

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

**Title: BRIEFING BY ICRP/NCRP ON THE PRINCIPLES
 OF RADIOLOGICAL PROTECTION AND THEIR
 APPLICATION IN SETTING LIMITS AND
 CONSTRAINTS FOR THE PUBLIC FROM
 RADIATION SOURCES - PUBLIC MEETING**

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2 NUCLEAR REGULATORY COMMISSION

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5 RADIOLOGICAL PROTECTION AND THEIR APPLICATION IN
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8 ***

9 PUBLIC MEETING

10 ***

11
12 U.S. Nuclear Regulatory Commission
13 One White Flint North
14 Rockville, Maryland

15
16 Thursday, January 12, 1995
17

18 The Commission met in open session, pursuant to
19 notice, at 2:00 p.m., Ivan Selin, Chairman, presiding.

20
21 COMMISSIONERS PRESENT:

22 IVAN SELIN, Chairman of the Commission
23 KENNETH C. ROGERS, Commissioner
24 E. GAIL de PLANQUE, Commissioner
25

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1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:
2 JOHN C. HOYLE, Acting Secretary
3 MARTIN MALSCH, Deputy General Counsel
4 CHARLES MEINHOLD, Vice Chairman, ICRP and Senior
5 Scientist, Brookhaven National Laboratory
6 PROFESSOR ROGER CLARKE, Ph.D., Chairman, ICRP and
7 Director, National Radiological Protection
8 Branch, U.K.

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P R O C E E D I N G S

[2:03 p.m.]

1
2
3 CHAIRMAN SELIN: Good afternoon, ladies and
4 gentlemen.

5 We are very pleased today to welcome Mr. Charles
6 Meinhold, the President of the National Council on Radiation
7 Protection and Measurements and the Vice Chairman of the
8 International Commission on Radiological Protection, and
9 Professor Roger Clarke, the Chairman of the International
10 Commission on Radiological Protection to brief us on the
11 conceptual framework and technical basis for the ICRP and
12 NCRP radiological protection approach.

13 I remind you that Mr. Meinhold previously briefed
14 the Commission in September of 1992 on the 1990
15 recommendations of ICRP which were formalized in Publication
16 Number 60.

17 The conceptual framework, the ICRP/NRCP approach
18 to radiological protection, forms the general underlying
19 basis for radiation protection standards as practiced at the
20 NRC. It's no exaggeration to say that everything we do
21 depends on and is supposed to be informed by the work that
22 you gentlemen do and the Commissions do. We therefore
23 consider it beneficial not only to be updated periodically
24 on the most recent results of your deliberations, but have a
25 chance to speak to you somewhat informally across the table

1 about the meanings of some of these standards and to be
2 informed in our own work.

3 Commissioner de Planque has several words to say
4 also.

5 COMMISSIONER de PLANQUE: Not several, I just
6 wanted to offer my personal thanks to both of you for coming
7 today. It's sometimes the case in the day to day work of
8 regulating we get lost in the details and sometimes forget
9 that radiation protection is really the basic reason we're
10 all here. So, I welcome this opportunity to go back and
11 revisit again what are the health effects of radiation, what
12 do we know about them, what don't we know about them and how
13 do you convert that into a framework for radiation
14 protection which then we can use in our regulatory business?
15 So, I thank you personally for coming today.

16 CHAIRMAN SELIN: Thank you.

17 Mr. Meinhold, is it your intention to start?

18 MR. MEINHOLD: Yes.

19 CHAIRMAN SELIN: Thank you.

20 MR. MEINHOLD: Well, thank you very much for the
21 kind words, Mr. Chairman and Commissioner de Planque and
22 Commissioner Rogers for having us here. It's always helpful
23 to us to be able to discuss the recommendations of both of
24 these groups, the NCRP and the ICRP, because of course it's
25 only through the practical application of our

1 recommendations that they're worth anything. We're not in
2 the position of requiring anything, we just make the best
3 advice we can and the success of our advice depends on how
4 it's adopted, accepted and put into use by people like
5 yourselves. So, I do want to thank you for that.

6 My presentation is really going to be introductory
7 in nature to Professor Clarke and I did want to say,
8 although I know it isn't necessary, sir, to invite you to
9 ask questions to go along.

10 With that, I'll ask for the first --

11 CHAIRMAN SELIN: So you're going to do the
12 introduction, but you're inviting us to question Professor
13 Clarke as he goes along?

14 MR. MEINHOLD: That's good. That's good. Yes,
15 that's good.

16 [Slide.]

17 MR. MEINHOLD: If I could have the first overhead.

18 I'm going to talk a little bit about risk
19 estimates for radiation protection in the context of what do
20 we know and then how well do we know it. I think that
21 there's been a problem in the community thinking that the
22 NCRP and the ICRP don't really look at anything except the
23 data they want to look at and get the answers they want to
24 get, and I wanted to try to talk to you a little bit about
25 the information that we have and what we do know and how

1 well we know it to see if I can put that at least somewhat
2 in the perspective that we put it in as we come to our
3 conclusions.

4 To do this, I've decided to try to look at four
5 levels of certainty. We could use the word "uncertainty"
6 just as well. But I'm trying to say that let's ask what is
7 it we think we really do know, and that's my level A
8 certainty. These are the things that I think we really do
9 know. First of all, the thing I think we know pretty well
10 is that there is excess cancer in the Japanese survivors who
11 received high doses. I'll go to that in a little more
12 detail.

13 We also know that there's excess lung cancer in
14 the miners, those who did uranium mining. We know that. We
15 also know that for very simple biological systems and one
16 that I'm particularly familiar with having done some
17 analysis on that in previous years, is that there is a
18 linear and then a quadratic responses at lower and then at
19 higher doses in simple biological systems, among other kinds
20 of interactions. I say that we know these with class A
21 certainty because, as I'll show you, I think we don't have
22 to make a lot of estimations, we don't need to make a lot of
23 conjecture, we can see the data as it exists.

24 If I could have the next overhead, please.

25 [Slide.]

1 MR. MEINHOLD: This is one of my favorite
2 overheads and I think I showed it perhaps the last time I
3 was here because I think it's so important for people in the
4 radiation business to understand. I go to the total at the
5 bottom because I think one of the things that people say all
6 the times is there are 76,000 people in the study population
7 and yet there are only 260, if you read under the excess
8 column, 260 total cancers that are non-leukemia and 80
9 leukemia cancers. We usually hear the word 350. It turns
10 out to be 340 cases. There are only 340 excess cancers in
11 that population. So, the idea being, well, then you can
12 possibly believe that that really exists. But if you look
13 at the line just above it where you've got 100 to 200 rem,
14 that's one to two Sieverts. We'll do that as we go through.
15 We're talking about 100 to 200 rem. Here there are only
16 2,000 people who are in that study group that had that
17 exposure. When you go across and look at that, you'll see
18 that in fact it's not difficult in 2,000 people to decide
19 that you've got excess leukemia that should have been 3
20 cases and it's 23 cases, 20 plus 3, or even the non-leukemia
21 that's 147 that you'd expect and another 71, another 50
22 percent in 2,000 people.

23 The point I want to make is that the data is
24 pretty clear that at high doses there is a risk that's
25 clearly demonstrable and easy to see and it isn't witchcraft

1 or clever epidemiology. It's a very forthright analysis
2 that you can make.

3 COMMISSIONER ROGERS: Excuse me. Just before you
4 leave that, the expected numbers, how are they obtained,
5 because they're not the same percentage of the survivors in
6 each case? That fluctuates a little bit from dose to dose
7 level here. What's involved in the --

8 MR. MEINHOLD: It is fairly proportional. This is
9 simply the expectation that you would have. You'd have to
10 look at the age distribution, see, in each one of these
11 categories because it's the age distribution of the
12 population that's in that category that would determine what
13 you'd expect as the cancer probability --

14 COMMISSIONER ROGERS: So that might give rise to a
15 little bit different --

16 MR. MEINHOLD: Right. I should point out that --
17 and we'll see that a little bit later. Right now I'm trying
18 to relate this to dose, but only to the fact that there's
19 excess cancers. Perhaps we'll come back a little bit more
20 as I get a little bit further on in the particular numbers.
21 But that's the reason. There's a different age distribution
22 in each of those.

23 The next overhead is one that I'll do very
24 quickly. It's just simply the same kind of information for
25 the miners, that if you look at the Colorado miners you go

1 all the way across to the right. The number of lung cancer
2 deaths, you have seen 157 cases of lung cancer when you
3 would have expected in that population 50. That's true
4 pretty much as you go through that list and I don't want to
5 spend any time on it. I'm merely making the point that at
6 high levels of some kind of effect in those mines there's
7 excess lung cancer.

8 The next one again is the Tradescantia that I
9 mentioned earlier. It's a system that I had examined with
10 Vic Bond and Hal Rossi when we were trying to sort out the
11 difference between x-rays and gamma-rays actually. But
12 what's interesting with this particular model, and these are
13 actual experiments, that you can see that you can take this
14 effect on stamen hair color change all the way down to
15 extremely low levels. It's that kind of thing that
16 convinced us that many of these biological effects or end
17 points had a linear component down at low range and then had
18 a quadratic component later on .

19 But let me say that when I talk about Type A I'm
20 only talking about knowing it for simple cells. That's
21 what's Type A certain, not how it applies to man. Simple
22 cell systems.

23 [Slide.]

24 MR. MEINHOLD: The next is my level B certainty
25 and here I say, "Okay. Well, now, what's happened between

1 level A and level B?" What's really happened is now we have
2 to add some more parameters in here, the first one being
3 that if we're going to do the risk at per unit dose, we need
4 to know the dose. Knowing the dose in the Japanese is the
5 issue that has a little more uncertainty than just the fact
6 that they're excess cancers.

7 The next is the model, a multiplicative model.
8 That is how do we assess the number of cancers we're going
9 to see in those Japanese over the whole of their lifetime
10 when only half of them have died up to this point? We have
11 to use some kind of projection model. That is now, I think,
12 a level B kind of certainty. That is we don't have it with
13 absolute certainty, but the evidence is pretty strong that
14 there's some kind of a multiplicative activity.

15 The last is that there are Mendelian effects in
16 man as well as there are in test animals. That is the blue
17 eyes and brown eyes kinds of things. Not the complicated
18 ones, but the simple Mendelian effects have been
19 demonstrated in man as well as in the system.

20 [Slide.]

21 MR. MEINHOLD: The next one gives you the
22 information we have and I would call your attention
23 primarily to the fact that we're talking about what the risk
24 is at 100 rads. This is one ray. It's 100 rads in the
25 terminology of the historical, for those interested in

1 history. When you look at 100 rad you say, "Well, what is
2 the risk?" UNSCEAR says that the risk in 1977, if you look
3 at the 1977 UNSCEAR number, you see 2.5.

4 PROFESSOR CLARKE: That's the wrong viewgraph.

5 MR. MEINHOLD: Oh, we've got the wrong viewgraph.

6 COMMISSIONER de PLANQUE: Just go up one more.

7 MR. MEINHOLD: Very good.

8 PROFESSOR CLARKE: Sorry about that.

9 MR. MEINHOLD: Thank you. Thanks for watching,
10 Roger. I appreciate that.

11 The UNSCEAR numbers -- again we're talking about
12 100 rads. The UNSCEAR number is 2.5 there in 1977. If you
13 drop on down about four lines you come to UNSCEAR 1988 and
14 you see four to five. The reason for that change has to do
15 with two things, additional cancer cases that have been
16 observed in the population and a change in dosimetry, a
17 change which is now under some question because of the
18 contribution of neutrons to the dose estimate.

19 More importantly then was another change. If you
20 look at UNSCEAR 1988 and we go across from the additive
21 column to the multiplicative column and you see that's gone
22 up by another factor of two. That's a very large part of
23 the change in our risk estimates has to do with the fact
24 that we now believe that there's multiplicative approach to
25 estimating exposure in later times for that Japanese

1 population is a valid approach.

2 [Slide.]

3 MR. MEINHOLD: The next overhead that I guess
4 you've seen now previously doesn't really define that
5 expectation, but it does give you sort of the approach and
6 you can see that it's reflected. If you look at the bottom
7 two lines over between 1966 to '75 and then look at it 1976
8 to 1985, you see that the expected cancers went from 66 to
9 76, an increase which you'd expect in a population that's
10 aging. That's really what this whole figure shows, is that
11 in 1950, '55, it was a young population that became older
12 and older as time went by.

13 You'll notice as the expected ones cancers
14 increase, because cancer is a disease of old age, that also
15 the excess cancers have increased. That is they've gone
16 along with that increase in natural cancer. It's this
17 information with other information like it that has led us
18 to believe that the multiplicative model, that is a model
19 which suggests that you will get the attributable cancer at
20 the same age you get the natural cancer, is the model that
21 is most applicable.

22 I might add that some of the recent data in Japan
23 is suggesting that may be a somewhat conservative estimate
24 and we'll have to wait to see what that does. Again, it's a
25 type B activity.

1 Now, when we get to level C, which I think is
2 really an important one for us to look at, then we're
3 talking about -- we come into the things which are of great
4 importance to radiation protection. That is the effects per
5 unit dose at very low dose rates, the kinds of exposures we
6 receive in everyday work. I particularly use the word "low
7 dose rates," because I'm a little nervous about low doses.
8 When we think about the doses in Japan, we're talking about
9 100 rem, 200 rem being the numbers that the data is at. If
10 we look at a worker who would receive the maximum exposure
11 over his lifetime, he's in the same range. So, the
12 difference that we're interested in, it isn't really so much
13 the dose as it is in the dose rate. So, we're looking at
14 that question as a serious question for radiation
15 protection, how do we go from those exposures experienced by
16 the Japanese down to the exposures that we expect for our
17 workers?

18 The next that accompanies that is the organ risk,
19 and the last one is one that I think is a level C certainty
20 is that, in fact, there is a pure dose grid term for bone,
21 for potential alpha emitters in the bone, which is
22 interesting because what we don't know there is whether
23 that's simply because the time it takes for that cancer to
24 occur is longer than the life in the individual or whether
25 there's some mechanism that says that it doesn't have a

1 linear component to it.

2 [Slide.]

3 MR. MEINHOLD: If we look at the next one, I'm not
4 going to go through this in detail. I think I may have
5 previously. Remember what we're talking about is that up
6 where it says curve A is where the data is. That's up at
7 about 200 rads. Where we need to have it is all the way
8 down in the corner where it says slope alpha 1. Trying to
9 get from up there to down there cannot be done from the data
10 we have in Japan. It has to be done with the use of a
11 model. The model that we've used is the alpha plus beta D²,
12 very much like that model that you saw with the
13 Tradescantia. It's the solid line on the curve. It merely
14 says that there's a linear portion down low that's about
15 half of the risk that you would get if you'd drawn the
16 straight line from zero on up to those high numbers. It's
17 about one-half of that and that slope would increase all the
18 way out as you receive exposure over long periods of time at
19 those low dose rates. That basically is the model that we
20 adopted.

21 COMMISSIONER ROGERS: Excuse me.

22 MR. MEINHOLD: Excuse me.

23 COMMISSIONER ROGERS: Yes. But that won't bend
24 over. What gives the bending over?

25 MR. MEINHOLD: The bending over is when you get

1 above about 20 rads, which is about the break point, what
2 will happen is that the mechanism that we believe is going
3 on which has to do with DNA strand breaks and that kind of
4 thing, at that point you get enough additional hits in the
5 cells so that you get more effective damage to those DNA
6 organisms, if you like, or cell components which means that
7 you won't get as good repair. That's one of the approaches
8 in the model that has been taken. But it does turn over at
9 about 20 rads and 10 rad per hour.

10 Is that right?

11 COMMISSIONER ROGERS: I'm talking about just
12 bending down.

13 MR. MEINHOLD: Oh, I'm sorry. I'm very sorry.
14 Thank you.

15 COMMISSIONER ROGERS: That's the D2 term.

16 MR. MEINHOLD: Right. It's purely cell killing.
17 You kill enough cells so the cancer won't happen. That's
18 the cell killing part.

19 COMMISSIONER ROGERS: Okay.

20 MR. MEINHOLD: I'm sorry.

21 COMMISSIONER ROGERS: Yes.

22 MR. MEINHOLD: I could have answered it a lot
23 faster if I'd have known the question. Just pay more
24 attention, I'll be all right.

25 [Slide.]

1 MR. MEINHOLD: The next overhead is the nominal
2 risk estimates which I think again we're talking type C
3 certainty. We're way down from the kinds of things we know
4 with great certainty. We're down now to things that we have
5 to accept with an understanding of the fact that we're in
6 our third level of certainty here. That is that at high
7 dose rates we're talking about the UNSCEAR numbers for those
8 populations, 10 times 10 to the minus 4 per rem, which is
9 what you saw earlier. For the worker it's 8 times 10 to the
10 minus 4 per rem. And a dose and dose rate effectiveness
11 factor of 2 that you see ICRP has applied. When you do
12 that, you have those numbers to get 5 times 10 to the minus
13 4 per rem and 4 times 10 to the minus 4 per rem for the
14 worker and that's why you hear that we've essentially got a
15 factor of four greater in our risk estimates. As you
16 recall, used 1 times 10 to the minus 4 per rem in our
17 previous estimates of risk.

18 The NCRP looked at this and just to show you the
19 uncertainty, they thought, "Well, when our risk committee
20 looked at it they said probably the dose and dose rate
21 factor is two to three." I think that reflects the
22 uncertainty in this whole process of selecting the slope of
23 that curve, which is a tough issue.

24 I might add that some of the newer data from Japan
25 may be a stronger estimate that it's closer to one than it

1 is to two. What's interesting here is that the ICRP
2 Committee was essentially very much led by the
3 epidemiologists who have a stronger belief in the linear
4 response when they can't demonstrate otherwise and the NCRP
5 was strongly influenced by some of the animal people who
6 look at the animal data and say that there could be more
7 recovery and repair than we've been using. But you see,
8 even they talk about two to three. So, we're still talking
9 about relatively small numbers.

10 I might add that it's important to recognize, of
11 course, that these new numbers which are in Publication 60,
12 this 4 times 10 to the minus 4 per rem, are the numbers that
13 I believe the staff is using in all of its work now, so that
14 as I understand it the staff is already using the newer risk
15 estimates and not waiting for a regulatory change in terms
16 of adopting a new risk estimate.

17 [Slide.]

18 MR. MEINHOLD: The next one is just an example
19 what I want to do about the organs. When we set up the
20 system of looking at individual tissue sensitivities to
21 allow us to do the effective dose equivalent calculations
22 that you have in 10 CFR 20 Revised, we had to have a risk
23 for each individual organ in order to understand how to set
24 the limits on intakes, particularly for radionuclides that
25 were distributed to specific organs.

1 What I want to show you here is that the variation
2 between these five populations and ICRP averaged across
3 these five population groups in order to get its risk
4 estimates in order to set up the system of Ws or Ts. You'll
5 see that there's a big difference between the esophagus
6 between the United States and Puerto Rico, a big difference
7 between Japan and the United States in stomach cancer. But,
8 of course, what you recognize is that you've got to get that
9 cancer someplace, since this is a relative distribution
10 since it all adds up to one down at the bottom.

11 The fact is it's fairly robust for the total
12 effective dose equivalent that we use in the
13 recommendations. The thing that I'm always cautioning
14 people is they should never use those Ws or T values to
15 estimate a risk. That is you can't take the risk that we
16 give -- the Ws or T we give for the thyroid and determine
17 that you can estimate a risk that way. I might add that the
18 thyroid is particularly difficult because it's based
19 primarily on the x-ray exposures and we know that the data
20 that we have from materials that goes to the thyroid
21 indicates a risk that's even lower by a factor of two or
22 three than the risk you get from the x-ray exposures.

23 [Slide.]

24 MR. MEINHOLD: The last one is my level D
25 certainty. I put these on because I think it's important to

1 realize that these are the kind of things that we look at
2 each time the Commission or the Council reviews its
3 information.

4 The first is the existence of a hormetic effect
5 and I'm going to come back to that. This is an adaptive
6 response and I think that's an important issue for you to
7 know a little bit more about.

8 The second is the existence of the non-Mendelian
9 effects. Here the problem is that there is a suggestion
10 that all of human health is related to genetic component and
11 that there's an ionizing radiation detriment associated with
12 that ill health, not only in cancer but for everything else
13 that's wrong, including things like diabetes or rheumatism
14 or whatever else. So, that's a type C issue that we need to
15 do a lot more work to understand.

16 The third one I put down is the existence of the
17 Gardner effect, and Professor Clarke may want to talk about
18 this. But this was a study in the United Kingdom in which
19 Professor Gardner was suggesting that exposure of the
20 parents caused leukemia in the children. All of the
21 subsequent studies on this have indicated that that's not
22 true, but I indicate again that even as we looked at that it
23 was the kind of thing that we wouldn't have adopted because
24 of the uncertainty in terms of supporting data with regard
25 to it.

1 The one is the effects on health on other than
2 cancer and that's been seen in the Japanese more recently
3 and there may be some data on that. But that's, I believe,
4 certainly a type D certainty issue. We don't have
5 quantitative estimates of those kinds of things.

6 If I could come back to the hermetic effect real
7 quickly, the UNSCEAR for the first time had the courage, I
8 think, to do two things. They looked first at all of the
9 low dose epidemiological studies. That is everything that
10 exists in terms of workers or in terms of elevated
11 population, people who live in high elevations, all of those
12 kinds of things. But the second one was a report on
13 adaptive response, read hormetic response. That is is a
14 conditioning dose going to protect you from later exposure?
15 That's the issue. In fact, the Committee pointed out a
16 number of issues, a number of times in which the biology
17 does indicate an adaptive effect or a beneficial effect to
18 that exposure.

19 I wanted to show you the next two slides because I
20 think it's very important to understand what the UNSCEAR
21 said after they looked at first the epidemiological one,
22 that consequently the use of a nominal value of five percent
23 per Sievert, or that's the 5 times 10 to the minus 4 per
24 rem, for mortality due to leukemia and solid cancer from
25 radiation at low doses for population of all ages,

1 essentially 4 times 10 to the minus 4 per rem for the adult
2 working population still seems valid. So, essentially even
3 though they reviewed all of the low dose epidemiological
4 studies, there wasn't enough information or any information
5 there was indicated it was still within the bounds of these
6 risk estimates.

7 [Slide.]

8 MR. MEINHOLD: The next overhead has to do with
9 its conclusions on the adaptive response report, which I
10 think is very important, which is that the extensive data
11 from the animal experiments and limited human data provide
12 no evidence to support the view that the adaptive response
13 in cells decreases the incidence of late effects such as
14 cancer induction. The Committee looked very strongly at
15 this question and found that there's no way that they could
16 make that assumption. However, they did believe that it was
17 worth further experimental work, which is indicated in the
18 report itself.

19 Well, having said that, if there are any questions
20 I was really trying to point out to you that as radiation
21 protection people, we have a serious responsibility to make
22 some judgments. We have to use the best judgments we have.
23 The judgments that we have are all the type C certainties.
24 They're all things that require models. They require best
25 estimates, scientific judgment. They aren't clearly

1 observable and demonstrable. Until we know a lot more about
2 radiation protection and the cause of cancer itself, we're
3 always going to be somewhat weak in this regard. Our best
4 potential to get better information is on epidemiological
5 studies of workers and larger studies of those who have had
6 low exposures.

7 Having said that, I guess I'd --

8 COMMISSIONER ROGERS: What is the prognosis for
9 actually getting that kind of data within any time that any
10 of us might be interested in?

11 MR. MEINHOLD: Well, two things. First of all, I
12 think that for the worker, that risk, I think that we're
13 going to see perhaps an indication that we've under
14 estimated the number of cancer cases that actually happened
15 in Japan because you miss some cases when you do that kind
16 of epidemiological study. At the same time, we're going to
17 see that perhaps there's a little tailing off in the risk at
18 very late ages. I think overall the numbers that we have
19 now for the risk estimates are fairly robust. Professor
20 Clarke may want to reflect on this as well.

21 For the public, I think our only hope is to get
22 more mechanistic studies. As a matter of fact, the NCRP has
23 a committee right now doing two things in that regard. One
24 of them is asking are there ways to use animal data to
25 estimate human risk. Professor Hull from CDC is doing that

1 for us, chairing that committee. I think if there is a way
2 to get to the very low doses, it's going to be that kind of
3 information.

4 I might also add that another thing of interest
5 which isn't quite on your topic, but we're also working on
6 putting together a committee to look at really the basis for
7 the linear extrapolation. That is what goes into our
8 assumption of linearity. Is it just a practical problem or
9 do we have good biology other than a few Tradescantia buds
10 that went from blue to red? What else is there and how good
11 is that data? So, that's the kind of thing that may help us
12 go to low doses.

13 Professor Clarke may want to --

14 PROFESSOR CLARKE: May I just add that I don't
15 think epidemiology by itself is going to give us sufficient
16 information for the really low dose end and therefore I
17 think a joint approach with biological work, but
18 particularly we're looking at the molecular genetics now.
19 The work that is being understood about chasing down a
20 single chromosome, chromosomes are being associated with
21 particular forms of cancers, particular genes on a
22 chromosome and there are now the identification of things
23 called fragile sites, things which appear to show a genetic
24 or an inherited predisposition to respond to radiation
25 damage. I think that molecular biology work in conjunction

1 with epidemiology is the way forward, together with the
2 animal studies to which Charlie referred. But I think the
3 molecular biology has quite a lot to offer and ICRP has a
4 task group seeing what we can derive from this area.

5 COMMISSIONER de PLANQUE: Going back to the worker
6 data, Charlie, for the U.S., do you think there's potential
7 for more information to come from worker data in the U.S.,
8 nuclear power plant workers, and what would it take to get
9 anything useful?

10 MR. MEINHOLD: Well, I'm glad you asked. As you
11 may know, the Academy had a committee that was looking at an
12 EPRI proposal on looking at the U.S. nuclear utility
13 workers, which the Academy committee endorsed fully. I
14 think that would be an extraordinarily helpful study,
15 primarily because one of the difficulties in any
16 epidemiological study is the power of the study, have you
17 got enough dose and enough people in order to even see the
18 effect if our risk estimates were right or if they were
19 lower. That committee believed that there was enough power,
20 particularly even now for leukemia because leukemia is
21 easier to see because of it being a rare disease and the
22 risk is fairly high at high doses, that that would have been
23 possible even at the present time.

24 Now, the solid cancers, of course, will take a
25 long time. Since most of the utility workers got their

1 exposures in the late '70s, it's going to take awhile for
2 that population to get to the age where we would see a lot
3 of the cancers, the attributable cancers. So, that would be
4 a long time off. But again, if ever we want to either
5 verify or demonstrate either that these risk estimates are
6 good or bad, it's those kinds of studies which we'll need to
7 do.

8 COMMISSIONER de PLANQUE: But do I understand EPRI
9 has not funded this?

10 MR. MEINHOLD: Well, no, the utilities didn't buy
11 into the program and it's going to take them to do it
12 because it's going to be an expensive and time consuming
13 process for them.

14 COMMISSIONER de PLANQUE: Is there any other way
15 such a study could be funded?

16 MR. MEINHOLD: I can't answer that. The trouble
17 is I think it would really require the industry to be
18 partners in it because so much of that data is in their
19 health records and in their exposure records and all the
20 rest of it that it would be, I think, a hard thing to do
21 without the cooperation of the industry. I think it just
22 needs a little more -- the workers as well.

23 COMMISSIONER de PLANQUE: Yes.

24 CHAIRMAN SELIN: Thank you.

25 Professor Clarke?

1 PROFESSOR CLARKE: Thank you very much, Chairman.

2 May I just echo what Charlie said? I'm very
3 grateful to you and your colleagues for this opportunity to
4 come as Chairman of ICRP and run through some of the ideas.

5 What I'm going to do is look at the conceptual
6 framework that we've used and the way we've set limits and
7 this new thing called constraints, particularly for members
8 of the public, and explore with you some possible
9 applications in the practical field of this.

10 I think that it was principally the new estimates
11 of risk of exposure to ionizing radiation that motivated us
12 to produce our new recommendations. But we took the
13 opportunity to consider a number of developments since we'd
14 produced the recommendations in Publication 26 in 1977.
15 Those 1977 recommendations were principally for a system of
16 dose limitation. It looked at normal operations and how you
17 controlled exposures and set dose limits for workers and for
18 the public.

19 But in the subsequent years, we developed
20 guidance, recommendations in a number of other areas. For
21 example, we gave advice on the control of exposure to radon
22 in homes, a situation where dose limits didn't apply. We
23 gave guidance on principles for protecting the public in a
24 radiological emergency where dose limits don't apply. We
25 were outside the normal system of dose limitation. We

1 developed some criteria for dealing with solid waste
2 disposal where you haven't got a certainty but only a
3 probability of being exposed. So, dose limits as such don't
4 necessarily apply.

5 So, we had gone off on several tangents from our
6 core recommendations and we tried to put them altogether in
7 this new system of radiological protection as we called our
8 new recommendations, a system of protection not just dose
9 limitation.

10 [Slide.]

11 PROFESSOR CLARKE: So, if I have the first
12 overhead, one of the things that we found useful in
13 explaining to people the way in which we make our
14 recommendations and the framework is to distinguish between
15 practices and intervention. Now, if you put a new nuclear
16 power station up, if you construct a new facility, if you
17 put a new x-ray set into a hospital or you introduce a new
18 consumer product which contains radioactive materials, no
19 matter how careful you are and how good your design, you are
20 adding doses or the possibility of people receiving doses.
21 So, that class of activities we've called practices.

22 On the other hand, there are situations where you
23 find that there is already exposure taking place. Whatever
24 action you take is designed to reduce, to take away some of
25 the dose. The obvious examples there are accidents where

1 there's an accidental release of radionuclides or radon in
2 homes. Whatever actions you take are designed to reduce an
3 existing level of exposure. We have found it useful to
4 distinguish this second class factor which we call
5 intervention.

6 [Slide.]

7 PROFESSOR CLARKE: I was going to go through the
8 principles which we apply to both of these and on the next
9 viewgraph I've run through the principles that we use for
10 the practices where we're introducing new sources of
11 exposure. The principles are familiar. They're the ones
12 essentially that were in the old recommendations of
13 Publication 26, that a practice has to be justified, there
14 must be a positive benefit from introducing this practice.
15 Each source has to give doses that are as low as reasonably
16 achievable within the dose limits.

17 But there are, in this viewgraph, two subtle
18 changes from what we said in 1977. The optimization
19 principle now says for each source, doses or probability of
20 being exposed. So, we've introduced the idea of risk or
21 probability of being exposed. Not just the doses but the
22 probability of being exposed should be as low as reasonably
23 achievable and constrained by restrictions on doses to
24 individuals, so-called dose constraints. So, those are the
25 two new things that are in there. The limitation principle

1 now doesn't just say dose limits, but the exposure and the
2 risk should be limited. So, we changed these things.

3 [Slide.]

4 PROFESSOR CLARKE: On the next viewgraph, I'd say
5 that in the optimization procedure we introduced this
6 concept of a constraint to dose or risk. Now, the limit
7 protects the individual from all of the sources which are
8 being controlled. The limit is an individual related
9 criteria. Optimization is for a single source, a single
10 power plant. You optimize protection for that source. But
11 we've introduced in the constraint an individual related
12 criterion from a single source to ensure that dose and risk
13 limits aren't exceeded. We expect the constraint to be set
14 at a fraction of the dose limit because the individual is
15 exposed to a number of sources. There can be global
16 circulation of radionuclides. So, if you're optimizing your
17 single source, you're only entitled to use a fraction of the
18 limit for that source. So, it's a boundary on your
19 optimization. If you optimize and you come up with doses
20 that are at the dose limit, it's not acceptable. It's too
21 near the limit.

22 So, we, in our recommendations, suggested that
23 constraints perhaps could be set on the basis of general
24 knowledge about the performance of a source from past
25 facilities in a similar practice or by some sort of generic

1 optimization. We saw it really as a regulatory tool, for
2 the regulator to set this, but perhaps for the operator to
3 continue to try and do better below by using the ALARA
4 culture, to always be thinking of how to do better.

5 We didn't see it as a design target in the same
6 way that the limit is not a design target. In no way. I
7 would expect the designer to set a fairly low level as a
8 design target. Then, of course, in operation, you've got a
9 margin to go up towards a constraint and perhaps you'd
10 investigate. If you operate and you're above your design
11 target, you would investigate to find out why, what's
12 happened. So, that's the way we see constraints working.

13 I just want to mention the principles for
14 intervention as well. So, if I could have the next
15 viewgraph.

16 [Slide.]

17 PROFESSOR CLARKE: For intervention where we're --
18 remember, we're taking actions usually in the environment or
19 with people and countermeasures forming an intervention have
20 disadvantages. So, they have to be justified as doing more
21 good than harm. So, you have to look at the difference
22 between the detriment of intervening and the detriment of
23 the radiation dose that you're saving. That's equivalent to
24 a justification. Then, the duration and the scale of the
25 intervention should maximize the benefit of taking a

1 countermeasure.

2 There are no limits for intervention because we're
3 looking at reducing the dose from an existing situation.
4 We're not limiting additional doses from a new source. So,
5 dose limits as applied to practices aren't relevant for
6 decision making in intervention. The Commission -- sorry,
7 ICRP. Forgive me if I said the Commission. ICRP has now
8 decided on levels of intervention that can be applied for
9 the public in the event of a radiological emergency or for
10 control of exposures to radon at home and at work. Those
11 we've published in Publication 63 for radiological emergency
12 and Publication 65 for the control of radon at home and at
13 work. These are examples of the application of the
14 principles for intervention.

15 I want to return to practices and say that once we
16 know or we made our assumption about the risk per unit dose
17 which Charlie has gone through, in order to set a dose limit
18 we have to enter into the business of what's an acceptable
19 level of dose or, perhaps more importantly, what's an
20 unacceptable level of dose. This is a difficult area in
21 which to work for members of the public.

22 [Slide.]

23 PROFESSOR CLARKE: On the next viewgraph I say
24 that ICRP has found it convenient to use three words in
25 helping to describe the philosophy. The words really are

1 very subjective in character and have to be interpreted
2 depending on the type of exposure that we're talking about.
3 But for normal practices, we've used the word "unacceptable"
4 to indicate that exposure wouldn't be acceptable on any
5 reasonable basis in normal operations. Of course, it might
6 have to be accepted in the event of an emergency, but
7 unacceptable for normal practice. Then if exposures are not
8 unacceptable, we've subdivided them into those that are
9 tolerable, meaning they're not welcome, but they can
10 reasonably be tolerated, and then acceptable, which means
11 they're accepted without further improvement and that
12 protection has been optimized.

13 [Slide.]

14 PROFESSOR CLARKE: The next viewgraph puts this in
15 a visual form and I've tried to show that the dose limit or
16 the limit is really set on the boundary between what is
17 tolerable and what is unacceptable. The unacceptable region
18 is a forbidden zone which you're not allowed to enter.
19 Nobody is allowed to go above the limit into the
20 unacceptable region. Below that exposures are not welcome.
21 They're tolerable. It therefore follows that our
22 constraint, the maximum acceptable risk from a single source
23 is set somewhere below the level of unacceptability. That's
24 the maximum you're going to have for your single source.
25 You're still required to use the ALARA culture to get doses

1 as low as reasonably achievable after optimization and
2 that's indicating that there is a range of results which
3 will become acceptable as a result of optimization.

4 It also is true that probably there is a level of
5 risk which is so small as to be regarded as trivial where it
6 wouldn't be worth wasting resources on trying to improve
7 protection further. The protection is already optimized.
8 It would be a misallocation of resources to try and reduce
9 it further.

10 So, the dose limit is set at the boundary between
11 tolerable and acceptable and that protects the individual
12 from all of the sources under control and the optimization
13 is constrained so that no individual is exposed to more than
14 a fraction of the dose limit from a single source.

15 Now, the real task is to put some numerical values
16 on these words that we use.

17 [Slide.]

18 PROFESSOR CLARKE: On the next viewgraph, I
19 perhaps would show that maybe we start at the bottom and a
20 risk of one in a million per year, a risk of death of one in
21 a million per year seems to have commonly been regarded as
22 trivial by many organizations or groups. That risk of death
23 of one in a million per year, if we turn it into dosimetric
24 terms using the risk factors that Charlie has outlined for
25 us, would correspond to about 30 microSieverts or about

1 three millirem. And I apologize. I haven't put millirem on
2 the viewgraphs, but in the written text I tried to be
3 bilingual, although I have to say it's increasingly
4 difficult. But the trivial level of risk, if it's accepted
5 that it's about one in a million per year, corresponds to
6 somewhere around three millirem in a year.

7 In a number of countries, a number of studies, we
8 look at public inquiries and regulatory actions. It seemed
9 to us in ICRP that for a given source a risk of around about
10 one in 100,000 per year is about the most that's accepted
11 for an imposed or involuntary risk for members of the
12 public. Risks much beyond this probably verge on the
13 unacceptable and we set the dose limit for the public at one
14 milliSievert effective dose, 100 millirem per year, which
15 represents our judgment on the level of unacceptability, the
16 borderline of the forbidden zone of unacceptable risk. The
17 associated average annual fatal risk is a few in 100,000 per
18 year and therefore for a single source we might expect the
19 constraint to be set at a fraction of a milliSievert.

20 We made this judgment on these risk figures
21 bearing in mind that risk is a complex multi-attribute
22 quantity, includes things like the lifetime risk, the
23 maximum annual risk, the average annual risk and average
24 loss of life expectancy, but we also took into account the
25 existence of natural background radiation which gives an

1 annual worldwide average effective dose of about 240
2 millirem a year. Natural background may not be harmless,
3 but it makes only a small contribution to the health
4 detriment that society experiences. And it may not be
5 welcome, but the variations from place to place, excluding
6 the very large variations in dose from radon in dwellings,
7 but that variation from place to place can hardly be called
8 unacceptable.

9 So our figure of one milliSievert is a fairly
10 robust figure and I think perhaps if there were changes in
11 risk estimates per unit dose maybe the dose limit for
12 members of the public or the constraint at a fraction of the
13 dose limit would not change very much. In a number of
14 countries, the maximum value of what we now call a
15 constraint for a single source has been set at about 30
16 millirem in a year, .3 of a milliSievert, corresponding to
17 this annual average fatality of about one in 100,000 per
18 year, so this sets the sort of maximum acceptable level of
19 dose or risk from a single source. So 30 millirem is a
20 figure which looks like it's being used in a number of
21 countries. It's a third of the dose limit for members of
22 the public, or .3 to be strictly accurate, and that
23 represents the maximum bound to the optimization for a
24 single source.

25 I'd mention that the trivial level of risk seems

1 to come out at around 3 millirem in a year, and so we expect
2 constraints to be set somewhere in that range of a few to a
3 few tens of millirem a year.

4 I'd also mention that in the basic safety
5 standards of the International Atomic Energy Agency, which
6 together with five other agencies of the United Nations and
7 the Organization for Economic Cooperation and Development
8 have been approved by the member states, an individual
9 annual effective dose of one millirem, ten milliSievert, has
10 been used to establish activities or activity concentrations
11 which are exempt from the requirements of prior notification
12 and authorization in the standards. So here's another
13 figure, one millirem, which seems to be gaining acceptance
14 around the world as something around the trivial level, so
15 we bound it ourselves with these sorts of numbers for
16 practices.

17 Having established these numbers, I want to go
18 through several applications with you.

19 [Slide.]

20 PROFESSOR CLARKE: The first of these is medical
21 exposures and I've put a viewgraph here to say that really
22 in the case of medical exposures, to illustrate the use of
23 constraints here, the principle of limitation doesn't apply.
24 There aren't dose limits for people. I mean, the dose you
25 get is what the medical doctor requires to get the right

1 information or to give you the right treatment for diagnosis
2 or therapy, so there's no limits here.

3 The principle of justification is largely a
4 clinical judgment. Is there an indication for the
5 examination? So the principle radiological input into
6 medical exposures is in the optimization field, to look at
7 whether the equipment and the procedures are consistently
8 giving the minimum dose to give the required diagnostic
9 information or in the case of therapy to get the right dose,
10 enough dose to the tumor and the optimization in the
11 radiological sense is to minimize the dose to the other
12 organs and tissues, the non-tumor organs and tissues.

13 If we are looking at constraints for the
14 optimization, I mean, it seems obvious, therefore, that
15 constraints in the diagnostic field have to be specific to
16 particular types of examinations, what sort of procedure,
17 whether it's a barium enema or a breast screening program.
18 What is the bound to the optimized dose? It will be
19 different in the two cases.

20 In fact, because of the complication of clinical
21 judgment and what the doctor feels he needs to get the right
22 diagnosis, we don't see the constraint concept here being
23 something that's really a regulatory prescription. It's
24 more an investigation level. For those hospitals which are
25 doing a given examination and giving more dose than other

1 hospitals for the same examination we might ask the question
2 why. Is there something different in the procedure or the
3 equipment? So, that's one application of this.

4 [Slide.]

5 PROFESSOR CLARKE: My second application on the
6 next viewgraph looks at in fact solid radioactive waste
7 disposal underground where in the view of ICRP the principle
8 of justification doesn't really apply because the
9 justification was considered when the practice which gave
10 rise to the wastes was first admitted.

11 When you introduce a practice there are
12 considerations much wider than those of radiation protection
13 and all sorts of practices can be justified which then give
14 rise to radioactive wastes, so the disposal I don't think
15 has to be justified. It's a question of optimizing the
16 protection and perhaps we're talking here now about the
17 disposal of solid radioactive wastes underground where there
18 is probably not a certainty of exposure, but a probability.
19 There's a potential for exposure at some point in the
20 future, either because there will be human intrusion, people
21 will dig into a waste repository, or that events in the
22 geosphere will lead to some probability of a release of
23 radioactive materials.

24 Therefore, we talk here about risks and not doses.
25 The individual in the recommendations that are being given

1 by ICRP is best protected by a risk constraint. We haven't
2 in the Commission recommended risk limits, although you
3 could by analogy with the dose limit have a risk limit. But
4 we've found it would be rather hard to regulate a risk limit
5 and how you do apportion risks? So, we've said maybe the
6 most practical way forward is risk constraints for
7 individual sources.

8 Now, a risk constraint is a constraint on
9 optimization of protection and optimization generally is
10 taken to include considerations of the total integrated
11 collective effective dose. But for waste disposal, for
12 solid waste disposal deep underground, the use of collective
13 doses is not very helpful. This is because the collective
14 dose is so dependent on detailed assumptions about the
15 biosphere and human behavior and the population size that
16 the results can be very variable and have to be treated with
17 extreme caution. Because of the uncertainties in collective
18 dose integrated over very, very long time periods, and we're
19 talking about tens of thousands or millions of years, as you
20 know, because of the uncertainties it's sometimes been
21 suggested that collective dose could be of use in comparing
22 options for disposal.

23 But I have to say if the absolute values are so
24 uncertain, what's the value in the difference, between
25 different options? And therefore, our view principally is

1 that the use of a risk constraint is the best way to go
2 forward for risk.

3 [Slide.]

4 PROFESSOR CLARKE: On the next viewgraph I've
5 suggested that by analogy with one in 100,000 and 30
6 millirem, for practices maybe the risk for a single
7 underground solid waste repository could be one in 100,000,
8 10 to the minus 5 per year, and you would require
9 optimization, ALARA, to get the risks as low as reasonable
10 below that.

11 I think again by analogy with the others, if the
12 risk to the individual turns out to be less than one in a
13 million per year, perhaps the requirements for demonstrating
14 ALARA could be relaxed because it's already low enough. So,
15 I'd use the same analogy.

16 [Slide.]

17 PROFESSOR CLARKE: My final example on the next
18 viewgraph, I'm afraid it's three examples really, and it
19 talks about restoration of contaminated sites and how we
20 might apply principles to contaminated ground. This is a
21 very difficult area where there isn't any international
22 guidance and the ICRP has set up a task group to consider
23 the radiological protection principles and their application
24 in this area. So, what I'm saying is speculative. It's not
25 on the basis of a task group report. That report would have

1 to go through the relevant committee and come through the
2 commission, to the ICRP main commission. It hasn't done
3 that. So, I'm really thinking of how we might be looking at
4 guidance here.

5 I thought there were at least three scenarios
6 which might involve different approaches. The first is
7 where ground is contaminated as a result of an accidental
8 release of radionuclides. The second example is where you
9 find suddenly a site which has radioactive contamination
10 that you didn't know had it before and that could be an old
11 radium luminizing plant which the records were lost. It's
12 now being used for something else. It's a factory to make
13 silicon chips and you didn't know it had previously -- and
14 the institutional memory had been lost.

15 The third example is restoration of a known
16 nuclear site, something that is a licensed site now and you
17 want to decommission it and release it.

18 So, how do intervention and practices and
19 constraints apply to these three different situations? So,
20 first the accidental release of radionuclides.

21 [Slide.]

22 PROFESSOR CLARKE: On the next viewgraph, ICRP has
23 given advice about countermeasures to protect the public in
24 the event of a radiological emergency. The intervention,
25 you remember, takes away dose, reduces risk and the action

1 levels that we set are in the region of typically, let's
2 say, tens of milliSieverts or a few rem. You would evacuate
3 population. In the extreme you would relocate them, take
4 them away from their homes permanently. We'd be talking
5 about taking those actions at levels of rems per year,
6 continuing ongoing exposures.

7 That's the sort of guidance that ICRP has in
8 Publication 63 and you in the U.S. and we in the U.K. and
9 various other people have these in the figures. So, if
10 you're then going to decontaminate this land, you're going
11 to restore it, maybe, and I'm speculating, maybe the result
12 of the optimization would be to conclude that normal living
13 should resume at a dose of a few milliSievert, a few hundred
14 millirem a year. Why? This is above the dose limits for
15 the public for sure. But you remember there were people
16 just below your intervention levels who you let carry on
17 living normally. So, you weren't relocating people or you
18 weren't evacuating them if they were going to get a few rem.
19 Above that you would.

20 So, what's the rationale for going much lower than
21 that? I remind you that for radon in homes the action level
22 is in the range of a few milliSieverts. So, somewhere
23 towards maybe ten milliSieverts a year. We allow that to go
24 on before we have the minor disruption of suggesting
25 remedial measures for radon in homes. So, here's an

1 intervention situation and probably the restoration of the
2 contaminated land is going to be a few milliSieverts, a few
3 hundred millirem in a year perhaps.

4 If we've got old premises where radioactive
5 contamination is found, in my second example, I would think
6 if you have workers working in a factory and you suddenly
7 find it's contaminated, maybe the right way to go forward is
8 to treat it as an interventional situation. You're going to
9 go in to try and reduce the exposures as much as you can.

10 We've gone one viewgraph ahead of where I'm
11 speaking actually, I think. Sorry.

12 Well, we then would expect perhaps an action level
13 to be set in the same way that we would for radon, for radon
14 in homes. You're going to intervene. You're going to try
15 and reduce the doses. Decontamination should be attempted
16 to get things down as low as is reasonable. I expect the
17 action level probably to be set not dissimilarly to the
18 figures we have for radon, a few milliSieverts or up to ten
19 milliSieverts or around a rem in a year.

20 I'd apply the same philosophy, I think, to
21 dwellings that are found where people are living on some
22 previously contaminated site. If you've got houses on old
23 mill tailings and you suddenly find that that's the case and
24 people are living there, then I would regard it as an
25 intervention and not apply the dose limits, but apply

1 intervention to try and get the doses down as far as
2 possible.

3 So, on my final viewgraph, I think Chairman, I'm
4 coming to the end of this story.

5 [Slide.]

6 PROFESSOR CLARKE: If a licensed nuclear site is
7 to be decommissioned or treated as unlicensed, then I'd
8 regard that as being much the same as a practice, as it says
9 at the bottom of the slide here. If while we've been having
10 a practice continuing and effluents, licensed discharges
11 from a facility, we've been talking about constraints which
12 are a fraction of the dose limit and figures in the region
13 of tens of millirem per year perhaps, a fraction of a
14 milliSievert for the most exposed members of the public, and
15 it would seem logical that that same figure of something
16 like 30 millirem would be the maximum constraint for the
17 unrestricted release of the site. Optimization would take
18 you down below that and a trivial level of risk leading to a
19 dose of around three millirem a year would be a lower bound
20 for the constraint.

21 So, if I have a licensed site that has been
22 operating allowing doses in the region of millirem to tens
23 of millirem a year, the logic seems to me that that would be
24 an upper bound for where you would release the site for
25 unrestricted access, in comparison with the unlicensed site

1 which you found where you're going to intervene. If I'd
2 intervened in an old site, in an old radium plant and then
3 having found it I've intervened and then I'm going to change
4 the use of that building, maybe that's when it makes the
5 transition into a practice. I now know it's contaminated
6 and all work is going to go away and it's going to be
7 something else. Maybe then it's a practice.

8 I'm speculating, Chairman. There is no
9 international guidance, but there is this question of when
10 does an intervention become a practice and here's one way
11 that we may be going. I don't know and I'd be interested if
12 you think this is a useful way forward or not.

13 So, in conclusion, Chairman, Commissioners, thank
14 you for your time and attention. I hope I've indicated
15 something about the conceptual framework within which ICRP
16 has now made its recommendations and how the ideas of
17 practices in intervention can help us understand why
18 different levels of dose are accepted in different
19 circumstances. For practices and for interventions, I've
20 indicated the sort of range of numerical values of dose that
21 seem to come out of our considerations. More work remains
22 to be done, but this is where we are at the moment.

23 Thank you.

24 CHAIRMAN SELIN: Thank you very much, Professor.

25 Commissioner Rogers?

1 COMMISSIONER ROGERS: Well, first, one question,
2 in the very beginning as you indicated that you'd added risk
3 to dose in your considerations, starting out with the dose
4 and for risk. Now, those risks, are they to be on a
5 comparable probabilistic basis to the affects of the dose?

6 PROFESSOR CLARKE: Yes. We've treated those as
7 separate and additive. There isn't an easy way of combining
8 these things, but traditionally the dose limit is set on
9 considerations of risk, but we're looking now at the control
10 of the risk of accidents, the potential for exposures and
11 certainly the constraint we were suggesting is at a similar
12 level of risk and added to. We haven't apportioned the risk
13 as between normal operations and accidents.

14 MR. MEINHOLD: I think there is another concept
15 too, that it has a little bit to do with the ration between
16 the probability of the event and the consequences.

17 COMMISSIONER ROGERS: Yes.

18 MR. MEINHOLD: That is if it's high probability
19 and very low consequence or very low probability and very
20 high consequences. There's a discontinuity and that's one
21 of the things that the task groups are looking at. When
22 you're down in the area where you're in non-deterministic
23 effects from that probabilistic event, then they probably
24 add quite well.

25 PROFESSOR CLARKE: Well, they may not do.

1 MR. MEINHOLD: But anyhow they're closer.

2 PROFESSOR CLARKE: I mean expectation value from a
3 PRA or PSA, expectation value is very difficult. Partly
4 it's a multi-attribute thing from a radiological protection
5 point of view. Let me just say that the consequences of the
6 accident can be early or late effects to individuals, the
7 interdiction of land, economic costs. I mean it's a complex
8 set of attributes and we haven't found any way of combining
9 those together into a single parameter in the way we have
10 dose for normal operations.

11 So, also, the expectation value, which is where I
12 was starting on from this, is very difficult. The
13 expectation value of an event with a probability of 10 to
14 the minus 3 per year and a consequence of 1,000 deaths, the
15 expectation value is one, but we know the answer is going to
16 be zero or a thousand. So, the expectation value of one is
17 difficult.

18 So, for these sorts of reasons, we have kept
19 separate the risk of accidents from -- one day maybe we'll
20 be able to do better.

21 MR. MEINHOLD: I think I was trying to say the
22 same thing. It's when the consequence is not large, then
23 it's closer to being additive than when the consequence is
24 large, when they become very non-additive.

25 PROFESSOR CLARKE: Yes.

1 COMMISSIONER ROGERS: When you try to apply this
2 combination of dose and risk to a particular practice where
3 there may be multiple sources involved, it isn't clear to me
4 how one does this in setting constraint levels. How do you
5 sort this out? If you had just a single source, a practice
6 that involves a single source, then I can see that's the
7 simplest elementary case. But when you have the possibility
8 of multiple sources with different probabilities that they
9 will, in fact, come into play, that there's where the risk
10 element comes in in addition to the dose, how does one then
11 sort it out and establish constraints?

12 PROFESSOR CLARKE: Well, that's one of the reasons
13 in our recommendations we didn't propose a risk limit. What
14 we said was that maybe you could think of a constraint for
15 each individual source in terms of risk. But we don't know
16 how many sources of risk there are.

17 So, I think just for the reasons you were asking
18 the question, we didn't go that far. We said maybe for a
19 single reactor, for a single solid underground waste
20 repository we could put a restriction on the risk from that
21 source, but we don't know how to deal with the totality of
22 it. Unlike the doses from normal operations where we've
23 apportioned the dose limit and got a constraint because
24 there are multiple sources that are controlled, you're
25 controlling the emissions from the sources. It's a very

1 difficult area, moving into risk.

2 I might add that the Commission did try to do this
3 on the waste disposal site in the previous document and is
4 working now on trying to do it for smaller systems, that is
5 to try to look at it for that x-ray set or for that cobalt
6 irradiating facility and ask if it works a little bit better
7 there.

8 We got ourselves into a little bit of hot water,
9 as Roger is trying to say, when we tried to apply it to,
10 again, that low probability, high consequence issue is when
11 things become very, very difficult to handle and I think
12 we've learned that we really need to try to do this for the
13 case where you're talking about the interlock on a --

14 PROFESSOR CLARKE: A irradiator or an irradiator
15 facility.

16 MR. MEINHOLD: Right. Exactly. Then the
17 principles may have more application and that's really what
18 the task group is trying to examine.

19 PROFESSOR CLARKE: Maybe, if I may just slightly
20 elaborate on that, Charlie has stimulated me to say that in
21 the radiological protection field we were aware that there
22 are accidents which kill people continuously all around the
23 world with irradiator facilities, with accelerators, with
24 medical sources, and we introduced this idea of the risk and
25 the potential for exposures to try and start improving

1 protection for those sorts of sources. We were not trying
2 to move into the nuclear safety field and try and deal with
3 what the reactor people have been doing in nuclear safety
4 for years. But it is important to show that there's a
5 coherence between criteria for nuclear safety and criteria
6 for radiological protection, which is what Charlie was
7 saying. Certainly just to emphasize again, we're not trying
8 to set criteria which would apply really the reactor
9 accidents. We're staying well away from that. But there
10 are these continual accidents which we feel require us to be
11 giving advice on improvement of protection.

12 COMMISSIONER ROGERS: It isn't really clear to me
13 just exactly how you feel towards ALARA in a certain sense
14 with respect to constraint levels from a single source. How
15 does one take ALARA into account in a sense? Is it a kind
16 of admonition to do good or is it really a kind of clear
17 expectation in a certain sense that it will be part of the
18 overall control mechanism that one is using? Could one just
19 simply proceed without any thought of ALARA and use your
20 constraint level philosophy?

21 PROFESSOR CLARKE: I think our idea was that the
22 constraint is a bound on the ALARA procedure. It tells you
23 that when you're optimizing, when you're trying to be as low
24 as reasonably achievable, if the doses to the individuals
25 come out to be too high, then that's not acceptable because

1 you're getting too near the dose limit. So, it's a bound,
2 but you're still required to do everything you can to get
3 exposures as low as reasonably achievable and I think our
4 thinking is that ALARA is an attitude. It's like safety
5 culture. You should always have in your mind whatever you
6 can do to make the doses lower than they are at the moment.
7 We should always be striving to ask ourselves whether we're
8 doing the best we can in all of these fields.

9 COMMISSIONER ROGERS: Well, that's fine. I
10 certainly subscribe to that thoroughly, but I'm just trying
11 to think about it from the standpoint of a regulator that
12 has to establish certain requirements. We seem to have a
13 rather different point of view from one of our sister
14 agencies with respect to the role that ALARA should play.
15 That point of view, if I understand it, in their case seems
16 to be to establish limits, hard fast limits and hold people
17 to those. Ours seems to be to establish a level of
18 expectation that is coupled also to the expectation that
19 ALARA will be pursued. In their case, they seem to not want
20 to use the ALARA concept other than some kind of a general
21 cultural expectation that everybody should always proceed in
22 that way, but it's sort of outside the notion of a
23 regulatory regime, whereas I think what we're trying to do
24 is to actually use ALARA as part of our regulatory tools.

25 I wonder if you could say anything to this that

1 you think might be helpful to us.

2 MR. MEINHOLD: I'd like to say a few things about
3 it. First of all, as a matter of fact, I've just drafted a
4 little note for the Health Physics Newsletter I hope they'll
5 do because I think probably the outstanding success story in
6 radiation protection has been the reduction in doses to
7 nuclear power workers in the United States. I think it's
8 absolutely amazing and it had nothing to do with regulation.
9 It had to do with a regulatory framework which said, "We
10 expect these considerations to go on," but it was the
11 industry working within itself and with people who care
12 about these matters sharing experiences and encouragement
13 and rewards for dose reduction which resulted, I think, in
14 an enormous reduction and a necessary reduction in the
15 exposure to the U.S. utility workers. So, in that sense, I
16 think you're absolutely right.

17 I'd like to go back though to clear up just a
18 little question that came up. When Roger talked about the
19 30 millirem, that that number comes from really
20 apportionment. It's really a dose limit. It's not derived
21 from some kind of an optimization study. It really says
22 that, "Look, if you're going to have 100 millirem as the
23 limit, the final limit, then we can't let any given person
24 or any given source or any given practice use it all up
25 unless we know an awful lot more about the way people

1 operate than we do." And the NCRP's number is 25 millirem,
2 so it's the same number for all intents and purposes. But
3 that's where those kinds of numbers come from, is
4 apportionment.

5 What the ALARA thing is saying is that if we can
6 demonstrate that when people go to do whatever practices you
7 have in mind, low-level waste sites or whatever, that the
8 intention that they demonstrate in their application to do
9 that is tied to an analysis that they have done this with
10 the lowest doses they can, that that dose that they come up
11 with is five millirem per year and that they have indicated
12 in their license to whoever licensed that system that they
13 are going to demonstrate with all of their might that they
14 can live with five millirem per year as part of their
15 licensing application telling you that they're going to do
16 that as part of ALARA, not a regulation you put on them but
17 a demonstration that they claim they will show you as they
18 go forward, then I think we're saying the same things. In
19 fact, that approach has been what's worked in the industry
20 up to this point.

21 Now, you didn't do that when you set the limit
22 from releases from nuclear power stations. You set an ALARA
23 limit and then wanted ALARA below it, as I recall. It was a
24 double ALARA whammy they got on that one. But the fact is
25 that I think you're absolutely right that I think that what

1 ICRP and NCRP have always said is you've got to be sure that
2 the dose limit is respected and that respect means don't use
3 it for design. Right? So, it would be inappropriate in a
4 sense to expect anybody who operates a low-level waste site
5 to use that apportionment. You would expect them to come in
6 at much lower than that. That would be the expectation that
7 you would have that they would apply the techniques
8 available to them to get below that limit because of the
9 unacceptability of that limit as a design.

10 So, we're trying to ensure that people don't come
11 in and say, "Well, I've done a good job and I can do it
12 under 30 millirem." That really wouldn't be good enough, I
13 don't think, in an application. I think they would have to
14 show you how they're going to come in below the 30 and how
15 far below and why they couldn't really do any better than
16 that as part of the ALARA program.

17 So, in a sense, I'm not sure that your sister
18 agency and you are that far apart, depending upon how
19 aggressive you are in the way you review those applications,
20 if I can put it that way.

21 PROFESSOR CLARKE: I agree with that. The way
22 ICRP has expressed the use of a constraint is it's very much
23 the maximum figure and then you do the optimization. Now,
24 in one case, the regulator can do the optimization and
25 decide what the best result is for a practical practice.

1 That's not actually what ICRP says. ICRP doesn't quite go
2 that far. ICRP says, well, you put the maximum value that
3 you are prepared to consider and then you require people to
4 do as best they can to demonstrate that they're doing as
5 much as it's reasonable to do to get below that.

6 The difference between you and your sister agency,
7 if I understand it, if I may say so from outside the
8 country, is that you do the optimization, they require
9 optimization. But they have set a lower figure for the
10 constraint to bound the optimization than perhaps I have
11 done in my presentation to you. So, conceptually what
12 they're doing is more or less precisely what we've written
13 here, but it's how you choose the apportionment, as Charlie
14 has just said. We've said the apportionment gives you
15 perhaps 30 millirem to start with. Then you can optimize
16 and maybe you'll decide for a diagnostic x-ray suite in a
17 hospital you might end up with 500 millirem or less than
18 that probably. It depends on the practice and what you know
19 about it.

20 COMMISSIONER ROGERS: Yes. Well, it's just that I
21 do think there is a difference in that I think that if you
22 establish firm limits and you say those are exactly what you
23 have to meet, that my expectation is that it's exactly what
24 you will get. If you allow, not only allow but expect
25 ALARA, you may get a lot less on the average and I think

1 that's exactly what's happened in the nuclear power plant
2 example. If you're looking for the best possible result for
3 the nation, there is a difference in these philosophies, I
4 think, and in the consequence of these philosophies.

5 I think that ALARA has an enormous possibility
6 from a psychological point of view, that if people can
7 strive to get things as low as they can and continue to work
8 on that, but at no point are they hitting a regulatory
9 limit, then I think you can expect that they will do in
10 general a pretty good job and sometimes they will fail.
11 Sometimes it will rattle around a little bit, but below some
12 other limit.

13 Now, that other limit has to be an acceptable --
14 well, it has to have a good basis, let's put it that way. I
15 think that from the standpoint of what you get from your
16 fleet of licensees is going to be very different, whether
17 you build ALARA in or you don't build it in. So, I think
18 that there is a difference in what the final outcome may be
19 on the average for all practices.

20 MR. MEINHOLD: I guess my only response would be I
21 think much of that can be controlled by the way the NRC or
22 the whatever licensing jurisdiction expects of the licensee
23 in their application. If the application expects that to
24 come in to meet a dose limit, then I think you're in a lot
25 of trouble. If the licensing organization expects the

1 licensee to come in demonstrating a small fraction of the
2 dose limit or else comes in and says, "There's no way that I
3 can do this," and then you agree with that, then I think
4 you'd have a different situation. But I firmly believe that
5 if they do this appropriate you'll come out with virtually
6 the same approach that if the staff is aggressive in the way
7 they review the applications, you can have the same answers.
8 I think for me it runs that way.

9 As long as they're an expectation out there in the
10 license community that you're not going to allow things to
11 happen at the limit, just like you don't allow things to
12 happen at the limit in the industry. You've never bought
13 that off. You've never accepted everybody in the plant
14 getting five rem. That's never been the kind of thing that
15 you'd stand for and there would be all sorts of regulatory
16 pressures that aren't related to any dose limit but just to
17 good performance that would say no, and I think the same
18 thing would happen with a waste site or whatever else.

19 COMMISSIONER de PLANQUE: I want to go back to the
20 study of workers again from your presentation and from what
21 we all know. It's clear that we have a good handle on
22 what's happening in the 10 rem, 20 rem and above area and
23 the big question is the models and how you extrapolate down
24 to low dose rate, low doses. The study that was done or
25 presented in Lancet recently which combined some workers

1 came to about 90,000 workers. I think from reading it, it
2 more or less confirms that what's been recommended by ICRP
3 and NCRP makes some sense. But it still doesn't hit at the
4 heart of answering low dose rate, low doses.

5 Do you think a study of the U.S. utility workers
6 would help in that regard or would it just be more
7 supporting data for what's already been done in this study?

8 MR. MEINHOLD: I think it would be more supporting
9 data that's in that study. It wouldn't get you below the
10 occupational doses. It wouldn't get you to the public dose
11 question. Is that what you're asking?

12 COMMISSIONER de PLANQUE: Yes.

13 MR. MEINHOLD: I don't believe it will, but of
14 course it's another piece of scientific information because
15 it says, "Look, I've got information out here at 100 rem.
16 I've got information at 20. Now I've got information at 5
17 and everything is still linear. It's still doing what my
18 model said." Then I become more and more convinced of the
19 correctness of the model because now I need something magic
20 to happen below 5.

21 Right now you might say I need something magic to
22 happen below 50 rem or 100 rem, whereas the Lancet study
23 takes some of that uncertainty out that says that at those
24 doses our estimates are pretty good, so I think it gives you
25 more confidence in the extrapolation as you get further and

1 further down. Right? Because, you might have said, well,
2 where do you want to put this threshold? Is it going to be
3 magically at 100 millirem or is it going to be out at 10
4 rem? Is it going to be at 20 rem? For bone it's probably
5 at, you know, 1,000 rads to the bone. Right? But for a
6 cancer in the other organs of the body, I think that this
7 kind of data just leads you further to an expectation that
8 the linear quadratic function is pretty good.

9 You may want to respond as well, Roger.

10 PROFESSOR CLARKE: Well, it would certainly
11 improve the statistical power of the studies if extra groups
12 were brought in, so it would give tighter confidence
13 intervals down to lower doses. So I think internationally
14 pooling studies from different countries and getting the
15 biggest statistical base we can get must be a good thing in
16 principle.

17 COMMISSIONER de PLANQUE: Did the Academy when
18 they were recommending this give any indication of the cost
19 of such a study?

20 MR. MEINHOLD: I don't recall. It's been a while.
21 It's been three or four years. We can get that out, but I
22 think there were some estimates of the cost for dose.

23 You know, one of the big problems, the historical
24 dose, that's the expensive part because of course once a
25 licensee says they're going to give you the dose from 1972

1 they don't just want to go and pull whatever record they've
2 got out but they want to make sure that as they go through
3 the record there aren't errors or things all through it, and
4 so it becomes a big job.

5 I remember when we were talking about this there
6 were estimates. I wouldn't want this to be taken as an
7 absolute number, but it was several million dollars, as I
8 recall, for GPU to do its historical dose estimates which
9 they had done as part of the test study to help with that
10 whole study, so that I think it can be quite expensive
11 particularly in dose records. I think there were estimates,
12 discussions of those kinds of numbers in the report.

13 PROFESSOR CLARKE: I think from our experience of
14 trying to do this, the operators, the licensees do have to
15 bear a considerable cost in going back through their records
16 and finding -- you need good information about the
17 individual in order to be able to trace that individual
18 subsequently on some sort of national health register. I
19 mean, you've got to find the vital status.

20 It's no use the operator coming up and said, "We
21 had John Smith who worked from 1950 to 1955 and he got 20
22 rem," because John Smith is no good. You can't go and find
23 out whether he's alive or not, so the second major cost is
24 searching through the health service records. I mean, you
25 need an address. You need a Social Security number. I

1 mean, to actually do the epidemiology -- I know I'm not
2 telling you anything you don't know -- to do the
3 epidemiological analysis costs nothing in comparison with
4 finding out --

5 COMMISSIONER de PLANQUE: Getting the raw data.

6 PROFESSOR CLARKE: -- the raw data and the
7 utilities have to invest a lot.

8 You need the good will of the utilities and
9 certainly from our own experience, you know, putting on my
10 NRPB hat from the U.K., obviously you need worker
11 participation, which is what I was whispering to Charlie.
12 Are the workers willing to have their dose record data
13 handed over to a third party for whatever purpose?

14 And we then ran into difficulties as well after we
15 got agreement from the workers to analyze their dose records
16 for carcinogenic risk. Then something like the Gardner
17 hypothesis comes up with offspring of male workers and
18 suddenly you want to do an analysis of the offspring of the
19 male workers. Now you didn't get those data from the
20 workers for that purpose, so strictly in our case we have
21 problems about whether we can utilize those data for a
22 different purpose and this tends to cost money as you keep
23 going back through these things.

24 MR. MEINHOLD: One of the things that really we
25 were so intrigued about, the Academy Committee, was how good

1 the dosimetric data was for the U.S. utility workers since
2 most of that exposure was received in the middle '70s and
3 TLDs were pretty much becoming your standard. We didn't
4 have the problems that were in the old DOE records which
5 both were film badges and also internal doses which were a
6 major part of those exposures, so there was a nice clean
7 group in terms of the dosimetric problem. There were some
8 problems, of course, with partial body exposures being
9 recorded as whole body and there are some issues of the fact
10 that if somebody's dose record was missing he's given the
11 maximum dose for that quarter. There are those kinds of
12 things that are in all the data banks, but that was one of
13 the reasons that the Academy thought that was good data is
14 that the dosimetry was good.

15 COMMISSIONER de PLANQUE: Okay. Thank you very
16 much.

17 COMMISSIONER ROGERS: I have to say, Professor
18 Clarke, that you may be here under diplomatic immunity, but
19 I think John Smith may be after you because the John Smith I
20 know is really quite good.

21 The Chairman had to leave on a medical appointment
22 and he gives his apologies for having to leave before the
23 end of the meeting, but I'm sure he joins us both in
24 thanking you for coming today. I think we learned a lot.
25 We found it very useful and we hope that it will be a fairly

1 regular occurrence from time to time because I think it's
2 always stimulating and as developments take place within
3 your own organizations I think it would be helpful for us to
4 hear about them at the Commissioner level.

5 Thank you again. We appreciate your being with
6 us.

7 PROFESSOR CLARKE: Thank you very much indeed and
8 we'd just say we would always be very willing to come back
9 and try and assist in any way.

10 Thank you for the invitation.

11 COMMISSIONER de PLANQUE: And you'd be welcome
12 too.

13 [Whereupon, at 3:38 p.m., the above-entitled
14 meeting was concluded.]

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CERTIFICATE

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

TITLE OF MEETING: BRIEFING BY ICRP/NCRP ON THE
PRINCIPLES OF RADIOLOGICAL PROTECTION
AND THEIR APPLICATION IN SETTING
LIMITS AND CONSTRAINTS FOR THE PUBLIC
FROM RADIATION SOURCES - PUBLIC
MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Thursday, January 12, 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: Carol Lynch

Reporter: Peter Lynch

Risk Estimates for Radiation Protection

*What do we know?
How well do we know it?*

by
Charles B. Meinhold
Vice-Chairman, ICRP
President, NCRP
Senior Scientist, Brookhaven National Laboratory

Presentation to the U.S. Nuclear Regulatory Commission
January 12, 1995

Quantity	Historical Unit		SI Unit
Absorbed dose in tissue	100 Rad	=	1 Gray
Effective dose equivalent	100 Rem	=	1 Sievert

LEVEL A CERTAINTY

- **Excess cancer in Japanese survivors**
- **Excess cancer in uranium miners**
- **Simple biological systems demonstrate $\alpha D + \beta D^2$**

Table 1. Estimated Number of Expected and Observed Cancer Death by Categories of Exposure

Shielded kerma (Gy)	Approx. survivors	Nonleukemia		Leukemia	
		Expected	Excess	Expected	Excess
0.1	58000	4120	8	91	7
0.1 - 0.5	11500	866	61	20	12
0.5 - 1	3500	273	56	6	13
1 - 2	2000	147	71	3	20
>2	1000	68	64	2	28
Total	76000	5474	260	122	80

Table 2. Characteristic Data of Seven Study Cohorts of Underground Miners

Cohort study follow-up period	Number of miners	Mean cumulative exposure (WLM)	Number of lung cancer deaths	
			Obs	Exp
Uranium miners				
Colorado, USA, 1951-1982, cumulative exposure <2000 WLM ^a	2975	510	157	48.7
New Mexico, USA, 1957-1985	3469	111	68	17
Ontario, Canada, 1955-1981				
Beaverlodge, Saskatschewan, Canada, 1950-1980	11076	37	87	57.9
Bohemia, 1953-1985	6847	44	65	28.7
France, 1946-1985	4042	227	574	122
	1785	70	45	21.1

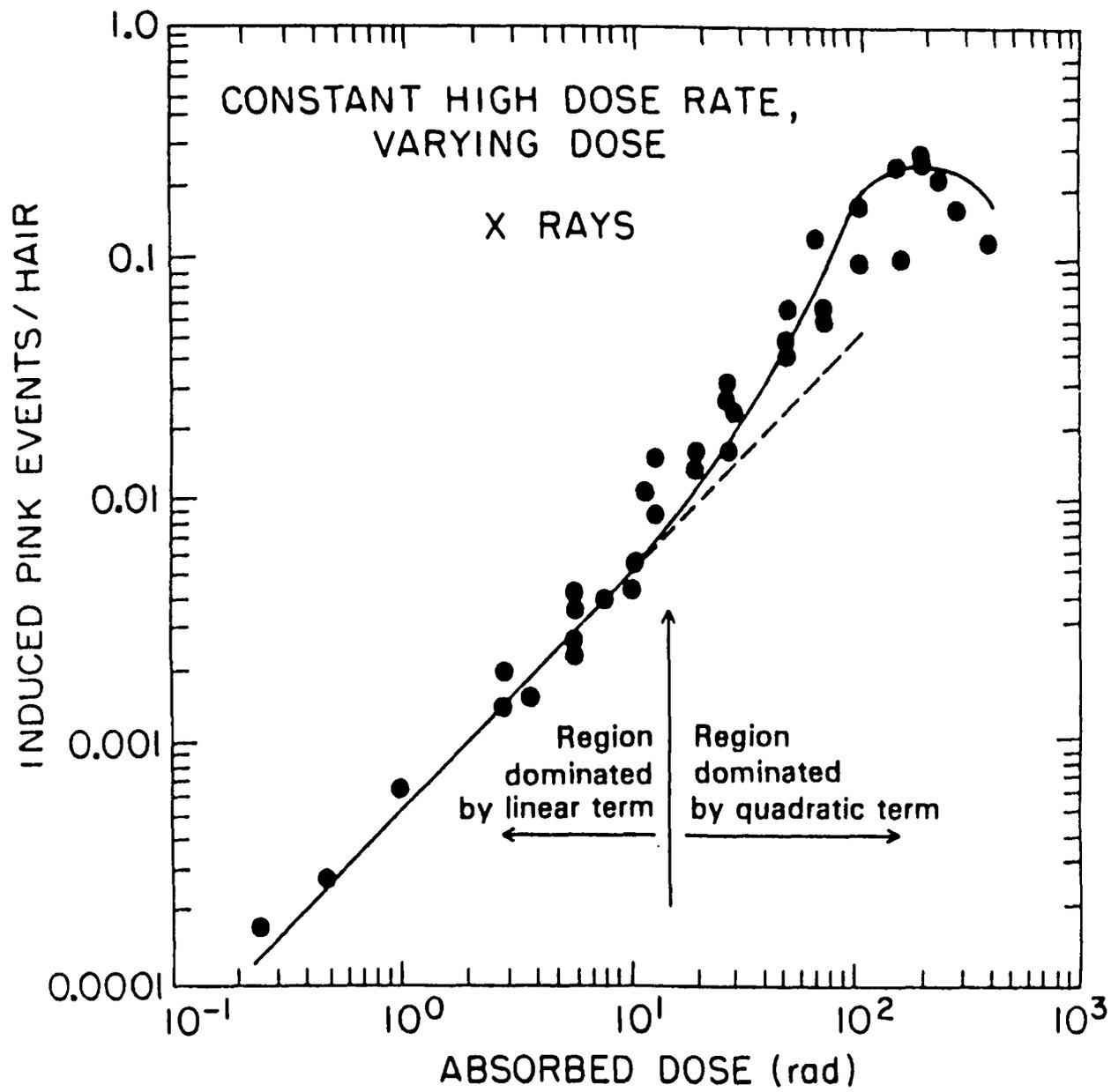


Figure 1. X-ray dose-response curve for induced pink mutations in *Tradescantia*, on a log log plot to show detail in the low-dose range.

LEVEL B CERTAINTY

- Risk per unit dose at high dose rates
- Multiplicative protection model
- Mendelian effects in man

**Table 3. Mortality Due to All Cancers Except Leukemia
by Intervals of the Follow-up Period**

Shielded kerma (Gy)		1950- 1955	1956- 1965	1966- 1975	1976- 1985
0.1 - 1	Expected	105	294	353	387
	Excess	8	3	37	69
>1	Expected	19	54	66	76
	Excess	9	27	40	59

Table 4. Excess Lifetime Mortality from all Cancer Attributable to 1 Gy Acute Uniform Whole-Body Low-LET Irradiation of the General Population (Upton, 1991)

Source of Estimate	Probability of Death (10^{-2})	
	Additive Risk Projection Model	Multiplicative Risk Projection Model
BEIR I, 1972	1.2	6.2
UNSCEAR, 1977	2.5	-
BEIR III, 1980	0.8 - 2.5	2.3 - 5.0
NUREG, 1985	2.9	5.2
UNSCEAR, 1988	4.0 ⁽²⁾ - 5.0 ⁽³⁾	7.0 ⁽³⁾ - 11.0 ⁽²⁾
BEIR V, 1990	-	8.85 ^(4,5,6)

- (1) Population of Japan
- (2) Estimate based on age-specific coefficients of probability.
- (3) Estimate based on constant (age averaged) coefficient of probability.
- (4) U.S. population - adjusted to high dose using values from Table 8.
- (5) Modified multiplicative model.
- (6) "Low dose" leukemia component multiplied by 2.

LEVEL C CERTAINTY

- Effects per unit effective dose equivalent at low dose rates
- Organ risk per unit equivalent dose
- A pure D^2 relationship exists for radiation in bone

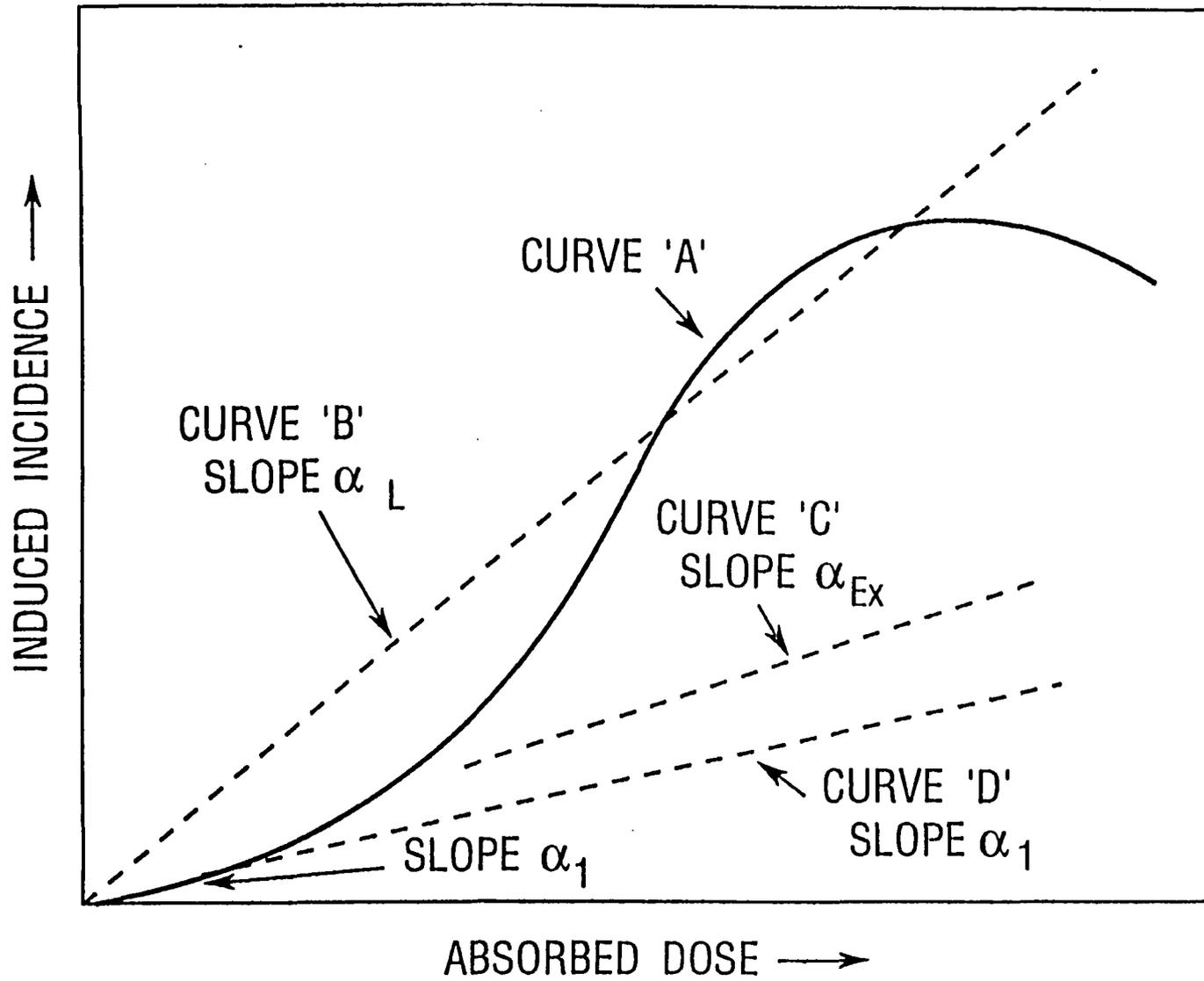


Figure 2. Schematic Curves of Incidence vs. Absorbed Dose

NOMINAL RISK ESTIMATES

	All Ages	Worker
ICRP		
High dose/dose rate	$10 \times 10^{-2} \text{ Sv}^{-1}$	$8 \times 10^{-2} \text{ Sv}^{-1}$
DREF	2	2
Low dose/dose rate	$5 \times 10^{-2} \text{ Sv}^{-1}$	$4 \times 10^{-2} \text{ Sv}^{-1}$
NCRP		
High dose/dose rate	$10 \times 10^{-2} \text{ Sv}^{-1}$	$8 \times 10^{-2} \text{ Sv}^{-1}$
DREF	2-3	2-3
Low dose/dose rate	$3.3 - 5 \times 10^{-2}$	$2.7 - 4 \times 10^{-2}$

Differences are unimportant so NCRP adopted ICRP values.

Table 5. Relative Probabilities of Fatal Cancer in Organs vs. Population Type, Male and Female, Age 0-90, Multiplicative Model

Organ	Japan	United States	Puerto Rico	United Kingdom	China
Esophagus	0.038	0.014	0.098	0.03	0.269
Stomach	0.291	0.033	0.136	0.05	0.224
Colon	0.18	0.32	0.206	0.225	0.103
Lung	0.174	0.205	0.141	0.274	0.097
Breast	0.023	0.075	0.048	0.085	0.022
Ovary	0.014	0.031	0.016	0.031	0.019
Bladder	0.052	0.076	0.078	0.09	0.036
Bone Marrow	0.077	0.096	0.127	0.064	0.079
Remainder	0.15	0.15	0.15	0.15	0.15
All Cancer	0.999	1	1	0.999	0.999
Risk (10⁻² Sv⁻¹)	10.7	11.2	9.5	12.9	6.3

LEVEL D CERTAINTY

- Existence of a hormetic effect
- Extent of non-Mendelian effects in man
- Existence of the Gardner effect
- Effects on health other than cancer, i.e., heart disease, diabetes, arthritis, etc.

"Consequently, the use of a nominal value of 5% per Sv for mortality due to leukemia and solid cancers from irradiation at low doses for a population of all ages (4% per Sv for an adult working population) still seems valid to the committee."

"Extensive data from animal experiments and limited human data provide no evidence to support the view that the adaptive response in cells decreases the incidence of late effects such as cancer induction in humans after low doses. However, further experimental studies should be conducted."

**The ICRP Principles of Radiological Protection and their Application in
Setting Limits and Constraints for the Public from Radiation Sources**

Professor Roger H Clarke

Chairman, International Commission on Radiological Protection

Director, National Radiological Protection Board, UK

Practices

add

exposure and risk

Intervention

subtracts

exposure and risk

Principles for Practices

Justification

Produce sufficient benefit to offset radiation detriment

Optimisation

For each source, doses or probability of being exposed should be as low as reasonably achievable within individual constraints

Dose and risk limits

Individual exposure and risk from all sources under control should be limited

Meaning of a "Constraint"

Maximum **individual** dose or risk **from a single source**

Ensures dose and risk limits are not exceeded

Fraction of the dose or risk limits

Upper bound on optimisation

Set on general knowledge or generic optimisation

Regulatory tool

It is not design target or operational investigation level

Principles for Intervention

Must do more good than harm:

reduction in radiation detriment must

exceed harm and social cost of intervention

Scale and duration of the intervention should be such

that the net benefit of reduction of radiation detriment

less detriment of intervention should be maximised

ICRP Vocabulary

Unacceptable

Not acceptable on any reasonable basis in the normal operation of a practice of which the use is a matter of choice

Tolerable

Not welcome, but can reasonably be tolerated

Acceptable

Accepted without further improvement, i.e., when protection has been optimised

Acceptability of Risk

Unacceptable

Level at which

limit is set

Tolerable

Maximum acceptable

risk from single source



Acceptable after optimisation



Trivial level of risk

Protection considered optimised

Public Annual Fatal Risk and Corresponding Dose

Unacceptable	> few in 100,000	> 1 mSv
Tolerable		0.5 – 1 mSv
<hr style="border-top: 1px dashed black;"/>		
	< 1 in 100,000	
Acceptable		fraction of 1 mSv
		
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Trivial	< 1 in 1,000,000	< 0.03 mSv



Medical Exposures

Justification	principally clinical judgement
Optimisation	equipment and procedures to give minimum dose for required diagnostic information
	minimum dose to non-tumor tissues in therapy
Constraints	guidelines on performance that trigger an investigation
Limits	do not apply

Waste Disposal

Justification

not applicable

Optimisation

collective (integrated) dose not helpful

Constraints

on individual risk

Limits

not applicable

Underground Solid Radioactive Waste Disposal

Limit of risk – 1 in 100,000 per year

**Major problem is uncertainties in result over
very long time periods**

**Solution may be prescribed biosphere and
defined time scale**

Site Restoration

Following an accidental release to the environment

**Discovery of an unsuspected site
e.g. old luminising plant**

Restoration of a known nuclear site

Restoration after Intervention

Intervention	averts dose and risk
Action levels	above 10s of mSv (rem) per year
Restoration	at few mSv (100s of mrem) per year

**Radon action level in range 3 – 10 mSv per year
(0.3 – 1 rem per year)**

RESTORATION AFTER PRACTICES

Old unlicensed site – use Intervention

- Action level 3 – 10 mSv (0.3 – 1 rem)
- Decontaminate
- Occupational exposure only above Action Level

Licensed site – treat as practice

- Constraint between 0.03–0.3 mSv (3 – 30 mrem)
- Exemption level 0.01 mSv (1 mrem)

**RISK ESTIMATES FOR RADIATION PROTECTION:
WHAT DO WE KNOW?
HOW WELL DO WE KNOW IT?**

Charles B. Meinhold
National Council on Radiation Protection and Measurements

INTRODUCTION

In 1977 the ICRP introduced the idea that dose limits should be based on the concept of acceptable risk. Thus began our fascination with risk estimation. The dose limits, the value of avoiding dose, i.e., the \$/Sv, probability of causation calculations, public perception, decisions on medical, x-ray or nuclear medicine examinations, decisions on decontamination & decommissioning are just some of the important societal issues tied to our estimates of risk. Just how good are they? In this presentation an attempt will be made to characterize our knowledge of radiation risks according to the robustness of the data, i.e., from fact to fancy. We can then review this breakdown of the information and choose those items that we need to make our judgments— at least for today.

Four levels of certainty or robustness have been chosen with the arbitrary designation of certainty levels.

LEVEL A CERTAINTY

There is excess cancer incidence in the Japanese survivors of the atomic bombings. An excellent demonstration of this can be found in an RERF commentary prepared by D.A. Pierce (reference) from which Table 1 is taken.

**Table 1. Estimated Number of Expected and Excess
Cancer Death by Categories of Exposure**

Shielded leukemia (Gy)	Approx. survivors	Nonleukemia		Leukemia	
		Expected	Excess	Expected	Excess
0.1	58000	4120	8	91	7
0.1 - 0.5	11500	866	61	20	12
0.5- 1	3500	273	56	6	13
1 - 2	2000	147	71	3	20
>2	1000	68	64	2	28
Total	76000	5474	260	122	80

First it is obvious that for the 1,000 people in the cohort under study who received more than 2 Gray (200 rem), the incidence of solid tumors is nearly doubled (sixty-eight expected to 132 (68 + 64) observed). For leukemia the increase is even clearer with from 2 expected to 30 (2 + 28) observed. Similarly, for those 2,000 in the cohort who had absorbed doses of 1 to 2 Gy, we can see an increase from 147 to 218 (147 + 71) in the incidence of solid tumors and an increase from 3 to 23 (20 + 3) in the incidence of leukemia. Such a breakdown gives a different picture than noting that there were only ~350 excess cancers in a background level of 5,474.

There is excess incidence of lung cancer in uranium miners. Perhaps, the most recent compilation is given in ICRP Publication 64, "Protection Against Radon-222 at Home and at Work" (ICRP 1994). From Table A.1 in that report one can find the following information:

Table 2. Characteristic Data of Seven Study Cohorts of Underground Miners

Cohort study follow-up period	Number of miners	Mean cumulative exposure (WLM)	Number of lung cancer deaths	
			Obs	Exp
Uranium miners				
Colorado, USA, 1951-1982, cumulative exposure <2000 WLM*	2975	510	157	48.7
New Mexico, USA, 1957-1985	3469	111	68	17
Ontario, Canada, 1955-1981				
Beaverlodge, Saskatchewan, Canada, 1950-1980	11076 6847	37 44	87 65	57.9 28.7
Bohemia, 1953-1985				
France, 1946-1985	4042 1785	227 70	574 45	122 21.1

In this data set, we note, for example, that the Colorado cohort had 157 lung cancer deaths when ~50 deaths would have been expected. Clearly the miners' cohort experienced an excess incidence of fatal lung cancer.

The last of the Level A certainties deals with one example of the basic radiobiological data that we have. Dose response curves for simple biological systems, such as *tradescantia* stamen hairs, demonstrate an $\alpha D + \beta D^2$ relationship. Figure 1 is taken from NCRP Report 64.

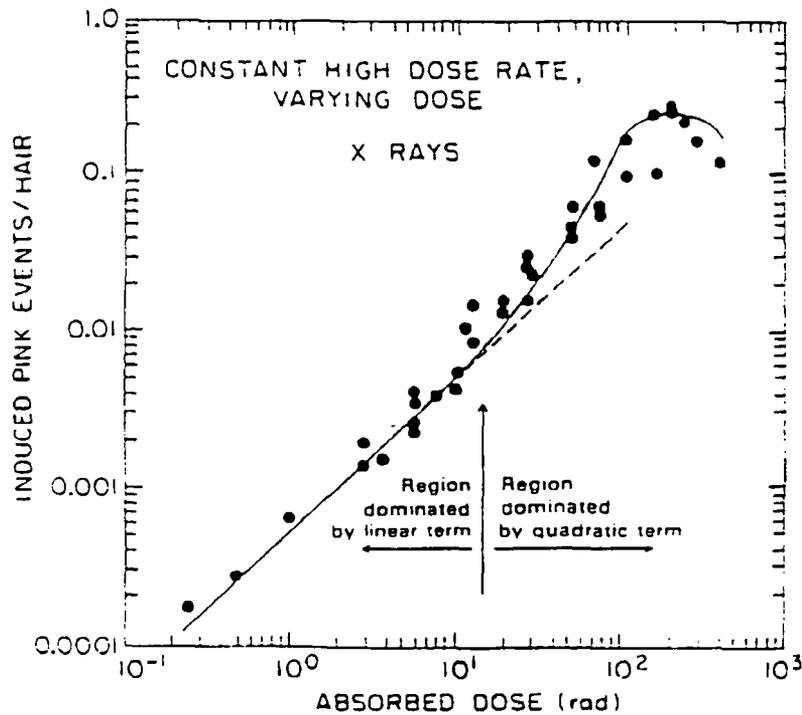


Figure 1. X-ray dose-response curve for induced pink mutations in *Tradescantia*, on a log-log plot to show detail in the low-dose range.

Note the linear response between 100 mGy (10 rad) and 2.5 mGy (250 mrad).

The last of the certainty A issues I want to mention is that genetic effects arising from exposure to ionizing radiation have been demonstrated in animals, plants, and insects.

LEVEL B CERTAINTY

Here again we deal with demonstrated conclusions although there is some judgment required.

First, the observed value of the risk per unit dose at high dose rate and at doses in excess of 0.2 Gy (20 rads).

The additional uncertainty is due to the need to know quite accurately the number of excess cancers in the population and absorbed doses in the cohort population. The dosimetry is improved although an uncertainty in the neutron dose introduces a potential error of about 20%. Another incremental level of uncertainty is introduced in accepting the multiplicative projection model. The evidence is now quite strong that with the exception of leukemia this projection model is correct. This can be seen in a quantitative way in Table 3, again from Pierce (RERF 1991).

Table 3. Mortality Due to All Cancers Except Leukemia
by Intervals of the Follow-up Period

Shielded kerma (Gy)		1950-1955	1956-1965	1966-1975	1976-1985
0.1 - 1	Expected	105	294	353	387
	Excess	8	3	37	69
>1	Expected	19	54	66	76
	Excess	9	27	40	59

If we look at the horizontal row for shielded kerma >1, we will note a rise in excess cancer which follows the expected cancers as the population ages. It would appear that the attributable cancers occur at the same age as non-attributable cancer, i.e., at the age people normally experience the cancer. The risk coefficient value depends upon careful assessments of the natural incidence of cancers in the exposed population, coupled with a reasonable knowledge of the increased incidence per unit dose in that same cohort as a function of time after exposure.

Table 4, taken from ICRP Publication 60, summarizes what we know about risks with Level B Certainty.

Table 4. Excess Lifetime Mortality from all Cancer Attributable to 1 Gy Acute
Uniform Whole-Body Low-LET Irradiation of the General Population (Upton, 1991)

Source of Estimate	Probability of Death (10^{-3})	
	Additive Risk Projection Model	Multiplicative Risk Projection Model
BEIR I, 1972	1.2	6.2
UNSCEAR, 1977	2.5	-
BEIR III, 1980	0.8 - 2.5	2.3 - 5.0
NUREG, 1985	2.9	5.2
UNSCEAR, 1988	4.0 ⁽²⁾ - 5.0 ⁽³⁾	7.0 ⁽³⁾ - 11.0 ⁽²⁾
BEIR V, 1990	-	8.85 ^(4,5,6)

- (1) Population of Japan
- (2) Estimate based on age-specific coefficients of probability.
- (3) Estimate based on constant (age averaged) coefficient of probability.
- (4) U.S. population - adjusted to high dose using values from Table 8.
- (5) Modified multiplicative model.
- (6) "Low dose" leukemia component multiplied by 2.

We see that the UNSCEAR 1988 estimates for a multiple risk projection model is about $10 \times 10^{-2} \text{ Sv}^{-1}$.

Next, radiation induced Mendelian genetic effects in man are adequately represented by animal and plant models. Here, most would agree that we are on fairly strong ground in that blue eyes and other simple Mendelian effects follow the same pattern in man that we see in animals and plants. I don't think much caution need be applied to this assumption. However, it is also true that an excess level of genetic effects has not been demonstrated in the Japanese survivors, although even this "non-finding" may be consistent with animal models.

Level A and Level B facts and conclusions form the basis for our realization that stochastic effects do occur in large population exposed to large individual doses. These facts and conclusions also lead to the realization that some techniques for estimating the dose response relationship in the low dose region in man are needed for radiation protection.

LEVEL C CERTAINTY

The most important Level C certainty issue here is estimation of effects per unit effective dose with low dose and dose rate exposure. Here we get into the detailed issues which must be examined to make judgments for both radiation protection.

Three issues are important. First, our estimate of the total radiation detriment per unit effective dose in workers taken as an average of both the sexes and over ages 18-65 and in members of the public taken as an average over both sexes age 0-70. The values adopted by the ICRP and the NCRP are given in Table 5. Second, our estimate of the relative organ risk per unit effective dose in workers and in members of the public, particularly for the organs listed in the ICRP's table of w_T s. Third, our estimate of the risk per unit working level month (WLM).

Table 5. Nominal Risk Estimates

ICRP	All Ages	Worker
High dose/dose rate	$10 \times 10^{-2} \text{ Sv}^{-1}$	$8 \times 10^{-2} \text{ Sv}^{-1}$
DREF	2	2
Low dose/dose rate	$5 \times 10^{-2} \text{ Sv}^{-1}$	$4 \times 10^{-2} \text{ Sv}^{-1}$
NCRP		
High dose/dose rate	$10 \times 10^{-2} \text{ Sv}^{-1}$	$8 \times 10^{-2} \text{ Sv}^{-1}$
DREF	2-3	2-3
Low dose/dose rate	$3.3 - 5 \times 10^{-2}$	$2.7 - 4 \times 10^{-2}$
Differences are unimportant so the NCRP adopted ICRP values.		

These three issues have Level C Certainty characteristics because they depend first on a) linear non-threshold assumption, b) a dose and dose rate effectiveness factor taken to be 2, c) an estimate of the non-Mendelian genetic effects, d) transfer of the Japanese data from a Japanese population at the time of the bomb to any population at any time, and e) knowledge of the influence of mine atmospheres, smoking, age at exposure, etc.

An examination of the information available makes it evident that a pure D^2 relationship can not be ignored as a possibility and at least an apparent or practical threshold seem to hold for the radium cases.

The transfer of risk from the one population to another is particularly difficult as can be seen in Table 6 and adopted from (ICRP 1991), *Annals of the ICRP*, Vol. 22, No. 1, "Risk Associated with Ionizing Radiation." The marked comparisons show, for example, that the risk of esophageal cancer differs markedly between the U.S. and Puerto Rico populations.

**Table 6. Relative Probabilities of Fatal Cancer in Organs vs. Population Type
Male and Female, Age 0-90, Multiplicative Model**

Organ	Japan	United States	Puerto Rico	United Kingdom	China
Esophagus	0.038	0.014	0.098	0.03	0.269
Stomach	0.291	0.033	0.136	0.05	0.224
Colon	0.18	0.32	0.206	0.225	0.103
Lung	0.174	0.205	0.141	0.274	0.097
Breast	0.023	0.075	0.048	0.085	0.022
Ovary	0.014	0.031	0.016	0.031	0.019
Bladder	0.052	0.076	0.078	0.09	0.036
Bone Marrow	0.077	0.096	0.127	0.064	0.079
Remainder	0.15	0.15	0.15	0.15	0.15
All Cancer	0.999	1	1	0.999	0.999
Risk ($10^{-2} Sv^{-1}$)	10.7	11.2	9.5	12.9	6.3

For issues with a Level C certainty, it should be recognized by everyone that although the conclusions drawn may reflect our best estimates, the uncertainty is large, i.e., there may be no effect at low doses, the dose and dose rate effectiveness factor (DDREF) could range from 1 to 5, the risk coefficient for any specific individual is not known nor, at this time, knowable.

For radiation protection purposes this level of uncertainty must be accepted for practical reasons even in the face of uncertainty.

LEVEL D CERTAINTY

These conclusions are mainly untested hypotheses or episodic information without collaborative support. A few examples of this level of issue follow.

First, is the question of the existence of a hormetic effect of radiation on cancer induction. It is clear that there are beneficial or adaptive influences of irradiation for many endpoints in many biological species. How this relates to cancer induction in man is highly uncertain.

Second, the extent of non-Mendelian genetic effects in man is in question. A number of analyses are being made to try to estimate what fractions of human ill health is due to genetic influences, but quantifying this is, indeed, a formidable task.

Third, the existence of the "Gardner Effect," that is, the induction of leukemia in the offspring of an irradiated parent is unproven. This stunned the radiation protection world at the time it was first elucidated. However, many studies since have raised a number of important questions about the interpretation of that particular data.

Fourth, the detriment associated with high Z particles as encountered in space is an unanswered question. It is an interesting question as to whether this is different from our other "ho:" particle kinds of effects.

Lastly, the effects on health other than cancer or genetic effects, that is, heart disease, arthritis, diabetes, etc., is unknown. Some of this information is beginning to be generated by the RERF, but our knowledge of its quantitative relationship with dose is still extraordinarily weak.

These Level D issues are at a level of uncertainty at this time that does not permit reasonable people to adopt them for radiation protection.

SUMMARY

In summary, if we are to be responsible radiation protection individuals, we must certainly adopt those conclusions we know with Level A Certainty and it is reasonable to accept those parameters we know with Level B Certainty. The difficulty comes in our Type C Certainty, which in fact we must adopt as a matter of practicality for radiation protection. This means that we can expect that our knowledge of the total detriment to the worker over his lifetime and the member of the public over their lifetime is acceptably well known.

This review should suggest first of all that we need to encourage research to further understand all of our uncertainties, perhaps, even those attached to items we know with Level A Certainty. And furthermore, that we should continue to study those that we know with Level D Certainty, all of which, at the present time, are beyond the level of certainty which we can reasonably apply in our radiation protection system. I think it also means that each of the items anywhere on our list requires constant attention to its potential impact as we move forward in radiation protection.

PRESENTATION TO THE NUCLEAR REGULATORY COMMISSION

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**The ICRP Principles of Radiological Protection and their Application in
Setting Limits and Constraints for the Public from Radiation Sources**

Professor Roger H Clarke

Chairman, International Commission on Radiological Protection

Director, National Radiological Protection Board, UK

ABSTRACT

The International Commission on Radiological Protection published new recommendations in 1991 as Publication 60. This presentation outlines the conceptual framework of the System of Radiological Protection adopted by the Commission and shows how limits and constraints are derived for members of the public. The application of constraints is discussed for medical exposures, solid radioactive waste disposal underground, and restoration of contaminated land.

National Radiological Protection Board,

Chilton

United Kingdom

January 1995

INTRODUCTION

The International Commission on Radiological Protection promulgated its new recommendations in the Annals of the ICRP as Publication 60 in 1991. They replace the earlier Recommendations in Publication 26, upon which ICRP had been building since 1977 when they first appeared. The 1977 recommendations presented a '**System of dose limitation**' which was primarily designed for normal operations. Over the years ICRP has extended its advice away from the central core of dose limitation to deal with other exposure situations. These include: **radon**, for which a philosophy was developed that did not include dose limits; **criteria for solid waste disposal**, where exposures are not certain to occur and events are probabilistic, so that again dose limits are not directly applicable in all circumstances, now defined as **potential** exposures; and **principles for protection of the public in emergencies**, where again dose limits do not apply. In its new recommendations the Commission has tried to draw together all of these different situations in a '**System of radiological protection**'. In this note this conceptual framework is presented and examples are given of its application to the control of doses to members of the public.

CONCEPTUAL FRAMEWORK

To clarify the way the Commission has developed its recommendations, it is convenient to think of the processes causing human exposures as a network of events and situations. Each part of the network starts from a source. Radiation or radioactive materials pass through environmental pathways which may be simple in the workplace (eg inhalation of airborne activity), or very complex in the natural environment (eg. ground deposition-accumulation - animals - foodstuffs) with some pathways being common to several sources. Eventually individuals are exposed to one or many sources of radiation. It follows that

assessments of the effectiveness of protection can be related to the source giving rise to the individual doses (**source-related**) or related to the individual dose received by a person from all relevant sources (**individual-related**).

A source-related assessment enables a judgement to be made as to whether the advantages it brings outweigh the disadvantages, including the radiation exposures. The source-related assessment will take account of the magnitude and probability of occurrence of individual doses from that source, but **not** other sources. It is therefore necessary to consider the individual-related assessment to ensure that the total dose or risk from all sources is too high.

Some activities increase man's overall exposure to radiation by introducing new sources, pathways and individuals, or by modifying the network from existing sources to man. These activities which **ADD** radiation exposures or risks are called **PRACTICES**. Other human activities can decrease the overall exposure by removing the source, modifying the pathways or reducing the number of exposed individuals. These activities which **SUBTRACT** radiation exposures are called **INTERVENTION**.

For **PRACTICES**, the system of protection recommended by the Commission is based on the following general principles:

- (a) practices involving exposure to radiation should produce sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes (**justification**)

(b) for any source, individual doses, the number of people exposed and the likelihood of being exposed, should be as low as reasonably achievable and constrained by restrictions on the doses to individuals (dose constraints), or risks to individuals (risk constraints) from potential exposures (**optimisation**)

(c) individual exposure from all sources susceptible to control are subject to dose limits or some control of risk from potential exposures (**limitation**)

These principles mean that when they are implemented for practices, it is necessary to consider not only normal operation but also the **potential** for exposures from accidents. Once the practice is justified - and radiological protection considerations are only one aspect of decision-making over the introduction of a new practice - the doses and risks have to be optimised within the dose or risk limits specified for individuals. However, optimisation is a source-related process while limits apply to the individual to ensure protection from all sources under control.

The Commission has therefore introduced the concept of a **CONSTRAINT** to dose or risk. A constraint is an individual-related criterion, but applied to a single source in order to ensure that dose or risk limits are not exceeded. A dose constraint would therefore be set at a fraction of the dose limit as a boundary on the optimisation of that source. The Commission considers that a constraint should be set on the basis of general knowledge about the performance of the source or by a generic optimisation. For potential exposures, risk constraints should be established in the same way. A constraint is therefore seen as a regulatory requirement, rather than as a design target or an operational investigation level.

In some situations, the sources, pathways, and exposed individuals are all in place when a decision on control has to be taken. In this case, the reduction in dose is achieved by **INTERVENTION**. An important group of such situations is the exposure from natural sources of radiation. Accidents and emergencies will have been considered as sources of potential exposure when assessing a practice but, if they occur, they may call for intervention.

Intervention cannot usually be applied at the source and has to apply to the environment or people. Countermeasures forming the intervention have disadvantages, so they must be justified as doing more good than harm. Their scale should be optimised to maximise the benefit. The system of radiological protection recommended by the Commission for **INTERVENTION** is thus based on the following general principles:

- (a) Any intervention must do more good than harm so the reduction in radiation detriment must exceed the harm and social cost of the intervention
- (b) The scale and duration of the intervention should be optimised such that the net benefit of the reduction in dose, ie. the benefit of the reduction in radiation detriment less the detriment associated with the intervention, should be maximised.

Principles (a) and (b) will lead to intervention levels which are appropriate for the circumstances. However, there will be some level of projected dose above which, because of serious deterministic effects, intervention will almost always be justified. The dose limits applied to practices are not relevant in the decision-making on intervention and the Commission has now decided on the levels of dose at which intervention is justified for

protection of the public in a radiological emergency (Publication 63) and for exposure to radon at home and at work (Publication 65).

ACCEPTABLE LEVELS OF RISK

All human activities or lack of activities carry some risk. Some of the activities are accepted by most people even if the risks are rather high, eg. driving and traffic accidents. Other activities are not accepted because the risks are considered unjustifiably high in relation to the ensuing benefits even after reasonable attempts at risk reduction. Many attempts have been made to set an upper level of risk to an individual, i.e. a level of risk which would not be acceptable even if it could not be further reduced. There is a difference here between voluntary and imposed risks. For radiation protection purposes the relevant circumstances would be normal occupational or private life in what might be considered a safe society.

Normal Operations

ICRP has used the term Practice to describe those situations where normal operations add doses and the probability of receiving a dose for workers and the public. It is in the principles for Practices that mention is made of dose limits. The way in which dose limits are specified is of interest here and involves the establishment of an acceptable - or more importantly - an unacceptable level of risk.

In order to discuss the issues, it is useful to clarify the terminology and this has been attempted by ICRP in Publication 60. ICRP has found it useful to use three words to indicate the degree of tolerability of an exposure or risk. They are necessarily subjective in character and must be interpreted in relation to the type and source of exposure under consideration.

The first word is 'unacceptable', which is used to indicate that the exposure would not be acceptable on any reasonable basis in the normal operation of a practice, the use of which is a matter of choice. Such exposure might have to be accepted in abnormal conditions, such as those during accident situations. Exposures that are not unacceptable are then subdivided into those that are 'tolerable', meaning they are not welcome, but can reasonably be tolerated, and 'acceptable', meaning that they are in a range that can be accepted, although there is a continual pressure to ensure that protection or safety is as good as it reasonably can be. Finally, there will be some level of risk that is so low that it is regarded as trivial and it is not worth committing resources to reduce it further. This is shown diagrammatically in Figure 1.

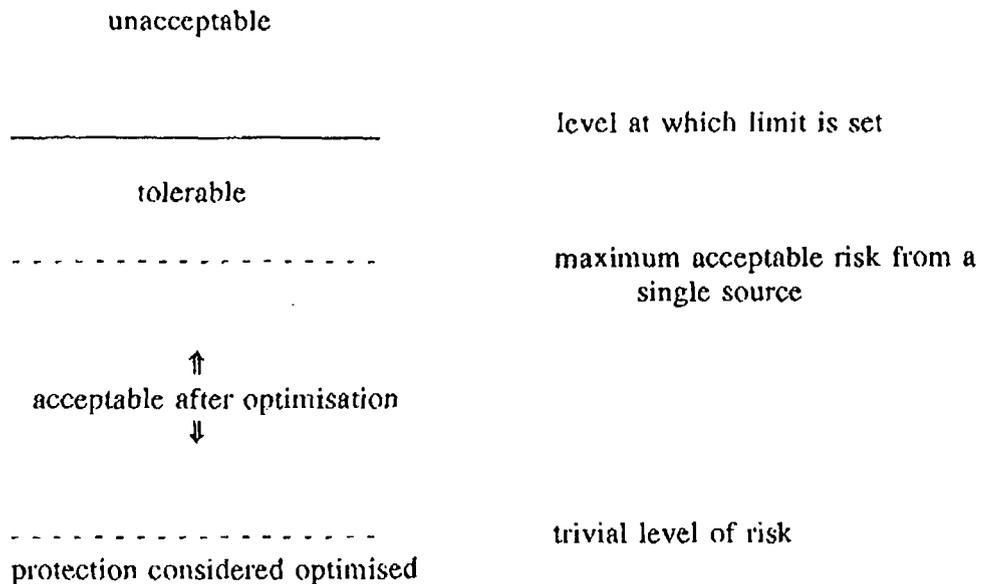


Figure 1. Schematic diagram of the acceptability of risk.

In this framework, a dose limit is set at a level of risk selected at the boundary in the region between "tolerable" and "unacceptable" for the situation in which dose limits apply - ie the control of the total dose from all specified sources. The limit then protects the individual from all sources under control by ensuring that the total risk is not unacceptable. It follows that the optimisation process for any single new source should be "constrained" to restrict individual exposure so that the risk from that single source is in the "acceptable" range and the total risk does not become unacceptable.

Having decided on the vocabulary to be used, it is possible to look at the various reports on risk acceptability in an attempt to derive the numerical value that may correspond to each word. The considerations are different for workers and members of the public but only the public is considered here.

Limits for the public

In the case of members of the public, it is much more difficult to decide what may be the level of unacceptability than it is for workers. A risk of 1 in 1,000,000 per year has commonly been regarded as trivial by many organisations and groups. A fairly widespread view seems to be that the maximum acceptable **imposed** annual fatal risk for a member of the public from a given source is around 1 in 100,000 and risks much beyond this probably verge on the unacceptable. ICRP has set the dose limit for the public at 1 mSv **Effective Dose** (100 mrem) per year which represents a judgement on the borderline of the level of unacceptability. The associated average annual fatal risk is a few in 100,000 per year. This judgement is made bearing in mind the various attributes of the attributable risk from the radiation exposure, including lifetime risk, maximum annual risk, average annual risk and

average loss of life expectancy. The Commission also took into account the existence of natural background radiation which gives an annual worldwide average effective dose of about 2.4 mSv (240 mrem). This natural background may not be harmless, but it makes only a small contribution to the health detriment that society experiences. It may not be welcome, but the variations from place to place, excluding the large variations in the dose from radon in dwellings, can hardly be called unacceptable.

However, limits apply to the total exposure of individuals from all sources under control. The Commission has introduced the concept of a constraint which is a restriction of individual dose from a single source and is used in optimisation. A constraint is therefore seen as a prospective upper bound to optimisation that ensures the risk from that source is acceptable and the total risk does not approach the unacceptable.

It follows that there is no single value of a constraint but rather that there are practice-specific or even equipment-specific constraints. Values will be different as between, say, a nuclear power plant and a hospital diagnostic x-ray department.

In a number of countries a maximum value of a constraint has been set at 0.3 mSv (30 mrem) per year corresponding to annual average fatality probability of 1 in 100,000. This figure would correspond to the tolerable level of risk for the public, while the trivial level of risk, 1 in 1,000,000 per year, would correspond to 0.03 mSv (3 mrem) per year. This sets the acceptable level of dose somewhere in the range between 0.03 and 0.3 mSv (3 and 30 mrem) per year. Constraints would be expected to be set in this range. It is of interest that an international consensus has been found, in the approved **Basic Safety Standards of the**

International Atomic Energy Agency and five other Agencies of the United Nations and the Organisation for Economic Cooperation and Development, for the use of an individual annual effective dose of 0.01 mSv (1 mrem) to establish activities or activity concentrations which are **exempt** from the requirements of prior notification or authorisation. ICRP also endorsed this value for exemption in Publication 60. The associated annual attributable fatal risk would be a few in 10,000,000.

APPLICATIONS OF THE CONCEPTUAL FRAMEWORK

Medical exposures

The application of the system of radiological protection in medical exposures involves the principles of justification and optimisation. The requirement for justification of the exposure is exercised at two levels. One is the level of the use of radiation for a particular purpose, whether it is mass examination such as screening for breast cancer, directed diagnosis for a particular condition initiated by some specific indication, or treatment for a disease already diagnosed. Justification at this level is a matter primarily for the medical profession but could also be examined by authorities in the area. The second level of justification is with respect to the individual patient, when it is clearly a clinical decision.

The requirement for optimisation of protection applies in full to all medical exposures. It can be implemented in both the selection and procurement of equipment and in the use of correct procedures, all aimed at delivering the required diagnostic information for the lowest dose that can be reasonably achieved. Optimisation in the context of therapy has a different meaning since the intent is to deliver enough dose to the tumour. Here the dose to be optimised in a radiological protection sense is that to other organs or tissues.

The use of dose constraints has considerable potential to supplement the procedures of optimisation and to provide guidelines against which to assess performance. It is clear that constraints must be specific to each particular type of examination, and it appears that they are best set by inspection of the range of doses delivered by different institutions in carrying out the same examination. In this context **constraints seem closer in concept to reference or investigation levels** than to regulatory limits that must not be exceeded. The importance of the use of constraints is that they will cause an investigation to be carried out if average doses in a particular institution for a particular procedure are consistently higher than the constraint. If there is clinical or other justification for the situation then it should clearly continue, if not then appropriate steps should be taken to improve performance. Care needs to be exercised, however, in the setting of constraints that it is not automatically assumed that performance below the constraint is optimised. **The constraint is more of a trigger to investigate situations that are probably well away from the optimum** than an indication of the optimum level.

Solid radioactive waste disposal

In the case of radioactive wastes the principles to be applied are those of optimisation and limitation. The principle of justification applied when the practice giving rise to the wastes was approved and would have involved considerations much wider than those of radiological protection. Governments justify the development of nuclear weapons, or nuclear submarines, or civil nuclear power, or the use of nuclear medicines to treat patients, on a broad basis of overall net benefit. The arisings of wastes are an inevitable consequence and **their disposal does not need to be justified.**

The disposal of solid radioactive wastes does not provide a certainty of exposure, rather there is the **potential for exposure at some point in the future**. The individual is therefore best protected by a **risk constraint**, which can be set by analogy with the dose constraint. The maximum risk constraint from a single repository would then be set at no more than 1 in 100,000 per year. If the annual risk is predicted to be less than 1 in 1,000,000 per year, the risk could be regarded as trivial and there would be no requirement to demonstrate that protection could be improved. Between these two levels there would be the requirement to ensure exposures are as low as reasonably achievable.

The main input to optimisation of protection has generally been taken to mean the total (integrated) collective effective dose. However for solid waste disposal, the use of collective dose is far from ideal. This is because the collective dose is so dependent on detailed assumptions about the biosphere, human behaviour and population size that the results must be treated with extreme caution. Because of the uncertainties in collective dose integrated over very long times, it has sometimes been suggested that collective dose is of more use in comparing options for disposal. However, if the absolute values can be so variable (depending particularly on the assumption about the future population size) then the difference is of little benefit for deciding on the allocation of scarce resources.

Collective dose conceals a great deal of information and it is more useful to use the dis-aggregated temporal and spatial distributions in a multi-attribute decision-aiding method, in which **less weight may be associated with those contributions to collective dose that arise at very low levels of individual dose and at times very far into the future**.

Site-specific calculations relating to the biosphere and human behaviour cannot reliably be calculated for more than about 10,000 years and beyond this perhaps a reference hypothetical biosphere should be adopted and the risk constraint converted into a constraint on the radionuclide release rates from the geosphere. This would ensure the protection of future generations by assuming reference communities with habits broadly typical of those of subsistence communities in the present day.

Restoration of contaminated sites

This is an area in which there is no international guidance and ICRP has established a Task Group to consider the issues. It seems that there can be at least three scenarios which may involve different approaches: the aftermath of an accidental release of radioactive material; the discovery of contamination at a site not known to have been contaminated, such as an old luminising plant; and lastly, the release of a decommissioned nuclear site.

Following the accidental release of radionuclides to the environment, intervention may be undertaken in the form of advice for the public to shelter, evacuate or in severe cases, to relocate. In this interventional situation dose limits will not apply and ICRP has recommended action levels, for example, the one for evacuation is set to avert a dose of more than about 50 mSv (5 rem), while that to permanently relocate people is to avert doses above about 10 mSv (1 rem) per month. In this case decontamination of land may well be undertaken and the degree of decontamination may be decided by the principle of optimisation. The result of the optimisation may be to conclude that **normal living should resume at a level of dose of a few mSv (few hundred mrem) per year**. This is above the dose limit for the public but it has to be remembered that those members of the public who

were below the action level were not relocated and would have received nearly as high doses, and finally that the action level for radon levels in homes, where remedy involves minimal disruption, is about 1mSv (100 mrem) per month.

Collective dose in its normal sense is not applicable in an interventional situation although the number of people involved in a countermeasure does affect both its benefit and detriment and therefore is important in the optimisation. The criteria for intervention are therefore expressed in terms of individual projected dose averted.

In the case of old premises where radioactive contamination is found, the situation may be treated as an intervention by analogy with the ICRP advice on exposure to radon-222 since it will probably be the natural radionuclides which are involved and the premises are most likely to be industrial. An **Action Level** for the workplace can be set, below which the exposure is not treated as occupational. If the levels of dose are above the action level, the decontamination should be attempted to reduce the exposure below the action level. Only if the doses are above the action level should the workers be treated as occupationally exposed and dose limits applied. The action level at which intervention is certainly justified for Radon has been set by ICRP at 10 mSv (1 rem) per year and optimisation is unlikely to reduce this by more than a factor of three, so that the **Action Level is expected to be set in the range between 3 and 10 mSv (0.3 to 1 rem) per year**. The situation is less likely to arise for dwellings, but were it to do so, the same Radon philosophy might apply and an action level be set above which remedial measures should be undertaken, but the dose limit for the public would not apply.

When a licensed nuclear site is to be decommissioned and treated as unlicensed, the situation seems to be the same as a practice. The dose limits apply for the public and constraints can be set. Since during normal operation, a maximum constraint for environmental releases is not expected to exceed 0.3 mSv (30 mrem), it seems logical that the same figure, **0.3 mSv (30 mrem) should apply as the maximum constraint for unrestricted release of the site.** Similarly as the trivial figure is 0.03 mSv (3 mrem) and the exempt level is 0.01 mSv (1 mrem), these would appear logical lower bounds for constraints. There is no reasonable possibility of removing all traces of artificial radionuclides and it would be a mis-allocation of resources to try. Since the restoration is being dealt with as a practice, collective dose considerations will arise in the optimisation. In this case again, the collective dose may best be presented in ranges of individual dose and in discrete time frames so that in a multi-attribute decision process, less importance may be placed on very low doses or those received in the very far future.

CONCLUSIONS

The new recommendations from ICRP have proposed a conceptual framework for the continued development of radiological protection. This framework has been accepted by the International Atomic Energy Agency and is in process of being accepted by five other Agencies of the United Nations and the Organisation for Economic Cooperation and Development. It has also been adopted by the European Commission for the Council of Ministers to approve as a Euratom Directive, which will become legally binding on Member States. There is clearly widespread acceptance of the ICRP recommendations which are seen as both scientifically defensible and practical to apply.

It has been shown that for practices, excluding medical exposures, constraints for the public are likely to be set in the range 0.03 to 0.3 mSv (3 -30 mrem) per year, with the annual dose limit being 1 mSv (100 mrem) and the exemption level at 0.01 mSv (1 mrem) per year. For intervention situations where dose limits do not apply, remedial measures are recommended between about 10 mSv (1 rem) per year for simple non-disruptive anti-radon measures in homes, to about ten times higher for highly disruptive actions such as relocation.

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