Commissioners.

Before I turn it over to Billy Morris who will do the main part of the presentation, I would like to say that the challenge to us has been to assess this divergent views discussed by Mr. Taylor, taking into account the relevant technical information and develop a policy which achieves the resource utilization goal mentioned earlier but also assures that the health and safety of the public is protected.

The staff has now proposed resolutions to

the significant issues related to this policy statement in the Commission paper SECY-89-184, which is in front of you for your consideration, of course.

The presentation today will provide an opportunity to focus on these issues; issues such as whether justification of practice and a collective dose criteria should be part of the policy, and the different views of EPA on some key elements of the policy such as the individual dose criteria.

As I said already, Billy Morris of the Office of Resource will make the presentation. He will be assisted by Bill Lahs, sitting next to him. He has been the task leader for the policy development.

Also we have with us Don Cool sitting back here, who has recently been appointed as Chief of the Radiation Protection and Health Effects Branch and he will also be available to answer some of your questions.

I would also like to recognize others who have played a significant role in the development of this policy from the other offices, especially Mr. Bernero from NMSS and Frank Congel from the Office of NRR. And also sitting back here Dick Cunningham from the Office of NMSS.

I will now turn the presentation over to Billy Morris, Mr. Chairman.

MR. MORRIS: During the presentation this afternoon I will be generally following the outline shown on the first page of the handout. We'll briefly summarize the activities which culminated in issuance of the advanced notice of policy development last December and the more recent milestones which led to the staff's recent proposal for a revised policy.

I will only briefly review the objective of the policy statement and examples of practices for which we believe the policy can be applied, but then discuss in some more detail the basis for the staff's recommendation on the major policy elements and additional factors the Commission should be aware of as it considers how it wishes to proceed.

The second page of the handout shows the pertinent chronology of events which have led us to where we stand today. In November of 1987 the staff was asked to initiate development of a proposed policy statement which would identify a risk level below which government regulation becomes unwarranted. In SECY 88-69 and during the related Commission meeting on that paper, various concepts and approaches and the relevant issues involved in developing such a policy

were discussed. The concept of risks which are below regulatory concern was discussed in the context of establishing a floor to the ALARA process and was proposed as being potentially different from the concepts of de minimis or negligible risks.

Staff plans for organizing an international symposium or workshop to be attended by national and international regulatory authorities on this subject were also presented at that time.

Following that meeting the Commission asked for the development of a proposed policy to be acted on by the Commission prior to the international meeting. This was provided in SECY paper 88-257 in which a policy was proposed which relied on adherence to basic radiation protection principles in evaluating exemption proposals and suggested compliance with certain dose criteria as a basis for cutting off the ALARA process. The Commission modified that paper and that policy statement and recommended that comment be sought on certain major policy provisions that were of significant interest to the Commission. They directed the issuance of an advanced notice, which was then published on December 12, 1988.

Going on to page three, and with this background in mind, I'll briefly note that then the

purpose of today's presentation is to discuss the policy statement as it has been revised based on the information from the international workshop, public comments received between December of 1988 and April 1989, proposed policy. And finally, on the public meeting held in January of this year.

On page 4 we just briefly note that the objective of the policy statement is to establish guidelines and criteria for development of regulations or licensing decisions which could exempt practices from some or all regulatory controls. Such guidance, when available, would led to a more efficient and consistent decision making process related to these exemption proposals.

Some specific examples of how the policy could be applied are indicated on page 5 of the handout. These include application to practices such as disposal of very low level radioactive waste; release of lands and structure with small residual levels of radioactivity; distribution of consumer products containing small amounts of radioactive material; recycle and reuse of residually contaminated materials and equipment.

Now, there are various ways that either rulemaking or licensing decisions could be initiated.

With regard to the first of these items on this page, we do expect petitions from the industry for rulemaking under the Commission policy for disposal of the below regulatory concern waste streams which implements the Low Level Radioactive Waste Policy Amendments Act of 1985.

Alternately, there may be applications for license amendments or the action that could be involved could be a decision of the Commission or something that the staff would initiate and propose to the Commission. I want to just mention that in each of these cases the focus of the regulatory decision would be on an exemption of a practice from some or all regulatory controls. And just because we'll be using the word time and again during this presentation, let me mention that "practice" is defined in the policy statement as an activity or a set or combination of a number of similar sets of coordinated and continuing activities aimed at a given purpose which involve the potential for radiation exposure. That rather involved definition is one that we found useful. It is essentially from the IAEA Safety Guide No. 89.

With this objective and these potential applications in mind, let me now mention, on page six

now, the actions the staff has taken to use the information from the international workshop, the public meeting and the public comments on the proposed policy. We were able to categorize the information we had collected into 18 subject areas or issues where we felt either we would need to be resolving or an issue or where we would need to communicate better to the public what the intent of the policy was. We then revised the policy statement in key areas or clarified Commission positions in other areas. These were either included in the revised policy itself or was put into the responses to public comments and which then were transmitted to the Commission SECY paper 89-184.

Some of these issues were more important than others. And what I hope to accomplish in the remainder of this presentation is to focus on the key issues for which Commission decisions would be most crucial. In the *Federal Register* notice, which was issued on December 12 of last year, there were several major policy elements in which comments were sought. These are summarized on page 7 of the handout.

One question was how should fundamental principles of radiation protection be applied in establishing an exemption policy? Specifically, what

role should justification of practice, dose limits and ALARA play in such a policy.

Another question raised by the Commission related to the use of the collective dose criterion in establishing a floor to ALARA or a level of risk below which further efforts to reduce doses would be unwarranted. The question then is whether a collective dose criterion is needed.

Finally, among the major issues was that associated with the potential that exposures to multiple practices could result in receiving cumulative doses near the public dose limit even though each contribution would be only a small fraction of that limit. That is, how should cumulative effects from multiple practices be dealt with?

Now, on page eight of the handout we've provided a diagram which we find useful in reflecting on the policy statement and its various elements. I'll be continuing the discussion today along the lines indicated in subsequent pages of the handout, but you've been provided an extra copy so you won't have to flip back and forth between the handout and that figure.

Let me first call your attention to the

title of the figure, which indicates that it applies to justified practices. This brings up one of the major policy issues which we discussed earlier on page nine of the handout, which we discussed earlier and which is a lot more thoroughly discussed on page nine now.

The staff is proposing that justification of practice is a needed element of the current policy. This would continue the precedent established by the Commission's 1965 policy on consumer products. The point we're making here is that no practice involving potential for exposure of the public to ionizing radiation from radioactive material should be permitted without a policy judgment by the Commission that there is a commensurate net benefit to society which would result from that exposure.

COMMISSIONER ROBERTS: That's a terrible subjective standard.

MR. MORRIS: There are a number, as we noted in the policy statement and in the response to comments. This an area where a broad range of factors can be considered by the Commission in making such policy judgments. But it is one that, as policy makers, we're recommending that you face up to. And we don't place limits here on what any of you might

wish to consider, but it does seem to us that you should be looking for some benefit in your minds that would justify this release of radioactive --

COMMISSIONER ROBERTS: Well, what's a benefit to me is not necessarily a benefit to somebody else.

I don't play golf, but if I did, maybe I'd want those funny little balls that you can find in the high weeds. It would be of no benefit to me whatsoever, but some other person might think it was a great benefit.

MR. TAYLOR: I believe the staff's intent that this is probably the best body to make that type of determination in examining the various practices in order to address the problem.

MR. BERNERO: And we have had in the regulatory arena on the issue of gemstones an example where there's kind of a sitergitism at a very low level of radiation, it is possible to justify a cosmetic benefit as a justifiable practice. And the issue in gemstones is you can get gemstone activity so low as to be almost off scale on this chart here and then say, "Well, is it a reasonable justification of practice that it's simply an ornament?" So that's possible. But if those golf balls, if they've, let's

say, a radioactively traced golf ball had a more significant dose associated with it or dose rate, then we'd have to say is that modest benefit? Can that be obtained some other way? Is it justified to put more radioactive material into the biosphere for that purpose? And that's part of that 1965 policy and it's continuing.

CHAIRMAN CARR: But you're at the point where you're regulating a voluntary practice.

COMMISSIONER ROBERTS: Regulating people's choices.

MR. BERNERO: Yes. Yes, indeed.

CHAIRMAN CARR: And if we could apply the same thing to tobacco, we'd have it made, right?

COMMISSIONER ROBERTS: To what?

MR. TAYLOR: Fortunately, that's not under our jurisdiction.

MR. BERNERO: No. But we have from time-to-time applications for what some would call frivolous uses, you know, luminous fishing lures, the necktie that glows in the dark, that sort of thing. And the doll's eyeballs, another example that glow, that light up.

We do justify the use of radioactive material in exit signs under general license. But

there are other things, the radioactive fishing lure, we do not justify. We don't consider that a sufficient justification for that distribution of radioactive material.

The gemstones being only cosmetic in their benefit, are justified because of the extremely low level of radiation. In fact, that's basically the quality assurance we provide on it, that they're down so low a radiation --

COMMISSIONER ROGERS: Why do you have to do anything more than that?

CHAIRMAN CARR: If you determine that it's truly below regulatory concern, then you shouldn't have to justify it at all.

MR. BERNERO: No. But there's a difference. The gemstones aren't just at 10 mrem per year. They're way below that.

CHAIRMAN CARR: Oh, no. I know that.

MR. BERNERO: Way below that. There you're really arguing more a de minimis that it's virtually none radioactive.

COMMISSIONER ROGERS: Why do you have to really introduce anything except a health and safety consideration?

MR. BERNERO: Other than the justification

of practice. I mean, that is the issue. Should radiation --

COMMISSIONER ROGERS: Well, the thing I have a lot of trouble with is this social benefit. Who is going to judge a social benefit?

MR. BERNERO: Absolutely.

COMMISSIONER ROGERS: And what's my concept of a social benefit might be somebody else's concept of a social disease. And I think that it is subjective, it's cultural.

MR. BERNERO: It is.

COMMISSIONER ROGERS: It's not absolute and I don't see why we have to interject this into the process if we can properly pay attention to the health and safety aspects.

MR. BERNERO: Okay. But you see, we're dealing with radiation exposure, which by definition, we consider harmful and under the linear hypothesis we consider it harmful even down into undetectable levels. And we say it is ALARA, it is as low as reasonably achievable considering the radiation exposure, which is a cost, and the benefit of the practice, whatever it is. Whether it be a gemstone or it be a nuclear power plant or x-ray --

COMMISSIONER ROGERS: But we can't avoid

radiation. We're being exposed right here as we sit here. We know that.

MR. BERNERO: Certainly we know that.

COMMISSIONER ROGERS: And, you know, there's going to be a certain arbitrariness in this whole business as your whole policy statement illustrates. You can't really be sure, so you have a couple of different criteria that you're going to apply. And interjecting a social benefit, to me, is a very questionable kind of area for us to get into.

I can see strong concern for any kind of health and safety question. We're jumping the gun, but I can see questions about toys and cosmetics and things of that sort, things you ingest or rub on your skin. But once you put into the hands of a collection of people such as us who have no special claim to distinction in this business a judgment of social benefit, I think we're out of our depth, frankly. And I can see a strong concern for health and safety. I see absolutely no justification for adding on to this a layer a judgment of social benefit.

MR. TAYLOR: That may be an element that the Commission directs the staff to revise. It still doesn't negate the attempt of the staff to set what is attempted --

CHAIRMAN CARR: It's one of those policy issues, that's right.

MR. BERNERO: It is a major policy issue.

CHAIRMAN CARR: Okay, then let's proceed.

MR. MORRIS: What we have mentioned here would be that what a decision by the Commission to do something different than the earlier precedents would be a significant one. And I would call to the attention --

COMMISSIONER ROBERTS: But that's why we're here.

MR. MORRIS: -- the 1965 policy statement and the fact that --

COMMISSIONER ROBERTS: I don't want to hear about the 1965 policy statement. This is 1989.

MR. MORRIS: Understood, sir. But it still is there and it may be that you would want to look at that statement again and decide whether it was something you wanted to change or not because it does have embodied within it this concept of justification of practice, even for very low risks for certain kinds of uses. And that's the reason we have called it to your attention here.

MR. LAHS: Well, but you may point out also that in the Presidential guidance that is on the books

right now and also the Presidential guidance which is being proposed for the public also has justification of practice principle embodied within it.

COMMISSIONER ROGERS: Well, you can justification of practice without necessarily basing that on a social benefit.

MR. LAHS: But didn't you raise before in your mind you said well there would be certain things that you would -- in toys. You just made that decision right there.

COMMISSIONER ROGERS: Sure.

MR. LAHS: And that's what we're saying we should continue to do.

COMMISSIONER ROGERS: But I would make it on the basis of we don't know enough to be able to ensure that there isn't a negative health effect. Not because it has some other abstract benefit. If you can connect it to health and safety, then I'm happy. If you can't, I'm not very happy.

CHAIRMAN CARR: Some of those policy things we have to look at. Let's proceed.

MR. MORRIS: The next issue on page 10 is whether a collective dose criterion should be included in the policy and be coupled with an individual dose criterion as a pair of criteria to define a floor to

the ALARA process. Referring back to the figure, what we now propose in the policy is a 500 person-rem per year per practice of value for this purpose. We believe that such a criterion is important and should be included for several reasons.

The collective dose has been commonly used by regulatory bodies, including the NRC, as a measure of societal detriment in ALARA or optimum assessments.

CHAIRMAN CARR: Is it really a measure of societal detriment or has it not been what I would call a safety factor, a fudge factor? We don't know what might happen, so let's pick a number and hope that's it.

MR. MORRIS: No, I think it has been the former, rather than the latter.

CHAIRMAN CARR: What if I had 510 or 490?

MR. MORRIS: Yes. Understood that what we're talking about in this policy statement are criteria to assist us in judging exemption proposals. They are not limits. And if a proposal came in and the analyses said, well the collective dose is 510, or any number above this criterion, doesn't mean that the proposal would be denied. It would simply mean that you would look at whether there are ways to practically reduce that dose in a cost effective

manner. And if you found out there were none, this policy would not prohibit the exemption being granted on that basis.

And what it does do is, you know, if you look -- well, referring back to the 1965 policy statement and to the 1986 policy statement. Each of those policy statements refers to an assessment of collective dose as a factor in the assessment. And neither one of them, however, gives any criteria for what is a small enough collective dose that you need not bother with further efforts to reduce these doses any lower. And so, what the criterion would do would be to afford a method to truncate that ALARA process. And that's the way we envision it being used, too.

CHAIRMAN CARR: When you add this in, it means that nothing is below regulatory concern because you have to look at everything.

MR. MORRIS: Well, we believe you should look at everything that you're considering exempting anyway.

CHAIRMAN CARR: But then the term "below regulatory concern" means nothing.

MR. MORRIS: Well, we are in this policy statement somewhat diminishing the use of the term "below regulatory concern" because --

CHAIRMAN CARR: But that doesn't seem to be what we asked you to do, though.

MR. LAHS: It's really creating the basis for when we can allow radioactive material to be transferred from control, from control of our licensees to someplace where it is not under our control of our licensees. Isn't that what we're doing? I mean, the consumer products for low level waste disposal in other than licensed sites when we release a facility that's been contaminated, you know, which has some residual contamination on the walls. We're eventually going to terminate the license and walk away from it. We're trying to set up the criterion of which you're going to make those types of judgments. Remember that the --

CHAIRMAN CARR: That's what you're trying to do.

MR. LAHS: Yes.

CHAIRMAN CARR: But what I'm trying to do is to find some level of radioactivity that I'm not going to worry about.

MR. LAHS: Well, that's what we discussed with you, you know, as Bill mentioned in the earlier discussions we've had. And that's why --

CHAIRMAN CARR: Yes.

MR. LAHS: -- he was saying in a way you're looking --

CHAIRMAN CARR: We're still looking for that.

MR. LAHS: -- you're grasping for the de minimis or negligible risk. And when we went into this, if we tried to go that way, I think we'd fight a lot of battles, but I think you'd find out we'd be talking about negligible risk which would involve individual doses that are in the micro-rem range. I mean, we'd be -- EPA, FDA talk about negligible risks as being ten to the minus 6, lifetime risk. Whether you agree with that or not, if you think that-- because a lot of people, including myself, feel that number is too small. And when you translate that back into individual doses, you're talking about small numbers, not 10 mrem.

COMMISSIONER ROGERS: Well, I understand what you're trying to do and I'm somewhat sympathetic to it. But the problem I have with the collective dose is how you really determine it, because how far do you trace these things out into possible eventualities before you give up? And the multiple paths, the -- all these questions. It seemed to me that it leads you into something that you really can't

be awfully sure about in every case. Maybe in some you can, so that it might be a useful number guide in some situations. And in others, almost hopeless to verify.

MR. LAHS: That's probably true. I mean, a lot of what you are saying is true. What we're trying to do on this collective dose criterion, as we brought out I think in your comments the last time we put the policy to you, is really to develop that criteria which really separates practices into two major categories. One, those practices such as walking away from facilities with residual contamination or low level waste disposal and specific sanitary land fills, for example, as opposed to those practices where you'd be talking about widespread distribution of radioactivity to large numbers of people. Consumer products. If we ever get into things like recycle of contaminated materials or equipments.

So from what I've seen, a number in the range of 500, a 1000, you know, you can vary that number up high probably in order of magnitude. You're really -- what you're doing is really creating a found which really applies to the practices involving widespread distribution of radioactivity. And for the low level waste disposal and for terminating the

licenses on contaminated facilities you're going to find you're talking about collective doses that are, you know, less than 10 person-rem per year per package.

MR. MORRIS: With regard to the concept that you're discussing here, we had looked at in the previous version of this the idea of setting up some criterion in the policy for truncating the calculation of collective dose. That's the issue. How far out do you go, how long in time do you calculate, how small a dose do you chase in time to do these very elaborate calculations. And we believe that later on in the implementation phase of the policy we would want to go back to that issue. But at this time -- which would ultimately be one of what's practical to do, what's possible to do in practical terms that would allow us to distinguish between alternatives or make resource optimization calculations.

At this stage of the policy development, we think we have focused on the major policy issues; whether you should have a criterion in mind as you go forward. And really not --

COMMISSIONER ROGERS: Well, I'll tell you what we're trying to do is map out some kind of a boundary that --

MR. TAYLOR: That is correct.

COMMISSIONER ROGERS: -- gives us a guide as to where to look very hard and where not to look so very hard.

MR. TAYLOR: If you can't show it as being within that boundary, then it lies outside. I mean, you have to have sufficient information to establish that it falls within that former --

COMMISSIONER ROGERS: These are really aids, in a sense, to --

MR. TAYLOR: That's correct.

COMMISSIONER ROGERS: -- in administering the policy and not absolute measures in their own right?

MR. TAYLOR: If there's not a reasonable basis to show that, then it would not fall within the exempt category, right, Bill?

MR. MORRIS: Yes. Now, what we're saying is that if you --

CHAIRMAN CARR: But nothing is.

MR. MORRIS: -- cannot fall within this box here, that you would then simply do a more elaborate calculation.

CHAIRMAN CARR: Right. Nothing is going to just fall within the exempt category. We're going to

have to look at everything.

MR. MORRIS: Yes.

CHAIRMAN CARR: And it's all going to be a case basis. So there is nothing that is BRC.

MR. MORRIS: I believe that's one of the reasons we felt that it might be appropriate not to focus on that term in this policy. And it gives a signal to the public that there would be -- you know, that for instance, licensees would be making these decisions.

CHAIRMAN CARR: But I personally think that's the wrong signal and that I happen to be one of those guys that don't necessarily believe that a little radiation is harmful because I live in it. I go outside. I wouldn't hesitate a minute to move to Denver and you would argue that I really ought to consider that.

MR. MORRIS: No. What we're saying is that a little more -- every time you add a bit more radiation to the environment and you keep on doing that, then eventually what you could add up to is something that is comparable to the radiation background we live in. Double it or comparable to it so you have an extra element.

CHAIRMAN CARR: But background, as I

understand, varies somewhat --

MR. MORRIS: Yes, it does.

CHAIRMAN CARR: -- doubled for certain parts of the world. And if I fly in the Concord all the time instead of a Cessna, why I'd probably get more radiation. But I don't want to alarm the public that they should always not ever fly the Concord. I don't think that's the message I want to send.

MR. MORRIS: We do not either.

CHAIRMAN CARR: No matter how small it is, any increment of radiation is bad for you.

MR. LAHS: Well, what you're really challenging, and certainly a lot of people do, is challenging the low threshold hypothesis.

CHAIRMAN CARR: Well, it considerably rates being challenged because nobody's brought any data out to prove it's otherwise.

MR. LAHS: That's right. That's right. So it's either way.

CHAIRMAN CARR: So you can really defend the argument that you ought to use it just per se.

MR. MORRIS: But neither can you dismiss it easily either just because --

CHAIRMAN CARR: I wouldn't dismiss it easily, but I might dismiss it.

MR. LAHS: We've been asked that question a number of times and I think I would be willing to lay a wager, I don't know if I'd win it, but I believe if you looked at most of the people that deal in evaluating the possible cancer from radiation exposure, even chemicals for that matter, I think you're going to find the vast majority of people believe there's more support for the no-threshold hypothesis than there is against it.

CHAIRMAN CARR: But not measurable.

MR. LAHS: Pardon me.

CHAIRMAN CARR: Not measurably. They admit they aren't going to be able to determine that they can measure the additional numbers of cancers.

MR. LAHS: Yes, that's correct. But, I mean, if I'm going to add ten mrem or 20 mrem on to what you're getting now, say 300 mrem, am I really assured? If we believe that that little delta can lead to an increased probability of someone getting cancer, shouldn't we be concerned about that?

CHAIRMAN CARR: That's why you're here. I don't -- it's a policy statement.

Let's proceed. Yes, sir?

MR. MORRIS: Well, along this same line, we do want to point out additional factors that are in

our minds as we propose this to you. Other agencies have used the concept of collective doses, some other measure of societal detriment -- the criterion of collective doses included in the recent international guidance, which I mentioned earlier, which addresses this subject of exemptions, that's IAEA Safety Guide No. 89, which uses 100 person-rem.

Furthermore, the use of the collective dose criterion provides added assurance that the public dose limits of 100 person-rem -- mrem will not be exceeded because of the exposures to --

CHAIRMAN CARR: How does it do that? I couldn't figure out a way to do that.

MR. MORRIS: For instance, if you took the case of how many people would be exposed to 10 mrem at -- if we used the 500 person-rem criterion as opposed to no criterion. If you use no criterion, the entire U.S. population could be exposed to a level of 10 mrem for any given practice we might exempt.

If you use something like 500 person-rem, or maybe some other -- maybe larger number, you would be making a limitation of the number of people that would get an exposure near that level.

In the case of 500 person --

CHAIRMAN CARR: How would you limit? Where

would you use that? How do you --

MR. MORRIS: It would just be --

CHAIRMAN CARR: You'd say, "Okay, you can't put 10 in that practice?"

MR. MORRIS: When you assess the collective dose, you would determine whether or not you were within or without the box on the figure. And --

CHAIRMAN CARR: But that's only for one practice?

MR. MORRIS: Yes.

CHAIRMAN CARR: Now, how does that assure me that I won't be exposed to more than one practice and get over that number? I don't understand the added assurance.

MR. MORRIS: The likelihood of being exposed to more than -- to be exposed to more than one practice in sufficient number of practices at or near the 10 mrem level is certainly truncated or limited by the collective dose figure. As I said, 50,000 people would be the total number that would be exposed for a given practice. 50,000 is a small fraction of the total population of the country.

CHAIRMAN CARR: So you wouldn't approve it if more than 50,000 were going to get that -- see something that's a --

MR. MORRIS: But at least you're taking the step of looking at the -- doing the cross benefit calculation to determine whether you could reduce that dose effectively somewhat, to a somewhat lower value.

CHAIRMAN CARR: So do I know have to say, examine that same 50,000 people for the next practice to make sure?

MR. MORRIS: One of the things -- we could not go that far, but we could --

CHAIRMAN CARR: Really this doesn't make sense to me that it adds assurance because the dose limit is really the assurance.

MR. MORRIS: I think it has to do --

CHAIRMAN CARR: You're just multiplying dose limit times the number of people that might happen to get exposed to it.

MR. MORRIS: But by doing that, what we're doing is saying that the probability of being exposed to multiple practice is somehow related and it isn't a tight relationship, there's no formula that I can provide to you. It's somehow related to the collective dose criterion and the maximum number of people exposed.

CHAIRMAN CARR: It's that somehow I'm trying to get to the bottom of.

MR. MORRIS: It is a qualitative judgment based on the likelihood of being exposed to multiple practices, add-on year, a number such as 10 mrem.

CHAIRMAN CARR: Let's proceed. You're not going to solve my problem.

MR. MORRIS: And we had to make the point earlier and in the paper that the collective dose criterion does seem to us to be indicated because the individual dose criterion in the policy is not claimed to be a de minimis or negligible risk level. 10 mrem is a value chosen on the basis of resource utilization rather than a statement that it's a trivial dose to tolerate. And so that is an added feature, in our thinking, that would -- that has persuaded us to propose to you the collective dose criterion.

Let me go on. On page 11, we discuss a third major policy element, the issue of multiple exposures, which we were just talking about a moment ago, of course. Referring back to the figure, yes, I agree, the likelihood or the possibility of being exposed to multiple practices to the extent that you could get a total cumulative dose up near the dose limit at 100 mrem is somewhat -- is certainly dependent on what the maximum individual exposure is. And in addition, we note that in the policy we state

that in defining practice we will be doing this in a broad sense, which will avoid what is called fractionation of practice. And this way the number of potential exemption decisions will be limited so we would not have a proliferation of practices of a similar nature, but rather they would be lumped together in an assessment under the policy. It just cuts down the number of practices.

COMMISSIONER ROGERS: Just in a practical way, how would you do that, though, if a practice is examined and just barely meets both your criteria of the 10 mrem and 500 person-rem? And then a few years later somebody else comes along and wants to do the same thing. What do you tell them? You can't do it because we're saturated?

MR. MORRIS: Well, we're not setting any hard criteria on how you would do that.

COMMISSIONER ROGERS: How would you envision dealing with that situation?

MR. MORRIS: What we have said that we would do in the policy is we had to continue. Every time a new submittal or a new proposal for exemption comes in, we need to look at this issue of whether we believe there are similar practices which could involve or impact on the same set of people in a way

that they would be cumulative doses built up. And we'll have to do that on a case-by-case basis, as we examine exemption proposals case-by-case.

When we have the opportunity to look at a cluster of similar activities so that we can put them, you know, consider them as a single practice, we would take advantage of that. In looking at waste streams from reactors, I believe, we're going to take a hard look at how that would be considered to be a single practice or whether there would be potential fractionation of practice.

COMMISSIONER CARR: Well, I read fractionization as not permitting the guy to dilute the stream so he can meet the criteria.

MR. MORRIS: Yes.

MR. LAHS: The other example, that would be in waste streams -- for example, you could talk about disposable dry active waste from a reactor as one waste stream. And then you could consider another waste steam as being contaminated sand or, you know, you could come up with three or four waste streams from a power plant in the submission. The submission we'll be getting, I believe, from NUMARC had to do with waste streams from power plants. That's going to be considered a single practice. In other words, all

waste streams, all waste coming out of power plants will be treated as a practice.

CHAIRMAN CARR: But it seems the objective in the whole thing is to find something that we don't have to look at. You're still having to look at everything.

MR. LAHS: Well, I guess that's correct. If you say that you have to look at it to determine, you know, if you're going to establish a level below which you're going to allow this material to go to a sanitary landfill, certainly you have to look at it hard enough to define what that level is.

CHAIRMAN CARR: Yes, that's what I'm trying to do.

MR. BERNERO: But that's exactly it. If it's atomic energy --

CHAIRMAN CARR: I only want to look at it once.

MR. BERNERO: But if it's Atomic Energy Act, radioactivity, you have to look at it once. Now, it may be demonstratively exemptible. It may be in that one look it's demonstrably well below 10 mrem per year individual, 500 person-rem --

CHAIRMAN CARR: I'd want to generically then say --

MR. BERNERO: And you say, yes, but you looked at it.

CHAIRMAN CARR: -- is it within that box, fine.

MR. BERNERO: But you looked at it, sir.

CHAIRMAN CARR: I only looked at one case. I didn't look at every case.

MR. MORRIS: I think the way this would be implemented would be that would happen would be in using these criteria the staff would, based on proposals from the licensees or others, would go through rulemaking and during the rulemaking they would establish detailed exemption criteria based on these broad policy criteria that would be in the policy.

For instance, a set of volumetric or surface contamination levels for different isotopes could be established as the basis for decommissioning a structure, a soil. And having done that, that would be done one time, those concentrations would be placed in the regulations for a category of practices or a practice, and would then allow the licensee to proceed to clean up that site to the point that he reached those levels. And then all that would be left would be the record keeping or the things he would have to

do to demonstrate that he had complied with that.

So I believe your objective would be met by the way we envision implementing the policy by establishing those -- that's a second tier criterion. It would be established based on the risk levels that would come from the policy. Those specific contamination levels would be determined as levels which would demonstrate that the risk objective of the policy statement had been met. And that will be the way you would --

CHAIRMAN CARR: Then I guess what I don't understand is why we need a two step process. If we can do that, why don't we just do it now?

MR. MORRIS: Well, we could. At one time when we spoke to the Commission about this policy, one option that was available and still would be available, would be to do those rulemakings on a case-by-case basis. What the policy would provide would be a consistency so that for, say, if we compared a decommissioning rulemaking step to one involving distribution of recycled material or to one involving low level waste streams, the same risk criterion or the same how you determine the low regulatory concern criteria of 10 mrem or 500 person collective dose would be applied to each of those exemption decisions.

So this would be guidance that the staff would then use to go and develop the rulemaking decision.

It could be done without the intermediate step of making the policy decision. But I think the policy decision would provide very useful guidance on how both the proposers of these exemptions and the staff would deal with this. And it would lay out the risk framework for how this could be done.

CHAIRMAN CARR: Okay. Let's proceed.

MR. MORRIS: Okay. Going on to page 12, we're not proposing a change in the individual dose criterion that was recommended earlier in the previous policy statement, which would be 10 mrem annual individual dose. There were, however, comments favorable to both higher and lower values, including EPA's comment that this value is too high as a generic criterion. However, as we point out in the policy, based on two prospectives, that is that most individuals would not spend resources to avoid the risk associated with this dose level and, furthermore, it's comparability with variations in background radiation, which were tolerated by most people without concern, we believe this value should be retained.

Similarly, the policy still provides, as I mentioned earlier, for the possibility of Commission

consideration of exemptions and practices in which the numeric criteria are exceeded. This policy is indicated on the figure in the cross hatched area as being possibly exemptible. However, in clarifying this point in the revised policy, we've emphasized that exemptions for such practices would be relatively rare and we would look at them fairly carefully before granting them.

The Commission paper indicated that this is still a point of some concern with EPA, the issue of whether or not these criteria should be thought of as limits or whether we should allow exemptions in the range in the cross hatched area. And we believe this has been somewhat alleviated by the clarification I just mentioned.

I would point out also that the Advisory Committee on Nuclear Waste has suggested establishment of variable what they call limits on individual and collective dose or any exemption. In that case what they would propose would be a kind of a sliding scale in which the collective dose that would be in the criterion would be variable with the individual dose. But they would view that line that they would draw, which would not be a simple square but a more complex curve, as a limiting line. However, we are

recommending that flexibility be retained in the policy.

Turning now to page 13, we indicate four areas where we felt some clarification would be useful in better communicating the intent of the policy. Some comments which were opposed to the exemption policy believe the Commission was giving cart blanche to the licensees to implement the exemption policy. However, many nuclear utility comments fully recognized that monitoring, record keeping on their part, and perhaps inspections occasionally by the NRC, would be necessary parts of the process of assuring that radioactive material will be transferred from a controlled to an uncontrolled state in a proper way.

The policy now emphasized that there would be some kinds of conditions associated with exemption decisions with which licensees would have to comply. An example of that would be the surface contamination levels of the volumetric contamination levels that would be examined as material went out of a site.

A second point is that the intent of the policy is to make it clear that the numerical criteria for curtailing incremental class with ALARA are not limits. I've already discussed that. I won't refer to it any further.

Third point is to emphasize the importance placed, again, on defining what constitutes a practice. By defining practices broadly, the multiple exposure is addressed by reducing the number of practices for which exemptions would be considered.

And finally, as I mentioned earlier, we are suggesting that the reference to the term below regulatory concern be reserved for the possibilities of waste disposals under the Low Level Radioactive Waste Policy Amendments Act of 1985 and suggesting by that that applying that term, BRC, to a policy proposed for a spectrum of possible exemptions has caused some confusion among commentors.

On page 14, I just want to point out --

COMMISSIONER ROBERTS: Well, wait a minute. Back up.

MR. MORRIS: Yes, sir.

COMMISSIONER ROBERTS: I think you short changed the last bullet.

MR. MORRIS: Page 13.

COMMISSIONER ROBERTS: How does that square I'm reading from the SECY paper, 88-69 of March 8, page 3, second paragraph. Current NRC regulations includes several instances of implied or defacto BRC levels although they are seldom referenced to as such.

Then there's an enclosure which lists these implied or defacto BRC levels, which include things other than waste disposals under what you cite. Now, is there--

MR. LAHS: That's right. At that time my decision, which probably was wrong at the time, we tried to use a terminology that was used in the Low Level Radioactive Waste Policy Amendments Act, which was pointing toward waste disposal practice. And there they talk about waste streams that were below regulatory concern. And so, in trying to carry that concept over into this exemption policy at that time that that Commission paper was written, we used that term. We talked about exemptions from regulatory control. I think we said for practices whose health and safety significance were below regulatory concern.

Looking back on that, that was a big mistake on my part.

CHAIRMAN CARR: I thought it was a good use.

MR. LAHS: Is that right?

COMMISSIONER ROBERTS: I did, too.

MR. LAHS: The commentors we got -- many commentors felt this policy was only directed toward waste disposals. And it got very confusing in many people's mind that this -- why this policy was different than the Commission's '86 policy. And so we

were always explaining to people, "No, this is broader in context and we're not just talking about the possibility of waste stream as going to other than the licensed sites, but the other exemption decision which could be involved in radioactive material going from a controlled to an uncontrolled status.

COMMISSIONER ROBERTS: All right.

MR. LAHS: So, yes, we've gone full circle on that and it's --

MR. MORRIS: This is really a matter of communications. It's not a real health and safety issue here. It's just a matter of better communicating to the public is the reason for our recommendation.

Back to page 14, there's some other issues we want to just focus on for a moment. There were views expressed by EPA and the Advisory Committee on Nuclear Waste and which we infer on the international level which are different from those that have been expressed by the staff regarding the magnitudes of the exemption of those criteria. The Commission should be aware of those differences.

The EPA, at least in their comments, documented a date, considers the value of 10 mrem too high as an individual dose criterion. In the IAEA

Safety Guide No. 89, this criterion is proposed as few mrem. And, as I mentioned before, the collective dose criterion is proposed 100 person-rem. Although I do recall that at the international workshop there was some support for higher values, specifically the Canadian representative noted their values as higher.

We believe that in the absence of any technical basis for alternate values in the absence of either federal guidance or specific EPA exemption criteria and their regulations, it's the Commission's for making prerogative to select criteria such as those we've recommended. As was discussed earlier for the ACNW, the individual and collective dose criteria would follow a more complex relationship than that proposed by the staff.

Furthermore, compounding this issue -- this situation regarding the individual dose criteria, over the years EPA has proposed or developed several standards which place numerical dose, and I'll use the word now, limits on various exposure pathways or sources of radiation. These include low level waste, drinking water standard, the fuel cycle standard, and most recently EPA has proposed Clean Air Act national emission standards for hazardous air pollutants involving regulation of radio neutrons. These

standards provide dose criteria, perhaps is a better word, in the range from four to 25 mrem per year, which are viewed by many as establishing a bright red line boundary between acceptable and unacceptable dose levels.

We believe in our thinking that a more appropriate candidate for this hard boundary would be the 100 mrem dose limit for members of the public proposed in 10 CFR 20 which is shown on the figure here. The former view, however, leads to an impression that the proposed exemption policy provides an individual dose criterion for curtailing compliance with the ALARA process which is comparable to basic radiation protection dose limits.

While this issue cannot be easily resolved by policy decisions, we believe better mutual understanding between the agencies could alleviate the situation.

Furthermore, I need to call to your attention the trend in risk coefficients which are developed from exposures at higher doses. The Commission should know that the risk coefficient developed for higher doses and dose rates have recently been revised upward by the United Nations Scientific Committee on the Effects of Atomic

Radiation. A similar conclusion is expected to be reached by the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation in their forthcoming Five report. This increase has been recognized in the proposed policy. There will be some reviewing the policy who would give significant weight to these changing estimates of risk factors.

CHAIRMAN CARR: But those are only at higher doses?

MR. MORRIS: What has happened is that they are raising their estimates of the risk at higher doses, but then there are those who would project these down into the low dose range. And those projections are, admittedly, judgments by these experts not demonstrated as yet by scientific data, but they do represent some judgment by experts in this field. However, because the individual dose criterion proposed in the policy is based on the perspective of both variations in background as well as the quantitative risk prospective evolving from the risk coefficient, the increase in risk coefficient has not caused any changes in the policy.

Just a minute then to summarize on page 15. The proposal that we've provided to you would require practice justification as a basic policy element. It

provides numerical criteria on both individual and collective dose levels as a basis for curtailing ALARA. It includes several features we believe are important to assure that exposure to multiple practices will not result in doses near the limit for public exposure. Finally, it permits exemptions based on demonstration of ALARA even if the numerical criteria are not met.

On page 16 of the handout, we indicate that the staff proposes that in view of the comments from EPA which raised several concerns they had about the earlier version of the policy and the need to further clarify the views of the two agencies, that the resolution of differences that remain with EPA could best be accomplished through the process of development of federal guidance by an interagency task force. This would be a way of following EPA's proposal in their formal comment on this policy that the two agencies should work together. It would also help to clarify some of those issues relating to the comparability of the EPA standards and the proposed exemption criteria that I was discussing a few minutes ago.

And finally, on the last page, the staff believes that based on the progress made to date in

resolving the issues related to policy development, it would be appropriate for the Commission to approve publication of the proposed policy and the response to public comment in the *Federal Register* and the continuation of staff efforts to work with EPA to plan for development of federal guidance.

That concludes our presentation.

CHAIRMAN CARR: Any comments?

COMMISSIONER ROBERTS: Not at this time. You and I can fix this thing.

CHAIRMAN CARR: Mr. Rogers?

COMMISSIONER ROGERS: Just picking up on just what you just finished saying. You're proposing that the policy be published again for comments. Why? What do you expect to happen with another publication of this policy? After all, we've done it what? Twice.

MR. MORRIS: No, once.

COMMISSIONER ROGERS: Once is all?

MR. MORRIS: Only once.

COMMISSIONER ROGERS: But we've had quite a bit of comment.

MR. MORRIS: We have had a number of public comments and I believe that as this evolved and we've had letters from congressmen reflecting, you know,

relaying the concerns of their constituents and a number of others have been writing to us about this issue, we have noted in -- these have been signed and sent out by the agency. We've indicated that the public will get another chance to look at this. I don't know that that commitment would preclude issuing it as a final policy statement now, but it seems that although I -- in my mind, I feel that there's not a lot that we on the staff could learn by those new comments. I believe it would give a more thorough airing of this relatively complex and controversial issue. And it might be worth the effort to go through that next step in the --

COMMISSIONER ROGERS: Well, I'm a little concerned about the empty gestures. If we really don't think we're going to change it because we think we've pretty well exhausted ourselves and the possibilities, then putting out for public comment is really an empty gesture. If you really don't think anything is going to change as a result of that, what is accomplished by it other than the frustration of having to see the thing go out and then finally go into final form without any change whatsoever after the second issuance for public comment?

So, it's not clear to me that this is

necessarily --

CHAIRMAN CARR: You wouldn't expect any new comments, would you?

MR. MORRIS: What I would be hoping to see, I think, would be some indication that in our clarification and the way we've expressed the resolution of some of these issues that a larger segment of those reviewing the policy would understand it better. We could be more confident then that it was going to bear the test of time.

CHAIRMAN CARR: It might get a fewer comments.

MR. MORRIS: And that last point I made would be that it would give us some more confidence that we had capture the best thinking of those out there, look for any new ideas, perhaps, that could come in. Part of this is a communication effort. An effort to outreach to those who are reading this to let them understand what the Commissioner's views are and have, yes, the opportunity, perhaps -- we did not prejudge whether you would have other questions that you would want to raise in another round.

So, that was also --

CHAIRMAN CARR: It does look like the facts are all in. What we're talking about now is policy.

MR. MORRIS: It's policy.

MR. TAYLOR: And the comments, there were diverse comments and it tells people how those comments were handled and I think to the best of the staff's ability. That's the benefit. For a very important policy.

DR. SPEIS: But at the same time, it has received intensive scrutiny over the last six months. The advanced notice, the international workshop, the public workshop. It's more clarification, more digestion, you know.

COMMISSIONER ROGERS: Well, I don't think there's any rush on this. I don't know that there's something that this has to be done by a certain date. It's just really when do you come to closure on an issue and whether there is something to be gained by putting out again.

MR. TAYLOR: It's a judgment call and the staff thought it would be better to do this.

CHAIRMAN CARR: It's on my hurry up list.

MR. TAYLOR: Oh, I see. Okay.

MR. LAHS: It would also give you the chance, if you wanted to, to allow EPA to modify its comments, many of which I think --

CHAIRMAN CARR: I'm not sure I want to do

that.

MR. LAHS: Many of which have been modified by --

CHAIRMAN CARR: I may want to get my policy on the street before EPA does.

MR. BERNERO: Mr. Chairman, if I could add a comment on the priority or urgency for it. I feel compelled to say it's one of the most long awaited and hardy standards of all is how clean is clean enough. And this is an elemental part of that whole policy.

I've been in this agency for 17 years and when I first entered it, it was just around the corner we'd have a standard. And it just gets dragged out and gets dragged out.

MR. TAYLOR: It takes most of our attention.

CHAIRMAN CARR: But I'm not sure I can tell them how clean is clean enough from this.

MR. BERNERO: Yes, this is a part of that.

CHAIRMAN CARR: They won't know. They'll say, well we have to go and get at this issue.

MR. BERNERO: When we decommission a site, what we are doing every day when we approved remedial actions for the removal or stabilization of radioactivity, this is one part of the residual activity.

CHAIRMAN CARR: But what's clean enough for a site in the middle of Nebraska might not be clean enough for a site in the middle of the New York.

MR. BERNERO: Certainly. You just used a collective dose to get that --

CHAIRMAN CARR: And that's what you're using. And I think the two things ought to be the same.

MR. MORRIS: I believe that we think that this policy would allow for consistent -- would promote that those two would be the same. I think it would involve a decision on your part that this would be a policy applicable to Nebraska and New York, applicable to consumer products, residual radioactivity in the lands instructors. So that would be the significance of your issuance of the policy.

CHAIRMAN CARR: But using your collective dose, it wouldn't seem that we could do that.

MR. LAHS: That just means we would have to evaluate all practices having to do with, let's say, decommissioning facilities as we --

CHAIRMAN CARR: Or we would have to evaluate how many kids are going to play in the park in New York versus how many were going to play in the park over in the middle of Nebraska?

MR. LAHS: That's right.

MR. BERNERO: Yes. Yes, indeed. Just like we do for a reactor site.

CHAIRMAN CARR: Yes. And this is the number we're looking for.

COMMISSIONER ROGERS: Well, just touching on this kind of thing. There are the two different situations, the low level waste streams and the consumer products applications of this. Are you totally sold on the notion that you don't want to have separate levels for these two different types of practice? Do you think that they really should be coupled up together in one policy?

MR. MORRIS: I think it's the consensus of the staff that, yes, we had fully in mind that they would be in this policy, yes.

MR. BERNERO: It's the principle.

MR. MORRIS: It's a risk policy principle that we're following and I don't think people would be concerned about whether the risk came from one practice or another. It's --

MR. BERNERO: Yes, it's really a threshold of concern and then the secondary concern of more than one practice piling on, you know, the multiple practice issue. Now, the collective dose, it does

have a role, as it was said, in the consumer products because they're more generally distributed. The multiple practice issue is much simpler in the reactor waste stream. You know, do they all go to the same landfill.

The principle of a risk basis for a threshold of concern, regulatory concern, is --

COMMISSIONER ROGERS: Well, it's just that I'm not sure we really have such a wonderful bases for those numbers in these cases.

CHAIRMAN CARR: It seems to me you're struggling against the threshold. I'm for threshold, but I can't find it here.

MR. BERNERO: Well, let me try it. The public dose limit that our regulations, the new part 20, adopts 100 mrem per year as a level of clear unacceptability. One doesn't want an individual exposed to that. And what this exemption policy --

CHAIRMAN CARR: Over background?

MR. BERNERO: Yes. From artificial radiation. It happens to be less than or equal to background. AEA regulated radioactivity.

Now, 10 mrem per year is another threshold, you could call it or a line, that below which with only one other test you can say it's clearly

acceptable, exemptible. A practice that produces less than 10 mrem per year can be set aside from any further consideration with, of course, the proviso that it's not close to that limit and with the sufficient number of people to have this population dose in it. To exceed the population dose.

CHAIRMAN CARR: I was with you to a point.

MR. BERNERO: Yes, I recognized you got off the bus at the second half of the sentence.

CHAIRMAN CARR: I can agree if it's 10 MR or below, I'm not going to worry about it because I'm really worried about the 100 MR number and the odds of somebody having 10 of those 10 MR numbers doesn't worry me.

MR. BERNERO: When we look at the reactor waste stream that would go to, say, a landfill and might produce an off-site dose to a handful of people who live near there down water from the landfill and the imputed dose is 2 mrem per year, that is a far different thing than if NMSS gets consumer product licensing of 2 mrem per year for everybody in the United States from a new kind of smoke detector or something like that. That is a very large population dose.

COMMISSIONER ROGERS: Yes, but aren't you

just saying --

CHAIRMAN CARR: It doesn't worry me because I'm only getting 2 millirems

MR. BERNERO: Yes, they're very different. And this policy lets me distinguish between those two.

MR. TAYLOR: It's a decision making.

MR. BERNERO: It lets me distinguish that that few people exposed to that one landfill practice is clearly exemptible. But that one that's 2 mrem per year at the 250 million people is something I'd better think about.

CHAIRMAN CARR: Well, I'm more worried about the 2 mrem discharge going to the same landfill for a long period of time and concentrating at the landfill.

MR. BERNERO: Yes, indeed. That's why it has to be looked at. Or if we say that the practice is the reactor spent resins, the low level trash, the residue from the incinerator, etcetera, etcetera. You know, maybe four different streams, each of which is bumping the clearly acceptable limit, we license a licensed landfill, namely a low level burial ground, on a 25 mrem per year limit to the critical individual. So, you know, we have to look at that.

COMMISSIONER ROGERS: I think I'll pass.

MR. BERNERO: I'll pass out some gemstones

here.

COMMISSIONER CURTISS: I just have one question on the EPA issue. If the disagreement between the EPA and the Commission continues on both collective dose and the individual dose criteria, I guess the question I have is what's the consequence of us establishing a BRC policy if the other agency here which, according to the paper, has cited other overlapping authority as the basis for their standard setting authority, if the other agency comes in and says we disagree with that and we're going to regulate at a lower level? All in favor of a BRC policy, or whatever we're calling it today. And it seems to me that the simplicity approach that the Chairman's outlined makes a good deal of sense. It could not avoid some of the complexity that we have here, but at the same time if the upshot of it is that we deregulate and end up turning that over to EPA for regulation because they disagree, I'm not sure I'm much in favor of that outcome either. How do you reconcile that disagreement?

MR. MORRIS: Well, I think the first point we'd make is that we believe that it's very important that we begin to work with EPA to develop federal guidance that would allow us to have a uniform top man

approach to this issue that not only EPA and NRC would be involved in, but DOE and other government agencies. That, we think, should be a very important step.

If that does not take place and if we were to promulgate regulations that were based on this policy and EPA felt that they wanted to promulgate other regulations that would be more stringent, then I think, maybe Mr. Parler will have to speak this, the EPA regulations would then obtain and it would have been a somewhat idle gesture on our part, except for the fact that it would deal with an issue on a short term basis and we don't know when EPA would come along and take that next step. We don't know what their time table would be.

MR. PARLER: EPA has the authority for radiation status with the ambient environment. They have had that authority since they were created by reorganization plan, I think it's number three, in April of 1970. And so the approach would have to be either get the law changed or to get together and reason together with them so that, presumably, something that would be acceptable to both could be worked out.

MR. LAHS: I might point out that one of the EPA challenges to the advanced notice was the fact

that they read that advanced notice that we were proposing a policy without a collective dose. And so that was one of their major arguments against the policy. Well, obviously now that we have a collective dose in the policy, so certainly that's mollified them in that --

COMMISSIONER CURTISS: And they disagree with the number now.

MR. LAHS: I don't think they disagree with, I might be putting words in their mouth, so much with the 500 person-rem number as with the 10 mrem individual dose number. And they referred back to the international precedence, a few mrems. So we're talking about maybe a factor of four, something like that.

COMMISSIONER CURTISS: I'm not sure I have an answer to the question how you solve that problem. Federal guidance, I think, is going to postpone the inevitable, and that is that we're going to -- we've worked on EPA for six or seven years in this area and longer in other areas, and I'm not sure the technical basis for a consensus exists. And I guess I am concerned that postponing for federal guidance or leaving it in the hands of their BRC policy for low level waste or their Clean Air Act authority or

whatever is going to result in the two agencies proceeding in the matter where we deregulate with an eye towards saying, this isn't significant from the standpoint of the agency that regulates radiation and as a consequence of the disagreement, we end up turning over a junket of the jurisdiction at the lower end to EPA, which continues to regulate on behalf of the federal government.

MR. TAYLOR: I think the staff's proposal was if we did publish again, we'd have time to continue to try to work with EPA.

MR. MORRIS: That's the basis.

COMMISSIONER CURTISS: Okay.

MR. TAYLOR: And I think if we're unsuccessful in that, we ought to talk to the Commission.

MR. MORRIS: Also I think that we need to make the point that in this proposal for developing federal guidance we would not stop our activities, that we would propose to issue this policy. Work with EPA on the federal guidance and go ahead and proceed with our rulemaking actions under this policy. And then revisited what the ramifications of that would be after we had arrived at the federal guidance consensus.

COMMISSIONER CURTISS: In one respect, the advantage that we have now is that we regulate the waste streams at the individual reactors, for example, just to take one category. And it seems to me that there's some basis for saying that we ought to have a policy that addresses that, that we call BRC or exemptions from regulation. But I'm not sure the upshot of a technical disagreement here where EPA regulates the waste streams at the reactors is an outcome we want to see either.

That's all I have.

CHAIRMAN CARR: Well, I think it's obvious that we, the Commission, have to do a little getting together on what we really want to do and provide you some policy. I guess my personal feeling is that we told you to go do something and you came back and told us that you didn't want to, you wanted to do it the way it was.

We did tell you in a different way, I guess. We said let's go out and get all the comments we can get and then come back. And that's what you've done and so you've done good at doing that part of what we asked you do. We've got a lot of comments. There's about as many on one side of the question that I worry about as there is on the other. And so I think it's

up to us to decide where we want to come down on this issue and just come down and hand you the policy and say use it.

I hope we can do that rather quickly. I'm not sure that we need to put it out as a proposed policy statement again. We'll have to decide that when we take a look at it and give you an SRM. You may come back and say we have to if we veer it in a direction that goes completely opposite what you've already commented on. But I hope we won't do that. And it's just one of those decisions we'll have to make. But we've toyed with it long enough. It's been on and off the plate for 17 years, Mr. Bernero?

MR. BERNERO: Oh, far longer than that. I'm just a child.

CHAIRMAN CARR: It probably hasn't been around longer than 1936 or so.

MR. BERNERO: The 1965 policy statement might give you a clue.

CHAIRMAN CARR: So, we need to do that and so I think it's up to us now to -- you've done your homework. You've done a good job in presenting the issues and I think it's up to us to decide where we want to come down on it.

Any other comments?

MR. PARLER: Mr. Chairman, there's no legal requirement that this policy statement be put out for comment again that I know of. It's a policy call.

CHAIRMAN CARR: Thank you.

In that case, we stand adjourned.

(Whereupon, at 2:48 p.m. the public hearing was adjourned.)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON POLICY STATEMENT ON RULES FOR EXEMPTION FROM REGULATORY CONTROL
PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JULY 11, 1989

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.

Carol Lynch

Reporter's name: Peter Lynch

PROPOSED POLICY STATEMENT
ON EXEMPTIONS FROM REGULATORY CONTROL

STAFF PRESENTATION TO COMMISSION

JULY 11, 1989

OUTLINE OF PRESENTATION

- BACKGROUND
- PURPOSE OF PRESENTATION
- OBJECTIVE OF POLICY STATEMENT
- ACTIONS TAKEN IN RESPONSE TO COMMENTS
- POLICY CLARIFICATIONS
- PROPOSAL ON MAJOR POLICY ELEMENTS
- SUMMARY-KEY POLICY ELEMENTS
- OTHER IMPORTANT POLICY CONSIDERATIONS

BACKGROUND

- SRM-Nov 1987-Identify risk level below which Gov't regulation unwarranted
- SECY 88-69, Mar 1988-concept discussion
- SRM-Mar 1988-Requests Policy Statement
- SECY 88-257, Sept 1988-Proposed Policy
- Commission authorizes publication of Adv. notice soliciting comments on several major policy elements

PURPOSE OF PRESENTATION

TO DISCUSS REVISED POLICY STATEMENT AND THE RATIONALE FOR STAFF PROPOSALS ON KEY POLICY ELEMENTS CONSIDERING INPUTS FROM:

- THE INTERNATIONAL WORKSHOP-OCT 1988
- PUBLIC COMMENTS RECEIVED ON ADVANCE NOTICE ISSUES (DEC 1988-APR 1989)
- PUBLIC MEETING-JAN 1989

OBJECTIVE OF POLICY STATEMENT

TO ESTABLISH GUIDELINES AND CRITERIA FOR DEVELOPMENT OF REGULATIONS OR LICENSING DECISIONS WHICH COULD EXEMPT PRACTICES FROM SOME OR ALL REGULATORY CONTROLS

POTENTIAL POLICY APPLICABILITY
TYPICAL PRACTICES

- DISPOSAL OF VERY LOW LEVEL RADWASTE
- RELEASE OF LANDS AND STRUCTURES WITH RESIDUAL LEVELS OF RADIOACTIVITY
- CONSUMER PRODUCTS CONTAINING SMALL AMOUNTS OF RADIOACTIVE MATERIAL
- RECYCLE AND REUSE OF RESIDUALLY CONTAMINATED MATERIALS AND EQUIPMENT

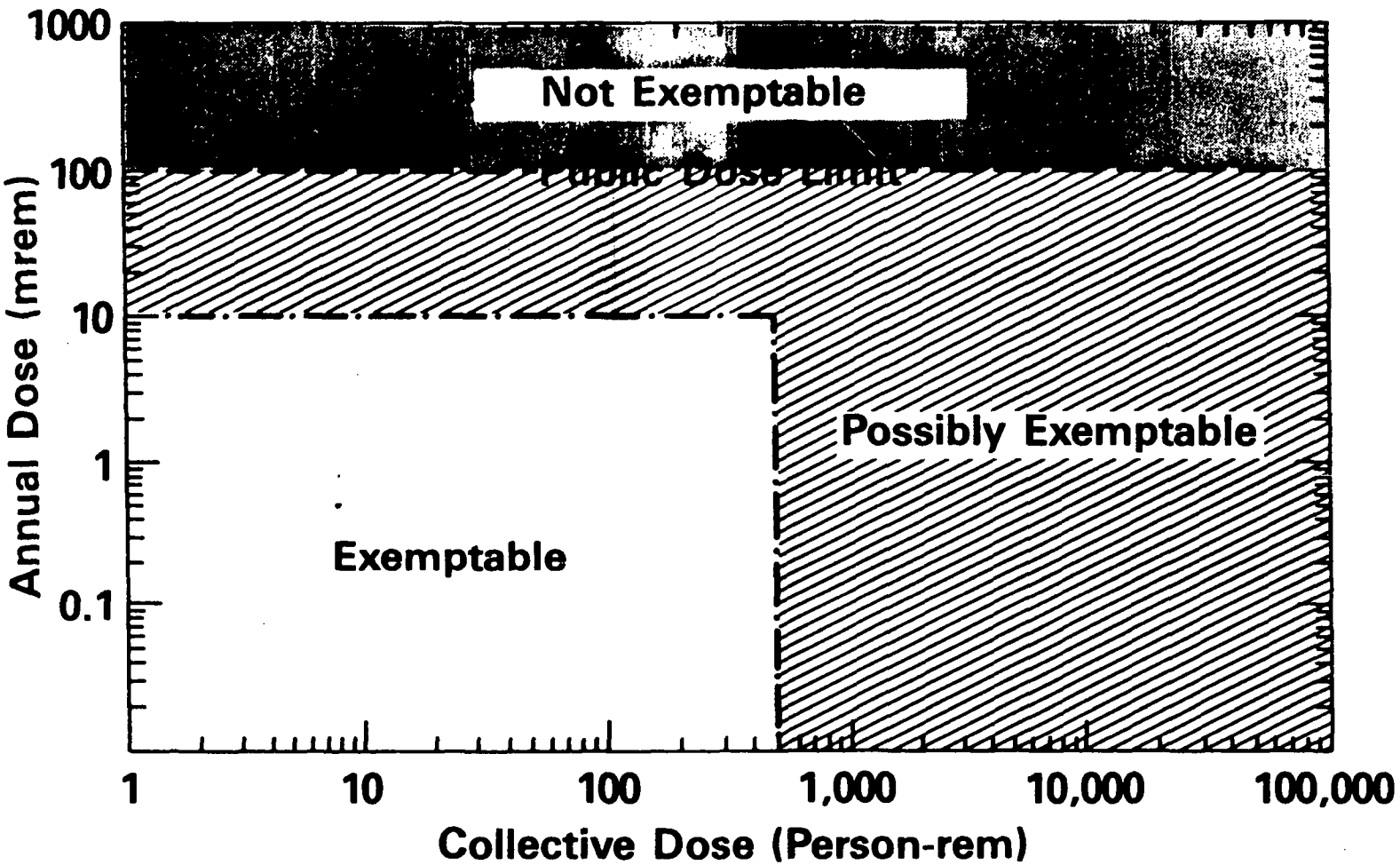
ACTIONS TAKEN AS A RESULT OF COMMENTS ON ADVANCE NOTICE OF POLICY DEVELOPMENT

- CATEGORIZED AND RESOLVED ISSUES IN 18 SUBJECT AREAS
- REVISED POLICY IN KEY AREAS
- CLARIFIED COMMISSION POSITIONS IN OTHER AREAS

POLICY ELEMENTS ON WHICH COMMENTS SOUGHT

- How should fundamental principles of radiation protection be applied? (Justification of practice, dose limits, and ALARA)
- Is a Collective Dose Criterion Needed?
- How should cumulative effects from multiple practices be dealt with?

PROPOSED EXEMPTION POLICY FOR A JUSTIFIED PRACTICE



PROPOSALS ON MAJOR POLICY ELEMENTS

- "JUSTIFICATION OF PRACTICE" NEEDED
  (1) NO EXPOSURE TO IONIZING RADIATION PERMITTED W/O COMMENSURATE BENEFIT
  (2) WIDELY-ACCEPTED RADIATION PROTECTION GOAL

PROPOSALS ON MAJOR POLICY ELEMENTS (CON'T)

COLLECTIVE DOSE CRITERION ADDED TO DEFINE "FLOOR" TO THE ALARA PROCESS

(1) COMMONLY USED BY REGULATORY BODIES AS MEASURE OF SOCIETAL DETRIMENT IN OPTIMIZATION ASSESSMENTS

(2) USED BY OTHER U.S. AGENCIES & INCLUDED IN INTERNATIONAL GUIDANCE

(3) ADDS ASSURANCE THAT DOSE LIMITS NOT EXCEEDED (EXPOSURES TO MULTIPLE PRACTICES)

(4) REFLECTS POSITION THAT INDIVIDUAL DOSE CRITERION NOT "DE MINIMIS"

PROPOSALS ON MAJOR POLICY ELEM'TS (CONT.)

° MULTIPLE PRACTICE ISSUE ADDRESSED BY:

(1) BROAD DEFINITION OF "PRACTICES"

(2) REQUIRING PRACTICE JUSTIFICATION

(3) COLLECTIVE DOSE CRITERION

(4) APPROPRIATE PERIODIC ASSESSMENT

(5) COMMITMENT TO CONSIDER ISSUE IN EACH EXEMPTION DECISION

OTHER MAJOR POLICY ISSUES

- RETENTION OF 10 MREM ANNUAL INDIVIDUAL DOSE CRITERION
- ALLOWS EXEMPTIONS WHEN ABOVE NUMERICAL CRITERIA

POLICY CLARIFICATIONS

- CONSTRAINTS ARE ASSOCIATED WITH EXEMPTION DECISIONS
- NUMERICAL ALARA CRITERIA ARE NOT LIMITS
- EMPHASIS INCREASED ON NECESSITY TO DEFINE SCOPE OF PRACTICE APPROPRIATELY
- REFERENCE TO "BRC" RESERVED FOR WASTE DISPOSALS UNDER LLRWPAA OF 1985

OTHER IMPORTANT POLICY CONSIDERATIONS

- DIFFERING VIEWS ON MAGNITUDES OF EXEMPTION DOSE CRITERIA
  - EPA, ACNW, AND INTERNATIONAL
- COMPARABILITY OF EXEMPTION DOSE CRITERIA AND "ACCEPTABLE" DOSE STDS.
- TREND IN RISK COEFFICIENTS DEVELOPED FROM EXPOSURES AT HIGHER DOSES

SUMMARY - KEY POLICY ELEMENTS

- REQUIRES PRACTICE JUSTIFICATION AS BASIC POLICY ELEMENT
- PROVIDES CRITERIA FOR "CURTAILING" ALARA - "OPTIMAL" RESOURCE USE
- INCLUDES FEATURES TO ADDRESS THE "EXPOSURE TO MULTIPLE PRACTICE" ISSUE
- PERMITS EXEMPTIONS BASED ON DEMONSTRATION OF ALARA IF NUMERICAL CRITERIA NOT MET

INTERACTIONS WITH EPA

STAFF PROPOSES THAT RESOLUTION OF ANY RESIDUAL DIFFERENCES WITH EPA CAN BEST BE ACCOMPLISHED THROUGH THE PROCESS OF DEVELOPMENT OF FEDERAL GUIDANCE BY AN INTERAGENCY TASK FORCE.

RECOMMENDATIONS

° THAT THE COMMISSION APPROVE:

(1) PUBLICATION OF THE PROPOSED POLICY AND RESPONSE TO PUBLIC COMMENTS IN THE FEDERAL REGISTER.

(2) CONTINUING STAFF EFFORTS TO WORK WITH EPA TO PLAN FOR DEVELOPMENT OF FEDERAL GUIDANCE.

June 16, 1989

POLICY ISSUE
(Notation Vote)

SECY-89-184*
(Reissued)

For: The Commissioners

From: Victor Stello, Jr.
Executive Director for Operations

Subject: PROPOSED COMMISSION POLICY STATEMENT ON EXEMPTIONS FROM REGULATORY CONTROL

Purpose: To provide, for Commission consideration, a revised proposed policy statement on exemptions from regulatory control.

Summary: This paper discusses the development of the enclosed policy statement (Enclosure 1). The purpose of the policy is to define the bases upon which Commission exemption decisions are made involving the release of certain radioactive materials from the full extent of regulatory controls. The principles underlying this policy are outlined and the criteria applicable to the decision-making process are presented. The principles and criteria are essentially those which were (1) originally presented in SECY-88-257; (2) issued for public comment in a Federal Register advance notice (53 FR 49886), published on December 12, 1988; and (3) considered and discussed by international regulatory authorities at an October 1988 workshop.

The three fundamental principles of radiation protection have been used in formulating the proposed exemption policy; namely: (1) justification of practice, (2) compliance with applicable dose limits, and (3) optimization of protection (i.e., the application of the as-low-as reasonably achievable (ALARA) principle). The policy, however, does specify maximum individual and collective dose criteria, which, if met by a practice under consideration for exemption, would delineate conditions such that further incremental compliance with the ALARA principle is not warranted. The maximum individual dose criterion is 10 mrem (0.1 mSv) per year per practice and the

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* SECY NOTE: This copy of SECY-89-184 is being reissued to correct a number of pages in the enclosures. Prior copies of the paper (those without this note) should be destroyed.

collective dose criterion is 500 person-rem (5 person Sv) per year per practice.

Although fundamental principles of radiation protection have been considered in recommending the individual and collective dose criteria, the specific values selected represent a policy judgement based on risk and resource allocation considerations. As a result, the criteria do not exactly agree with the bases for, or magnitudes of similar criteria selected or under consideration nationally by the U.S. Environmental Protection Agency (EPA), by other countries, or by international agencies. An explanation of the reasons behind these differences is provided below. Also provided is a discussion of the policy implications related to (1) EPA-proposed dose and risk standards and (2) recent increases in cancer risk estimates per unit dose developed at high doses and dose rates.

Enclosure 2 includes the staff's current analysis of and proposed responses to the major comments received from the international workshop, the public meeting, and the solicitation made in the December 12, 1988, Advance Notice. Following Commission approval the staff will prepare a Federal Register notice issuing the proposed policy, accompanied by this analysis and response to comments.

Discussion: Background

On September 8, 1988, the staff, in SECY 88-257, provided for Commission consideration a proposed Commission policy statement on exemptions from regulatory control for practices whose public health and safety impacts are below regulatory concern (BRC). In staff requirements memoranda (SRM's) of September 29 and 30, 1988, the Commission requested the staff to (1) raise several specific issues with foreign regulatory authorities attending an NRC-sponsored workshop on Rules for Exemption from Regulatory Control and (2) make available for comment, to the workshop participants and to the public, a Commission-modified advance notice of a Commission Policy on Below Regulatory Concern [Exemption Policy]. The advance notice subsequently became a major topic for discussion at the international workshop (NUREG/CP-0101) and was published for comment in the Federal Register on December 12, 1988 (53 FR 49886). The Federal Register notice also announced a public meeting which took place on January 12, 1989.

In response to the Federal Register publication, over 225 comment letters have been received, most during the months of February and March, after the official January 30, 1989 closing date, but with responses continuing to be received to

the present time. (In California, a movement is taking place among county boards of supervisors to oppose the exemption policy as it applies to low level waste disposal practices, and to restrict any disposal of radioactive material at local disposal sites.) The comment letters were almost evenly split with regard to support or nonsupport for a Commission exemption policy.[1] The issues raised in these letters and at the international workshop and public meeting have been categorized into 18 subject areas which include the subjects for which comment was specifically solicited by the Commission. The principles underlying the proposed policy, and the dose criteria used in the exemption decision-making process, have been revised and clarified based on the insights gained through these review and comment processes.

The Proposed Exemption Policy

The proposed exemption policy statement recommended by the staff is attached as Enclosure 1. This policy statement includes the following major features:

The Justification of Practice Principle

Following consideration of the responses to questions raised in the advance notice, the staff believes this basic radiation protection principle must underlie any exemption decision. Decisions on "justification of a practice" may be based on a broad range of qualitative and quantitative factors. Basically, however, it involves a Commission determination that an activity resulting in exposure of individuals to radiation or a release of radioactivity to the environment must also result in a commensurate benefit to society, i.e. a net enhancement to human life and health. This is now emphasized in the proposed policy statement and the staff has attempted to provide clarifications to eliminate any confusion between the principle of "justification of practice" and the principle of as low as reasonably

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1 The comment letters included about 149 from individuals, of which about a quarter identified themselves as health physicists. Four of these letters from individuals were petitions expressing opposition to policy development. There were 21 letters from public interest groups, 19 from utilities or their representatives, 9 from industry, 1 from a university, 10 from state or local government organizations, 4 from professional societies, 2 from members of the National Council on Radiation Protection and Measurements (NCRP), one each from the U.S. Environmental Protection Agency and the Department of Energy, and two from members of Congress.

achievable (ALARA) or its international equivalent, "optimization of protection." Recognizing that factors important to the justification determination can be weighted differently by different individuals, the staff intends to seek Commission concurrence on any exemption denials based on staff findings that a practice is not justified.

Criteria for Establishing a "Floor" for ALARA

The proposed policy defines individual and collective dose criteria which would delineate a region where further incremental compliance with the ALARA principle is not warranted. The selected maximum individual dose criterion of 10 mrem per year per practice is based on absolute and comparative risk considerations. The collective dose criterion of 500 person-rem per year per practice serves two purposes. First, it represents a policy judgement regarding the level of population dose below which Commission resources are better applied to other radiation protection issues (provided the individual dose criterion is met). Second, it provides additional assurance that the total dose to any individual from all practices should not exceed 100 mrem per year. In practical applications, the collective dose criterion will assure that the ALARA principle is applied when considering potential exposure of individuals to wide-ranging practices (e.g., in the form of consumer products or recycled equipment or materials containing residual levels of radioactive contamination). The magnitude of the value is such that, for any single exempt practice meeting this criterion, a hypothetical health effect would not be expected on an annual basis.

Important Policy Considerations

The magnitude of and bases for the individual and collective dose criteria in the proposed policy do not agree with those under international consideration, as described in IAEA Safety Series No. 89, "Principles for the Exemption of Radiation Sources and Practices From Regulatory Control," (e.g., the magnitude of the maximum individual dose criterion and the collective dose criterion are higher in the proposed policy by factors of about 3 and 5, respectively). With regard to the policy's individual dose criterion, the difference occurs as a result of the international definition and use of a quantified level of insignificant or trivial individual risk. The proposed policy defines and uses a level of dose based on (1) a risk level which the staff believes an individual will not spend resources to avoid and (2) a small fraction of

background radiation and a level of variation in exposure which individuals tolerate in their daily lives. Regarding the collective dose criterion, the internationally proposed value is based on consideration of the minimal costs associated with formal optimization procedures. The proposed policy includes a collective dose value (500 person-rem per year per practice) which, in the staff's judgement, not only demonstrates practical compliance with the ALARA principle, but also provides additional assurance that total dose to any individual from all practices should not exceed 100 mrem per year.

Nationally, EPA has expressed its view that the individual and collective dose criteria are too high and are also inconsistent with many Congressional and regulatory actions being taken relative to other environmental contaminations. EPA has also stated that exemption policy is an area in which the NRC and EPA have overlapping authorities under the Atomic Energy Act. The EPA noted that it has sole responsibility for regulating environmental radiation under a number of other statutes (e.g., the EPA, is proposing 4 mrem per year as a "below regulatory concern" value for land disposal of low level waste at other than licensed sites). In response to this EPA concern, the revised policy includes a statement which encourages the development of Federal Guidance on this subject, and points out that, when signed by the President, this Federal Guidance could supplant the Commission's policy statement.

The Commission should also be aware that the U.S. Environmental Protection Agency has proposed National Emission Standards for Hazardous Air Pollutants; Regulation of Radionuclides, with lower radiation protection standards (refer to SECY-89-150). This results in a situation in which proposed or defined "acceptable standards" of public health risk (or dose) are essentially equivalent to risk and dose levels being proposed as exemption criteria (i.e., levels below which no further efforts need be taken to comply incrementally with the ALARA principle in the exemption decision-making process). Although the staff believes that the bases for the Commission's exemption policy, in general, and the proposed numerical criteria, in particular, are sound, the promulgation of this exemption policy could enter the Commission into a much broader debate on acceptable risk levels.

Also, published cancer risk estimates per unit dose, derived for higher doses and dose rates, have increased (UNSCEAR 1988, Sources, Effects and Risks of Ionizing Radiation). When coupled with the application of the "no-threshold hypothesis," this suggests that the risks at low dose levels (all of which include a "background" base) are higher than previously

thought. The proposed policy incorporates a risk coefficient for low linear energy transfer radiation which has been extrapolated from results in UNSCEAR 1988 and anticipated to be included in the forthcoming BEIR V report (National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation).

Coordination: The Office of General Counsel has reviewed this Commission paper and has no legal objection.

The policy statement has been discussed with the Advisory Committee on Nuclear Waste (ACNW) over the course of several meetings, the latest on April 28, 1989. The ACNW has stated its views in a May 3, 1989 letter to Chairman Zech. Two outstanding differences with ACNW recommendations remain. These differences are discussed in Enclosure 3.

The revised policy has also been discussed with EPA representatives (Office of Radiation Programs) in meetings on January 25 and April 18, 1989. EPA has been provided with a copy of the revised policy and the analysis of and response to comments.

Recommendation: That the Commission:

Approve publication of the proposed policy statement in the Federal Register. The Federal Register notice would include a summary and response to public comments and would request public comment on the basic foundations and key elements of the proposed policy.

Victor Stello, Jr.
Executive Director for
Operations

Enclosures:
1. Policy Statement
2. Analysis of and Responses to Comments
3. Response to ACNW Comments

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Friday, July 7, 1989.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Wednesday, June 28, 1989, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE 1

Enclosure 1

PROPOSED COMMISSION POLICY ON EXEMPTIONS FROM REGULATORY CONTROL

PROPOSED COMMISSION POLICY ON EXEMPTIONS FROM REGULATORY CONTROL

I. INTRODUCTION AND PURPOSE

Over the last several years, the Commission has become increasingly aware of the need to provide a general policy on the appropriate criteria for release of certain radioactive materials from the full extent of existing regulatory controls. The need has been driven by two recurring realizations. The first is the recognition that, for certain practices involving minimal public health and safety concerns, the imposition of undue and unnecessary regulatory controls could prohibit a practice which should otherwise be permitted because of reasonable social, economic, or industrial benefits. The second results from the nation's focus on fiscal responsibility and the knowledge that resources expended for regulatory control of practices with minimal radiological impacts could be better used to address more significant radiological and non-radiological health and safety concerns. To address this need, the Commission is expanding upon its existing regulations and policies for protection of the public from radiation which currently define a number of long-standing exemptions from regulatory control.[1] The expansion includes the development of an explicit exemption policy for those Commission-regulated practices which involve minimal public health and safety impacts. The Commission, however, recognizes the benefits of uniform regulation and, therefore, supports the development of broader Federal Guidance regarding exemption policies. In doing so, the Commission realizes that, when signed by the President, the Federal Guidance could supplant this policy.

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1 The existing radiation protection regulations (Title 10, Code of Federal Regulations, Part 20) contain provisions which allow certain disposals of radioactive material (e.g., into sanitary sewer systems). Other parts of the regulations (Parts 30 and 40) define specific quantities of radioactive material which may be possessed by unlicensed individuals. Several policy statements also have addressed the transfer of radioactive material from a controlled to an uncontrolled status (47 FR 57446, Licensing Requirements for Land Disposal of Radioactive Waste, dated December 27, 1982; 51 FR 30839, General Statement of Policy and Procedures Concerning Petitions Pursuant to § 2.802 for Disposal of Radioactive Waste Streams Below Regulatory Concern, dated August 29, 1986; and 30 FR 3462, Use of Byproduct Material and Source Material (Consumer Products), dated March 16, 1965).

In this policy, a practice is defined as an activity or a set or combination of a number of similar sets of coordinated and continuing activities aimed at a given purpose which involve the potential for radiation exposure. Disposal of very low level radioactive waste; the release for unrestricted public use of lands and structures with residual levels of radioactivity; the distribution, use, and disposal of consumer products containing small amounts of radioactive material, and the recycle and reuse of residually contaminated materials and equipment are examples of classes of practices for which this policy is judged to have potential applicability. It is the Commission's intent to broadly define specific practices so that any individual or population will be precluded from being significantly affected by similar activities within a given practice. At the same time, the practice must be identified and described in terms which will facilitate reasonable impact analyses and allow imposition of appropriate constraints as the radioactive material passes from a controlled to an uncontrolled status (i.e., the material is no longer under the control of Commission or Agreement State licensees). Under this policy, the definition of a "practice" is a critical feature which will assure that the formulation of exemptions from regulatory control will not allow deliberate dilution of material or fractionation of a practice for the purpose of circumventing controls that would otherwise be applicable. The definition will also provide the framework for taking into account the possible consequences of accidents or misuse associated with exemption decisions.

The purpose of this policy statement is to establish the basis upon which the Commission may initiate the development of appropriate regulations or make licensing decisions to exempt certain practices from some or all regulatory controls. This policy is directed principally toward rulemaking activities, but may be applied to license amendments or license applications involving the release of licensed radioactive material either to the environment or to persons who would be exempt from Commission regulations.

It is important to emphasize that, in this policy, the Commission does not assert an absence or threshold of risk at low radiation dose levels but rather establishes a baseline where further government regulation to reduce risks is unwarranted. The presence of natural background radiation and variations in

the levels of this background are used to provide a perspective on which to judge the relative significance of the radiological risks involved in the exemption decision-making process.

The concept of regulatory exemptions is not new. The Atomic Energy Act of 1954, as amended, authorizes the Commission to exempt certain classes, quantities, or uses of radioactive material when it finds that such deregulation will not constitute an unreasonable risk to common defense and security and to the health and safety of the public. In 1960 and 1970, the Commission used this authority to promulgate tables of exempt quantities and concentrations for radioactive material which a person, under certain circumstances, could receive, possess, use, transfer, own, or acquire without a requirement for a license (25 FR 7875 and 35 FR 6427). Other exemptions allowing distribution of consumer products or other devices to the general public, or allowing releases of radioactive material to the environment, have been embodied in the Commission's regulations for some time. For example, regulations currently specify conditions under which licensees are allowed to dispose of radioactive material into a sanitary sewer system (Title 10, Code of Federal Regulations, Part 20, Section 303). That is, the regulations specify requirements which a licensee must meet if radioactive material is to be "transferred" from a controlled to an uncontrolled status. More recently, Section 10 of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA) of 1985 directed the Commission to develop standards and procedures for expeditious handling of petitions "...to exempt specific radioactive waste streams from regulation... due to the presence of radionuclides... in sufficiently low concentrations or quantities to be below regulatory concern." The Commission responded to this legislation by issuing a policy statement in August 1986 (51 FR 30839). That statement contained criteria which, if satisfactorily addressed in a petition for rulemaking, would allow the Commission to act expeditiously in proposing appropriate regulatory relief on a "practice-specific" basis consistent with the merits of the petition.

The Commission believes that these "practice-specific" exemptions should be encompassed within a broader NRC policy which defines levels of radiation risk below which specified practices would require only minimal, practice-specific NRC regulation based on public health and safety interests. For such

practices, the Commission's regulatory involvement could be essentially limited to licensing and inspection activities associated with the transfer of the radioactive material from a controlled to an uncontrolled status. That is, the Commission would define constraints and verify that these constraints are adhered to by NRC licensees when radioactive materials are to be transferred from a controlled to an uncontrolled or exempt status.

The Commission recognizes that, if a national policy on exemptions from regulatory control is to be effective, Agreement States will play an important role in its implementation. Pursuant to the LLRWPAA, States are responsible for providing, either alone or in cooperation with other States, for disposal of certain low-level radioactive wastes. In the past, some States have been encouraging findings that certain wastes are below regulatory concern and the Commission believes that States will benefit from the application of a national policy on exemptions for specific practices involving distribution or release of radioactive material. The Commission therefore intends that rulemakings codifying exemptions for practices under this policy will be made a matter of strict compatibility for Agreement States to the extent that States, under the terms of the Agreements, are responsible for exemptions in their States. Consequently, this policy development effort and those rulemakings involving State Agreements that evolve from this policy will continue to be closely coordinated with the States.

The Commission recognizes that its policy will potentially have a significant impact on nuclear regulation in the international community. The approach and criteria in this policy differ in some respects from those selected or under consideration by other countries. It is the Commission's intent to continue its dialogue with the international community in order to resolve, or foster mutual understandings of the rationales behind, differences in exemption policies.

II. RADIATION PROTECTION PRINCIPLES

The Three Fundamental Principles of Radiation Protection

The Commission recognizes that three fundamental principles of radiation protection have historically guided the formulation of a system of dose

limitation to protect workers and the public from the potentially harmful effects of radiation. They are (1) justification of practice, which requires that there be some net societal benefit resulting from the use and disposition of radiation or radioactive materials, (2) dose limits, which define the permissible radiation doses for workers and members of the public, and (3) ALARA, which requires that radiation dose be as low as is reasonably achievable, economic and societal factors being taken into account. The term, ALARA, is an acronym for As Low As is Reasonably Achievable.

Dose Estimation

In estimating the dose rates to members of the public that might arise through the use of various practices for which exemptions are being considered, the Commission has decided to apply the concept of the "effective dose equivalent." This concept, which is based on a comparison of the delayed health effects of ionizing radiation exposures, permits, through use of weighting factors, the calculation of the whole body dose equivalent of partial body and organ exposures. This approach was proposed by the International Commission on Radiological Protection in its Publication 26, issued in 1977. Since that time, the concept has been reviewed, evaluated, and adopted by radiation protection organizations throughout the world and has gained wide acceptance. The "effective dose equivalent" concept is incorporated in "Radiation Protection Guidance to Federal Agencies for Occupational Exposure - Recommendations Approved by the President," that was signed by the President and published in the Federal Register on January 27, 1987 (52 FR 2822). The Commission recognizes that in considering specific exemption proposals, both the annual effective dose equivalent and the committed effective dose equivalent must be taken into account.

Estimating Health Effects From Radiation Exposure

a. Individual Risks

In the establishment of its radiation protection policies, the Commission has considered the three major types of health effects which can be caused by relatively low doses of radiation: cancer, genetic effects, and developmental anomalies in fetuses. The NRC focuses on the risk of fatal cancer development principally because, at relatively high radiation

doses: (1) the strongest basis exists for quantifying the risk of cancer mortality in humans, (2) the mortality risk represents a more severe outcome than the non-fatal cancer risk, and (3) the mortality risk is thought to be higher than the risk associated with genetic and developmental effects on fetuses.[2] However, even though radiation has been shown to be carcinogenic, the development of a risk factor applicable to continuing radiation exposures at levels equal to natural background[3] requires a significant extrapolation from the observed effects at much higher doses and dose rates.[4] The result is a significant uncertainty reflected by the views of experts in the field. For example, the National Academy of Science's Committee on the Biological Effects of Ionizing Radiation, has cautioned that the risk values are "...based on incomplete data and involve a large degree of uncertainty, especially in the low dose region." This Committee also stated that it "...does not know whether dose rates of gamma or x-rays (low LET) [low linear energy transfer radiation] of about 100 mrads/year (1 mGy/year) are detrimental to man." The Commission understands that the Committee's statement is a reflection of the uncertainties involved and does not imply either the absence or presence of detrimental effects at this dose level.

In addition, the Commission is aware that the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), in their 1988 Report to the General Assembly, has stated that "...there was a need for a

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2 Further discussion on these topics is provided in "Sources, Effects and Risks of Ionizing Radiation," United Nations Scientific Committee on the Effects of Atomic Radiation, 1988 Report to the General Assembly with Annexes.

3 Natural background radiation can vary with time and a person's location. In Washington, DC natural background radiation (excluding radon) results in individual doses of about 90 mrem per year (0.9 mSv/year), while in Denver, Colorado the value is about 160 mrem per year (1.6 mSv/yr) including, in both cases, a contribution of about 40 mrem per year (0.4 mSv/year) from naturally occurring radioactive material contained in the human body (NCRP Report No. 93, Ionizing Radiation Exposure of the Population of the United States).

4 The health effects clearly attributable to radiation have occurred principally among early radiation workers, survivors of the atomic bomb explosions at Hiroshima and Nagasaki, individuals exposed for medical purposes, and laboratory animals. Natural background causes a dose over a one year period which is at least two orders of magnitude less than the dose received by populations from which the cancer risks are derived.

reduction factor to modify the risks [derived at high doses and dose rates]... for low doses and dose rates ... an appropriate range [for this factor] to be applied to total risk for low dose and dose rate should be between 2 and 10." [This factor would lead to a risk coefficient value between $7x10^{-5}$ and $3.5x10^{-4}$ per rad ($7x10^{-3}$ and $3.5x10^{-2}$ per Gy) based on an UNSCEAR risk coefficient of $7.1x10^{-4}$ per rad (7.1% per gray) for 1 gray (100 rad) organ absorbed doses at high dose rates]. The report also stated, "The product of the risk coefficient appropriate for individual risk and the relevant collective dose will give the expected number of cancer deaths in the exposed population, provided that the collective dose is at least of the order of 100 man-Sv (10,000 person-rem). If the collective dose is only a few man-Sv (a few hundred person-rem), the most likely outcome is zero deaths."

In view of this type of information, the NRC, the Environmental Protection Agency, and other national and international radiation protection authorities have established radiation protection standards defining recommended dose limits for radiation workers and individual members of the public. As a matter of regulatory prudence, all these bodies have derived the value presumed to apply at lower dose and dose rates associated with the radiation protection standards by extrapolation from values derived at higher doses and dose rates. The extrapolation is frequently referred to as the no-threshold hypothesis in which the risk factor at low doses reflects the slope of the dose-effect relationship.

The Commission, in the development of an exemption policy, is again faced with the issue of how to characterize the individual and population risks associated with low doses and dose rates. Although the uncertainties are large, useful perspective on the bounding risk associated with very low-levels of radiation can be provided by continued use of the no-threshold hypothesis. Consequently, such risk estimates will be a factor in establishing individual and collective dose criteria associated with this policy. The estimations of the low risk from potentially exempted practices can be compared to the relatively higher potential risks associated with other activities or decisions over which the NRC has regulatory responsibility. Through such comparisons, the Commission can assure that its radiation protection resources and those of its licensees

are expended in an optimal manner to accomplish its public health and safety mission.

In this context, the risk to an individual, as calculated using the no-threshold model, is shown in Table 1 for various defined levels of annual individual dose. The values in the hypothesized lifetime risk column are based on the further assumption that the annual dose is continuously received during each year of a 70-year lifetime. To provide further perspective, a radiation dose of 10 mrem per year (0.1 mSv per year) received continuously over a lifetime corresponds to a hypothesized increase of about 0.25% in an individual's lifetime risk of cancer death. Ten millirem per year (0.1 mSv per year) is also a dose rate which is a small fraction of naturally occurring background radiation and not much larger than the temporal variations in natural background radiation due to fluctuations which occur at any specific location.

Table 1

Incremental Annual Dose			Hypothesized Incremental Annual Risk[2]	Hypothesized Lifetime Risk from Continuing Annual Dose[2]
100	mrem[1]	(1 mSv)	5×10^{-5}	3.5×10^{-3}
10	mrem	(0.1 mSv)	5×10^{-6}	3.5×10^{-4}
1	mrem	(0.01 mSv)	5×10^{-7}	3.5×10^{-5}
0.1	mrem	(0.001 mSv)	5×10^{-8}	3.5×10^{-6}

[1]Unless otherwise indicated, the expression of dose in mrem refers to the Total Effective Dose Equivalent. This term is the sum of the deep dose equivalent for sources external to the body and the committed effective dose equivalent for sources internal to the body.

[2]Risk coefficient of 5×10^{-4} per rem (5×10^{-2} per Sv) for low linear energy transfer radiation has been based on results reported in UNSCEAR 1988 (footnote 2). Also, refer to NUREG/CR-4214 (Rev. 1).

b. Collective or Population Risk

In the application of the fundamental principles of radiation protection, collective dose provides a useful way to express the radiological impact (i.e., potential detriments) of a nuclear activity on the health of the population subject to radiation exposure. Collective dose is the sum of the individual doses resulting from a practice or source of radiation

exposure. It has been used in comparative cost-benefit and other quantitative analysis techniques. It is therefore an important factor to consider in balancing benefits and societal detriments for practice justification and in applying the ALARA principle. The NRC has used collective dose in this manner in a number of rulemaking decisions and decisions involving resolution of a variety of generic safety issues.

Derivation of Measurable Quantities from Dose/Risk Estimates

The Commission recognizes that it is frequently not possible to measure risk to individuals or populations directly, and, that in most situations, it is impractical to measure annual doses to individuals at the low levels potentially associated with its exemption decisions. Typically, radioinuclide concentrations or radiation levels from the material to be released from regulatory control are the actual measurements that can be made, and doses are then estimated by exposure pathway analysis using assumptions related to the ways in which people might become exposed. These assumptions incorporate sufficient conservatism in modeling to account for uncertainties so that any actual dose would be expected to be lower than the calculated dose. The Commission believes that this is the appropriate approach to be taken when determining if an exemption from some or all regulatory controls is warranted.

III. APPLICATION OF RADIATION PROTECTION PRINCIPLES TO EXEMPTIONS FROM REGULATORY CONTROL

The following sets forth guidelines about how the Commission will apply the fundamental principles of radiation protection in consideration of practices which are proposed to be exempt from certain regulatory controls. These practices, if approved, would result in low levels of radioactive material being transferred from a controlled to an uncontrolled state (1) in products being distributed to the general public and (2) on lands and structures and in effluents and solid waste being released to areas of the publicly-accessible environment.

- Justification - Decisions regarding justification of practice usually derive from considerations which are much broader than those based on

radiation protection alone. Therefore, these decisions may be made in a broader context before the need for regulatory control is addressed (or the need for exemptions from certain aspects of control, as addressed in this policy). The Commission continues to believe that any practice causing a potential radiation exposure should be justified; however, as lower levels of individual and population dose are projected, lower levels of benefit may be sufficient to achieve a positive balance although other societal impacts of a practice must also be considered. The Commission will continue to identify or characterize certain practices for which benefits are considered marginal and for which there appears to be no reasonable justification.

° Dose Limits - Individual doses from individual practices exempted under this policy should not, with rare exception, exceed a small fraction of 100 mrem per year (1 mSv per year). This is the non-occupational dose limit recommended by the International Commission on Radiological Protection and the National Council of Radiation Protection and Measurements for continous exposure from all practices using man-made sources of radiation other than medical. It is also the value specified in the recent major revision of 10 CFR Part 20, Standards for Protection Against Radiation. The dose limits in the major revision of 10 CFR Part 20 apply to all sources of radiation exposure under a licensee's control (natural background and medical exposures are specifically excluded).

° ALARA - Once a practice has been justified and controls are in place to assure that dose limits are not exceeded, it is necessary to design and plan the subsequent use and disposal of the sources of radiation in a manner which ensures that exposures are as low as reasonably achievable, economic and social factors being taken into account. As a result, this principle applies when considering a practice for possible exemptions from some or all regulatory controls. This requirement that doses be ALARA has been a part of NRC regulatory practice for a number of years and is now formally embodied in the revisions to Title 10, Code of Federal Regulations, Part 20. However, no policy or criteria have been provided which

would establish the bases for defining a generic "floor" to ALARA. A major purpose of this policy is to establish criteria which would delineate conditions such that additional expenditure of regulatory and licensee resources would not be necessary to further reduce radiation exposures from a practice for which an exemption has been granted.

Although it is possible to project what the dose will be from a practice , and then take this information into account in controlling regulated practices so that the dose limits are not exceeded, exemptions involve a reduction or elimination of some or all controls. In view of this, the Commission believes that a key objective in establishing a policy for exemptions, is to provide adequate assurance that individuals will not experience radiation exposure exceeding 100 mrem per year (1 mSv per year) through the cumulative effects of all exempted and regulated practices even though the exposures from any single exempt practice would be expected to be a small fraction of this value. By appropriate choices of exemption criteria and constraints, and through its evaluations of specific exemption proposals, the Commission intends to assure that it is unlikely that any individual will experience continuing exposures which exceed 100 mrem per year (1 mSv per year).

IV. PRINCIPLES OF EXEMPTION

A major consideration in exempting any justified practice from some or all regulatory controls hinges on the general question of whether or not application or continuation of regulatory controls is necessary and cost effective in reducing dose. To determine if exemption is appropriate, the Commission must determine if one of the following conditions is met:

1. The application or continuation of regulatory controls on the practice does not result in any significant reduction in dose received by individuals within critical groups (i.e., the group expected to receive the highest exposure) and by the exposed population or;

2. The costs of the regulatory controls that could be imposed for dose reduction are not balanced by the commensurate reduction in risk that could be realized.

For purposes of implementing its policy, the Commission recognizes that only under unusual circumstances would exemptions be considered for justified practices which could cause continuing radiation exposure to individuals exceeding a small fraction of 100 mrem per year (1 mSv per year). The Commission will consider such circumstances on a case specific basis using the general principles outlined in this policy statement. However, as the doses and attendant risks to members of the exposed population decrease, the need for regulatory controls decreases. At a sufficiently low level of individual risk, decisions granting specific exemptions from some or all regulatory controls, for a justified practice, may be reduced to an evaluation of whether the overall individual and public risk are sufficiently small.

The Commission therefore proposes that two numerical criteria should be established in defining the region where the risk reduction does not warrant the expenditure of Commission or licensee resources to bring about a further incremental compliance with the ALARA principle. They are (a) a criterion for the maximum individual annual dose reasonably expected to be received as a result of the practice (e.g., an average dose to individuals in a critical group) and (b) a measure of societal impact to the exposed population. In combination, these criteria are chosen to assure that, for a given exempted practice, no individual will be exposed to a significant radiological risk and that the population as a whole does not suffer a significant impact.

The Individual Dose Criterion

If the doses to individuals from a practice under consideration for exemption are sufficiently small, the attendant risks will be small compared to other societal risks and there would be little merit in expending resources to further reduce the dose or risk from a justified practice. The Commission believes the definition of this risk or dose level can be developed from two perspectives. The first of these is related to quantitative risk levels. The Commission believes that most members of society will not expend resources to reduce an annual

individual fatality risk below approximately 10^{-5} (i.e., 1 chance in 100,000). This risk level is comparable to that (i.e. $2x10^{-6}$) selected by the Commission in the development of its safety goal policy - (i.e., a risk level equal to 0.1% (1/1000) of the sum of cancer fatality risk from all other causes). Using the no-threshold hypothesis, the incremental continuing annual individual exposure level comparable to this "safety goal" risk level can be estimated as 4 mrem per year (0.04 mSv per year). The second perspective is based on those variations in dose, and hence risks, knowingly or unknowingly tolerated by individuals because of factors such as their lifestyle or place of residence. The Commission notes that resources are not expended to reduce differential exposures associated with variations in natural background radiation (e.g., the 60-70 mrem per year difference between annual doses received in Denver, Colorado vs Washington, DC). Nor are resources spent to reduce (1) the difference in doses between living in a brick vs a frame house, (2) the 5 mrem dose which an individual would receive during a single round trip coast-to-coast aircraft flight, or (3) the dose from other activities which involve doses representing a small fraction of background radiation.

In view of the uncertainties involved (such as, the applicability of the no-threshold model itself and its input data) and taking into account the the aforementioned risk and dose perspectives, the Commission finds an individual dose of 10 mrem per year (0.1 mSv per year) to be appropriate for use as one of two boundary criteria which would define whether or not additional resources need be spent to comply further with the ALARA principle. The Commission considers this value to be appropriate given the uncertainties involved and notes that, at this value, implementation of this policy in future rulemakings or licensing decisions should be a practical undertaking. Given the Commission's intent (1) to define practices broadly, (2) to evaluate potential exposures over the lifetime of the practice, (3) to monitor and verify how exemptions are implemented under this policy, and (4) to impose a companion collective dose criterion in defining when further compliance with the ALARA principle is unwarranted, the Commission believes that reasonable assurance can be provided that individual exposures from all practices should not exceed 100 mrem per year (1 mSv per year).

The Societal Impact Criterion

In proposing criteria which would demonstrate practical achievement of ALARA, the Commission seriously considered whether the imposition of the individual dose criterion would also provide a sufficient measure to judge societal impact, and, thus, could stand alone as a basis for determining when further resources need not be expended to comply with the ALARA principle. The Commission finds that the individual dose criterion should not stand alone and believes the need for a companion collective dose criterion has two bases.

First, these criteria are being put forward as a means of demonstrating practical compliance with the ALARA principle. The ALARA process involves, among other considerations, the trade-offs between cost of dose or risk reduction and the magnitude of the reduction in population dose achieved. The Commission believes that if a justified practice involves an appropriately small potential for individual risk and societal detriment, efforts directed toward further reduction of this risk and detriment are not likely to represent an optimum use of either the Commission's or a licensee's resources from an overall public health and safety standpoint. The Commission is therefore proposing that a collective dose criterion be used, with the individual dose criterion, to define this minimal societal detriment. This criterion is considered necessary since the individual dose criterion is not claimed to represent a negligible or de minimis individual dose; and thus, the sum of the individual doses from a given practice cannot necessarily be considered negligible.

Second, the Commission believes a collective dose criterion, in conjunction with the individual dose criterion, is necessary to provide additional assurance that the curtailing of the ALARA process will not lead to total individual doses from all exempted and regulated practices exceeding 100 mrem per year (1 mSv per year). The collective dose represents a summation of all individual doses resulting from a practice, independent of any pattern of individual dose distribution. However, collective dose is most likely to be the overriding consideration for those practices or classes of practices involving potential widespread

distribution of radioactive material to members of the public (e.g., in the form of consumer products, or recycled equipment or materials containing residual levels of radioactive contamination). The Commission notes that the uncertainties in establishing reasonable scenarios through which the public may interact with these products, equipments or materials, creates uncertainty in the calculation of individual doses, and as a result argues for a compensatory provision of collective dose as a matter of regulatory prudence. Furthermore, for these practices, effective dose reductions may be possible at relatively small costs. As a result, a practice must also result in a collective dose of less than 500 person-rem per practice per year in order for the Commission, based on these criteria alone, to agree that no further resources need be expended to comply incrementally with the ALARA principle.

The Commission stresses that adoption of the individual and collective dose criteria should not be construed as a decision that doses below these criteria are necessary before a practice can be exempted, while doses above the criteria would preclude exemptions. On the contrary, the criteria simply represent a range of risk which the Commission believes is sufficiently small compared to other individual and societal risks that further cost-risk reduction analyses, (or more broadly, ALARA analyses) are not required in order to make a decision regarding the acceptability of an exemption. Practices not meeting these criteria may be granted exemptions on a case-by-case basis in accordance with the principles embodied within this policy. To further emphasize that a rigid limitation is inappropriate, the Commission notes that for some practices, such as use of smoke detectors, collective doses have been estimated to exceed 500 person-rem per practice per year, yet appreciable benefits can only be attained through extensive utilization and, hence, with a commensurate collective dose.

The Commission is aware that existing and future regulations of the Environmental Protection Agency for environmental protection may establish criteria for specific practices more restrictive than exemptions which may be granted under this proposed policy. Any affected NRC regulations developed on the foundations of this policy may need to be reviewed and, if necessary, revised. With regard to its own regulations, the Commission will consider whether there are exemption criteria embodied therein for which modification, according to the principles of this policy, would be beneficial.

V. UNJUSTIFIED PRACTICES

Since it is not possible to foresee every use of radioactive material that may be proposed in the future, the Commission does not believe it should prejudge any class of practices as innately unjustifiable. However, the Commission continues to believe that there are certain classes of practices involving radiation or radioactive materials which potentially have little or no benefit to society (e.g., consistent with the policy statement on consumer products, March 16, 1965, 30 FR 3462). These practices could include, but are not limited to, the intentional introduction of radioactive material into toys, novelties, and non-medical products intended for ingestion, inhalation, or direct application to the skin (such as cosmetics). The Commission's determinations regarding the justification of practices will also include consideration of any non-radioactive alternatives; that is, there should be a net benefit of the radioactive over the non-radioactive alternative.

VI. PROPOSALS FOR EXEMPTION

A proposal for exemption must provide a basis upon which the Commission can determine if the basic conditions described above have been satisfied. In general, this means that the proposal should address the individual and societal impact (i.e., benefits and detriments) resulting from the expected activities under the exemption, including the uses of the radioactive materials, the pathways of exposure, the levels of activity, and the methods and constraints for assuring that the assumptions used to define a practice remain appropriate as the radioactive materials move from regulatory control to an uncontrolled status.

If a proposal for exemption results in a rule containing specific requirements, a person applying to utilize the exemption would not need to address justification or ALARA. The Commission decision on such proposals will be based on the licensee's meeting the conditions specified in the rule. The promulgation of the rule would, under these circumstances, constitute a finding that the exempted practice is justified, and that ALARA considerations have been dealt with. This approach is consistent with past practice, e.g., consumer product rules in 10 CFR Part 30.

In evaluating proposals for exemption under this policy, the projected exposures to different components of the exposed population will be considered with regard to the potential that some individuals may receive doses from other practices. If exposures from multiple practices can occur which are significantly beyond the individual dose criterion (10 mrem per year (0.1 mSv per year)), the exemption will not be granted without further analysis. As experience is gained, this policy and its implementation will be reevaluated with regard to this issue to assure that the annual exposures to individual members of the public from exempted and regulated practices remain below 100 mrem (1 mSv).

In addition to considerations of expected activities and pathways, the Commission recognizes that consideration must also be given to the potential for accidents and misuse of the radioactive materials involved in the practice. A proposal for exemption of a defined practice must therefore also address the potentials for accidents or misuse, and the consequences of these exceptional conditions in terms of individual and collective dose.

VII. VERIFICATION OF EXEMPTION CONDITIONS

The Commission believes that the implementation of an exemption under this broad policy guidance must be accompanied by a suitable program to monitor and verify that the basic conditions under which an exemption was issued remain valid. In most cases, the products or materials comprising an exempted practice will move from regulatory control to the exempt status under a defined set of conditions and criteria. The monitoring and verification program established by licensees, who propose to release materials under the provisions of regulations or licensing conditions developed from this policy, must therefore be capable of providing the Commission with the appropriate assurance that the conditions for the exemption remain valid, and that they are being observed. The Commission will determine compliance with the specific conditions of an exemption through its established licensing and inspection program and may, from time to time, conduct studies as appropriate to assess the impact of an exempted practice or combinations of exempted practices.

ENCLOSURE 2

Enclosure 2

ANALYSIS OF AND RESPONSE TO COMMENTS

INDEX

Enclosure 2

ANALYSIS OF AND RESPONSE TO COMMENTS -- ADVANCE NOTICE, POLICY STATEMENT ON EXEMPTIONS FROM REGULATORY CONTROL

In response to a December 12, 1988, advance notice (53 FR 49886) regarding the subject policy statement, over 225 comment letters were received. Most of these letters were received during the months of February and March, after the official January 30, 1989, comment closing date; however, receipt of additional comments has continued into late April. The comment letters included about 149 from individuals, of which about one quarter identified themselves as health physicists. Four of these letters from individuals were petitions expressing opposition to policy development. There were 21 letters from public interest groups, a union, and professional organizations; 19 letters from utilities or their representatives; 9 letters from industry; one letter from a university; 10 letters from state or local government organizations; 4 letters from professional societies; 2 letters from members of the National Council on Radiation Protection and Measurements (NCRP); one letter each from the U.S. Environmental Protection Agency and the U.S. Department of Energy; and two letters from members of Congress.

The issues raised in these letters have been categorized into 18 subject areas which include those for which comment was explicitly solicited in the advance notice. In the following paragraphs, the issues, comments, and questions in each category are summarized and the Commission responses are provided.

1. General Comment on Policy Need and Viability

Comments

The comment letters were approximately equally divided between those favoring and those opposing a Commission exemption policy.

Those opposed to policy development generally stated that any health risk should not be the subject of deregulation. Most of these commenters focused on low level radioactive waste disposal practices and believed that the disposal of radioactive material at licensed facilities should be considered a cost of doing business. Many, however, also specifically opposed (1) the use of radioactive material in consumer products and (2) the release for public use of any lands or structures or recycled equipment or materials with any level of radioactive contamination. Several of these commenters claimed that continuing regulation was especially important when the effects of low level radiation are unknown and the trends in the dose to health effect relationships are in a direction of increasing risk per unit dose.

Those favoring policy development focused on the issue of the optimum use of licensee and regulator resources, believing resources spent to control small or negligible risks could be better directed at more significant problems. These commenters viewed cost and regulatory savings in both parochial and national terms, e.g., the focusing of regulatory and industrial resources on more important public health concerns, including, but not limited to, radiological impacts on public and occupational health and on the environment.

Many of these commenters also pointed out that any potential exposure associated with a proposed exemption decision would be very low (e.g., frequently comparing the policy's 10 millirem per year (0.1 mSv per year) per practice individual dose criterion to (1) variations in background radiation across the United States (Washington, D.C. vs Denver, Colorado (60-70 mrem/year)), (2) exposures resulting from naturally occurring radioactive potassium-40 in the human body (30 mrem/yr), or (3) exposure resulting from airplane flights across the continent (5 mrem per 10 hrs. of flight).

Response

The Commission believes that its principal regulatory mission is to assure that proper protection of radiation workers, the public, and the environment is provided in the conduct of licensed activities involving the use of radioactive materials. The Commission considers that its existing 10 CFR Part 20 regulations, which provide dose limits and requirements that doses be as low as reasonably achievable (ALARA), form the basis for defining a proper level of occupational and public radiological protection. However, under provisions of the Atomic Energy Act (AEA), as amended (e.g., Sections 57d, 62 and 81), the Commission has also been given authority to exempt certain classes or quantities of material or kinds of uses or users from requirements for a license, if the Commission finds that its actions would not constitute an unreasonable risk to the health and safety of the public. This authority has been used in establishing exemptions for certain waste disposal practices which are codified in 10 CFR Part 20. Other exemptions from the requirements for a person to have a license to receive, possess, use, transfer, own, or acquire products or materials containing byproduct material appear in 10 CFR Part 30. More recently, the Low Level Radioactive Waste Policy Amendments Act (LLRWPAA) of 1985 reaffirmed both the need for exemption [below regulatory concern] decisions and the Commission's authority to develop implementing policies and regulations. The Commission believes that these provisions in the AEA and the LLRWPAA are well-intentioned and reasonable. Such provisions assure that licensing decisions can be made and regulations can be promulgated in a manner which allows the Commission to correctly direct both its own and its licensees' resources toward substantive radiation protection problems and issues. In this regard, the Commission would point out that exemption provisions have been embodied in the Commission's regulations for some time and that this policy is intended to broadly define the bases for future regulations or licensing decisions involving exemptions from some or all regulatory controls.

In response to commenters who contend that the regulated community is the only benefactor of this policy, the Commission is aware that, in many cases when the extent of regulatory activity is reduced based on health and safety considerations, a monetary benefit accrues to the regulated community. Thus, those

commenters opposed to this policy who cite the existence of such benefits are correct. However, the NRC believes its proposed policy is consistent with its regulatory mission. This mission is to assure proper protection of public health and safety. Since resources expended for regulatory control of practices with minimal radiological impacts could be better used to address more significant radiation protection concerns, the minimization of regulatory control at levels of radiation exposure well below acceptable limits can lead to an optimum use of regulator and licensee resources. As a result, a specific exemption decision, although producing a savings to the regulated community, can ultimately best serve the public.

The subjects of the effects of low level radiation and the dose to health effect relationships are further discussed in response to issues 3, 7, and 14.

2. Criteria For Establishing a "Floor" For ALARA

Comments

Most commenters supporting an exemption policy agreed that criteria should be defined to establish a "floor," below which it should be unnecessary to expend resources to further comply incrementally with the ALARA principle. Several stated that, to be effective, numerical criteria were needed rather than broadly defined ranges (e.g., a few mrem). Most reflected the position expressed by the Health Physics Society, believing the "floor" could be defined through sole use of an individual dose criterion without the need for a collective dose or societal impact criterion. The argument used by many of these commenters was that protection of the individual assures protection of society. Many of these commenters believed that any practical value in the use of a collective dose criterion is clearly outweighed by detriments associated with its use. Concern was expressed that the very act of calculating point values for collective dose and implied health effects misleads the public into thinking that precise quantitative results are possible when they are not.

Others specifically related their opposition to a collective dose criterion to the measure's uselessness when considering exemptions involving low level waste disposal practices. A number of these commenters recognized that in addressing other practices, such as consumer products, the magnitude of the number of people potentially receiving an exposure would have to be a consideration in the exemption decision-making process. Several of these commenters correctly recognized that the societal impact criterion was also being considered as a constraint to reduce the effects of uncertainties in dose projections when large numbers of people could interact with the exempted radioactive material. These commenters believed that this issue should be confronted directly and not through use of a collective dose constraint.

A few commenters, including the EPA, presented arguments for including a societal impact criterion which together with the individual dose criterion would either (1) determine if an exemption could be granted, or (2) define the "floor" below which further efforts to comply incrementally with the ALARA principle would not be warranted. These commenters believed that some

assessment of societal impact was mandatory to the decision process regarding an exemption from regulatory control. The Department of Energy also stated its belief that collective dose should be a part of the consideration in order to assess the total impact of the operation proposed for exemption. The Department encouraged NRC to define a de minimis dose level, so that summation of individual doses below this level could be ignored.

Response

In proposing criteria which would demonstrate practical achievement of ALARA, the Commission seriously considered whether the imposition of the individual dose criterion would also provide a sufficient means to judge societal impact, and, thus, could stand alone as a basis for determining when resources need not be expended to further comply incrementally with the ALARA principle. The Commission finds that the individual dose criterion should not stand alone and believes the need for a companion collective dose criterion has two bases.

First, these criteria are being put forward as a means of demonstrating practical compliance with the ALARA principle. The ALARA process involves, among other considerations, the trade-offs between cost of dose reduction and the magnitude of the reduction in the individual and population doses achieved. The Commission believes that if a justified practice involves an appropriately small potential for individual risk or societal detriment, efforts directed toward further reduction of the risk and detriment are not likely to represent an optimum use of either the Commission's or a licensee's resources from an overall public health and safety standpoint. Since the individual dose criterion is not claimed to represent a negligible or de minimis individual dose, as the Department of Energy has pointed out, the sum of the individual doses from a given practice cannot necessarily be considered negligible. As a result, the Commission believes a collective dose criterion is necessary. (Further discussion of the issue of collective dose truncations is provided in response to issue 12).

Second, the Commission believes a collective dose criterion is necessary and provides a simple and useful parameter through which added assurance can be

provided that total doses to individuals from all exempted practices will not approach 100 mrem per year (1 mSv per year). This consideration specifically applies to the potential exposure of some few individuals to multiple practices and, in particular, to those activities or practices involving potential widespread distribution of radioactive material to members of the public (i.e., in the form of consumer products, or recycled equipment or materials containing residual levels of radioactive contamination). The Commission notes that the uncertainties in establishing the extent of reasonable scenarios through which the public may interact with these products, equipments, or materials, in turn, create uncertainty in the calculation of individual doses. As a result, a compensatory provision could be considered a matter of regulatory prudence. Collective dose has been selected as this compensatory provision.

The Commission acknowledges that the use of a collective dose measure could imply a degree of precision in predicting health effects which is unwarranted; however, it is the intent within the proposed policy to emphasize (1) the relationship between the resource allocation issue and the establishment of a quantitative value of collective dose, and (2) the use of collective dose as a surrogate means to reduce potential <u>average</u> individual exposures resulting from practices involving widespread distribution of radioactive material to members of the public. As a result, the Commission has decided that a practice must also meet a collective dose criterion in order for the Commission, based on both the individual and collective dose criteria, to agree that further resources need not be expended to further comply incrementally with the ALARA principle.

3. Numerical Criteria Selected for Determining Compliance With The ALARA Principle

Comments--Individual Dose Criterion For Curtailing Incremental Compliance With The ALARA Principle

Almost all of the commenters favoring a Commission exemption policy expressed a view regarding the numerical value assigned to the individual annual dose criterion used to determine when incremental compliance with the ALARA principle is no longer warranted. This criterion, together with the collective dose criterion proposed for the same purpose, delineates a region where the risks are sufficiently small that expenditure of Commission or licensee resources to further reduce those risks is not warranted. Most of the above commenters stated that the 10 mrem per year per practice value for cutoff of ALARA evaluations was very conservative, with many suggesting a value in the 10-20 mrem per year (0.1-0.2 mSv per year) range.

A few commenters considered 10 mrem per year (0.1 mSv per year) a de minimis or negligible individual dose and referred to the Negligible Individual Risk Level (NIRL) defined by the National Council on Radiation Protection and Measurements in their NCRP Report No. 91. It was also pointed out by a commenter that others have stated that background radiation represents an unavoidable "noise level" in which human beings have evolved and prospered. Thus, in this commenter's view, it can be considered to be a benchmark for determining a level that should be "below regulatory concern." It was proposed that the temporal variation in the magnitude of background radiation levels (10-20 mrem/year (0.1-0.2 mSv per year)) at any specific location could also be used to establish such a "below regulatory concern" level.

A significant fraction of commenters suggested that a value as high as 100 mrem per year (1 mSv per year) could be used, while a few commenters suggested values above 100 mrem per year (1 mSv per year), ranging to as high as 500 mrem per year (5 mSv per year) (Note: Some of these commenters may be incorrectly considering the maximum individual dose criterion for cutoff of ALARA evaluations as an individual dose limit on exemptions. However, no such criterion has been included in the policy statement).

Five commenters favored a value less than 10 mrem per year (0.1 mSv per year) including the EPA, the DOE, and Dr. Warren Sinclair, President of the National Council of Radiation Protection and Measurements. The EPA believed that "10 mrem [for the individual dose criterion] is too high" and "...would confound assessment of doses allowed for most controlled sources." Dr. Sinclair stated that "...the NCRP [had] recommended an annual negligible individual risk level of 10^{-7} per year (corresponding to 1 millirem per year)" and "[f]or these reasons, the NCRP does not believe a blanket exemption of sources contributing 10 millirem in a year to individuals is sound radiation protection policy." He added, however, that "...a source producing 10 millirem in a year could be exempted provided justification and ALARA are applied." Another commenter "...agreed with the basic approach outlined in the NRC statement but ...[would] argue for different specific numbers for standards more aligned with the IAEA position." He noted that "...IAEA identifies a range of trivial individual risk as being from 10^{-6} to 10^{-7} per year, or in the range of 10-100 u Sv (1-10 mrem) per year" and "...has acceptance by many other countries." The DOE believed "...the proposed lower limit of 10 mrem/y may be too high considering other existing standards (e.g., the current 4 mrem/y drinking water standard). A fifth commenter suggested that a 5 mrem per year (0.05 mSv per year) value should be considered in light of impending revisions to the risk factor being proposed by the International Commission on Radiological Protection (ICRP) and others (refer to discussion issue 7). One commenter noted that a lower dose value would not only account for the impact of radiation induced fatal cancers but also the impact of non-fatal cancers.

For the most part, commenters opposed to the development of an exemption policy believed no individual dose criterion was appropriate for cutoff of ALARA evaluations, with one commenter pointing out that the 10 mrem per year (0.1 mSv per year) value was the same level which EPA proposed in 1983 as the limit for public exposures from NRC licensed facilities. The EPA also stated that the 10 mrem per year (0.1 mSv per year) value is too high and would not be consistent with many Congressional and regulatory actions being taken relative to other environmental contaminants (Refer to Issue 16).

Response

The Commission has seriously considered the wide range of comments on the individual risk issue. In considering this subject, it must be borne in mind that selection of the individual risk or dose criterion cannot be divorced from consideration of (1) other regulatory actions taken relative to public radiation protection limits (i.e., acceptable upper-bound limits on exposure) and (2) the policy's companion collective dose criterion.

Currently, the recent major revision to Title 10 of the Code of Federal Regulations, Part 20, requires licensees to conduct operations so that the total effective dose equivalent to an individual member of the public from those operations does not exceed 100 mrem per year (1 mSv per year). This is also the principal dose limit for members of the public as stated by the International Commission on Radiological Protection (ICRP) and National Council on Radiation Protection and Measurements (NCRP). Using the no-threshold hypothesis and a risk coefficient derived from effects observed at higher exposure levels, these 100 mrem per year (1 mSv per year) dose limits can be equated to a bounding hypothetical annual cancer fatality risk of 5×10^{-5}.

With this derived acceptable risk value in mind, the Commission believes that if the individual doses from a practice under consideration for exemption are sufficiently small, the attendant risks will be small compared to other societal risks and the merit of expending resources to further reduce the dose or risk from a justified practice can be seriously questioned. The Commission believes the definition of this risk or dose level can be developed from two perspectives. First, in absolute terms, the Commission believes that most members of society would not expend resources to reduce an annual individual fatality risk below approximately 10^{-5} (i.e., 1 chance in 100,000). This risk level is comparable to that (i.e., 2×10^{-6}) selected by the Commission in the development of its safety goal policy and equal to 0.1% (1/1000) of the sum of cancer fatality risk from all other causes. Using the no-threshold hypothesis, the incremental continuing annual individual exposure level associated with this 2×10^{-6} risk level can be estimated as 4 mrem per year (0.04 mSv per year).

The second perspective is relative and is based on those variations in dose and the associated risk tolerated by individuals because of factors such as their lifestyle or place of residence. The Commission notes that, although they may be unaware of the fact, individuals voluntarily accept certain variations in exposure to background radiation, and that resources are not expended to reduce differential exposures associated with variations in natural background radiation, e.g., the 60-70 mrem per year (0.6-0.7 mSv per year) difference between annual doses received in Denver, Colorado vs Washington, DC. Nor are resources spent to reduce the 5 mrem (0.05 mSv) dose received by an individual from cosmic radiation during a single round trip coast-to-coast aircraft flight, or the doses from other similar variations in normal activities (e.g., occupancy in granite structures). These latter examples involve doses representing a small fraction of background radiation.

In view of the uncertainties involved (such as the applicability of the no-threshold model itself and its input data), and taking into account the absolute risk and dose/risk perspectives, the Commission has found that an individual dose of 10 mrem per year (0.1 mSv per year) is an appropriate level for use as one of two boundary criteria which would define whether or not additional resources need be spent to bring about further incremental compliance with the ALARA principle. This value is an order of magnitude below the aforementioned NRC and ICRP public dose limits. The Commission considers this value to be appropriate given the uncertainties involved and notes that, at this value, implementation of this policy in future rulemakings or licensing decisions should be a practical undertaking.

Comments - Societal Impact Criterion for Curtailing Incremental Compliance With the ALARA Principle

As stated in the summary of Issue 2, most commenters agreeing with the need for a Commission exemption policy did not see the need for, or usefulness of, a definitive collective dose criterion which represents societal impact. Those commenters who supported the use of such a criterion generally referred to International Atomic Energy Agency Safety Series No. 89, "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control," and the 100 person-rem per year per practice value cited in that report as being a

total detriment low enough to permit exemption without more detailed examination of other options (i.e., ALARA evaluations). It was suggested that consistency with this international position may improve the policy's acceptance among the regulatory community.

Response

In formulating its exemption policy, the Commission has decided that if a justified practice involves an appropriately small potential for individual risk and societal detriment, efforts directed toward further reductions of this risk and detriment are not likely to represent an optimum use of either the Commission's or a licensee's resources from an overall public health and safety standpoint. In clarifying practical compliance with the ALARA principle, the Commission, as a policy judgment, believes that for practices resulting in a calculated collective dose of less than 500 person-rem per year (5 person-Sv per year) of practice, and for which the maximum individual dose criterion is not exceeded, no further resources need be expended to further comply incrementally with the ALARA principle. At this level of societal impact, resources are better directed at more significant radiation protection or other health-preserving issues. Yet, this level accommodates the possibility that for practices involving distribution of consumer products or recycled equipment and materials, effective dose reductions may, in fact, be possible at relatively small costs. The Commission also notes that 500 person-rem (5 person-Sv) represents an annual level of societal impact per practice which, using the no-threshold hypothesis in relating collective dose to health effects, would provide assurance that, on an annual basis, no potential health effect would be predicted from an exempted practice meeting this criterion.

Furthermore, the 500 person-rem per year (5 person-Sv per year) per practice collective dose criterion provides additional assurance that total doses to an individual from all exempted practices will not approach 100 mrem per year (1 mSv per year). This additional assurance is gained by the impact of this criterion on practices involving widespread distribution of radioactive material to members of the public in the form of consumer products or recycled equipment or materials containing residual levels of contamination. As an example of this impact, the Commission considered the potential for nationwide

distribution of a consumer product containing radioactive material for which a justification of practice determination is presumed to have been made. Distribution of this product (e.g., to 100 million people) would require predicted average individual doses to be less than 5 microrem per year (0.05 microSv per year) (i.e., if the collective dose is to be less than 500 person-rem (5 person-Sv)) before further resources would not need to be expended to incrementally comply with the ALARA principle. If this average is a true representation of the actual distribution of individual doses, then an individual could be exposed to 2000 of such practices and still not receive a total individual exposure approaching 10 mrem per year (0.1 mSv per year). On the other hand, if the distribution of individual doses from such a practice was more limited (e.g., exposure of about 50,000 people to doses approaching 10 mrem per year (0.1 mSv per year)), the probability of any specific individual in the nation's population being exposed to two or more such practices would be expected to be extremely small. As a result of either of these extreme examples, individual exposures from multiple exempted practices meeting the ALARA "cutoff" criteria would not be expected to approach 100 mrem per year (1 mSv per year) and added assurance would be provided that no individual would receive a dose exceeding this value from all exempted and regulated practices.

On these two bases, the Commission has determined that a practice must result in a collective dose of less than 500 person-rem per year (5 person-Sv per year) of practice in order for the Commission, based on both the individual and collective dose criteria, to agree that resources need not be expended to further incrementally comply with the ALARA principle. In this use of the collective dose criterion, the Commission stresses that the adoption of individual and collective dose criteria to demonstrate compliance with the ALARA principle should not be construed as a decision that doses below these criteria are necessary before a practice can be exempted, while doses above the criteria would preclude exemptions. On the contrary, the criteria simply represent a range of risk which the Commission believes is sufficiently small compared to other individual and societal risks that further cost-risk reduction analyses (or more broadly, ALARA analyses) are not required in order to make a decision regarding the acceptability of an exemption. Practices not meeting these criteria may be granted exemptions on a case-by-case basis in accordance with the principles (including ALARA) embodied within this policy.

4. Justification of Practice

Comments

On the questions related to justification of practice, most commenters agreed that in considering various practices, lower levels of projected radiation exposures would require lower levels of benefit to justify a practice. Some pointed out that this fact is inherent in the definition of justification (assuming radiation exposure is the primary adverse impact to be considered). Quite a number of commenters expressed the opinion that if the exposures were low enough (usually interpreted as meeting the dose criteria used to determine when further compliance with the ALARA principle is unwarranted), a practice need not be justified. Others presented arguments that even if exposures are negligible, a determination on the justification of a practice must still be made. (Note: Some of those arguing for a "cutoff" to the use of the principle of justification apparently incorrectly interpreted the dose criteria used in the policy as a determination of trivial or negligible risk).

Response

The Commission believes that justification of practice involves a finding that an activity, source, or practice involving exposure to radiation or release of radioactivity into the environment results in a net enhancement or benefit to human life and health. Many of the commenters did not appear to appreciate the fact that the justification principle may involve consideration of a broad range of qualitative and quantitative factors in establishing this benefit. Adoption of this principle reflects the Commission's view that releases of, or exposures to, radioactivity should only be allowed when necessary in order to provide a benefit to society.

If "justification of practice" were curtailed on a basis similar to that proposed for the ALARA principle, a proliferation of uses of radioactive material from numerous allowed releases may occur. Specifically, if such a proliferation of uses were to occur, it may complicate the Commission's task of assuring that multiple exposures of the public to many exempted practices will be unlikely to result in individual exposures approaching 100 mrem/year (1 mSv

per year) even if most of these uses are projected to involve extremely small doses to the public. The Commission believes that it is not appropriate to use the smallness, or even the triviality of exposures alone, to determine the justification of a practice. However, the Commission does agree with a number of commenters who pointed out that many existing practices have already been "justified," in some cases by Congress through the enactment of Public Law, and in other cases by previous determinations of the Commission. The Commission does not intend, for example, to reconsider the justification of nuclear power or the use of radioactive material by its existing licensees, although a few commenters do not consider that these practices are justified.

Comment-Waste Disposal

Some commenters also expressed the opinion that exemptions for waste disposal options need not involve consideration of practice justification because the need for waste disposal results from sources or more broadly defined practices which have been justified.

Response

Although the impacts from waste disposal operations should rightly be considered in a determination of net benefit for a practice resulting in the waste needing disposal, the Commission does not agree that any option for waste disposal should automatically be considered a justified practice. Various options for waste disposal constitute separate practices and must be "justified" independently of the practice that produced the waste. However, a waste disposal practice is unique in that "no action" is not a viable alternative; that is, waste must be disposed of in one way or another. The number of factors affecting a justification decision tend to be reduced by this fact and may not be significantly different from those factors affecting an ALARA determination.

Comments-Unjustified Practices

On the question of exclusions from consideration for exemption of practices for which there appeared to be no reasonable justification, there was a diversity

of opinions; those opposed to blanket exclusions pointed to the difficulty of prejudging any category of practice, or were of the opinion that the Commission should be careful not to interfere with the conduct of business or free enterprise.

Those who specifically commented on a prohibition against the intentional addition of radioactive material into toys or products intended for ingestion, inhalation, or direct application to the skin were in favor of such prohibitions, although many of the same commenters thought that the Commission should not be trying to judge social acceptability. Most of those opposed to using social acceptability as a criterion were concerned about the difficulty of making such a judgement and a few alluded to the fact that relying on social acceptability could sometimes be contrary to the best interests of the public.

Response

Since it is not possible to foresee every use of radioactive material that may be proposed in the future, the Commission does not believe it should prejudge any class of practice as innately unjustifiable. However, the Commission continues to consider the use of radioactive material in toys, novelties, and adornments to be of marginal benefit to society (consistent with the policy statement on consumer products, March 16, 1965, 30 FR 3462). In the case of direct, purposeful addition of radioactive material to products intended for ingestion, inhalation, or direct application to the skin, it appears unlikely that a net benefit of such a use, other than a medical use, could be shown. (Administratively, the Commission has not exempted medical uses of radioactive material; however, this does not indicate that such exemptions would not be considered under appropriate circumstances). In judging any particular practice, social acceptability cannot be eliminated as a consideration, in spite of the difficulties of making such judgments. Input from the public on this and all aspects of a potential rulemaking is obtained through the rulemaking process. As noted by a few of the commenters, because of the broad range of factors which can affect a decision on justification, some subjective judgment will be necessary on the part of the Commission.

Comments-Nonradioactive Alternatives

On the question of excluding the use of radioactive material in products for which there is a clear economic alternative and no unique benefits from using radioactive material, again, comments were mixed. The commenters opposed to such an exclusion felt that the marketplace is adequate to eliminate less preferable alternatives. The primary specific point made by a number of these commenters, was that there could be non-radiological risks associated with the alternatives. Others noted that "economical" is not clearly defined.

Response

Although it was not made clear in the advance notice, the Commission would not attempt to eliminate radiological risks without consideration of other risks. It is acknowledged that the unique benefit of using radioactive material, and hence a factor in justification, could be the reduction or elimination of a non-radiological risk associated with the alternative. Because of the need to consider a number of different factors such as relative economic costs of alternatives, potential impacts other than radiological, and relative benefits of alternatives, it does not appear practical to develop criteria to clearly define when radioactive material should not be used in a product because of the existence of a non-radiological alternative. However, in determining whether a proposed practice is justified, consideration will be given to the existence of any alternatives. Specifically, it would be expected that to be justified the use of radioactive material should present a net benefit over any non-radioactive alternative taking into account any factors otherwise affecting justification.

5. Maintaining Flexibility in the Exemption Decision-Making Process

Comments

Most commenters supporting a Commission exemption policy believed that flexibility should be maintained. Specifically, if a practice is justified and an exemption decision is supported by a defensible ALARA analysis, the exemption could be allowed even if doses could exceed either or both the 10 mrem per year (0.1 mSv per year) individual dose criterion, and the 500 person-rem (5 person-Sv) per year collective dose criterion. The regulatory authorities at the international workshop agreed that the magnitude of the collective dose alone should not arbitrarily preclude a practice from being exempt from some regulatory controls. These same authorities were split, with regard to the application of flexibility, if individual exposures exceeded a fraction of a trivial individual risk criterion (i.e., a few millirem per year or a few 10's of microSv/year) proposed in the IAEA document, Safety Series No. 89, "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control." The Commission's Advisory Committee on Nuclear Waste and the Environmental Protection Agency supported the view that no exemptions should be considered for practices involving potential individual exposures exceeding a defined limit, which in their opinion should be a small fraction of applicable dose limits. Some commenters believed that the Commission's advance notice reflected this viewpoint. On the other hand, the EPA expressed the belief that the advance notice indicated Commission willingness to routinely consider exemptions involving individual doses which could approach public dose limits.

Response

The Commission's intent in the advance notice was to provide for regulatory flexibility; however, as reflected by the comments received, the policy intent on this issue was not clear. A large part of this confusion occurs as a result of differing views on the meaning and scope of the numerical criteria associated with exemption or "below regulatory concern" decisions.

As stated in the advance notice and in the proposed policy statement, the overall Commission intent regarding its exemption decisions is to assure that exposures to individual members of the public from all such decisions do not approach 100 mrem per year. Within the spectrum of exemption decisions, however, the Commission believes there may be instances where exemptions, defended on the basis of justification of practice and a defensible ALARA analysis (i.e., a reasonable optimization evaluation), could be granted for practices where some individuals could receive doses above 10 mrem per year (0.1 mSv/year). Such exemptions are expected to be rare and certainly would not be granted without a high level of confidence that the conditions of exemption would assure protection of the public against undue risk. With regard to practices exceeding the collective dose criterion, the Commission is in agreement with other national regulatory authorities, and believes that, if supported by a defensible ALARA analysis, a justified practice can be exempted from some or all regulatory controls.

Further clarification in terminology is discussed in the response to comments under issue 11.

6. Federal-State Authority-State Compacts for Disposal of Low-Level Radioactive Waste

Comments

A number of commenters, mainly utilities, but including two responders from State departments of health, stated that it would be crucial that Agreement States adopt verbatim any Commission exemption regulations. These commenters, for the most part, believed that the goal of establishing appropriate national criteria would be undermined if individual States are able to abstain or to establish more restrictive exemption criteria.

Response

The Commission agrees with these comments and, as stated in the advance notice and the proposed policy statement, intends that rulemakings codifying exemptions from some or all regulatory controls will be made a matter of compatibility for Agreement States. As reflected by many of the commenters, the degree of compatibility must be such that national consistency is achieved--a requirement which the Commission agrees is necessary.

Comments

A few commenters, including two who are members of county boards of supervisors, argued that their State, working together with other States, is making good progress toward the establishment of low level radioactive waste disposal facilities as required by the Low Level Radioactive Waste Policy Amendments Act (LLRWPAA) of 1985. These commenters thought that the NRC's exemption policy initiative is unnecessary since the State's low level radioactive waste disposal facilities, being sited under LLRWPAA, are designed to handle all radioactive waste identified under current rules as "low-level." These same commenters noted that using local facilities such as public landfills and incinerators to handle low-level radioactive materials, even though defined as "below regulatory concern," would make the siting of these waste disposal facilities extremely difficult and would put an extra burden on existing facilities.

Response

In Section 10 of the LLRWPAA of 1985, the Commission was directed to establish standards and procedures, pursuant to existing authority, and to develop the technical capability for considering and acting upon petitions to exempt specific radioactive waste streams from regulation due to the presence of radionuclides in such waste streams in sufficiently low concentrations or quantities as to be "below regulatory concern." The Commission responded to the LLRWPAA by issuing a "General Statement of Policy and Procedures Concerning Petitions Pursuant to §2.802 for Disposal of Radioactive Waste Streams Below Regulatory Concern." This general statement of policy was published for comment in the Federal Register on August 29, 1986. Thus, the same piece of legislation that defined the State's responsibilities for low level radioactive waste disposal directed the Commission to develop a "below regulatory concern" policy. The Commission's response to this legislation was the August 1986 general statement of policy (51 FR 30839) which provided criteria which, if met, would allow the Commission to expeditiously evaluate petitions for "below regulatory concern" waste disposals. The purpose of this proposed policy is to establish the basis upon which the Commission may initiate the development of appropriate regulations or make licensing decisions to exempt certain practices from some or all regulatory controls, including those related to low level radioactive waste disposal.

The Commission acknowledges that its exemption policy may increase difficulties in the siting of waste disposal facilities. The Commission believes, however, that as enhanced public understanding of the underlying rationale, the technical basis and the resource utilization implications for its policy occurs, such difficulty will be reduced. One objective of issuing the policy statement is to so enhance the public understanding of these matters.

7. Value Used for Risk Coefficient

Comments

The EPA and others, in their comments, stated that the dose-to-risk conversion factor used in the advance notice (i.e., $2x10^{-4}$ latent cancer fatalities (LCF) per rem ($2X10^{-2}$ LCF per Sv) of low linear energy transfer radiation) was out-of-date and did not reflect extensive new information gained in the last decade. Two commenters questioned the adequacy of this value in accounting for all health and genetic effects in the first two generations. [Note: Other relevant comments are discussed under issue No. 14, Applicability of the No-threshold Hypothesis - Hormesis].

Response

In the establishment of its radiation protection policies, the Commission has considered the three major types of health effects which can be caused by relatively low doses of radiation: cancer, genetic effects, and developmental anomalies in fetuses. The NRC and EPA focus on the risk of fatal cancer development principally because (1) the strongest basis exists for quantifying the risk of cancer mortality in humans (2) the mortality risk from fatal cancer represents a more severe outcome than the risk from non-fatal cancers, and (3) the mortality risk is believed to be higher than the risk associated with genetic and fetal effects. Therefore, the Commission believes this to be an appropriate basis for its decisions at this time.

The Commission notes that, even though radiation has been shown to be carcinogenic, the development of a risk factor applicable to continuing radiation exposures at levels equal to natural background[1] requires a

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1 Natural background radiation can vary with time and a person's location. In Washington, DC natural background radiation (excluding radon) results in individual doses of about 90 mrem per year (0.9mSv/year), while in Denver, Colorado the value is about 160 mrem per year (1.6mSv/year) including, in both cases, a contribution of about 40 mrem per year (0.4mSv/year) from natural radioactive material contained in the human body.

significant extrapolation from the observed effects at much higher doses.[2] The result is a significant uncertainty reflected by the views of experts in the field. For example, the National Academy of Science's Committee on the Biological Effects of Ionizing Radiation, has cautioned that the risk values are "...based on incomplete data and involve a large degree of uncertainty, especially in the low dose region." This Committee also stated that it "...does not know whether dose rates of gamma or x-rays (low LET) [low linear energy transfer radiation] of about 100 mrads/year (1 mSv/year) are detrimental to man." The Commission recognizes that the Committee's statement is a reflection of the uncertainties involved, and does not imply either the absence or presence of detrimental effects at this dose level.

In the face of this and similar cautions, the advance notice contained an estimate of the lifetime risk of cancer mortality from low LET radiation which was based on the following table.

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2 The health effects clearly attributable to radiation have occurred principally among early radiation workers, survivors of the atomic bomb explosions at Hiroshima and Nagasaki, individuals exposed for medical therapy purposes, and laboratory animals. Natural background causes a dose over a one year period which is at least two orders of magnitude less than the dose received by populations from which the cancer risks are derived.

Estimates of Lifetime Risk of Cancer Mortality
from Low LET Radiation Received at Low Dose Rates*

Type of Cancer	Number of Cancer Deaths (per 10^6 person-rad) or (per 10^4 person-gray) ---Range of Estimates--- lower	Central	Upper
Leukemia	4.8	14	48
In Utero	1.2	1.2	3.0
Bone Cancer	0.2	0.6	12.1
Breast Cancer	4.4	60	87
Lung Cancer	5.3	20	245
GI Cancer	9.1	57	327
Thyroid Cancer	7.2	7.2	7.2
Other Cancer	5.1	29	169
In Utero	1.2	1.2	3.0
Whole body (rounded)	40	200	900

* less than 5 rad/day (50mGy/day)

These risk estimates were taken from NUREG/CR-4214, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," Rev. 1, 1989. The risk estimates were based primarily on the 1980 Report of the Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences entitled, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," (BEIR III). However, radioepidemiological data that became available since the publication of BEIR III were utilized in the development of NUREG/CR-4214 risk estimates.

In estimating the somatic health effects, the BEIR III report utilized epidemiological data obtained from studies of survivors of Hiroshima and Nagasaki and, to a lesser extent, other irradiated populations. In BEIR III there are variations in risk estimates which are due to factors in addition to uncertainties in the Japanese and other epidemiological data bases. Excess cancers have been observed mostly following relatively large doses delivered at

high dose rates. Moreover, the observation time of the exposed populations does not yet extend through the lifetimes of the irradiated individuals. Therefore, assumptions must be made about how observations at high doses and dose rates should be applied at low doses and low dose rates for radiation of a given type and how risks from radiation might vary long after the time of exposure.

The BEIR III report examined three dose response functions in detail: (1) linear, in which effects are directly proportional to dose at all doses; (2) linear-quadratic, in which effects are very nearly proportional to dose at very low doses and proportional to the square of the dose at high doses; and (3) quadratic, in which the risk varies as the square of the dose at all dose levels. All mathematical functions in BEIR III assume that there is no dose below which there is no health risk. For low LET radiations, BEIR III recommended the use of a linear-quadratic dose response function. To estimate the risk of radiation exposure beyond the years of observations, either a relative risk or an absolute risk projection model (or suitable variations) must be used. The relative risk projection model projects the currently observed percentage increase in cancer risk per unit dose into future years. An absolute risk model projects the average observed number of excess cancers per unit dose into the future years at risk. Because the baseline rate of cancer incidence rises dramatically with age, the relative risk projection model predicts a larger number of radiation induced cancers in the aging population for years beyond the periods of observation; consequently, the average lifetime risk calculated according to the relative risk model is higher than that which would be calculated using the absolute risk model. The BEIR Committee did not specify which projection model is the appropriate choice for most radiogenic cancers.

NUREG/CR-4214 provided upper, central, and lower risk estimation models for leukemia and cancers of the bone, breast, lung, gastrointestinal tract, thyroid, skin, and other organs. Models for cancers due to prenatal irradiation were also given. For the central estimates considered most realistic by the scientists who prepared NUREG/CR-4214, linear-quadratic dose response models were used for all cancers except those of the breast and thyroid, and those due to prenatal irradiation. The linear dose response model

was used for these cancers. The relative projection model was used to estimate the risk of breast, lung, gastrointestinal, and other cancers. In estimating the potential radiological impact associated with the individual dose values used in this policy statement, the central estimate was used. For alpha emitters, a Quality Factor (Q) of 20 would be applied.

The reevaluation of the doses received by the survivors of the atomic bombs in Hiroshima and Nagasaki is expected to affect the aforementioned estimates of risk of increased incidence of cancer in an irradiated population. The cancer risk estimates in BEIR III and NUREG/CR-4214 are based on the tentative 1965 dosimetry system (T65D). Only recently, reports have been published comparing the risk coefficients for cancer mortality based on the revised dosimetry system (DS86) (Preston and Pierce, 1987, Shimizu et al., 1987). Complete assessment of the data has not yet been published. However, based on results given in the above mentioned reports, the risk coefficient for low LET radiation in the proposed policy has been tentatively changed to a value of $5x10^{-4}$ latent cancer fatalities per rem ($5X10^{-2}$ LCF s per sievert).

The Commission also recognizes that irradiation of the reproductive organs may cause increased incidence of disorders of genetic origin among the offspring of irradiated people. Such disorders may manifest themselves in the first generation following parental irradiation and/or in future generations. The NRC has derived estimates for genetic effects based on experimental animal data, since no suitable human data is available. These estimates are provided in NUREG/CR-4214. However, because these estimates are primarily based on animal data, and their magnitudes are somewhat less than for fatal cancers, they have not been used in developing this policy. Thus, although the Commission has focused on the risk of fatal cancer in the development of its exemption policy statement, the Commission has evaluated the possibility of genetic disorders occurring as a result of low level exposures to ionizing radiation.

8. Public Perceptions and Need for Added Perspective on Risk Levels

Comments

A number of commenters raised concerns regarding public perceptions of the numerical values of individual and collective dose used in the proposed policy statement. One commenter stated that the 10 mrem per year (0.1 mSv/year) individual dose criterion for a practice was unnecessarily low and that the public would perceive this value as a threshold of harm. This commenter believed that NRC must provide a better basis for public understanding of the significance of "low level" radiation exposure (<100 mrem per year or 1 mSv per year), and stated that a considerable fraction of the regulatory efforts are concerned with radiation exposures much smaller than those received from variations in natural radiation due to altitude changes or other causes. Another equated 10 mrem per year (0.1 mSv per year) with 1/3 the dose received in a chest X-ray. Several other commenters also suggested comparisons to variations in background radiation and to doses received during high altitude aircraft flights due to increased levels of cosmic radiation. One commenter suggested comparisons to radiation doses received in use of coal or cement which contain low levels of naturally occurring radioactive material. Another commenter provided the following tabulation of annual risk levels:

Table
Some "Annual" Risks of Dying

Condition	Risk	Risk Normalized to: That from One Year's Exposure to Natural Background	Risk Normalized to: Normal Cancer Incidence
Being age 60	2×10^{-2}	200	10
Being age 50	7×10^{-3}	70	4
Heart disease	5×10^{-3}	50	3
Being age 40	3×10^{-3}	30	2
Cancer or being age 30	2×10^{-3}	20	1
Being 1 or 20 years of age	1×10^{-4}	10	0.5
Accidents (total, all kinds)	6×10^{-4}	6	0.3
Being age 10, flu, etc.	3×10^{-4}	3	0.2
Natural background	1×10^{-5}	1	0.05
Fires, drowning, poisoning	3×10^{-6}	0.3	0.02
Electric current	5×10^{-6}	0.05	0.003
10 mrem/yr "BRC" dose	3×10^{-7}	0.03	0.002
Lightning	6×10^{-7}	0.006	0.0003

Commenter's note: (The risks from radiation cited above were calculated using the EPA risk coefficient of 400 fatal cancers per million man-rem, yielding results about twice those calculated by NRC.)

Other commenters, on the other hand, objected to presentations which compare actuarial risks (e.g., risk of death by drowning or fire) with hypothetical risks from radiation exposure. These commenters pointed out that the radiological risk depends on extrapolation of risk coefficients derived at high exposure levels to the levels of dose received from background radiation or even lower levels reflected by the 10 mrem (0.1 mSv) individual dose criterion included in the Commission's proposed exemption policy statement.

Another commenter took exception to any regulatory policy which, as a basis, measures human life against economic benefits. This commenter believed that it is only acceptable for regulators to allow practices which add risk to human health and life if, and only if, the benefits of these practices actually enhance human health and life to a greater degree.

Response

The Commission sees merit in many of the perspectives presented. However, the Commission believes that care must be taken to clearly distinguish those perspectives which support the basis for the Commission's exemption policy and those which are presented only to provide a perspective on the individual and societal risk levels under discussion. The Commission believes that comparisons, such as those presented in the table, are proper in establishing a perspective on the magnitude of the hypothesized risks associated with potential exemption decisions. However, these comparative values should not, by themselves, be used to justify the risk levels of any practice considered for exemption from some or all regulatory controls. The Commission further realizes that comparisons of hypothesized and actuarial risks can be misleading, if a fair characterization of the processes and assumptions leading to the hypothesized values are not provided. The Commission, in the supplemental information discussion accompanying this proposed policy statement and in the policy statement itself, has attempted to reflect these distinctions in the perspectives it has provided.

In responding to the commenter who took exception to trade-offs equating human life and economic benefits, the Commission would point out that before considering a practice for exemption from some or all regulatory controls, the Commission must decide that the practice is justified. This determination, in its broadest sense, derives from many considerations beyond those based solely on radiation protection and economics, and must find that allowing the practice results in a net enhancement to human health and life. In many cases, this justification of practice determination may involve a balancing of risk against obvious benefits to the person exposed to the radiation, as in the case of smoke detectors. In other cases, the benefit may be more obscure, perhaps relating to the fact that the practice under consideration for exemption may (1) have a societal benefit which exceeds the total societal risk to human health and safety or (2) be associated with an already justified "source" or physical entity whose use, manipulation, operation, decommissioning and/or disposal constitute the coordinated set of activities defined as a practice. Thus, through application of the justification of practice principle, the Commission believes that a determination is made that the benefits to human

health and life of a specific practice or source exceed all associated real or hypothetical risks.

9. Monitoring

Comments

Many of the commenters were concerned about the issue of monitoring. A concern of many who were opposed to the policy was that there may not be adequate verification of compliance with any release limits or with the assumptions made to estimate the effects from releases. Some thought adequate verification was impossible or, more specifically, that prevention of dilution of waste to meet criteria would be impossible. These concerns were mainly in connection with "deregulation" of waste. Among those in favor of an exemption policy, the primary concern was that the Commission might require additional environmental monitoring or, more specifically, monitoring of municipal landfills by licensees. This was seen as unnecessary, counter-productive, and contrary to the BRC concept. Some felt that it was also inappropriate for NRC to monitor landfills.

Many of the commenters expressed agreement that there is a need for adequate controls at the point of radioactive material release from regulatory control to verify that applicable constraints and criteria are complied with. A few commenters indicated that some offsite verification may be appropriate when individual doses exceeding 10 mrem/year (0.1 mSv/year) are projected. One pointed specifically to the need for NRC to monitor quality control in the production and distribution of consumer products and to check actual distribution vs that estimated.

One commenter suggested that only "in house" monitoring was appropriate and that no documentation should be required.

Response

None of the comments changed the Commission's position on monitoring and verification as presented in the advance notice; however, some points may need to be clarified. The term "below regulatory concern" may have implied that the Commission would allow licensees to determine what materials or products could be released without any oversight by the

Commission. Exemptions, however, do and will continue to involve survey and recordkeeping requirements to show compliance with applicable criteria governing the exemption. In some cases, reporting to NRC is also required, while, in others, oversight is exercised through inspection and enforcement. In granting an exemption, the Commission will evaluate the potential for intentional or inadvertent releases of radioactive material in excess of the proposed exemption criteria to determine the type and extent of regulatory controls and constraints which should be applied. These evaluations will also determine the level of inspections and enforcement which will be established.

The Commission does not intend, as a result of this policy, to specifically introduce added environmental monitoring requirements. However, the Commission does intend to occasionally reconsider assumptions made when granting exemptions and may conduct research or other confirmatory studies to verify that individual and population exposures are not exceeding expected levels.

10. International Consistency

Comments

The comments on the importance of international consistency ranged from "not important" to "very important." The predominant opinion of those commenting specifically on this issue was that consistency is desirable but not necessary, and/or that the Commission should proceed with developing the policy while encouraging consistency through continued information exchange. At least one commenter indicated that the U.S. NRC should be the leader for the development of rational standards. One pointed out that in attempting international consensus, the most restrictive position tends to rule the outcome. Two commenters expressed the concern that an indefensible standard could be adopted on the basis of the childish rationale, "everyone else is doing it." Two others expressed the opinion that the individual dose criterion should not be higher than the international position because they believed a negligible risk was the appropriate basis for this criterion. A few were concerned about potential inhibition of international trade if there were inconsistencies on standards for consumer products or recycled materials.

Response

The Commission agrees that international consistency is desirable but not necessary. This policy covers a broad range of activities, some of which do not have international significance. The specific differences between this policy and the international position expressed in IAEA Publication 89 and the rationale behind each are discussed under other specific issues, primarily the issues on individual and collective dose criteria (issues 2 and 3). The Commission believes that the main concern related to international consistency would be standards directed at products or materials in international trade. The effect on trade of international inconsistency is one factor that would be considered in the development of specific standards affecting such products or materials.

11. Concept and Terminology Clarification

Comments

Several commenters believed that clear definition of the concepts and terminologies used in the policy statement would be important. These commenters stated that confusion exists between the terms "de minimis," "negligible individual risk level," "trivial risk," and "below regulatory concern" as well as between the principles of "justification of practice" and "as low as reasonably achievable." Furthermore, many commenters believed that the exemptions addressed in the advance notice would typically result in the complete elimination or loss of all regulatory controls. This need for clarification of terminology was also discussed by international regulatory authorities at the NRC-sponsored workshop in October 1988 and at the public meeting held on January 12, 1989 in Bethesda, Maryland. Several of the commenters suggested appropriate definitions for these concepts, terms, and principles.

On a separate topic, many commenters supporting an exemption policy believed that the discussion in the advance notice confused the "justification of practice" and "as-low-as-reasonably-achievable" principles.

Response

The Commission acknowledges the need for clear definitions and understandings of the concepts, terminologies, and principles used in the proposed policy statement. Numerous national and international efforts have been undertaken to develop both broad-based and specific, practice-related exemption policies or to define small levels of risk upon which regulatory decisions may be based. In these efforts, a number of concepts and terms have been put forward; however, in many cases, different terms have been used to describe similar concepts.

In the Commission's view, the terms de minimis risk, negligible individual risk level, and trivial risk are essentially synonymous. These terms have

been used in the literature to represent what is believed to be the level of annual risk of death which is held to be of no concern to most individuals in society. This level of risk is selected on the basis of being trivial compared to the risk of fatality associated with ordinary, normal societal activities and is therefore proposed to be a risk level which can be dismissed from consideration. This definition is similar to that proposed by the National Council on Radiation Protection and Measurements (NCRP) to describe the basis for their definition of a negligible individual risk level (NIRL).

The Commission, in this proposed policy, is not intending to establish a de minimis, negligible, or trivial risk level. The Commission believes that such a level of risk should be defined independently of considerations regarding the compensatory benefit to society from the activity causing the negligible risk. This determination is a controversial and complex social evaluation which need not be the foundation of the Commission's proposed exemption policy. Instead, the Commission believes that its exemption policy can be developed from an extension of the existing system of dose limitation which includes the elements of: (1) justification of practice, (2) limitation of individual doses or risks below existing acceptable limits, and (3) the optimization of radiation protection or the application of the as-low-as reasonably achievable principle. Following this approach, the Commission's exemption policy: (1) requires a justification analysis which demonstrates a net positive benefit for the practice (i.e., the benefits exceed any detriment associated with the practice), (2) specifies that the individual risk level should be a suitably small fraction of applicable, acceptable public dose limits, and (3) requires the use of ALARA analyses in the evaluation of exemption proposals but includes a Commission judgment on when Commission and licensee resources need not be spent to further incrementally comply with the ALARA principle. The Commission believes this approach, in considering a broad spectrum of practices, is consistent with the intent of Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985, which specifically applies only to the practice of low level waste disposal. This Act directed the Commission to "...establish standards and procedures, pursuant to existing authority,

and develop the technical capability for considering and acting upon petitions to exempt specific radioactive waste streams from regulation by the Commission due to the presence of radionuclides in such waste streams in sufficiently low concentrations or quantities as to be below regulatory concern." The Commission believes the terminology, "below regulatory concern," has a meaning which allows considerations, including costs, to be used in establishing practice-specific regulations for low-level radioactive waste disposal at other than licensed sites. The Commission is broadening the application of this concept to address other practices such as the distribution of radioactive materials in consumer products and the reclamation of decommissioned land, facilities, equipment, and materials which have been used in nuclear operations. The Commission notes that the EPA, in developing its proposal for environmental radiation protection standards for management and disposal of low-level radioactive wastes, appears to be using a similar approach in defining the term, "below regulatory concern."

Initially, in its Advance Notice, the Commission used the terminology, "below regulatory concern," to describe the health and safety impacts from practices which could be exempted from regulatory control under the developing policy. Based on the comments received, the Commission has noted that the use of this terminology when coupled with the concept of justifying practices by balancing benefits of the practice against its detriment, has caused considerable confusion. Many commenters believed that the policy was singularly directed at low-level waste disposal practices or that the exemptions resulting from the policy provisions would eliminate all regulatory controls on any exempted practices. Neither assumption is correct. First, the policy is directed at a variety of practices (e.g., consumer products containing small amounts of radioactivity, the release for public use of lands and structures containing residual levels of radioactivity, etc.) including, but not limited to low level radioactive waste disposal. Second, while it is true that the practices considered for exemption could result in radioactive material being used, possessed, or interacted with by individuals not licensed by the Commission, most practices will include conditions or constraints which must be adhered to by Commission or Agreement State

licensees before radioactive material can pass from a controlled to an uncontrolled status. These conditions and constraints will be inspectable and enforceable by the Commission. As a result of the significant comments on this issue, however, the Commission has attempted to refrain from using any of the above terms in describing its proposed exemption policy statement.

The policy statement has also (1) added language clarifying the definition of what constitutes a practice and (2) emphasized the fact that most exemption decisions will include suitable conditions or constraints which must be complied with by Commission licensees and others using the exemption.

In responding to those who believed that confusion was in evidence regarding differences between the "justification of practice" and "as-low-as-reasonably-achievable" principles, the Commission notes that a decision regarding "justification of practice" can be based on a broad range of qualitative and quantitative factors beyond those related to radiation protection and economics. Basically, it is a finding that an activity, source, or practice results in a net enhancement to human life and health.

The ALARA principle, on the other hand, requires, given a justified activity, source, or practice, that potential doses to occupational workers or members of the public be as low as reasonably achievable, economic and societal factors being taken into account (e.g., state of technology, economics of improvements in relation to the benefits to the public health and safety, and socio-economic considerations). This policy statement provides the bases upon which further incremental compliance with the ALARA principle can be determined to be unwarranted. The policy requires that exemptions may only be granted for practices which have been or can be justified.

12. Truncation of Collective Dose Calculations

Comments

Most of those that commented specifically on the issue of truncation noted and agreed with the position of the NCRP that 1 mrem/year (0.01 mSv/year) could be considered a "negligible individual risk level" and any individual doses below this level could be ignored in calculating collective doses. A few also supported 1 mrem/year as a cutoff to collective dose calculations but supplied their own rationale, e.g., that it was 10% of a negligible individual dose, that it was 10% of the below regulatory concern (BRC) individual dose level, or that the cost of calculating the smaller doses was greater than any benefit that can be achieved by including these doses. One commenter suggested that a much higher individual dose, at least 10 mrem/year (0.1 mSv/year), could be used for truncation of collective doses. Only a few commenters specifically opposed any truncation.

Response

The Commission does not agree that the calculation of collective dose for purposes of this policy should be truncated at 1 mrem/year (0.01 mSv/year) simply because of the smallness of the individual dose or risk. Although such a risk may not be significant to the individual, the summation of such doses when large populations are exposed may result in a large collective dose and potentially significant number of hypothesized health effects to the population. A number of potential health effects should not be ignored simply because they occur in a large population. As far as the position of some that the uncertainty of the dose/risk relationship increases greatly as individual doses get smaller, at least one commenter correctly pointed out that these very small doses are incremental increases to the doses that people otherwise receive (background, medical); thus, the actual risks, if any, from, for example, 0.1 mrem/year, 1 mrem/year, or 10 mrem/year are about equally uncertain.

Calculation of such risks assumes only that the dose/risk relationship derived from observed effects at high doses and dose rates is applicable in the vicinity of 200 - 300 mrem/year (2-3 mSv/year).

The Commission is not including any individual dose criterion for the truncation of collective dose calculations in this policy, but notes that there are circumstances where some truncation is appropriate such as (1) when the "tail" of the collective dose calculation cannot be accurately calculated but can be projected to be a relatively small portion of the total collective dose or (2) when, in comparing alternative actions, the part of the collective dose being truncated is approximately the same for each alternative such that calculation of the additional doses would not be expected to affect overall conclusions concerning the comparison. The acceptability of such truncations will be determined on a case-by-case basis.

13. Definition Of What Constitutes A Practice

Comments:

The principles used in establishing the size, scope, and time duration of what is considered a practice can have a significant impact on the potential for individuals to receive, from several practices, multiple exposures which in magnitude could approach or exceed public dose limits (refer to issue 17). The importance attached to the definition of a practice was raised by several regulatory authorities attending the NRC-sponsored international workshop in October 1988. The EPA commented that practice optimization involves minimizing the sum of societal risks from exposure to radiation and the costs of avoiding those risks. Exemption, in the EPA's thinking, will be the optimum choice when there is no regulation which already achieves the minimum net effect on society. In EPA's view, the proposed policy was considered arbitrary since it did not specifically define a practice, make estimates of the societal risk, or define the minimum cost of regulation.

Response:

The Commission agrees that in proposing rulemakings or in making licensing decisions under the proposed policy, the definition of what constitutes a practice is important to establish "justification" as well as to conduct ALARA or optimization evaluations. The proposed policy statement has been clarified to not only support the use of these basic radiation protection principles in the exemption decision-making process but also to define individual and collective dose criteria which, if met by a practice, would define when further incremental compliance with the ALARA principle is no longer warranted.

The policy statement contains a definition of "practice" as an activity or a set or combination of a number of similar sets of coordinated and continuing activities aimed at a given purpose which involves the potential for radiation exposure. This definition is essentially the same as that included in the IAEA's Safety Series No. 89, "Principles for the

Exemption of Radiation Sources and Practices from Regulatory Control." The policy indicates that the Commission's intent, in proposed rulemakings and licensing decisions, is to broadly define specific practices in terms which will preclude any individual or population being significantly affected by similar activities within a given practice. The Commission's intent is also to prevent the possibility of deliberate dilution of material or fractionation of a practice for the purpose of circumventing controls that would otherwise be applicable. By broadly defining what constitutes a practice, the Commission will limit the number of practices for which exemptions may be considered. This limitation on the number of practices will provide added assurance that individual exposures from multiple, exempt practices are not likely to reach levels approaching public dose limits. The Commission recognizes that, in certain cases, practical considerations will prevent definition of a practice in the broadest possible sense. For example, regulations applicable to public distribution of certain consumer products using small amounts of radioactive material have historically been considered on a product-by-product basis and, in the future, will not likely be developed on a generic basis. In addressing this type of exemption possibility, the Commission intends to be mindful of the potential for cumulative impacts from all similar practices (i.e., other consumer products).

It should be noted that the definition of what constitutes a practice will provide the framework for taking into account other aspects of the exemption decision-making process, i.e., the possible consequence of accidents or misuse, occupational exposures, non-radiological impacts, etc.

As a result of the above, the Commission does not believe specific definitions of practices are needed to outline, in the proposed policy statement, the principles and criteria which the Commission will use in making its exemption decisions.

14. The No-Threshold Hypothesis Relating Dose to Health Effects - Hormesis

Comments

Many commenters opposed to the exemption policy argued that since the Commission is subscribing to the no-threshold hypothesis, it is admitting to the potential for health effects at any level of radiation exposure. As a result, these commenters believed that the Commission is obligated to regulate the practices causing these exposures. Other commenters opposed to the policy erroneously concluded that the Commission was denying the possibility of harmful effects from low levels of exposure to radiation.

Several commenters supporting the exemption policy stated that there are no valid scientific findings supporting the existence of a linear relationship between dose and health effects at low dose levels. Others referred to the conservative assumptions embodied in the linear, no-threshold hypothesis and stated that this hypothesis has overwhelmed the possibility of more reasonable regulatory approaches. A few of these commenters referred to the phenomenon of hormesis (i.e., a proposed benefit to human life and health from exposures to low levels of radiation) and suggested that, if valid, the NRC may be harming public health, as well as causing the expenditure of needless effort by implementing overly restrictive regulations.

Reference was also made to the 1980 BEIR Committee (Committee on the Biological Effects of Ionizing Radiation) which concluded that the risk coefficients derived from the study of the atomic bomb survivors and other studies are statistically inadequate for use at doses less than 10 rad or dose rates less than 1 rad per year. A commenter stated that the linear no-threshold hypothesis persists in regulatory matters largely because the effects data are not sufficiently robust to distinguish between linear and non-linear models and this insufficiency has resulted in a regulatory position misnamed as "conservatism." Furthermore, this commenter stated that the hypothesis persists partly because EPA and others jump from the fact that cancers are frequently monoclonal (derived from a single cell) to presume that cancer yield is linearly related to the number of cells

affected by radiation, no matter how few. The latter approach, this commenter claimed, ignores the existence of an immune system in animals which is not present in the in-vitro systems in which many studies on response curve shape have been done. In this commenter's view, the immune system seems to be very efficient in preventing diseases from developing when only small numbers of attacking cells are present. In addition to infectious diseases, this commenter suggested the consideration of the fact that in various animal experiments many tumor cells (typically hundreds to millions of cells) must be injected into test animals before cancer develops in the test animals. Finally, this commenter cited the fact "...that billions of potentially initiating events occur in our bodies over our lives just from the [body's natural] ^{40}K content, and the annoying but persistent observation that cancer rates are generally lower where background radiation levels are higher." Along this same line, a commenter stated that millions of people have lived for hundreds of years with background radiation levels 2-10 times above the U.S. average, with no evidence of excess cancer deaths.

Another commenter, who also discussed his views at the NRC's January 12, 1989 public meeting, presented arguments to indicate that reliance on in-vitro systems and repair processes alone leads to unwarranted unconservatism in estimating the carcinogenic potential of low doses of radiation, or higher doses delivered at a low dose rate. This commenter believed that experimental evidence indicates that, in order to explain a reduced frequency of expressed tumors as a function of reduced dose rates, a mechanism other than intra-cellular repair must exist. To explain this phenomenon, this commenter postulated a mechanism, whose existence is well established, that can seek out and kill malignant cells. This commenter believed the factor of 2-3 currently used to account for the "dose rate effect" may in actuality, be much larger than 10.

Response

The Commission acknowledges that radiation has been shown to be carcinogenic at high doses and high dose rates (~50 rads absorbed dose at high dose rate for low linear energy transfer radiation). However, the

development of a risk factor applicable to continuing radiation exposures at levels comparable to natural background requires a significant extrapolation from these effects observed at much higher doses. (Here, the Commission would point out that the natural background level represents a base on which all other exposures to man-made sources of radiation must be added.) The need for extrapolation results in expressions of uncertainty reflected by the views of experts in the field. For example, as stated in the proposed policy statement, the National Academy of Science Committee on the Biological Effects of Ionizing Radiation has cautioned that the risk values are "...based on incomplete data and involve a large degree of uncertainty, especially in the low dose region." This Committee also stated that it "...does not know whether dose rates of gamma or x-rays (low LET) [low linear energy transfer radiation] of about 100 mrads/year [1mGy/year] are detrimental to man." The Commission recognizes that the Committee's statement is a reflection of the uncertainties involved, and does not imply either the absence or presence of detrimental effects at this dose level.

In addition, the Commission is aware that the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) in their 1988 Report to the General Assembly has stated that "...there was a need for a reduction factor to modify the risks [derived at high doses and dose rates]...for low doses and dose rates...an appropriate range [for this factor] to be applied to total risk for low dose and dose rate should lie between 2 and 10." [This factor would lead to a risk coefficient value between $7x10^{-5}$ and $3.5x10^{-4}$ per rad ($7X10^{-3}$ and $3.5X10^{-2}$ per gray)] based on an UNSCEAR risk coefficient of $7.1x10^{-4}$ per rad (7.1% per gray) for 1 gray (100 rad) organ absorbed dose at high dose rates.

Given this information, the NRC, the Environmental Protection Agency, and other national and international radiation protection authorities have established radiation standards defining recommended dose limits for radiation workers and individual members of the public. As a matter of regulatory prudence, all these bodies have derived the risk value presumed to apply at lower dose and dose rates associated with these radiation protection standards by extrapolation from values derived at higher doses

and dose rates. While some have suggested a reduction factor to modify the risks for low doses and dose rates, others have presumed a linear quadratic relationship between dose and cancer mortality risk. In either case, the coefficients applied to estimate the risks from low doses and dose rates are similar.

While the Commission has used this hypothesis in establishing the risk basis for decisions regarding dose limits for workers and the public, it is guarded in totally relying on this hypothesis when establishing criteria for "cutting off" the need for further incremental compliance with the ALARA principle. The Commission notes that the individual dose value proposed for this purpose is well below (i.e., 1/10) applicable dose limits and only a fraction (1/30 to 1/10) of background radiation. The Commission, therefore, has combined its consideration of the absolute risks predicted by the no-threshold hypothesis with a comparative risk perspective. It has used both in establishing the individual dose criterion applicable to exemption decisions when considering if further incremental compliance with the ALARA principle is warranted. These perspectives are discussed further in the response to Issue 3.

The Commission also notes that the annual risk of cancer in the United States is 1.9×10^{-3} which leads to almost ½ million cancer deaths each year. As a result of this large number of cancer deaths from all causes, observations relative to potential thresholds, hormesis, or repair mechanisms for those potentially caused by radiation in the low dose regime are extremely difficult to statistically verify. The Commission, therefore, is supportive of continuing efforts to better quantify the relationship between risk and low radiation dose which are ongoing at both the international and national level.

15. Accidents and Misuse

Comments

Some commenters raised concerns that some licensees would misuse exemption regulations or specifications, either intentionally or inadvertently, in a way that would result in releases exceeding those allowed.

Response

The Commission notes that this issue is common to all areas of regulation including those related to exemptions from some or all regulatory controls. The Commission views these concerns as a compliance issue which will be addressed through licensing, inspection, enforcement, and monitoring. The subject of "Monitoring of Exempt Practices" is discussed under issue #9.

Comment

Other commenters were apparently concerned that once radioactive material is released from a licensee's control, there would be significant uncertainty about the possible exposures that could occur. Accidents, misuse of products containing radioactive material, or the occurrence of unlikely scenarios involving interactions between individuals and exempted radioactive material were inferred. The IAEA addressed this issue in Safety Series No. 89 by stating that "The [regulatory] authority will also need to take into account the severity of possible consequences of accidents or misuse. Such considerations may contra-indicate the exemption of a practice, even if it gives rise to very small doses under normal conditions."

Response

The policy indicates that a proposal for exemption must address potential accidents and misuse. The proposal must address the probabilities of such events and the resulting individual and collective doses. The exemption

decision-making process would consider both these factors, including any uncertainties associated with their estimation.

The Commission believes that the impact of potential accidents and misuse events, in the context of the exemption decision-making process, can only be judged properly on a case-by-case basis. However, the Commission would expect that, for a practice to be granted an exemption from some or all regulatory controls, both the risks (i.e., probability times consequences) and consequences from all potential accidents and misuse events should be small. The Commission believes these considerations are in concert with the intent expressed in the IAEA Safety Series No. 89 document.

16. National Consistency in Risk-Based Radiation Protection Standards

Comments

Several commenters, including the U.S. Environmental Protection Agency (EPA), noted that inconsistencies exist in the risk basis used for decision making throughout the Federal regulatory process. Specifically, the EPA pointed out that exemptions based on individual risk levels associated with doses in the range of 10-100 mrem per year (0.1-1 mSv/year) would not be consistent with the many Congressional and regulatory actions being taken relative to other environmental contaminants.

Response

The Commission recognizes that different numerical risk bases are used in decision-making processes involving a wide range of regulatory actions. Logical differences in risk bases can occur when consideration is given to factors such as populations impacted, the distribution of individual impacts, the relative uncertainties in health effect predictions, the persistence of the purported hazard, the potential for multiple exposures, and many other issues. Furthermore, the rationale used in defining a safe or acceptable level of risk could differ from that used to establish a basis for considering exemptions from some or all regulatory controls. The Commission believes that all these factors and considerations must be addressed in establishing any "risk-based" regulatory policy and that, if properly addressed, a logical consistency between different risk-based standards should result.

In proposing its exemption policy, the Commission notes that under the Atomic Energy Act authorities, which have been in place for thirty-five years, the NRC and its predecessor, the Atomic Energy Commission, have been regulating source, special nuclear, and by-product material under a program that applies internationally-accepted standards. The NRC's radiation protection program is based on principles that will ensure that exposures are, first, justified, second, adequate to protect health and

safety, and third, "as low as reasonably achievable," taking into account costs and the state of the art of technology for reducing exposures. The risk basis used to define the public dose limit is described in ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," as clarified by the ICRP's "Statement from the 1985 Paris Meeting of the ICRP." With this risk basis in mind, the Commission has developed individual and collective dose criteria within its proposed exemption policy which define a region where the risk reduction does not warrant the expenditure of resources to bring about further incremental compliance with the ALARA principle.

The Commission is aware of apparent differences between the risk basis used for its standards and policies and those used or proposed by other Federal Agencies (e.g., the U.S. Environmental Protection Agency). The Commission is actively attempting to resolve these differences through interagency contacts and proposals for development of appropriate Federal Guidance. The Commission believes a public airing of the respective risk bases for all Federal public protection standards is the preferred method which must be used to institute rational and consistent risk-based public protection policies. The Commission therefore proposes that the U.S. Environmental Protection Agency chair an interagency committee whose charter would be to develop a framework for public radiation protection. This framework could be promulgated as Federal Guidance, which upon signature of the President, would be implemented by all Federal Agencies.

17. Cumulative Effect of Exposures to Multiple Exempted Practices

Comments

Many commenters opposed to the proposed exemption policy, and a few supporting the development of such a policy, expressed their concerns regarding the potential exposure of individuals to several exempted practices. These commenters believed that the summation of doses received from multiple individual practices could result in a total which could approach or exceed existing public dose limits. This possibility led several commenters, who supported development of an exemption policy, to recommend that continued incremental compliance with the ALARA principle be maintained if individual exposures could exceed 1 mrem (0.01 mSv) per year per practice. Some of these commenters cited the internationally accepted, "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control," described in IAEA Safety Series No. 89, as an acceptable approach to resolve the multiple exposure issue. A comment letter from the National Council on Radiation Protection and Measurements (NCRP) expressed the view that a blanket exemption of sources contributing 10 millirem in a year is not negligible and exposure to a few such sources could bring an individual close to the annual limit of 100 millirem in a year. Many responders opposed to the exemption policy believed that a significant buildup of radioactive materials with long half-lives could occur in the environment over time. Those in opposition to policy development also stated that the "bottom line" result of the proposed policy would be to increase existing background levels.

Responses

The Commission agrees that the issue of potential individual exposures to multiple exempted practices, and from any cumulative buildup of long-lived radioactive material is important and has attempted to address this issue in both the advance notice and the proposed exemption policy statement. Contrary to the comments submitted by the NCRP, the policy is not intended to grant a blanket exemption of sources contributing 10 millirem per year to individuals. Rather, as the NCRP suggests, "...a source producing 0.1

millisievert (10 millirem) in a year could be exempted provided justification and ALARA are applied." This, in essence, is the approach the policy statement is attempting to convey. As a result of the many comments on this issue, the proposed policy has been revised to clarify this point. The Commission has also attempted to broadly define what constitutes a "practice" so as to assure that the granting of any exemptions from some or all regulatory controls will not allow deliberate dilution of material or fractionation of practice. Under this broad definition, the radiological properties of the material associated with the practice must be characterized on a national basis which takes into account the potential for increased individual exposures resulting from multiple sources encompassed within any defined practice. The NRC must, in its rulemaking and licensing processes, take account of potential exposures from multiple practices. Furthermore, the potential annual individual and collective dose resulting from an exempted practice must be evaluated over the lifetime of the practice. The evaluation must take into account the effects of any accumulation of radioactive material in the environment over time. Based on the above discussion, the Commission has concluded that few, if any, individuals are likely to receive exposures approaching applicable public dose limits from exposure to multiple sources or practices because:

(1) multiple sources within a practice must be considered in an application for exemption (e.g., multiple waste paths from a nuclear power reactor and all nuclear reactors are included in one practice);
(2) exposures to the same individuals from multiple practices will be considered in the process of developing specific exemption decisions, and the potential for overlapping impacts will be accommodated or controlled;
(3) the requirement that each practice be justified will limit the number of practices exempted and
(4) the exposures associated with any exempt practice will be limited because of the requirement to apply ALARA to each practice as appropriate.

Finally, for those practices meeting the dose criteria which define when further incremental compliance with ALARA is unwarranted, the satisfaction

of the criteria provides additional assurance that the distribution of individual exposures is such that only a small fraction of the national population could receive exposures approaching 10 mrem per year. The likelihood of one or more individuals receiving doses at this level from more than a very few practices is expected to be very small. In making its exemption decisions, whether through the rulemaking process or individual licensing decisions, the Commission intends to be vigilant in assuring that individuals are not likely to approach public dose limits through multiple exposures to exempt practices.

18. Federal Responsibilities and Authority

Comments:

The Environmental Protection Agency (EPA), in its comment letter, pointed out that the EPA and NRC have some shared and many complementary responsibilities under the Atomic Energy Act (AEA). The letter stated that although NRC regulates onsite activities of its licensees, as defined in 1970 by Reorganization Plan No.3, the primary responsibility for regulating offsite levels of radiation, as well as for recommending the general principles which govern all radiation protection activities of Federal Agencies, is assigned to EPA. This division of responsibilities, it was pointed out, applies to the AEA; however, it was noted that EPA has sole responsibility for regulating environmental radiation under a number of other statutes. The EPA recognized that the Low Level Radioactive Waste Policy Amendments Act of 1985 required the Commission to establish a policy for exemption of specific radioactive waste streams from regulation by NRC, but believed the proposed policy, by virtue of its potential application to all aspects of regulation, goes far beyond the 1985 Act. It would, it was claimed, define a general principle for radiation protection accompanied by a numerical, generally-applicable standard. Almost any conceivable application of the proposed policy, it was believed, would directly affect public exposures and the release of radioactive material to the general environment, an area of primary concern to the EPA.

Response:

The Commission agrees with EPA's assessment of the NRC and EPA authorities; however, in the absence of Federal Guidance, the Commission believes that its authorities under the AEA allow for exemptions from its regulation to be granted (e.g., Sec. 81) "... when it makes a funding that the exemptions ... will not constitute an unreasonable risk to common defense and security and to the health and safety of the public." In fact, such exemptions are currently included in the Commission's

regulations. The Commission, however, recognizes the benefits of uniform regulation and, therefore, in the proposed policy statement, supports the development of broader Federal Guidance regarding exemption policies. In doing so, the Commission realizes that, when signed by the President, the Federal Guidance could supplant the proposed policy.

The Commission would also highlight the fact that its actions under consideration here involve the development of a policy statement. Any regulations formulated from the principles in this policy statement will be subject to the Commission's rulemaking procedures. These procedures include a public process which assures that the EPA and others can comment on the health, safety, and environmental impact of proposed Commission exemption regulations. The Commission, however, would intend to work closely with EPA to develop a unified Federal Position on any such regulation.

ENCLSOURE 3

Enclosure 3

RESPONSE TO ACNW COMMENTS

The policy statement has been discussed with the Advisory Committee on Nuclear Waste (ACNW) over the course of several meetings, the latest on April 28, 1989. The ACNW has stated its most recent views regarding the proposed policy statement in a May 3, 1989 letter to Chairman Zech. Although the staff has reached agreement with the ACNW on most issues, two outstanding differences with ACNW recommendations remain.

First, the staff has not proposed, as the ACNW has suggested, any specific "limit" on an individual dose which may result from an exemption decision, other than the existing dose limits applicable to members of the public. Instead, the proposed policy states that practices, which are candidates for exemption for some or all regulatory controls, should not result in individual doses greater than a small fraction of these existing annual dose limits. The policy also includes a statement that ".....the Commission recognizes that only under unusual circumstances would exemptions be considered for justified practices which could cause continuing radiation exposure to individuals exceeding a small fraction of 100 mrem per year (1 mSv per year)." The staff believes that this approach provides flexibility which should be maintained.

Second, the staff does not believe, as the ACNW has recommended, that "....the permissible annual collective dose "limit" [for a practice to be exemptable] should be reduced as the allowable dose rate to members of the public from individual practice increases." The staff believes the annual collective dose associated with a specific exempted practice should be derived through an appropriate ALARA analysis. The collective dose criterion as used in the proposed policy is not a "limit", but instead provides one of two criteria which define a basis for curtailing or "cutting off" the need to further comply incrementally with the ALARA principle. Evaluations applying the ALARA principle would be used to determine whether a collective dose greater than this value should be accepted as a result of any particular exemption decision.