The new ICRP System of Radiological Protection

Roger Clarke, ICRP Chair

(2004/07/28 Tokyo)

Thank you chairman, good morning colleagues, it is my honor to have been invited here, and I'm extremely grateful to my good friends in the NEA for facilitating the meetings which have taken forward our ideas on the new recommendations. I would also like to thank Dr. Oda and Commissioner Kusumi for their personal welcome. I am grateful and I take note of what was said, and, since I am a native English speaker, I will be simple, clear, and easy to understand. Sorry Commissioner. (Joke)

The draft recommendations, now, are meant to represent an evolution in our presentation of radiological standards, not a revolution. The science has evolved since the last recommendations were made in 1990, and societal expectations have progressed since 1990, so this is what leads us to our 2005 recommendations. The recommendations will be supported by a number of foundation documents. And we hope that the 2005 recommendations will, perhaps, be *Publication 100*, I do not know, *Publication 1* was in 1959, as was already said. The issues which are covered in the recommendations include the quantitative, use of radiological protection, which will be subject to a foundation document, a supporting document, prepared by Committee II. The biological aspects, which include the work on the nature of the dose response relationship, and the risk factors, will be covered by two reports from Committee I. So, our recommendations will describe the general system of protection that we now are evolving, the quantitative, or numerical values that we recommend, followed by how we now see optimisation being undertaken. We deal with medical exposures, potential exposures, exclusion to try and clarify the difference between exemption from regulatory control and exclusion from consideration in any way. And, finally, we address protection of the environment.

So, let us start with the various issues, and the first is on the dosimetric side, where we are continuing to use the quantity effective dose. There are some changes taking place, as you know, in the development of voxel phantoms, rather than the old MIRD phantoms, the old mathematical phantoms. The changes to effective dose are basically, firstly, there are new values of the radiation weighting factor following a review of the RBE data and those considerations are in *Publication 92*.

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The major changes are reductions, a reduction in the radiation weighting factor for protons, of all energies from 5 to 2. This, I emphasise, is the result of a review of the RBE data. For neutrons of energies less than 1 MeV, again there is the reduction, by about a factor of two, in the recommended values for neutrons less than 1 MeV. And the radiation weighting factors are applied to the external incident neutron fluence and the neutron spectrum is degraded as it passes through the body.


And so there is an increasing contribution from gamma rays to the deeper organs. The net result is that we recommend a reduction in the factor. We also propose new values of tissue weighting factors, following a review which will be published by Committee I, a review of the risk data for somatic and hereditary defects. As you well know, because the *2001 UNSCEAR Report*, the risk of hereditary disease is now significantly less, in our estimates, than previously. So the radiation weighting factors, here we see on the first. In *Publication 60* we recommended a histogram for incident neutron energy,
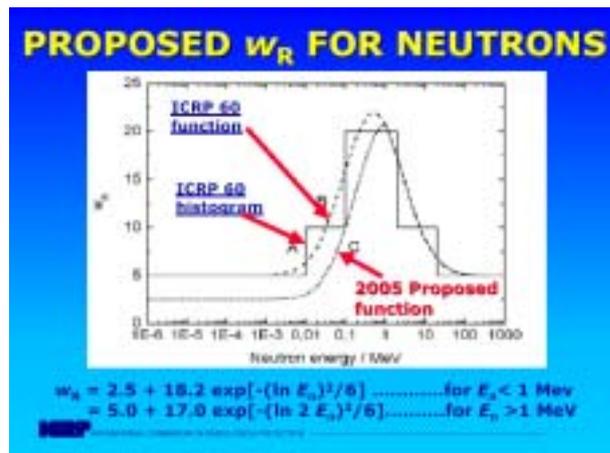
we gave a function which is Curve B on the slide, and now, for the reasons that I have outlined, with regard to the degradation of the spectrum of the neutrons through the body, you see the new function, Curve C, which represents low energies, about a reduction of 2 in the radiation weighting factor. And, for calculational convenience, we express it in mathematical terms at the bottom of the slide there.

Now for the tissue weighting factors, you will find some of this work described in Annex A of the draft recommendations. The highest tissue weighting factor had been previously assigned to the gonads. As a result of the review of the data, the gonad weighting factor has been reduced. We have tried to keep the numerical values of the tissue weighting factors as they were in *Publication 60* and only make the minimum changes. The evidence for risk to the female breast suggests that we should increase the tissue weighting factor which we have done there so that the breast now appears in the highest grouping of organs with a weighting

factor of 0.12. Skin and bone surface stay with their existing weighting factor, but Committee I feels that there are some other organs and tissues where the risks are small, but quantified, which should be added to this group, and that includes the brain, kidney and salivary glands. We now give more, an increased tissue weighting factor, to the remainder because Committee I feels that there are a number of organs and tissues for which the risks are small, uncertain, but should be included in the system.


So, if we go on to the next slide, the remainder weighting factor of 0.1 is averaged equally over 14 organs and tissues which I have listed here and I apologise that the small intestine here has been abbreviated, I hope you have all of the others. Now the point perhaps to make here, is that now in this formulation, effective dose becomes an additive quantity. In the past, ever since effective dose has been introduced, it has not been able to add the effective dose from exposures to different radioisotopes or fields, because the remainder was treated as being the 5 organs receiving the highest dose in a list of remainder tissues.

So, between, the intake of one radionuclide, for example cesium 137, and the intake of another radionuclide plutonium 239 for example, in each case the identified root 5 remainder tissues would be different. So when there would be a combined intake of cesium 137 and plutonium 239, together, then there would be different set of 5 remainder tissues receiving the highest dose. So the effective dose from an intake of cesium 137 could not be added to the effective dose from the intake of plutonium 239. You have to do a new calculation. We have removed that difficulty; one step towards simplicity. We now have a linear system and I think that it is a step forward.

Let me go on to the biological aspect and talk about the induction of tissue reactions. Again, for simplicity, and for ease of translation, we are now speaking not of deterministic effects, the word deterministic is ambiguous, it is used in different ways by ICRP and I am sure that many of us know the reactor accident consequences are frequently performed in a deterministic manner, as opposed to a probabilistic manner. So, even ICRP was using the word deterministic in different ways. Now we speak of tissue reactions and again, to be clear, we want to ensure that when we are looking at tissue reactions people do not use
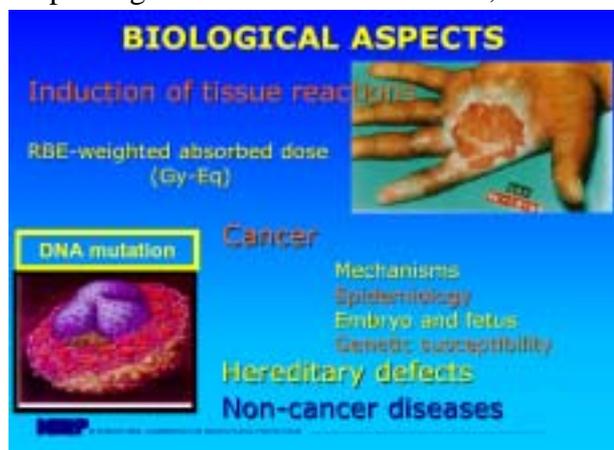
effective dose. Effective dose is meant for protection purposes where you do not expect threshold effects, tissue reactions, and again, for clarity and simplification, we are now proposing that the quantity is a gray equivalent, we will use that name for tissue reactions, to avoid confusing people about effective doses. It is a weighted absorbed dose, gray equivalent; it really means the absorbed dose being multiplied by the relevant RBE for the tissue reaction. I might just mention at this point that we also are trying to avoid the confusion in translation about the radiation weighted effective dose. I have been asked many times to explain the difference between equivalent dose and dose equivalent. Apparently native English speakers find it easy, but translating that expression, or those expressions, have proven difficult. So now we are going to speak about the radiation weighted dose and we would like to have a new unit, the unit will be joules per kilogram, but we would like to give it a name other than sievert, Sv, to avoid the confusion with the special name sievert being used for effective dose. So in the same way the special name here is the gray equivalent, Gy-Eq. That is ICRP trying to be helpful, clearer, and easier to translate. So for the other effects, the cancer, the report covers and the foundation documents from Committee I will cover the mechanisms of ontogenesis, review the results of the epidemiological studies, consider specifically the embryo and the fetus, and any genetic predisposition to cancer induction following radiation exposure.

Hereditary defects, which I have already mentioned, following the *UNSCEAR 2001 Report* and finally we will consider non-cancer diseases, although I can tell you that the conclusion from Committee I is that the evidence on the non-cancer diseases is not sufficient to incorporate any allowance in recommendations. For the detriment coefficient, again as a result of this work we again see a reduction. The estimate of detriment for a population of all ages is now about 10% lower than it was in 1990, largely because of the reduction in the estimate of hereditary defect. But also because the estimate of fatal cancer probability is also 10% lower than in 1990. And what Committee I has done here is to come up with a new definition of detriment which you will find in the recommendations, in Annex A, and they have commenced their calculations by using cancer incidence data as opposed to the mortality data used previously. They believe that the incidence data is more certain than the old mortality data and then they allow for a mortality fraction, they allow for a loss of life, and they allow for the loss of quality of life from hereditary defects. And, putting all these things together, we end up with both a fatal cancer nominal probability coefficient and a detriment estimate,

DETRIMENT COEFFICIENTS
(% Sv⁻¹)

Exposed population	Lethality adjusted cancer risk	Lethality adjusted heritable effects	Detriment 2005	Detriment Pub.60
Whole population	5.5	0.2	5.8	7.3
Adult workers	4.1	0.1	4.2	5.6

*Fatal cancer nominal probability coefficient 4.4% Sv⁻¹ compared to 5% Sv⁻¹ in Pub. 60

both of which are lower than we used before. This is very reassuring because it means that our standards essentially may remain, because there is no reason to think that we were under-protecting, not sufficiently protecting, workers and the public.

So the 2005 system of protection starts by explaining the principle of justification, followed by our

quantitative recommendations, the numerical restrictions on individual doses, and followed by the principle of optimisation this time, because whenever you optimise you need some sort of restriction on the maximum individual dose to undertake an optimisation. That was said in *Publication 60*, but never pursued.

So, let us start with justification, the justification of controllable sources and justifying the fact that there is an overall benefit is the responsibility of national authorities, it is not for the ICRP. Radiological considerations are only one input. I have been asked many times to justify practices


which occur in some countries but not in other countries. But it is not for ICRP to justify these practices. A country may decide allow a practice for a number of reasons: strategic reasons like trying to get a proportional energy supply secure from oil fluctuations on the global market, for economic reasons, for defense reasons, for medical reasons, and for safety reasons. Individual countries may make their own decisions that there is positive benefit

and it is not for ICRP to justify why a particular defense activity utilises radiation and gives rise to radiation exposures. Radiological considerations are an input but are not usually the determining feature and ICRP recommendations can only apply when the government and the regulatory bodies have declared the practice justified. And we also apply our recommendations to those natural sources which are controllable. And, as we will see later, patient exposures need separate consideration. So our new 2005 system then moves from the justified practices to the quantitative recommendations.

Now here I need to explain some conceptual points. The public is protected from a single source of ionising radiation in all situations, normal operations, emergency situations, in controllable exposure situations that is where there is an existing source of exposure which can be controlled. In all situations you are going to optimise protection and in order to perform an optimisation you need a constraint. You constrain the exposure from a single source. That is what you tell the designer of a facility. That is what you tell the designer to achieve. The constraint, the maximum dose that you are

going to allow from that single source in comparison and of course what we have had in the past has been the concept of dose limits which protect the public from all the regulated sources but only in normal operational conditions. So the limits are what you tell the designer that he should use to design the maximum effluence or maximum dose to the public from a single source. Any one of these sources, whether it is the radiology department
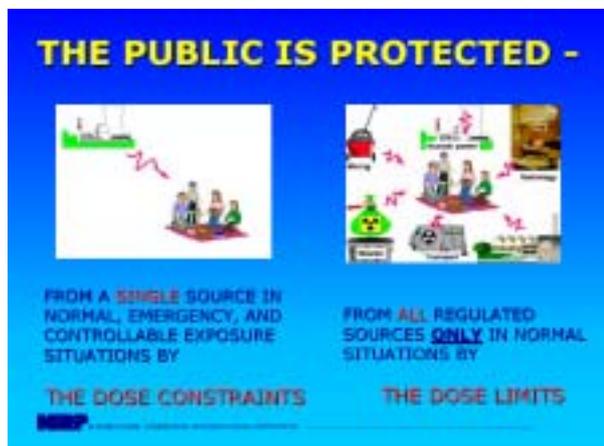
of a hospital, whether it is a power station, or a mine, in each case the regulator will authorise operation against a discharge or fluence from that single source facility. And that is the constraint; the concept was introduced in *Publication 60* but was never developed by ICRP. So the constraint to the optimisation equally applies in non-normal situations.
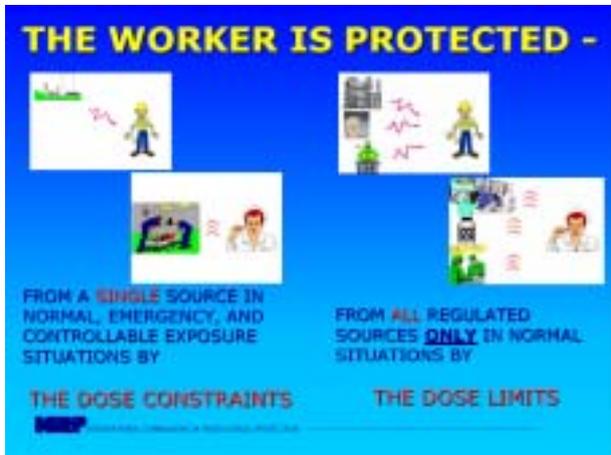

Similarly for the worker, the worker is protected from a single source, the worker in the industry, the worker in the hospital, protected from any single radiation source in all situations by the relevant constraint, whereas the worker is equally protected from all occupational sources by the dose limits, but only in normal operations. You cannot use the dose limit to design a facility because there are other sources. You cannot monitor the public against the dose limit because you do not know the origin of all sources of exposure. What you do is check individual sources, to comply with their authorised limits, their authorised releases, i.e., the authorized levels at which to operate. And these authorised levels are the results of applying constraints. I am sure you will have questions, but this is not a revolution, this is an evolution. The concept was introduced in *Publication 60* and not developed. Now we are developing it to be useful, more useful to the regulator, more useful to industry, more clarification, more simplicity, easier to translate. So, on the next slide, let us look at

the quantitative recommendations, and the principle recommendations that we are providing this time are of course the constraints. The restrictions that are established for the most exposed individuals are figures which can be set internationally and used by national regulators. So, constraints, we see being set by ICRP, and on the next slide we want to have fewer numerical values than we have had in the past.

If you have read what we have previously written, since 1990 we have advised the use of nearly 30, different numerical restrictions on individual dose in different circumstances. We would like to reduce those numbers but the reduced values will be numerically the same as some existing ones so as to achieve continuity. We want to try and explain them in terms of multiples or fractions of their natural background radiation, which I believe, and we believe, can be simple to explain to people, to politicians, members of the public, others who need to have explained to them the standards of protection, And, as I said before, constraints are required, they are a necessary criterion, but not a sufficient criterion, for protection, which means that after you have sufficiently protected the most

exposed individuals you must achieve a higher level of protection while optimising protection from the source. And it is the source from which you optimise protection. It is not all sources, so you need the constraint and not the limit. So, constraints can be explained in terms of multiples or fractions of the natural background. When using the natural background we have excluded radon, because we regard radon as technologically enhanced exposure or a manmade source of exposure. That is because the indoor levels of radon are of magnitude of level higher than the outdoor levels and we make recommendations to control radon at home and at work. So it is excluded from the inescapable
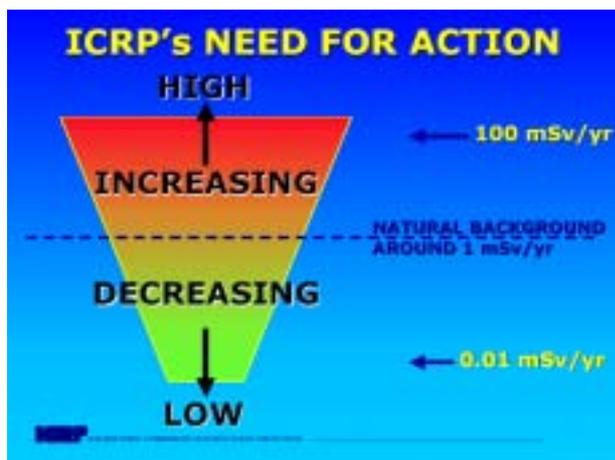
natural background which we used to compare and above that natural background increasingly ICRP would see sources giving rise to higher doses, increasingly needing action. And there is a high need for action when doses get to be of the order of 100 milli sieverts per year. Similarly, before the natural background, ICRP sees a decreasing need for action with sources giving doses below 100 milli sieverts per year with a very low need for action when we get down to as little as 10 micro sieverts per year. Now, basically, this is the scheme we see as a way of explaining our need for action. The actions we have taken have been, in the past, derived as a whole variety of bases, but now we think we can explain it in terms of their background. So let us move on to our maximum constraints.

The maximum constraints we have suggested is 100 milli sieverts in a year, a 100 milli sieverts is a figure where we still believe we can use effective dose. And it is a number which you will find in ICRP documents dealing with emergencies. So it is the maximum dose which we think you should plan for emergency workers other than those voluntarily undertaking lifesaving actions. It is the maximum value that ICRP has suggested for relocation or evacuation of the public in emergency situations and it is the level where we have recommended it is virtually certain to take action to protect people from existing high levels of controllable exposure. So, this number, or numbers very like it have been used for workers, for the public, for emergencies, for normal situations, for existing situations, and we characterize this highest constraint as one where there are really not any individual or societal benefits for individual exposures greater than this. You do not want people to receive higher doses. And if you think people might receive higher doses than they are informed about the risks, about the doses and the circumstances in which they might receive them, they receive training and they are monitored directly or their doses are assessed. And if you think about it, this is true for workers, it is true for members of the public who may be affected by an accident, they are informed – you assess the doses. So we see here a common constraint which is almost 100 times background, it is a number that has been used before, it is in the *Basic Safety Standards*, it is in ICRP documents. But now we can just use one number rather than a series of numbers derived in different ways.

Our second constraint is 20 milli sieverts in a year, it is recommended in *Publication 60* as the

maximum constraint from a single source for workers, but we have also recommended similar numbers for simple countermeasures such as sheltering of the public or the distribution of stable iodine in emergency situations. We have a very similar number that we have used for radon indoors, at home and at work. We have used a number for comforters and carers of patients undergoing treatment with radionuclides. And here we characterize this group as one in which there is a direct or an indirect benefit to the individuals who are exposed and they are informed, they receive some training, and there is some monitoring or assessment of the dosage. If it is a comforter for a patient, you assess the dose that carer or comforter receives. What I want to emphasise is that we have used this figure of about 10 times the natural background as a level where we want to take action for workers, in normal situations, for the public in emergencies, for workers and the public for existing exposures – such as radon and for people involved with patients undergoing therapy. We have used a series of rationale to arrive at the number, but the basic observation is that at the end of the day we have a number that is about 10 times the background.

Our third constraint again recommended in *Publication 60* and maintained here for continuity, is 1 milli sievert per year and the key thing is this could apply in situations where there is a societal benefit but not necessarily individual direct benefit; it is where there may be an imposed burden. So it applies in normal situations, you generally do not inform people about this, they are not trained and you do not assess individual doses. You may monitor the environment.

And lastly, we have the value of 0.01 milli sieverts in a year, or 10 micro sieverts in a year, which we say is the minimum constraint that should ever be applied. There is no justification, in our view, for trying to set a restriction on an individual source lower than 10 micro sieverts. You may still apply the system of protection but you do not attempt to get the dose lower.

These are the constraints: radon, I said, was treated separately and since in *Publication 65* we established a system which seems to have been adopted all around the world, we now see that what we have done in *Publication 65* was to set constraints on the radon source, where action is almost certainly warranted, we did not describe it as a constraint but we now see that conceptually it is a constraint, it is the most that you are prepared to let a worker or a member of

the public receive. It was derived on the basis of an exposure leading to dose of about 10 milli sieverts in a year, and we said that these were the activity concentrations of radon, or the constraints which regulatory authorities should start with and apply. The national authority optimizes protection and establishes a lower level where at work you do not take the exposures into the system of protection. Radon exposures below these levels are not subject to the system of protection. And, at home, you do not try to reduce the levels further. So you end up by deriving a level at which you take action which will be a national level, because the optimised result of considering action against radon will be different in a Scandinavian country, say Finland, in comparison with England, the circumstances, the situation, is different. So the result will be different. But, ICRP can express internationally the standards on which the regulators will start.
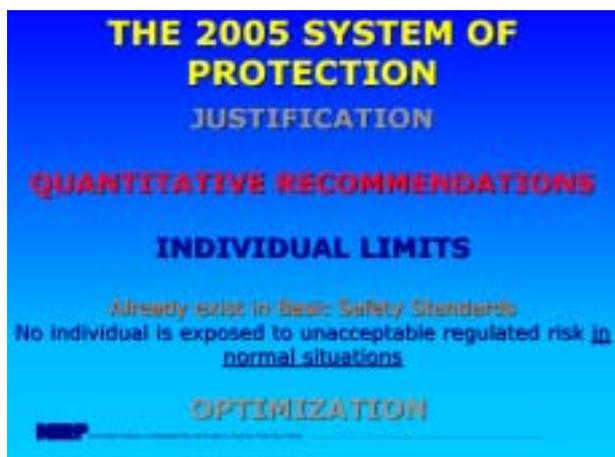
So now our quantitative recommendations also include the individual limits. The individual limits already exist in the *Basic Safety Standards* and they are there to protect workers and the public against all the regulated sources in normal situations – but only in normal situations. And we see no reason to change the dose limit. And you know that for the public there is exceptionally a 5 year averaging allowed. We maintain the averaging that we recommended in *Publication 60* for workers that the dose limit is 20 milli sieverts per year averaged over 5 years as long as no more than 50 milli sieverts in a single year, which explains why we can have a constraint for a single source of 20 milli sieverts in a year. No averaging because that is what you are going to design against, that is what you are going to monitor against. And of course we maintain the organ restrictions which are not sufficiently protected by the effective dose. So this is stability in the system, it means that perhaps


Basic Safety Standards from the international agencies do not need to be revised because the limits are the same, they can be complemented or supplemented with the development of advise on the constraints which are identified in the *Basic Safety Standards* but not developed. So our recommendations can clearly be seen as an evolution, to build from the *Basic Safety Standards*.

So now I turn to optimisation. Having ensured that no individual is exposed to undue risk from a source, there is a duty to do better and it is the responsibility of operators and national authorities. It is not the duty of ICRP. ICRP can advise on how it might be undertaken optimisation is a national issue. The level of protection which you aim to achieve in Japan is a Japanese issue and it will be

different for nuclear power, for hospitals, for a waste repository, for individual applications. You will optimise protection in all those situations for workers and for the public and you come up with authorised levels for operation. And your levels will be different to the levels in the UK, at which operation is authorised by the regulator, different to the figures that the French will authorise, and all will be very different to the level which the US authorises. But optimisation is a national issue and we believe that we are best advising the world in optimisation if we advocate of basic safety culture which is defined in the *Basic Safety Standards*. It requires cooperation between all of those involved and tomorrow you will about this in much more detail. The *Basic Safety Standards* of the NEA and the other international agencies define safety culture as the assembly of characteristics and attitudes which establishes that, as an overriding priority, protection and safety issues receive the appropriate attention. So, it is the idea; the idea, the noun, English noun, my thinking, that is what I am emphasising, optimisation is about thinking, it is not mathematics.
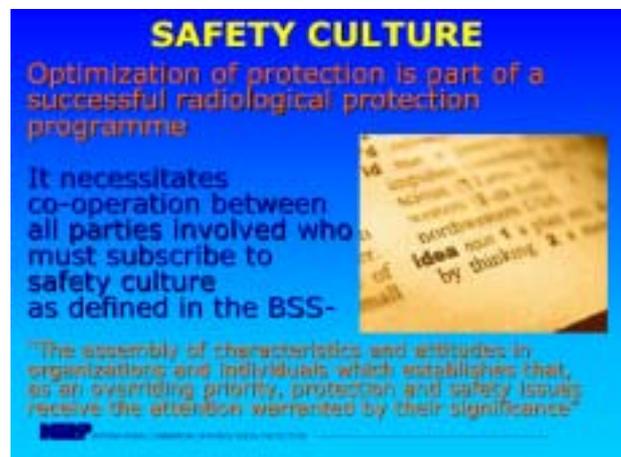
So we are recommending to you all and you will spend tomorrow looking at stakeholder involvement involving those who are actually exposed. It may be very challenging for the regulator, to have to engage with the public, to empower the workforce, but this is the job of the national authorities and the operators together, to get the best level of protection in the circumstances.
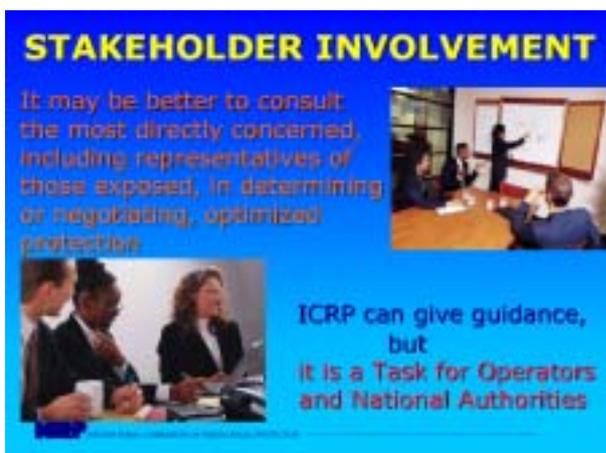
Now for the protection of groups we have to recognise that in the past collective dose has been defined as the double integral, but it is difficult to use because it aggregates, it brings together, a vast amount of information into a single number which can then be misused. So what we think is needed for decision-aiding is the dose matrix, I will leave the rest to you John. We want to see individual doses when they are received. It is important when you make a decision to know whether the dose is going to be received 1000 years

from now, in the year 3000, or whether it is going to be received tomorrow. And it was argued to me that for the workforce collective dose is useful but I would disagree with that, I think you need at least the number of workers involved, it is no use just to say the collective dose has been reduced if you have many more workers exposed. Or even the other extreme, only one or two workers are receiving the entire dose. That may not be the optimised protection. So you will discuss this more tomorrow.

I move on to Exclusion. ICRP is recommending levels of activity concentrations below which effectively you do not treat the materials as radioactive. For artificial radionuclides these are below 0.01 Bq per gram for alpha or 0.1 Bq per gram for beta gamma emitters. For the natural radionuclides, we recommend activity concentrations of 1 or 10 Bq per gram for potassium 40. This has been a difficult issue for international agencies for many years. Which level of activity in a foodstuff should not demand intervention by the regulator? And, clearly, we have had exemption levels, regulators use exemptions, it is a valuable tool. But an exemption is no different really from an authorisation to discharge; the regulator loses control of the radioactive material. But there will still be some considerations of the system of protection. What we have done is look at where exemption levels have been devised in different circumstances and decided that at these sets of activity concentrations nobody has gone lower than this, essentially to exempt. So let us treat these as levels below which you regard the materials as not radioactive.

Protection of the patient, as I come towards the end of my presentation, is different, as I have said, here I will not speak very extensively on this today, but justification is somewhat different in the case of patients because you are deliberately irradiating the patient and in a sense you are doing it for the benefit of the patient, you are going to diagnose something which will increase the probability of good health in the patient. So firstly you have to

ensure that the general procedure is okay. So the regulator is going to say that PET scans are justified generically and there are some things which you may decide are not generically justified. But you may decide PET scans are a good thing. Then when a patient presents with symptoms, you are going to refer that patient for a diagnostic X-ray or some diagnostic technique. The referring physician has a job of justifying why that patient needs the exposure that it has to be a CT rather than a simple chest X-ray, why it has to be a combination of CT and PET. No problem, as long as it is justified that the benefit to the patient is greater than the detriment from the exposure, the dose that the patient receives. Which is exactly as it ought to be, because if you find the early stages of a tumor or some other problem that will reduce the life expectancy of the patient, then the doses were justified – you are going to improve the health of the patient? What is not justified is routinely giving a CT to every member of the public every year just in case they might have a cancer. I would say that is not justified. Optimisation of the procedure should be undertaken, and we believe that diagnostic reference levels as indicated in good practice are an aid to optimisation. And you need the constraints, the maximum doses that you are going to allow for comforters and carers. And the actual doses that are applied may be different, in different countries, because of different social situations, and it is a matter for the regulatory authority and for the medical people, ICRP can give generic guidance.

Potential exposures, we also deal with those events which have a probability but not a certainty of occurring and here we turn our dose constraints into risk constraints, we say you have to be careful about using effective dose, and here you can see the figure of a 100 milli sieverts again that we have decided is about as far as you can go in using effective dose, because above that individual organ doses may be sufficiently high that there can be tissue reactions. What we used to call deterministic effects here, tissue reactions. And for events that may affect large numbers of people of course, there can be a range of consequences, early effects of tissue reactions, late effects, such as cancer, you can get contamination of the ground, you can get economic losses by contaminating factories' property, it can multi-attribute a situation which no-one has managed to resolve by use of a single quantity and therefore we think you have to restrict the probability of the event occurring.

Protection of the environment you know about because ICRP decided at the end of last year to establish its fifth standing committee to develop a policy and a framework for

environmental radiation protection. Committee 5 will be establishing the reference and environment which you will know about from *Publication 91* and you will also know that one of the reference fauna is a duck, so here is my duck, this is one of the standard reference fauna and I think that reference flora involve things like seaweed, but I thought this lily was rather prettier for my reference flora.

So, I end, Chairman. As you know, we have released the text in the last month - it is on the web – the supporting documents, the foundation documents are courtesy of Committees 1, 2, and 4, which meet courtesy of Prof. Pan, in Beijing in October to finalize the supporting documents and we will consider, as a main commission, early next year all the comments that we get back from the web. Thank you for your attention.

PROPOSED TIMESCALES

Release of text on web	June	2004
Supporting documents finalized by ICRP Committees	October	2004
Consideration of comments	April	2005

FINAL TEXT - 2005