UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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NUCLEAR REGULATORY COMMISSION

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BRIEFING ON RISK HARMONIZATION RECOMMENDATIONS

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PUBLIC MEETING

Nuclear Regulatory Commission
Commissioners Conference Room
One White Flint North
11555 Rockville Pike
Rockville, Maryland

Monday, November 6, 1995

The Commission met in open session, pursuant to notice, at 9:42 a.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission

KENNETH C. ROGERS, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

J. HOYLE, SECY/NRC

M. MALSCH, OGC/NRC

J. TAYLOR, EDO/NRC

M. KNAPP, NMSS/NRC

C. PAPERIELLO, NMSS/NRC

R. TROVATO, Office of Radiation and Indoor Air/EPA

A. RICHARDSON, Office of Radiation and Indoor Air/EPA

M. WEBER, NMSS/NRC

P R O C E E D I N G S

[9:42 a.m.]

CHAIRMAN JACKSON: Good morning, ladies and gentlemen. Today we are being briefed by both the NRC staff and the Environmental Protection Agency staff on the progress that has been made in exploring common approaches to managing and assessing risk from radiative materials.

Both agencies share a common responsibility for protecting members of the public from exposure to radioactive material. For various reasons over the years the two agencies on occasions have developed conflicting positions on radiation protection standards. These conflicting requirements serve no one least of all the public.

A major step was taken in 1992 when both agencies signed a Memorandum of Understanding that established a framework for resolving differences between NRC and EPA that relate to the regulation of radionuclides.

One of the provisions of that MOU stated that the agencies will actively explore ways to harmonize risk goals and will cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides.

Since that time the staffs of both agencies have been working very hard to resolve differences. The Commission looks forward today to hearing from both staffs

on the progress that has been made in this very important area and before I ask Commission Rogers if he has anything to add, I would like to in addition to welcoming our own staff to particularly welcome Ms. Trovato from EPA.

MS. TROVATO: Thank you.

CHAIRMAN JACKSON: Commissioner Rogers, do you have any opening comments?

COMMISSIONER ROGERS: No, not just at the moment. Thank you.

CHAIRMAN JACKSON: If not, you may proceed.

MR. TAYLOR: Good morning. I would also like to note that the staffs have cooperated, EPA and NRC, on the paper that we have prepared and provided to the Commission. We have worked hard on recommendations on how to resolve the differences between the agencies in both risk assessment and risk management.

I would also note that this cooperative effort this year was expanded to include active participation by other federal agencies including the Departments of Energy, Defense, Transportation and Labor.

Chairman Jackson, you have already acknowledged Ramona Trovato and we appreciate her work in this area. I would note that she began her career at EPA working at a research laboratory in Annapolis and has assumed progressively responsible positions including the position

as the director of EPA's Groundwater Protection Division and she is now the Director of EPA's Office of Radiation and Indoor Air. I think I got that right.

MS. TROVATO: You did.

MR. TAYLOR: Good. Sitting behind us joining her is Allan Richardson who is deputy director of the Radiation Protection Division at EPA. Also behind us are two of our own hard-working staff who have worked in this area, Mike Weber and Judi Greenwald. You know the gentleman sitting on both sides of me and I will now ask Mal Knapp, the deputy director of the Office of Nuclear Materials Safety and Safeguards to start the formal brief.

MR. KNAPP: Good morning.

CHAIRMAN JACKSON: Good morning.

[SLIDE.]

MR. KNAPP: If I may have the first slide, what we propose to do this morning is to cover three areas in this discussion. We would like to briefly review the background that has gotten us to where we are.

Then we would like to talk about the risk harmonization activities which are divided we find most conveniently into risk assessment and risk management. To preview that, risk assessment is the effort involved in determining what a risk is, where one might expect that different scientists working independently would arrive at

about the same results.

Risk management constitutes the policy and societal decisions made as informed by that risk where reasonable people might well arrive at different answers because of their societal judgments.

After we discuss these differences in assessment and management, we will also discuss recommendations that have been brought forward and finally the next steps that will be taken depending on the extent to which the Commission wishes to adopt the recommendations that have been made.

A few things that I might mention, although today we will emphasize differences there are, in fact, many similarities particularly in the area of risk assessment. With respect to differences, we will be talking about four differences that we find in assessment and six in risk management.

[SLIDE.]

MR. KNAPP: If I may I would like to turn to the next slide and briefly review the background. Chairman Jackson, you have already discussed the 1992 MOU that NRC and EPA share. Moving on, in 1994 in the fall of last year although we had initiated efforts under the MOU, the General Accounting Office issued a report which found that the agencies still needed to reach better agreement on dose and

risk calculation methods for radiation and that among other things radiation standards reflected a lack of general agency consensus.

At the same time the staff had brought to the Commission for the first time a draft of the White Paper which is a part of the Commission paper supporting this briefing now in final form. Even at that time we had recognized that there were differences in both assessment and management. We differentiated the areas and had recognized that there were still very similar levels of protection achieved by the agencies.

Again in the same time, October of 1994 was a busy month, Senator Glenn concurred in the GAO Report and wrote to a number of agencies including EPA and NRC asking us to develop a path forward to resolve these differences.

We committed to that in January of 1995 by participating in a letter which EPA sent to the Senator among other things committing to the completion of the White Paper on risk harmonization which you have before you and to expand the scope of the interagency steering committee then called the Interagency Steering Committee on Clean-Up Standards.

That led to perhaps one of the most significant actions that has been taken within the last year which was the formation of what is now called ISCORS or the

Interagency Steering Committee on Radiation Standards.

As you may recall from the charter among other things that committee will facilitate reaching consensus on radiation risk and will promote consistent risk assessment and management approaches.

[SLIDE.]

MR. KNAPP: In the next slide I would like to go on to the subject of risk assessment and briefly overview that. As I said earlier, although there are some differences between the EPA and NRC in risk assessment as I will say shortly, there are I think probably more similarities than there are differences.

As we talk about the differences though one thing you will notice in both the discussion of risk assessment and later on in risk management, the recommendations that the staffs and the ISCORS members are bringing forward are more in the line of a pathway not inconsistent as a matter of fact with what Senator Glenn sought but we are recommending procedures and methods to resolve the differences rather than specific resolutions for very many of the issues here.

This intent of providing a path occurs in part because resolving these things is labor intensive and a number of policy decisions need to be made. With the time we had available it seemed most appropriate to provide

recommendations of a sound pathway than to attempt to provide recommendations to resolve the differences. There are several cases where we do make recommendations on resolution.

Another reason that the pathway approach seemed to us to be appropriate is that it gives the Commission more of an opportunity as these decisions are formulated over what will be largely the next year or two. It gives the Commission an opportunity to see how these decisions are being put together in draft form and to provide additional guidance.

CHAIRMAN JACKSON: Is that why the recommendation is that it be done through what is called federal guidance, that is, the guidance that comes from this working group as opposed to ISCORS itself being the mechanism?

MR. KNAPP: Go ahead.

MS. TROVATO: We had recommended that it be through the federal guidance process because that has been in place for a long time and it is also the formal way that we go about setting the standards that we then ask the other agencies to use in their rulemaking.

That process includes all the other federal agencies as we develop those and it includes them through cooperative activities in developing the federal guidance and in addition to which the federal guidance then goes to

OMB where further discussions can occur if resolution has not been reached before then.

CHAIRMAN JACKSON: Has it worked?

MS. TROVATO: I would prefer to let Allan Richardson answer that because he has been writing that and this is my first time through the federal guidance process. Allan.

MR. RICHARDSON: I would say yes emphatically it has worked. It is a process which dates back to the late 1950's and has provided the basis for most radiation protection policy in the U.S. since then. The most recent example of that was the Occupational Guidance which was issued in the late 1980's which provided the basis for the Commission's Part 20 standards for workers.

[SLIDE.]

MR. KNAPP: What I would like to do now is to move on to the fifth slide to briefly go over the similarities that the staffs of the agency found and there are quite a number of them.

The measure of risk used by both agencies is cancer mortality, that in general, both agencies use international consensus standards for translating dose to risk such as those of ICRP, NCRP and the BEIR recommendations.

Both agencies generally look at a reasonably

maximum exposed individual. I think this is an important point. The absolute maximum individual can result in ultra conservative calculations and the idea of finding a reasonable individual is one which this is a first of several of the risk assessment similarities which are, in fact, related in part to risk management.

You will see that the break is not entirely clean particularly as we go on through the rest of the discussion of risk assessment but in this particular case, again, we are similar in our choice of a reasonably maximum exposed individual.

Although both agencies use deterministic and probabilistic assessments, they tend to be used in similar situations. For example, in decommissioning and as in the EPA Superfund we tend to be deterministic whereas in our high level program and in EPA's standards for high level that are now under consideration, a probabilistic approach is envisioned.

In general, both agencies use the same set of exposure pathways. Frequently one may dominate over another and that will lead to a regulation in that particular area but the selection of pathways is similar.

Finally, both agencies truncate assessments in time. We decided there was a time after which it is inappropriate to pursue the risks that may be associated

with something such as high level waste disposal.

A difference that we will get to later though is that the agencies truncate assessments in space differently and we will speak to that shortly. I have taken the easy part of talking about the similarities and I am now going to ask Ms. Trovato to take a few moments and talk about the differences.

[SLIDE.]

MS. TROVATO: Good morning. These are the four risk assessment differences that we have identified through this process. I am going to talk briefly about each of these and then Mal and I are going to talk in more detail about numbers two and four.

In the first one we go about calculating risk slightly differently. We often come out in the same place. What we do, what EPA does is we calculate the dose to an organ, the risk to the organ, sum the risks and get a risk. What NRC does is they calculate the dose to the organ, apply appropriate weighting factors, calculate a whole body dose and convert that to a risk.

The main difference, I believe, comes with the actinides where sometimes NRC is much more conservative that EPA so this is an area where we think that we can come to some resolution through this federal guidance process.

In fact, right now Oak Ridge is developing some

more information to help us on the decision making and NRC, EPA and DOE are all funding this activity so it is a joint effort. I think the reason this exists is because it is a trade-off between really up-to-date science and maintaining some regulatory stability. So I don't think there is any fault or blame here. It is just a different approach and I think through the federal guidance, we can come to an agreement on what works best.

The second one I will talk more about on the next slide but EPA's Superfund program does use morbidity. This is very different from all of EPA's other programs which use mortality and NRC's program which also used mortality as the endpoint.

We also often use different exposure scenarios and I think I would like to look at the back-up slide number three, please.

[SLIDE.]

MS. TROVATO: EPA's Superfund programs uses 30 years as an exposure scenario whereas the rest of EPA's programs use a 70-year lifetime so that is one big difference. This does work out and I will talk about it on the next slide since they also use the morbidity rather than mortality.

There are also differences in the agencies' approaches to population dose and distances.

Number four, Mal is going to talk about in some detail and this one is interesting. In different instances we have used 100 years versus 1,000 years versus 10,000 years and in the most recent NAS report they have recommended that we look at a million year scenario for years.

Distance as Mal mentioned we do look at differences in the distance that we calculate dose and also there is a difference in magnitude. Below a certain dose to the individual, NRC does not calculate a population dose and EPA does in many cases. So we will talk about those in more detail.

CHAIRMAN JACKSON: Which will you be talking about, which of these give you the greatest variability in terms of differences in risk assessment?

Do you know?

MS. TROVATO: I am thinking.

MR. KNAPP: Let me think for a moment. There may not be an easy answer to this one but I am going to ask Mike Weber to think for a second and perhaps he can say more than I can. With respect to the first one, actually maybe my best answer is it depends.

For example, if you look at Thorium-232 our risk assessment would come out perhaps as much as 60 times higher than EPA. On the other hand, for many radionuclides the

risk and dose calculations come out to be very similar. So in part the answer might depend on what particular activity we would be looking at.

Again when we talk about such things as truncation if you consider use of low doses to large populations that can affect how we put together a regulation or how we regulate a particular activity. So my quick thought would be that there is no easy answer. It would depend on the circumstances but perhaps Mike can illuminate that further.

MR. WEBER: I think you have characterized it well that it really depends on the situation. For example, if you look at difference number three and you are examining different exposure scenarios, obviously if one assumes that an individual is going to be exposed, the exposure could be far greater than if no exposure at all occurs and thus it really depends on how these differences play out in the specific program areas.

CHAIRMAN JACKSON: All right.

COMMISSIONER ROGERS: Just before we leave this slide I wonder if you could say a little bit of what the rationale was for using a different approach, EPA, for the Superfund program from the other programs. That is the only one in which you are using morbidity rather than mortality. What is the rationale for that departure?

MS. TROVATO: Let me ask Allan. I am not sure why

Superfund chose morbidity.

COMMISSIONER ROGERS: And whether that in your opinion is less well founded scientifically or more well founded scientifically than mortality as an endpoint.

MR. RICHARDSON: I don't believe it is a question of whether it is well founded or not. It is just a policy decision about what kinds of health effects you want to consider in making a decision.

There are, of course as you know, a whole variety of endpoints that one could look at. One could look at genetic defects which cause sometimes serious things and many times trivial things. One could look at cancer death as an endpoint or you could just look at getting cancer as an endpoint and not dying from it.

The decision in the Superfund program which I cannot elaborate on in great detail was that one should look at all of these endpoints and there has been a variation in how they weigh the importance of those different endpoints.

The tendency in radiation programs since two-thirds of morbidity is mortality has been to look at mortality alone as being quite sufficient to characterize the risk.

COMMISSIONER ROGERS: All right. Thank you.

[SLIDE.]

MS. TROVATO: Page seven, risk assessment

difference number two, we were just talking about this. Interestingly enough as in the Superfund program as we went through working on the clean-up standards and trying to be consistent or as consistent as was appropriate with the Superfund program, we looked at their use of a 30 year time frame as opposed to a 70 year time frame for exposure and we looked at the fact that they were using morbidity rather than mortality to see what kind of difference this actually made in the risk assessment.

As it turns out the morbidity is about 50 percent greater than the mortality and the exposure time is a little less than half assuming that the large part of the exposure occurs in the first 30 years it worked out to be not much difference between the Superfund program risk assessment and the risk assessment that NRC would conduct or that EPA would conduct under its radiation programs because of how things worked out.

We do think though that we do need to come up with a way to approach this as opposed to hoping that it works out by chance and we are going to develop another federal guidance document to identify what biological endpoint is appropriate or how to decide of the many biological endpoints which one is appropriate for the particular standard that you are setting.

Again, this would be a process that EPA would

initiate in conjunction with the other federal agencies and we will work on these things through ISCORS because this one would be nice to have a way and a process, an approach, as opposed to lucking out. Mal.

[SLIDE.]

MR. KNAPP: All right. I will speak in slide number eight to the fourth risk assessment difference which is truncation. As we mentioned earlier, both agencies do truncate in time but with respect to distance generally NRC does and generally EPA does not.

For example, we truncate such things as assessments of fuel cycle facilities and severe accident analysis whereas EPA in its standard setting for a high level and uranium mill tailings has not truncated dose with distance.

I think the philosophical difference here is important because here we come to an area where risk assessment is driven in part by risk management. I think the question is how do you feel about extremely low doses spread across very large populations.

If you feel that they are very important and that they should be weighted as a part of your decision then one would not wish to truncate. One would wish to carry out at some length. On the other hand, if you believed that you really are not gathering very much information out there

then you might find it is much better to truncate.

This issue has been addressed in part in the proposed federal guidance on radiation protection. This is a document which we received for review in December of last year. We commented on it in April and the current schedule calls for EPA to forward in March of next year to OMB. The guidance that it provided was not as full as the guidance that we now think we might need.

Basically I believe the document said words to the effect that in some cases truncation may be appropriate. What we are looking to do, the recommendation of the ISCORS folks is that we provide more guidance than that and in particular they would like to see four sets of circumstances addressed in the guidance.

Very briefly they are that you want to ask whether you truncate in situations where first, truncation would not significantly affect a regulatory decision. You might want to truncate where you find that the cost of further analysis outweighs the benefit.

You might want to truncate where you find that calculated dose are less than the variation of background in a particular location and you might want to truncate where truncation would increase your ability to see real differences between alternatives and reduce uncertainties.

Talking about them likely most of those we would

agree that truncation is appropriate with the exception of the third one that I mentioned where calculated dose may be less than the variation of background and again this gets to the risk management concern even though it may be less than variation in background, is it still something to be considered when you look at low doses for large populations.

In any case, we will be addressing these or our proposal would be we will address these through ISCORS and its contributions to the radiation protection guidance to be completed next March.

COMMISSIONER ROGERS: Is it easy for you to give me an example of your last point that where truncation would increase the decision maker's ability to distinguish differences, real differences? Do you have in mind any kind of specific example of where that would take place? It wasn't clear to me.

MR. KNAPP: I could come up with some hypothetical cases but again, I would ask if staff knows of any specifics.

MS. TROVATO: Go ahead, Allan.

MR. RICHARDSON: One example would be a situation in which you are considering two different options and the uncertainty surrounding the collective dose which is what we are talking about here is large compared to the difference between the options, then it would make no sense and the

sensible course would be to truncate the analysis at the point where the uncertainties overwhelm the distinction between the two options.

COMMISSIONER ROGERS: Thank you.

[SLIDE.]

MR. KNAPP: If I may proceed to the ninth slide and just summarize the recommendations that ISCORS has made with respect to risk assessment. They recommend that we go forward with the Radiation Protection Guidance to be issued in March and that it be supported by ISCORS. This work as I mentioned just a moment ago should lead to resolution of the truncation difference, the fourth one.

Then ISCORS endorses the creation of two federal guidance reports, one to be issued in October of 1996 which would speak in part to the dose to risk conversion differences which were mentioned as the first difference in this presentation and then in the federal guidance report on implementation which would come about 18 months from now in May of 1997, the rest of the discussion of this difference would fall.

Generally the difference between those two is that the first report in October would provide a technical basis for how dose to risk conversion would occur and the report to be issued in May would be more in terms of providing policy guidance on dose to risk conversion.

That report would also address the concern of morbidity versus mortality. That leaves the third difference of scenarios without a particular guidance product associated with them and here the recommendation of ISCORS would be to deal with these on a case-by-case basis with the idea that by building a case history of how we can reach agreement on scenarios that will provide more general guidance in the future and it would be their intent to take advantage of the existence of ISCORS to identify and facilitate resolution of disagreements that would arise in that process.

COMMISSIONER ROGERS: What work is in progress now on dose to risk conversion that has to be accelerated? What is the nature of that work?

MR. KNAPP: I think the acceleration refers to the product of the Radiation Protection Guidance as a whole but again, let me turn to people who are more familiar than I am.

MR. RICHARDSON: About a year ago following on some work that had been done both here at the Nuclear Regulatory Commission and at EPA on basic risk factors for individual organs we initiated a project at Oak Ridge National Laboratory to calculate risks associated with intakes of specific radionuclides.

Always before these kinds of tables had dealt with

the doses associated with individual radionuclides and we are now one year into a project which should be completed by mid year of next year to produce tables of doses by various pathways of ingestion, inhalation or ingestion or external radiation, tables of the risks that are radionuclide specific.

COMMISSIONER ROGERS: Thank you.

[SLIDE.]

MR. KNAPP: In the next slide, number ten, we are going to turn from risk assessment to risk management and by way of overview, I would say that although the agencies come from fundamentally different approaches we do seem to arrive at very similar levels of protection where the endpoints are much the same.

By the difference in approaches what I refer to is that in general NRC's nominal limit if you like is about 100 millirem a year which one could say is equivalent to a lifetime cancer risk of around four times ten to the minus third whereas EPA defines its goals in terms of risk and they are looking at an upper level of somewhere in terms of a lifetime risk of around ten to the minus fourth. So although EPA initially sets a more stringent standard than the NRC, we find that the NRC standards with the application of ALARA tends to bring us reasonable close together.

I would also just like to note some of the

consequences of the differences of these approaches, some of which I think we are too familiar with. Conflicts can arise between the agencies. A great deal of time and energy has gone into activities such as mixed waste some years ago and more recently our work on Subpart I.

Obviously if we are unable to resolve these, we have additional costs to our licensees of dual regulation and the confusion appears in the mind of the public and I think it is correct to say that to build confidence in the two agencies, it is important to resolve these.

CHAIRMAN JACKSON: Out of this process would you say that the two agencies are any closer in terms of a common understanding of the use of ALARA from a risk harmonization point of view?

MR. KNAPP: I was going to answer your question more generally first. I think the agencies are a lot closer to a common understanding of the entire subject. I would say that as recently as eight months ago we were still debating the White Paper on Risk Harmonization as to what our differences are.

I think one of the achievements of the products that you see today is that both agencies are agreed as to these are our differences and we have been successful in reaching a common understanding of those differences.

My view of ALARA which I will give others an

opportunity to speak to is that in practice the way it works between NRC and EPA is that we would settle let's say on 100 millirem and we would below that limit ask or direct the licensee to achieve releases that are as low as reasonably achievable.

EPA would tend to start with a lower level but then they will consider various factors, economic and sociological factors, in some ways not very differently from the way that we consider ALARA.

Depending on how those things come out, they might ask their permittee to do better or they might permit the permittee additional freedom if it were shown to be economically extremely difficult to meet it.

So I think in a way the concepts are similar but the difference might be that NRC staffs with a higher limit and forces the licensee to go lower whereas the EPA starts with a more stringent standard but may permit a permittee to go somewhat above that in the event that it is not possible. Now I would like to make sure that nobody behind us disagrees with what I have said.

[No response.]

CHAIRMAN JACKSON: All right. I will come back to that.

MR. KNAPP: Fine.

[SLIDE.]

MR. KNAPP: I would like to turn to slide 11 and again take the rather easy part of the risk management activity by talking about what the similarities are. As I mentioned earlier in this presentation in risk management there are fewer similarities than there were in risk assessment.

One similarity which Allan Richardson spoke to earlier is that we are consistent with current federal radiation protection guidance, in particular the 1987 guidance on employee protection.

Another area where we are similar is that we use similar mechanisms to demonstrate compliance such as modeling future activities, monitoring ongoing activities or using design specifications.

For example, we would use a mechanism in a low level facility for how it should be designed, how the facility should be designed and similarly with respect to say a toxic waste facility, EPA uses design specifications such as liners and leachate collection systems.

Going from the similarities to the differences of which we found six, again I am going to give Ramona an opportunity to speak to those.

[SLIDE.]

MS. TROVATO: I want to start first with sort of a summary of these six differences. For the first one, the

primary risk management approach, NRC deals with dose; EPA deals with risk.

NRC sets a standard or believes that the appropriate dose should be 100 millirem per year which equates to a four times ten to the minus three risk. EPA believes a risk should start at ten to the minus four and work from there.

You asked the question before and Mal answered it and I just want to reiterate. In practice it tends to turn out that the 100 millirem per year plus ALARA and EPA's ten to the minus four risk as a place to start with then economic considerations and social consideration often results with us ending up in the same risk management place or very close if not in the same place.

The 100 millirem per year dose limit EPA believes that each source should be constrained to a fraction of the 100 millirem per year dose limits so that the individual gets 100 millirem per year or no more than 100 millirem per year. NRC believes that 100 millirem per year with ALARA is acceptable for a given source which means the source might be as high as 100 millirem per year.

The statutory basis for the development of radiation policy is the Atomic Energy Act for both agencies. However, EPA also has its environmental statutes at least three of which we have radiation control legislation. That

is under the Clean Air Act, the Safe Drinking Water Act and the Superfund law, CERCLA.

What these do is drive EPA to looking at media specific pathways whether it is drinking the water or breathing the air which is related to number six where we end up with specific differences in dose objectives because NRC wants to set a standard for a source, EPA as a result of our media specific statutes must set a limit or a permit level for that pathway.

So, for example, under the Safe Drinking Water Act we would set a four millirem per year limit in groundwater that is used as drinking water because that is what the Safe Drinking Water Act regulations say.

In terms of risk versus dose I don't think this one is really a big one. NRC limits dose. We limit risk. You can convert back and forth. One of the things we need to do however is make sure those conversions, that we agree on the conversion factors and the exposure scenarios so that we can do that, convert back and forth with ease.

In the population risk area I think Mal spoke to this already. NRC truncates with distance; typically EPA does not for population doses. This has on occasion resulted in EPA having more specific or stringent regulatory requirements than NRC would have imposed.

[SLIDE.]

MS. TROVATO: That is pretty much a summary of what is here of the major risk management differences. In terms of where we are going with this, I have pretty much spoken to this one already but it does drive the concern about source constraints and we want to have sources constrained at a lower than 100 millirem per year and NRC with 100 millirem per year plus ALARA believes that that will be sufficient.

Pathways I mentioned. I think groundwater is our next area where we need to come to some agreement and Mal has proposed and we are in agreement to get together and just spend some time and try to work through the issue on pathways especially the groundwater pathway at the moment.

[SLIDE.]

MS. TROVATO: These differences really result, I think, to a large part from our legal and regulatory framework and the policies our respective agencies have made. EPA has made a general policy that for our regulations we are going to try to shoot for a ten to the minus four to a ten to the minus six risk level. That then drives all our decisions.

So in order to be consistent with our other statutory requirements, we are looking for that risk level under our AEA standard setting authority. So one of the issues that needs to be asked is what is an acceptable risk.

We believe that there needs to be some consistency between our regulation of chemical and radiological carcinogens. Since we regulate both it is hard for us to say you must meet a ten to the minus five risk level for a chemical carcinogen and not say the same thing for radiation exposure.

What we believe is that on a philosophical global level we cannot at the staff level change this but what we also believe is on a case-by-case basis we are being successful in identifying ways to resolve these differences.

I believe we are doing it on the clean-up and the decommissioning standards right now that we are both developing and on the NESHAPS for the Clean Air Act, I think the air emissions we are also being able to do that and I think in the future there are some activities that we want to undertake where we can work through some of these on a case-by-case basis.

[SLIDE.]

MS. TROVATO: In terms of our recommendations we do want to avoid inappropriate transfer of numerical risk management objectives. The Superfund program is ten to the minus four to ten to the minus six clearly. We need to be sure and to choose an appropriate risk level when we deal with clean-up standards.

As we have been working through our clean-up

standards with the Superfund program and with the NRC, we are looking at a ten to the minus four risk level.

As I understand it in some cases the modeling is very conservative and NRC has some very conservative assumptions that result in causing the risk level that NRC finds appropriate to be lower and part of the result of that is that it comes closer to EPA's risk level but the other part of that is if you start with a very conservative risk level, you have to have a very realistic modeling so that you come up with reasonable permit limits or license requirements.

We also think that we ought to initiate a BEIR VII review and we think it is time to take a look at the new information from the Hiroshima and Nagasaki data. We think we need to look at genetic predisposition and we also think we need to look at departures from linearity and see if there is any new information that can shed light on what the appropriate approach to managing risk at low radiation doses should be.

CHAIRMAN JACKSON: How do you propose do this through this review?

MS. TROVATO: What we want to do is ask the National Academy of Sciences to take a look at all of the new data since the last BEIR review and I think the last one started in 1987. They looked at information from 1987

through about 1991 or so, I guess. So we would like for them to look at the new information available and see if there is any conclusions that they can draw from that new information that would shed light on this.

CHAIRMAN JACKSON: How would any of their findings or results factor into the recommendations you are making today?

MS. TROVATO: Part of the path forward would be to ask for this to be done and then to go back and take a look at the information we get from them when we get it from them which would probably be three years from when we initiate the process or so and then factor that into how we conduct our risk assessments, our risk managements and then ultimately what we actually put in our regulations and our standards.

CHAIRMAN JACKSON: How much do you think such a study would cost?

MR. KNAPP: We are currently estimating that it would run around $300,000 and in the event that the Commission chooses to endorse this, we have money set aside to be able to support such a study.

CHAIRMAN JACKSON: You are not going to have the EPA pay for the whole thing?

MR. KNAPP: We will share the expenses among the various agencies. We would hope because ISCORS has as many

as I believe about seven member agencies that all of them would choose to make a contribution but we believe there will be funding available to do this if that is what we decide to do.

CHAIRMAN JACKSON: All right.

MS. TROVATO: And we are not shy about asking those other folks to help us out.

[SLIDE.]

MS. TROVATO: We want to look in greater detail at the risk management consideration. We want to look at the statutes and policies in both agencies and find out where are the real differences, where can we come closer together, where should we change and then come back with some recommendations to both our administrator and to you about ways we might want to change the way we do business so we can come closer.

There are some specific areas that we want to work on in just a general way and groundwater is the biggest one for us right now because we are very concerned about groundwater pathway and NRC is very concerned about the groundwater pathway and the question is what kind of constraint if any should we place on the groundwater pathway separate from a source constraint. This is one we feel that we need to really carefully work through. I would now like to turn it over to Mal.

[SLIDE.]

MR. KNAPP: There are two other differences that were identified. Ramona spoke to them a moment or two ago, the fourth and fifth difference. One of them would appear to be fairly straightforward and one where we have come forward with a recommendation.

This is how to resolve EPA's basing their standards on risk; NRC's basing theirs on dose. The answer would appear to be fairly simple, simply do our assessments in terms of both and then express risk in whatever seems to be most appropriate to the circumstances of that product. That seems to make good sense to the ISCORS folks and it seems a reasonable recommendation for us to make to you.

On the fifth difference the difference and again this is one that is closely linked to that truncation concern mentioned earlier that EPA's consideration of population risk may well lead to additional requirements.

As a part of the development of the radiation guidance where we would look at truncation, we would also look at this issue and try to better look at the merit of regulation to protect populations as a whole as compared with protecting the population by protecting the maximally exposed individual and then making the assumption that will provide appropriate protection to the rest of the population. But we would resolve this and provide better

guidance through the guidance documents that we spoke to earlier in this briefing.

[SLIDE.]

MR. KNAPP: That leads to the last slide which speaks to the next steps that we would take depending on how the Commission reacts to the recommendations that we have made. If you adopt the recommendations some of the things that we would do is we will proceed with the federal guidance as described.

Members of ISCORS are interested in looking at recycling and one of the things that we feel would be appropriate to do if ISCORS pursues recycling and I think EPA has an interest in pursuing recycling is for us to coordinate as agencies on what the recycling scenarios would be. I think this is a very important area for the NRC to be and perhaps the right word is player but certainly to be cooperating with the development of recycling standards as they come up.

As Ramona mentioned a few moments ago, we would proceed with a detailed analysis of the risk management considerations. Again, this will give us a better understanding of the fundamental bases for some of the difference among the agencies which, I think, is important to proceeding with the resolution.

We would initiate the BEIR review which will give

us insight into a variety of things hopefully in part into the merit of the linear no threshold hypothesis and is it still an appropriate way of relating risk to dose or is there perhaps a change in it or some other departure.

Some of the things we would do would be to avoid inappropriate transfer of numerical risk; that is, make sure that the risk numbers are consistent with the scenarios selected. We would also use more realistic and less conservative modeling than we have in some cases in the past.

Finally or perhaps most immediately, as we proceed with the development of the decommissioning standards we would work with EPA closely to attempt to resolve the groundwater issue and if we are successful, generalize on that and resolve other pathway issues similarly and if not, continue on a case by case basis. Thank you.

CHAIRMAN JACKSON: I have a couple of follow-on questions for you. One, is there a role that cost benefit analysis plays in your efforts to reach common ground and should it play a role?

MR. KNAPP: In my view it must play a role. Without cost benefit, I think we face the possibility that one could attempt to reduce risk without end without recognizing that there is a point beyond which the cost to the public and the license community far exceeds the

benefits to be gained. So I think there is definitely a role and I would very much want to see that considered as we proceed in this work on guidance.

MS. TROVATO: We absolutely consider it as we have been developing our clean-up standards, as we look forward to the recycling issues we are certainly considering cost benefit and as we are looking at other rules or standards that we have written, yes, we believe it is important.

CHAIRMAN JACKSON: Let me go back. You talked about acceptable risk in terms of the 100 millirem per year standard that we use versus EPA's and so what you end up doing is you start out with a fundamental difference as to what in a certain sense constitutes acceptable risk. The question I have is will these recommendations or can you describe a little more fully how they might go to narrow the gap on defining what constitutes acceptable risk.

MS. TROVATO: I think that is the global difference that the staff has problems resolving. What we have found is 100 millirem plus ALARA for NRC brings it down into the risk range EPA is interested in. We found that the ten to the minus four risk that EPA starts with along with a consideration of costs and social and economic concerns often drives us up a little bit. So we come closer together.

I think we can continue to work on that on a case

by case basis as we work through the scenarios and the realistic modeling and what is the appropriate truncation and the actual risks to individual organs.

But in terms of whether the staff can come up with specifically what the risk ought to be on a global level, I am not sure that we can do that by ourselves but we can on a case by case basis work through it and we have and I think we are going to continue to do so.

CHAIRMAN JACKSON: Right. That actually led to my follow-on somewhat rhetorical but actually not question having to do with whether a case by case approach from a public policy perspective is one and in a certain sense you could argue that in certain instances it has to be that way but from a public policy and public comfort level whether that is helpful.

That leads to my real question. I noted that in one of the SECY papers that the paper indicated that the subcommittee in a certain sense was unable to resolve many of the risk management differences. So the question becomes are there issues which cannot be resolved in the absence of Congressional or some other action?

MR. KNAPP: We debated that and I think it was debated within the subcommittee and among the staff at all levels and I think it would be best to say that we are not ready to recommend that legislative relief be sought.

Frankly I am somewhat impressed and very pleased by the progress the staffs have made in producing these two documents. They may not be final by any means but they represent a significant step forward from where we were. I think we have momentum and I think we have a level of trust between the agencies that is higher than we have had in a number of years.

I think under those circumstances we would like to try to see what we can resolve before we seek legislative relief. That is not to say that we won't. We may very well be in here in two years saying that we have done our best and something else needs to be done but at this point we would like to proceed and see what we can do among ourselves.

MS. TROVATO: We want to work through the risk management differences and get a better handle on statute by statute, regulation by regulation, where we are really different and how we are different and we have begun this for NRC and EPA but some of the other federal agencies on ISCORS have not yet entered into this discussion in a detailed way with us and we would also like to do that before we request any legislative changes.

CHAIRMAN JACKSON: All right. The last sort of comment, I think I heard you say or at least my sum total that I draw out of this one sum total perception is that

what ISCORS has done and the process is to help you come to a more common understanding of at least what the differences are.

But it seems that much of the resolution is put back to this federal guidance process which presumably was a process that existed all the time. So the question becomes one of timeliness of resolution and working through the issues because presumably if this mechanism existed in the past before ISCORS and now having come to an understanding of your differences you are basically punting things back to that federal guidance process. Then when might we expect some answers to be forthcoming and how will the Commission have the opportunity to review what comes out of this process.

MR. KNAPP: You might say that you question is have we deferred the guidance process back to the EPA process and I don't think we have. I think as Ramona mentioned earlier in the briefing, what we have is a recognition that the procedure in place to promulgate federal guidance is through the federal guidance process and so forth and so on.

CHAIRMAN JACKSON: I guess my question is not so much that. I know that the issue has to do with are your recommendations recommended or are there recommendations even within that process to track things in a way to put

them on a timeliness track?

MR. KNAPP: That I would like to think is the difference that we have between say where we are a year or two ago. Right now in ISCORS we have a number of agencies that are committed to make this work.

We provided a forum which meets several times a year to discuss these things and very honestly the federal guidance is going to be put together in the process that you have heard about but the ISCORS members are frequently the same players, they will be active.

We have internal dates and in the event that those dates are not met, flags will be raised and I think it would be fair to say that Ramona and I have a commitment to work through ISCORS and on this guidance to meet those deadlines. I think that is the difference. The existence of ISCORS and the team work among the agencies should ensure that things happen in a reasonably timely manner.

CHAIRMAN JACKSON: And the opportunity for the Commission to revisit?

MR. KNAPP: The Commission is going to have a number of opportunities. As you may be aware the staff and I brief your assistants frequently on the progress of ISCORS and on what we consider issues that the Commission might wish to be aware of.

In addition, of course, any Commission

contributions that involve the management or policy issues will be brought to your attention before NRC makes a commitment as a part of the guidance. So I think we will give you early warning of issues that might arise and as the guidance is developed you will have an opportunity to contribute to them.

Of course, in the final analysis as Ramona mentioned earlier when EPA submits recommended guidance to OMB then there is a formal process in which NRC can participate had we been unable to resolve our differences up to that point.

CHAIRMAN JACKSON: Thank you. Commissioner Rogers.

COMMISSIONER ROGERS: This is a tough area and while we have folks from EPA here I wondered if we could get a little bit more light thrown on your basis for equating risk, chemical risk, to radiation risks.

I don't understand what the parallel to background radiation is in the chemical risk area. We all know that we are living in a sea of radiation and that that is there and that any federal regulations notwithstanding it is not going to disappear.

So when we start talking about treating radiation risks in exactly the same way as chemical risks in terms of numbers like ten to the minus four to ten to the minus six

and you use the linear hypothesis which I understand is a hot topic today in certain quarters but nevertheless no one has been willing to say that they have something to substitute for it at the moment, you come down to numbers that are very, very small fractions of natural background radiation.

Ten to the minus four takes you down to about three millirem and ten to the minus six takes you down to about three-hundredths of a millirem exposure per year. I don't see the reasonableness of a number like ten to the minus six using the linear hypothesis to equate risk to dose when you come down to a number which is a very tiny fraction of what every human being is exposed to every day.

So the parallel approach of treating radiation risk and chemical risk using the same set of numbers while it sounds good from a risk harmonization point of view, they really are it seems to me quite different situations, that one might be able to avoid living in an environment of carcinogens but you can't avoid living in an environment of radiation. I wonder how EPA could help me on this one.

MS. TROVATO: On the ten to the minus four to ten to the minus six, one of the recommendations we made in this is to use the appropriate risk levels and I think if you would look at EPA standards that we have set for radiation, they have been set near the ten to the minus four level and

if they are not at ten to the minus four, then slightly a greater risk is allowed based on the cost analysis of that.

COMMISSIONER ROGERS: But you did say that you start at ten to the minus four and you want to go to ten to the minus six.

MS. TROVATO: No, sir, I didn't. What I said is that EPA's policy is to set risk levels between ten to the minus four and ten to the minus six for all of its other programs. What we in the radiation program typically do is begin at a risk level of ten to the minus four and then we take into account cost and benefit and decide whether it needs to go higher or lower.

I believe that if you would look at most of our standards, it has typically gone slightly above that up to perhaps three times ten to the minus four or four times ten to the minus four.

COMMISSIONER ROGERS: That is where it winds up and maybe I didn't hear you correctly but I thought I heard you say that you felt that the chemical risk approach should be one which carries over into the radiation field risk approach and there the numbers are ten to the minus four to ten to the minus six.

Now if you are saying that ten to the minus four is where you stop and you look to see whether somebody can go a little bit higher than that or whether they can go a

little bit lower than that, that is different from saying ten to the minus four is the highest risk that you want to consider and that you really would like to go down to the ten to the minus six if possible. Those are very different.

MS. TROVATO: Right, they are and what I said was we in the agency the policy is ten to the minus four to ten to the minus six for risk level but what we typically do in the radiation program is look at ten to the minus four, take into effect cost and benefit and either go up or down based upon that cost and benefit analysis.

COMMISSIONER ROGERS: I don't know what you statement in the agency then means. What does that mean that in the agency it is ten to the minus four to ten to the minus six? You are part of the agency.

MS. TROVATO: That is the risk level that we regulate within and depending upon what is being regulated, it may be regulated at ten to the minus four or ten to the five or ten to the minus six depending on cost benefit analysis, depending upon what the statute says.

COMMISSIONER ROGERS: So you are saying that you don't intend to regulate radiation the same way you regulate carcinogens.

MS. TROVATO: We intend to look at the risk and then decide what the best standard level is based upon the risk and the cost and the benefits.

COMMISSIONER ROGERS: I think this is where part of our problem has been in the past and I think it is very important to try to understand exactly how NRC and EPA can come together on this issue because when I hear numbers like ten to the minus six for radiation protection and translate them as best we can using current assumptions they don't seem to make any sense at all.

MS. TROVATO: We agree with you.

COMMISSIONER ROGERS: Good. I am delighted to hear that.

CHAIRMAN JACKSON: The acceptable risk question.

MS. TROVATO: Right, it is the acceptable risk question.

CHAIRMAN JACKSON: The acceptable risk question requires a lot or focus.

MS. TROVATO: It does. Allan, did you want to add anything.

MR. RICHARDSON: Just two small points, one of them is that you mentioned background for radiation with the implication that there are not backgrounds of chemical carcinogens and there are and if you look at them they turn out to be roughly the same thing as the risk from background radiation. It is surprising but it is so.

The other point that is useful to keep in mind is that these risks that we are talking about are the

incremental risks due to man's activities above background. So when we talk about ten to the minus four we are talking about the additional risk from an activity. We are not talking about regulating background.

COMMISSIONER ROGERS: I don't know how to regulate background. I don't know if anybody knows how to regulate background. That would be very interesting though.

CHAIRMAN JACKSON: Any other questions?

COMMISSIONER ROGERS: No.

CHAIRMAN JACKSON: Yes.

MR. KNAPP: I just wanted to make one last point. The products that you have seen today represent some very difficult work on the part of the staffs of both agencies. In order to get this they had to set aside some of their personal views and step back and look dispassionately at the advantages and disadvantages of both agencies. I wanted to take a moment to publicly thank them for the emotional effort it took to bring this to you.

COMMISSIONER ROGERS: I am sure that is true.

CHAIRMAN JACKSON: Commissioner Rogers and I would like to thank the members from both agencies for really an excellent briefing on a matter that I consider of great importance to the NRC and I would think to the EPA.

MS. TROVATO: Yes.

CHAIRMAN JACKSON: In the interest of regulatory

effectiveness it is incumbent upon both agencies to make every effort to eliminate inconsistent standards, to ensure that duplicative or overlapping regulations are kept to an absolute minimum and to develop sensible common standards that will protect public health and safety and that your recommendations and the process you are working on tracks to those sorts of results.

From today's briefing, it appears that you are focusing on these goals. So I would encourage you to work together as you have been doing in a cooperative manner, the two staffs, to ensure that the regulation of radioactive material is accomplished with a reasonable, consistent, fair and efficient approach and that the public's health and safety is protected.

Again, I would like to thank all of the participants for a very informative and enlightening briefing. This meeting is now adjourned.

[Whereupon, at 10:48 a.m., the meeting was adjourned.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON RISK HARMONIZATION RECOMMENDATIONS - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Monday, November 6, 1995

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Marilynn Estep

Reporter: Marilynn Estep

BRIEFING FOR THE COMMISSION ON RISK HARMONIZATION

Monday, November 6, 1995

OVERVIEW

- **BACKGROUND:**
  - **Historical context**
  - **Commitments to Senator Glenn**

- **RISK ASSESSMENT and RISK MANAGEMENT: Discusses EPA/NRC differences and harmonization recommendations.**

- **NEXT STEPS: Describes Commission's options and summarizes next steps if recommendations are adopted.**

BACKGROUND

- 1992 Memorandum of Understanding
- 1994 GAO Report Findings
- October 1994 Draft EPA-NRC White Paper
- October 1994 letter from Senator Glenn
- January 1995 letter from EPA and NRC to Senator Glenn
- April 1995: formation of Interagency Steering Committee on Radiation Standards (ISCORS)

RISK ASSESSMENT OVERVIEW

- Although there are some differences, EPA and NRC generally assess risks similarly.
- Recommendations for resolving differences are process-oriented.
- ISCORS recommends that risk assessment issues be resolved through Federal Guidance.

RISK ASSESSMENT SIMILARITIES

- Cancer mortality is the primary measure of risk.
- International consensus factors usually used to translate dose to risk.
- Exposure usually assessed to a "reasonably" maximum exposed individual.
- Deterministic risk (dose) assessments generally used, but probabilistic assessments used in selected programs.
- Both agencies usually consider the same pathways of exposure.
- Both agencies truncate risk assessments in time.

SUMMARY OF RISK ASSESSMENT DIFFERENCES

1 In risk assessments, EPA uses multiple organ-specific dose to risk conversion factors; NRC uses a single whole-body dose to risk conversion factor.

2 EPA's Superfund program uses *morbidity*; NRC and all other EPA programs use *mortality* as biological endpoint.

3 EPA and NRC sometimes use different exposure scenarios for analyses of individual dose.

4 EPA and NRC perform truncation (time, distance, magnitude) of population dose calculation under different circumstances.

RISK ASSESSMENT DIFFERENCE #2

Difference:

- **EPA and NRC radiological programs, and EPA programs other than Superfund, use *mortality* as biological endpoint in evaluating radiological risk.**
- **EPA's Superfund program is outlier by addressing risk in terms of *morbidity*.**

Harmonization Recommendation:

- **The Federal Guidance Report on implementation should include guidance on the biological endpoint to be used, or on how multiple endpoints should be considered in setting standards.**

RISK ASSESSMENT DIFFERENCE #4

Difference:

- **EPA and NRC perform truncation (time, distance, magnitude) of population dose calculation under different circumstances.**
- **Already addressed in Proposed Federal Guidance on Radiation Protection**

Suggested Harmonization Approach:

- **The final Federal Guidance needs to specifically address whether truncation is appropriate in four sets of circumstances identified by the Risk Harmonization Subcommittee.**

SUMMARY OF RISK ASSESSMENT RECOMMENDATIONS

- Radiation Protection Guidance should be forwarded to OMB by March 1996. (Acceleration of work in progress.)

- A Federal Guidance Report on dose-to-risk conversion factors should be issued in October 1996. (Acceleration of work in progress.)

- The Federal Guidance Report on implementation should be finalized by May 1997. (New effort.)

RISK MANAGEMENT OVERVIEW

Similar levels of protection, despite fundamental differences in approaches.

- **application of ALARA below NRC's nominal limits bring actual risks close to EPA's nominal goals, so that endpoints are about the same.**

Consequences of differences in approaches:

- **conflicts between NRC and EPA when regulating in a common area**
- **costs to licensees of dual regulation**
- **confusion for the public**

RISK MANAGEMENT SIMILARITIES

- Both EPA and NRC consistent with existing Federal Radiation Protection guidance. (Guidance developed by EPA and approved by the President.)

- Use similar array of mechanisms (modeling, monitoring, or design) to demonstrate compliance.

RISK MANAGEMENT DIFFERENCES

1. Primary risk management approaches
2. Views on 100 mrem/year dose limit
3. Statutory basis for development of radiation policy
4. Use of risk vs. dose
5. Uses of population risk
6. Specific differences in dose objectives

RISK MANAGEMENT DIFFERENCES #1, #2, #3, AND #6

Differences:

(1) Appropriate ceiling on individual exposure (before considering costs)

- **NRC: 100 mrem/year annual dose standard (equivalent to a lifetime risk of 4×10^{-3})**
- **EPA: approximately 10^{-4} lifetime risk**
- **Drives debate on need for source constraints**

(2) How to address pathways

- **NRC: single standards for all exposure pathways combined.**
- **EPA: regulates pathway by pathway.**

RISK MANAGEMENT DIFFERENCES #1, #2, #3, & #6 (CONT'D)

- Reasons for differences: mission, legal and regulatory framework, and regulatory judgement.

- Policy Issues:
  - What is an acceptable risk?
  - Should there be consistency between regulation of chemical and radiological carcinogens?

- Global differences cannot be resolved by staff, but staff will work to resolve on a case-by-case basis.

RISK MANAGEMENT DIFFERENCES #1, #2, #3, & #6 (CONT'D)

Harmonization Recommendations:

- **Avoid inappropriate transfer of numerical risk management objectives from one program to another.**
- **In general, use realistic modeling in regulatory and compliance analysis.**
- **Initiate BEIR VII review, a reexamination of the risks of ionizing radiation.**

RISK MANAGEMENT DIFFERENCES #1, #2, #3, & #6 (CONT'D)

Harmonization Recommendations (cont'd):

- Identify, in detail, the risk management considerations each federal agency uses in establishing standards.
- Federal agencies should work together to develop consistent approaches for specific topics.
  - efforts to resolve decommissioning groundwater issue will guide decision as to how to proceed on pathway constraints:
    - case-by-case
    - groundwater issue in general
    - pathway issues in general

RISK MANAGEMENT DIFFERENCES #4 & #5

Difference #4:

- **NRC's regulatory decisions based on dose; EPA's based on risk.**

Harmonization Recommendation:

- ***Assess* standards in terms of both risk and dose; *express* standards in terms appropriate for demonstrating compliance.**

Difference #5:

- **EPA's consideration of population risk more likely to lead to additional regulatory requirements than NRC's.**

Harmonization Recommendation:

- **Follow upcoming Federal Guidance.**

NEXT STEPS

- **Adopt (with or without amendment) or reject Risk Harmonization Recommendations.**
- **If recommendations are adopted, staff will proceed with following actions:**
  - Federal guidance
  - Coordination of recycling scenarios
  - Detailed analysis of all federal agencies' risk management considerations
  - Initiation of BEIR Review
  - Making operational the recommendations to:
    - avoid inappropriate transfer of numerical risk management objectives from one program to another
    - use realistic modeling
  - Use the resolution of the decommissioning groundwater issue as the basis for deciding how to proceed on pathway constraints.