Evolution of the System of Radiological Protection

Second Asian Regional Conference
Tokyo, Japan
28–29 July 2004
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Co-organised by the Ministry of Education, Culture, Sports, Science and Technology of Japan (MEXT)
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In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

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FOREWORD

The most significant challenge facing radiological protection experts is how to better integrate radiological protection within the modern concepts of and approaches to risk governance. It is within this context that the International Commission on Radiological Protection (ICRP) decided to develop new general recommendations to replace its Publication 60 of 1990, upon which virtually all current national legislation is based. The process of developing these new recommendations began in 1999 with the publication of an article by Professor Roger Clarke, ICRP Chair, on what was at that time referred to as “controllable dose”. Since then, the views of the ICRP have evolved significantly, largely due to stakeholder involvement that has been actively solicited by the ICRP, as well as internal discussions within the ICRP Main Commission and its four committees.

The OECD Nuclear Energy Agency has also been developing suggestions on how to improve the existing system of radiological protection. The NEA Committee on Radiation Protection and Public Health (CRPPH) has therefore been an active partner in the ICRP review process since its beginning. The CRPPH is made up of regulators and radiological protection experts, with the broad mission to provide timely identification of new and emerging issues, to analyse their possible implications and to recommend or take action to address these issues to further enhance radiological protection regulation and implementation. The regulatory and operational consensus developed by the CRPPH on these emerging issues supports policy and regulation development in member countries, and disseminates good practice. Given this mission, the CRPPH is interested in helping the ICRP recommended system of radiological protection to evolve to better address national policy, regulatory and practical radiological protection needs.

Taking the view that the current system of radiological protection is well-presented, operationally workable, and does not underestimate radiological risks to the public or workers, the CRPPH feels that radical change is not necessary or warranted. However, it is widely agreed that several key areas of the system need an alternative approach to better respond to the needs of regulators, practitioners and other stakeholders. To address this, the CRPPH created an expert group in 1999 to identify areas where the system of radiological protection could be improved. This effort resulted in the publication, in early 2000, of A Critical Review of the System of Radiological Protection: First Reflections of the CRPPH. A follow-up CRPPH expert group published, in 2002, The Way Forward in Radiological Protection, that developed specific directions to improve what it identified as the most important areas. These suggestions were then “road tested” to see, if they were applied, whether they would result in better or more easily accepted decisions, the results of which were published in 2003 in A New Approach to Authorisation in the Field of Radiological Protection: The Road Test Report. All of these reports were transmitted to the ICRP for consideration.

In parallel with this work, the CRPPH has also been exploring, through its three Villigen Workshops (1998, 2001 and 2003) aspects, processes and implications of stakeholder participation in radiological protection decision making. Such processes are increasingly central to decision making in certain situations (for example, new facility siting, operational releases, decommissioning, and post-accident cleanup).
To further assist the process of new recommendation development, the CRPPH arranged a series of broad dialogue meetings with the ICRP and various stakeholder groups. This has included:

- The attendance of the ICRP Chair at several CRPPH-organised meetings with representatives from other NEA standing technical committees (radioactive waste management, nuclear regulation, nuclear safety and nuclear development).


- The organisation of the First Asian Regional Conference on the Evolution of the System of Radiological Protection (Proceedings, NEA, 2004), held in Tokyo in October 2002, with the support of the Japanese Ministry of Education, Culture, Sports, Science and Technology (MEXT). This conference provided the ICRP with specific views on how new recommendations could best be developed to address regulatory and implementation needs in the Asian context.

The release of the latest draft ICRP recommendations at the IRPA-11 Congress in May 2004, the completion of the CRPPH Third Villigen Workshop, and the preparation of CRPPH work on the regulatory process of authorisation provided ideal timing to hold the Second Asian Regional Conference on the Evolution of the System of Radiological Protection. With the final ICRP recommendations planned to be published in the 2005-6 time frame, this conference provided important input to the development process and facilitated the presentation of and dialogue on recent NEA work in this area.

The conference was organised in four sessions, covering the new system of radiological protection, regional views on the new system, and processes for stakeholder involvement in radiological protection decision making. In addition, the panel discussions configured for each of the sessions generated exciting scientific debates.

These proceedings include the presentations of the invited speakers, a summary of the conference and the list of conference participants. It will be submitted to the ICRP for consideration.

Acknowledgements

The NEA wishes to express its gratitude to the Japanese Ministry of Education, Culture, Sports, Science and Technology (MEXT) for co-organising the management of this conference.
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OVERVIEW OF THE CONFERENCE

The Committee on Radiation Protection and Public Health (CRPPH) of the OECD Nuclear Energy Agency (NEA) has been working for some time to achieve consensus with regard to the directions that the ICRP should follow in the development of new recommendations. The Asian Members of the NEA have actively participated in this process, and are supportive of this work. The specific views of the NEA Asian Members were first addressed through the 1st Asian Regional Conference on the Evolution of the System of Radiological Protection, held in Tokyo in October 2002. The success of this event and the development of new draft ICRP recommendations has led the CRPPH to organise a 2nd Asian Regional Conference on this subject, to provide a dedicated forum dealing with Asian views. This Conference, co-organised by the Japanese Ministry of Education, Culture, Sports, Science and Technology (MEXT), enjoyed the participation of 140 attendees from Australia, People’s Republic of China, France, Italy, Korea, United Kingdom, and Japan, including radiation protection professionals, scientists, regulators and representatives from the nuclear industry.

Specifically, the goals of this Conference were as follows:

- To present, for the first time in Asia, the latest draft recommendations from the ICRP, which were unveiled at the May 2004 IRPA-11 Congress in Madrid, Spain and to hold a dialogue with the ICRP Chair on the Commission’s current proposals, particularly with respect to Asian views of new concepts and their application in the Asian context;

- To present the recent work of the CRPPH and its Expert Group on the Regulatory Process of Authorisation (EGRA) on an approach that governments and regulatory authorities could use to implement the ICRP system of radiological protection in a simple, coherent and transparent fashion, and to hold a dialogue on this approach and its application in the Asian context;

- To present the results of the NEA’s most recent work on processes for the involvement of stakeholders in radiological protection decision making, and to discuss stakeholder involvement processes in the Asian context.

Eleven scientific papers were presented in four sessions, covering the new system of radiological protection, regional views on the new system, processes for stakeholder involvement in radiological protection decision making, and ways forward from the current system. In addition, exciting scientific debates were sparked in the panel discussions configured for sessions one, two and three.
MAIN POINTS OF THE CONFERENCE

Session 1: Towards the new system of radiological protection

The new ICRP system of radiological protection was presented by the ICRP chair. The key concepts of Justification, Quantitative Recommendation, and Optimisation were clarified following many comments and questions on the introduced concepts.

EGRA’s contribution to the regulatory process of authorisation was generally accepted in the conference. It is desirable to continue to develop a clear understanding of the regulatory concept of authorisation from a conceptual and practical standpoint.

Session 2: Regional views on the new system of radiological protection

Japanese regulators, researchers, and operators presented their regional views on the new ICRP recommendations. It was commonly expressed that an understanding of the background to the introduced concepts in the new recommendations is required.

Other regional views from Korea, Australia, and China were also explained based on their own regulatory system and referring to radiological protection topics in their countries.

Session 3: Process for stakeholder involvement in radiological protection decision making

After presentation at the 1st Asian Regional Conference of the concept of stakeholder involvement in radiological decision-making processes, the idea of stakeholder involvement seems to be increasingly prevalent. Presentation of lessons from case studies of the 3rd Villigen workshop, and from CRPPH activities helped participants to better understand the concept. Additionally it is widely understood that there have been similar approaches to stakeholder involvement in Japan.

Session 4: Where do we go from here?

After the discussions on the new ICRP recommendations and stakeholder involvement, it was widely accepted that the process is moving forward to a new evolved idea of ICRP recommendations. However, it was also noted that the many differences in regional legislative and cultural frameworks should be taken into account. There is an expectation that all the comments and questions concerning the new recommendations will be discussed internationally.

In order to evolve the recommendations, NEA and ICRP will continue to collaborate. To ensure appropriate consideration of specific cultural and socio-political contexts, a 3rd Asian Regional conference is being planned by the NEA.
The way forward to the future

The need to evolve the current radiation protection system was widely accepted in the conference, while it was noted that the implementation of a new system must allow for regional societal and cultural differences. From this perspective, the 2nd Asian Regional Conference was successful in expressing the different understandings, based on Asian, Oceania, and western ways of thinking, of how to improve the new radiation protection system. In order to implement the new ICRP recommendations, NEA and ICRP should further collaborate. To ensure appropriate consideration of specific cultural and socio-political contexts, a 3rd Asian Regional conference is being planned by the NEA.
WELCOME ADDRESSES

Kimihiko Oda
Shizuyo Kusumi
Kazuo Shimomura
Kimihiko ODA
Executive Director for Nuclear Safety, MEXT, Japan

On behalf of the Ministry of Education, Culture, Sports, Science, and Technology (MEXT) of Japan, I would like to express my deep appreciation for my colleague to give me an honourable opportunity of an opening statement in this 2nd Asian Regional Conference on the Evolution of the System of Radiological Protection. This conference is organized by the OECD NEA Committee on Radiation Protection and Public Health (CRPPH), and MEXT has also worked together as a co-organizer. We hosted the first conference successfully two years before. Today, it is our pleasure that we have a second opportunity to host this conference.

Since 1928, the International Commission on Radiological Protection (ICRP) has presented their recommendations and guidelines to the world. Their most recent and important general recommendations were presented in 1990, which is known as ICRP publication 60. This publication contained new basic concepts for the system of radiological protection, therefore, many countries including Japan introduced some of the concepts into their legislation system for radiation protection. Since regulatory authorities are accountable to their nations and stakeholders when they introduce a new concept to present regulations, regulatory authorities sometimes have to wait for sufficient explanation and evidence for the new concept.

The ICRP started to open their draft new general recommendations, the 2005 recommendations, on their internet web site, asking for public comments. I would like to welcome this open minded approach of the ICRP members and hope that the ICRP listens carefully to the voice of regulatory authorities, operators, workers and other concerned people. In addition, I would like to acknowledge the dedication of the persons concerned, including Professor Roger Clarke, the chairperson of ICRP who has played the leading role, and Dr. Yasuhiro Sasaki who has served as a member of ICRP main commission.

The CRPPH created the “Expert Group on the Implications of ICRP Recommendations for a System of Radiological Protection” (EGIR), in order to reflect the opinions from NEA member states regarding the ICRP new draft report. It is recognized that the activities of EGIR are very important for MEXT, also. Moreover, it is very significant for our country that this conference is held as part of the activities of EGIR, and I appreciate the activities of CRPPH.

In today’s meeting, first we are expecting a presentation by Professor Clarke regarding the ICRP new draft report. Then after, some distinguished guests from Asian-Pacific national regulatory authorities such as Korea, China, Australia and Japan, and the academic society and utilities in Japan, will give some comments on the draft report.

I think this conference might be a good opportunity for all the participants to exchange their knowledge and opinions among us with ICRP Chairperson. I wish you an enjoyable stay in my country and hope you bring back some fruitful discussions to your respective countries. Finally I hope that this conference will contribute to the further evolution of the radiological protection system in Asia.
Shizuyo KUSUMI  
Commissioner, Nuclear Safety Commission, Japan

First of all, I would like to express my sincere appreciation for the efforts made by the Nuclear Energy Agency and the Japanese Ministry of Education, Culture, Sports, Science and Technology to organize this timely and important Conference.

As you know, we learned only one year after the discovery of X-rays by Dr. Roentgen that radiation exposure could cause skin injury and depilation. Since then, as the utilisation of radiation increased, it has been understood that scientists and medical personnel handling radiation as well as radiotherapy patients have suffered from radiation-induced leukaemia and solid cancers.

As a result, radiation protection has been recognized as a key issue for the health of both the public and workers whose jobs have a potential for occupational radiation exposure in the peaceful use of nuclear energy.

Since its establishment in 1950, the International Commission on Radiological Protection (ICRP) has made significant contributions to the prevention and reduction of radiation risks for workers and medical personnel who deal with radiation and also for the general public. The ICRP’s evolving radiation protection system and concepts have been described in almost 100 documents since the appearance of ICRP Publication 1 in 1959. I respect the ICRP and those concerned with its activities for making every effort to establish the present radiation protection system on a firm scientific basis.

ICRP recommendations have been widely accepted and serve as the foundation for radiation protection throughout the world. In Japan, ICRP concepts and systems have been used as the basis for developing its national regulatory system.

In this context, I would like to stress that the Committee should kindly consider the importance of continuity of national systems and should continue to develop its recommendations with a firm scientific basis.

Recently, nuclear power generation and the number of nuclear power plants has been increasing rapidly in the Asian region, and the utilisation of radioisotopes and radiation in both medicine and industry has been expanding in almost all countries as well.

Today, globalisation is not limited to the economic sector but also applies to the spread of science and technology. It is therefore important to promote radiation protection based on common principles that are accepted throughout the world. Consequently, the ICRP recommendations have an even greater role in the provision of a fundamental basis for the establishment of national regulatory systems for radiation protection.

Now, I would like to note that the Asian region, in which about 60% of the world population lives, includes many countries, like Japan, where English is neither their mother tongue nor their official language. While English is now an international language, we have often experienced
difficulties in developing precise, clear interpretations of ICRP recommendations and in understanding the true meaning of statements that are crucial for incorporating the recommendations into our national system of radiation protection.

I would like to take this opportunity to ask the ICRP to carefully consider the need to produce documents that can be translated easily and accurately into other languages. Simple and clear descriptions with clear definitions of special terms will make such important recommendations more effective and useful to the people who are not native English speakers.

Finally, I hope all of you understand the contents of the new ICRP recommendations and contribute to making these recommendations more effective and workable.

I expect that ICRP will carefully consider the opinions expressed by member countries in the Asian region and will make the new recommendations more valuable and easily adaptable to national systems throughout the world.
I would like to welcome you on behalf of the Nuclear Energy Agency to this important conference on the evolution of the system of radiological protection. This area is of great interest to radiological protection experts in all NEA member countries. We are very grateful to MEXT for co-sponsoring this conference, and to Professor Roger Clarke, the chairman of the ICRP for the openness and close collaboration that we have enjoyed over the past several years as these new recommendations have been discussed and built. I am sure that we will enjoy a very interesting conference and discussion of this topic.

However, to appropriately frame this work, let me introduce the NEA and its Committee on Radiation Protection and Public Health, the CRPPH. The NEA was created in 1957, and currently has 28 member countries in North America, Europe and Asia. The objectives of the NEA are, broadly, to study the scientific, technical and legal aspects of nuclear energy, and to foster a common understanding of key issues in and approaches to safety.
Today, the NEA has 7 standing technical committees, including the CRPPH, which was the first technical committee created by NEA in 1957. The CRPPH has evolved over the years to best address the radiological protection needs of its member governments.

In recent years, the elements of the Committee’s programme of work have been increasingly inter-related and complementary. In collaboration with the ICRP, the CRPPH has extensively addressed the evolution of the system of radiological protection. In parallel to this, the Committee is developing a regulatory process to coherently implement the ICRP’s recommendations in the context of fulfilling the government’s mandate to protect the public, workers and the environment from radiological hazards, while allowing the beneficial activities that cause radiation exposure. You will hear more of this during the conference.

In looking forward, the CRPPH is also now working to identify emerging issues that could affect radiological protection policy, regulation and application in the next 5 to 10 years. It is hoped to publish a new collective opinion in 2006. Finally, in the more operational areas of emergency management and occupational exposure, the Committee continues to foster the international exchange of lessons and experience, and the improvement of national practices through the INEX and ISOE programmes.
CRPPH Approach:
Build Common Understanding

- CRPPH objective is to assure that new radiological protection recommendations address the needs of policy makers, regulators and implementers
- To accomplish this, the CRPPH:
  - Interacts with the ICRP, an independent body, issuing radiological protection recommendations
  - Provides the assets to build confidence based on common ownership
    - Active partnership of a broad set of communities
    - Consideration of Regional views essential
    - Consideration of existing national policies, socio-political background and cultural context

Throughout its work on the evolution of the system of radiological protection, the Committee’s objective has been to assure, through broad discussion with relevant stakeholder groups, that the new ICRP recommendations take appropriate account of policy-makers, regulators and practitioners needs. To accomplish this, the CRPPH has actively engaged with the ICRP to provide constructive comments and dialogues on key issues. An essential part of this is looking for as broad a base of relevant stakeholders as possible. It is for this reason that this conference, and the 1st Tokyo conference, which focus on views from the Far East and the Pacific Region, is so essential to the recommendations development process.

More concretely, the CRPPH Programme of Work has addressed the new recommendations development in a systematic fashion. By analysing draft material that the ICRP has most kindly supplied, we have tried to provide feedback to the Commission on user’s needs. By developing complementary concepts, such as the Process of Regulatory Authorisation, the CRPPH is trying to assist in the implementation of ICRP recommendations in a coherent, transparent fashion. And by studying how stakeholders interact in decision-making processes, and the implications that these lessons hold, the CRPPH has been working to develop understanding and tools to help governments develop and implement policy and regulations. All these, through broad stakeholder discussions, should lead to a new system of radiological protection that is accepted and agreed upon, and will thus be sustainable.
Objectives for this Tokyo Conference

- To present the new draft ICRP recommendations, and dialogue with the ICRP Chair, particularly with respect to Regional views of new concepts and their application in the Far East Asia and Pacific Regional Context
- Discuss recent CRPPH work on the Process of Regulatory Authorisation as a compliment to ICRP Recommendations, particularly its application in this Regional context
- Discuss the NEA’s most recent work on processes for the involvement of stakeholders in radiological protection decision making, and discuss stakeholder involvement processes in this Regional context

The New Steps
Build Common Understanding

ICRP issues Draft Recommendations:
- General
- Protection of Non-Human Species

CRPPH provides active partnership with a broad stakeholder community:
- Explore implications
- Discuss new concepts
- Road test

In this process, the Japanese, Korean and Australian Members of the NEA have actively participated, and are supportive of this work. The specific views from the Far East Asia and the Pacific Region were successfully addressed by the 1st Tokyo Conference on the Evolution of the System of Radiological Protection, held in October 2002. The success of this event and the development of new draft ICRP recommendations have led the CRPPH to organise a 2nd Tokyo Conference on this subject. The objectives of this conference, outlined on this slide, are broadly to provide a forum for relevant stakeholders from the Region to provide feedback to and dialogue with the ICRP and the NEA on the essential topics of the new ICRP recommendations, on the CRPPH Process of Regulatory Authorisation, and on the implications of stakeholders in decision-making processes.

I think that it is safe to say that the process of developing new ICRP recommendations has been very much geared towards identifying and addressing the views, concerns and needs of stakeholders. I am sure that this ongoing process will lead to broad agreement on the next steps forward in our profession, and will serve as a shining example of how the making of important radiological protection decisions should be addressed in the future. I wish us all a very useful, interesting, and enjoyable conference. Thank you for your attention.
SESSION 1

Towards the New System of Radiological Protection

Chair: Yasuhito Sasaki
THE NEW ICRP SYSTEM OF RADIOLOGICAL PROTECTION

Roger Clarke
Chair, ICRP

The new ICRP Draft Recommendations represent an evolution of the radiological standard and not a revolution after recommendations in 1990.

The principal features of the new recommendations include quantities in radiological protection, biological aspects, the general protection system, quantitative recommendations, optimisation, medical exposures, potential exposures, criteria for exclusion from the recommendations, and radiological protection of the environment. Quantitative aspects will be covered by a report from Committee 2. Biological aspects which include the dose response relationship will be covered by two reports from Committee 1. The new recommendations are expected to be published in 2005, perhaps as Publication 100.
The major changes are:

New values of \( w_R \) are proposed following a review of RBE data for:
- For protons, \( w_R \) is reduced from 5 to 2;
- For neutrons < 1 MeV, \( w_R \) is reduced by \( \approx 2 \) and recommended in the form of a continuous curve.

New values of \( w_T \) are proposed following a review of risk data for somatic and hereditary defects:
- For gonads, \( w_T \) is reduced by \( \approx 4 \) following UNSCEAR 2000.

The \( W_R \) histogram and function for neutrons are shown as curves A and B in the graph, respectively. In accordance with the new change of values as mentioned, we gain the 2005 proposed function, curve C. The mathematical term is as shown at the bottom.

Proposed \( W_T \) values are given in Annex A of the draft recommendations. In the 1990 recommendations, the highest value was assigned to the gonads. However it has been decreased in the draft recommendations following a review. Also according to the review, risk to the female breast is now in the highest group. Values for skin and bone surface remain the same.

We continue to use the quantity of effective dose. However new radiation weighting factors are proposed based on a review of RBE data. Major changes include reductions of the values. For protons, \( W_R \) changes from 5 to 2; for neutrons < 1 MeV, \( W_R \) is reduced by about 2. In addition, new values for tissue weighting factors, \( W_T \), are proposed following a review of risk data for somatic and hereditary defects.
Concerning deterministic effects, the word “deterministic” is ambiguous, and is now replaced by “tissue reactions”. When we are looking at tissue reactions, the effective dose absorbed dose in Gy-Eq is introduced for tissue reactions to avoid confusion in translation. Non-cancer effects are not included because evidence of occurrence is not sufficient at present.

The remainder Wt of 0.1 is given to the dose averaged equally over the following 14 tissues or organs listed in the slide, using a simple linear approximation.
The 2005 system of protection includes the concepts of justification, quantitative recommendations and the principle of optimisation. With regard to the latter, it is not intended to put some sort of maximum restriction under which the optimisation is set, as was done in Publication 60.

Justification is for all controllable sources. Though ICRP has been asked to justify practices in some countries, ICRP is not responsible for these practices. Each country must do its own justification based on country-specific reasons. Justifying net benefit is primarily the task of the appropriate authorities, of which radiological considerations are only one input. ICRP recommendations apply to practices only when declared justified and to natural controllable sources. Patient exposures need separate consideration.

In the next section, we will explain these concepts.
The public is protected from a single source in all exposure situations through the use of the source-related dose constraint, which is the maximum dose from a single source. In contrast, the public is protected from all regulated sources, but only in normal situations, through the use of the individual-related dose limit. However, whereas the regulator authorises the maximum effluent from a single source, the dose limit cannot be used by the operator or regulator to set this value. Both the constraint and optimisation are equally applied for non-normal situation.

The dose constraint is also used to protect the worker from a single source in all situations. The dose limit is used to provide protection from all regulated sources in normal situations. Operators regulate operations based on the calculation of effects from single sources.

The source-related dose constraints are established for the most exposed individuals. Values can be set by ICRP, and by International Agencies.
In order to reduce the number of different constraints, fewer can be set from existing numerical values in order to maintain continuity. Accordingly, they can be defined in terms of multiples or fractions of background in order to achieve simplicity. However, since values are a necessary but not sufficient criterion for protection, optimisation must also be introduced.

In using natural background as a reference, Ra is excluded because it is technologically enhanced and controllable. The ICRP proposes to set increased action for higher doses and decreased action for lower doses.

A maximum constraint of 100 mSv in a year is proposed for emergency workers; evacuation or relocation in emergencies; high levels of existing controllable exposures; and situation involving information, training, and monitoring. A constraint of 20 mSv is proposed for occupational exposure; sheltering and stable iodine in emergencies; existing exposures such as radon, etc. A value of 1 mSv is proposed for normal situations; no information or training; or no individual dose assessment. Lastly, we have 0.01 mSv as minimum for any constraint, below which justification is unnecessary.
We propose to adapt the values for radon given in Publication 65 as constraints. It is expected that the national authority will establish a lower level. Optimisation for radon will be different in each country.

Quantitative recommendations include individual limits, which already exist in the Basic Safety Standards.

There is no change in dose limits for public and workers. Therefore, national authorities will likely not need to change the basic safety standard concerning dose limits.
Concerning optimisation, there is a duty to achieve a higher level of protection than that provided by the dose constraints alone. This is the responsibility of operators and national authorities.

ICRP advocates optimisation of protection as part of a successful radiological protection programme. It necessitates co-operation between all parties involved who must subscribe to safety culture as defined in the BSS.

With respect to stakeholder involvement, it is necessary for national authorities and operators to consult the most directly concerned, including representatives of those exposed.

THE 2005 SYSTEM OF PROTECTION

JUSTIFICATION

QUANTITATIVE RECOMMENDATIONS

OPTIMIZATION

There is a duty to achieve a higher level of protection
-the responsibility of operators and national authorities

SAFETY CULTURE

Optimization of protection is part of a successful radiological protection programme

It necessitates co-operation between all parties involved who must subscribe to safety culture as defined in the BSS.

STAKEHOLDER INVOLVEMENT

It may be better to consult the most directly concerned, including representatives of those exposed, in determining or negotiating, optimized protection

ICRP can give guidance, but it is a Task for Operators and National Authorities
THE PROTECTION OF GROUPS

Collective dose is defined as

\[ S = \int_{0}^{\infty} \int_{0}^{E_{\text{max}}} \frac{E(t) dN}{dE} dt \]

It is of limited utility as it aggregates information excessively.

For decision aiding, the information should be presented as disaggregated data – the Dose Matrix.

For the workforce, the minimum information is the number of workers and their mean dose.

ICRP recommends that its system of protection not be applied to materials with activity concentrations of artificial radionuclides below 0.01 Bq/g for alpha, or 0.1 Bq/g for beta and gamma respectively.

With respect to the protection of groups, the collective dose is of limited utility as it aggregates information excessively. For decision aiding, the information should be presented as disaggregated data – the dose matrix.

PROTECTION OF THE PATIENT

GENERIC JUSTIFICATION

The radiological procedure must provide the necessary information to improve diagnosis or treatment.

APPLICATION OF THE PROCEDURE TO AN INDIVIDUAL PATIENT

Application of the procedure to an individual patient should be justified.

OPTIMIZATION

Diagnostic reference levels are indicators of good practice.

CONSTRAINTS

Needed for comforters and carers.

As for the benefit of the patient, diagnostic x-rays are one example. On the other hand, it cannot be justified to do CT-scans for everyone yearly. Diagnostic reference levels are indicators of good practice and an aid for optimisation. For medical practitioners, ICRP can provide generic guidance.
Concerning potential exposures, the effective dose should not be used if it is greater than 100 mSv, as there can be tissue reactions (formerly “deterministic effects”) in organs.

ICRP aims to develop a policy and a framework for environmental radiological protection, including the standard for a reference environment.

Release of the draft text on the web occurred in June 2004. Supporting documents will be prepared for Beijing in October 2004. All comments will be considered by April 2005, and the revised text will be finalised sometime in 2005.
IMPLEMENTING THE NEW SYSTEM: THE CRPPH CONTRIBUTION TO THE
REGULATORY PROCESS OF AUTHORISATION

Salvatore Frullani
Istituto Superiore de Sanita, Italy, and CRPPH Member

NEA CRPPH Expert Group on
the Regulatory Application of
Authorisation (EGRA)

Status of Ongoing Work

Report by the Expert Group Chair: Salvatore Frullani

This work was begun by the Expert Group on
the Evolution of the System of Radiological
Protection.

EGRA members
Salvatore FRULLANI (ISP-Rome) - Chair
Marissa BAILEY (USNRC-Washington)
John R. COOPER (NRFB - Chilton)
Stephen FENWELL (RPI-Dublin)
Piritta HANNINEN (STUK-Helsinki)
Helena JANZEKOVIC (SNS-Ljubljana)
Andre JOUVE (MEP-Paris)
Hirohiko KOBAYASHI (JNCI-Ibaraki)
Jan SALAVA (SUJ-Praga)
Martin STEINER (BFS-Oberschleizheim)
Anthony D. WIDJON (MEA-Vienna)
Bing CHANG, Edward LAZO, Stefan MUNZIGL,
Hans RIOTTE (NEA-Parka)
Concerning the background of this activity, there was a critical review to identify where Publication 60 could be usefully improved. The Expert Group on the Evolution of the System of Radiological Protection suggested an “umbrella approach” for the entire system of radiological protection.

An ideal system of radiological protection should provide guidance on virtually all types of exposure. This would give the positive message that the regulatory control flowing from an internationally agreed-upon system of radiological protection considers all sources, and then regulates them in a logical fashion.

The reason for “?” is indicated on a later slide.

Sources that do not fall within the definition of controllable are excluded from regulatory control. In its restated policy, the Commission defines sources and exposures which are to be excluded from the system of radiological protection.

Background: CRPPH Views

- Critical Review
  - Identified Where Publication 60 could usefully be improved

- The Way Forward
  - Suggested an “Umbrella” Approach

- A New Approach to Authorisation
  - Demonstrated that the CRPPH proposal could improve the situation

Background: EGRP (CRPPH) view

... an “ideal” system of radiological protection should provide guidance on virtually all types of exposure. Initially (?), all known radiation sources and exposures would be considered to be included within the system of radiological protection.

This would give the positive message that the regulatory control flowing from an internationally agreed-upon system of radiological protection considers all sources, and then regulates them in a logical fashion.

Background: ICRP memorandum - J.Rad.prot. 23 (2003)

The Commission intends its system of protection to apply to the deliberate introduction of a new controllable source or the continued operation of a controllable source that has deliberately been introduced or to controllable natural sources.... Sources that do not fall within this definition of controllable are excluded from regulatory control.

In its restated policy the Commission defines what sources and exposures are to be excluded from the system of protection (?)....
Background: Lanzarote Forum

- Broad Consensus on need to simplify ICRP 60
  - Publication 60 suggests Optimisation below limits, action above intervention levels, recommending abatement above radon action levels
  - Concepts of Practices and Interventions ambiguous
  - Exclusion and Exemption applied to natural and artificial radionuclides?
  - Need coherent basis for numerical criteria

- Umbrella approach suggested by the CRPPH seen as a good model for regulatory framework

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Background: ICRP draft Recommendations (June 2004)

- (25) Sources and exposures that are not excluded are within the scope of the system of protection (or within the scope of Recommendations or within the system of authorization - in its narrow “licensing” or “permitting” sense?)

Certainly cosmic rays and natural background exposures are not authorized but are they out of the system of radiological protection even if they could be out of the system of radiological control?

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EGRA Terms of Reference

Develop a more detailed understanding of the regulatory concept of Authorisation, from a conceptual and practical standpoint, to clarify for radiological protection regulatory authorities and practitioners how such a concept could be applied, and to help to assure a harmony between ICRP recommendations and their practical application.

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Some agreements and discussions were done at the Lanzarote forum, which lead to a broad consensus on the need to simplify and update ICRP 60, as Dr. Roger Clark explained. The CRPPH suggested an umbrella approach for regulatory framework.

In the draft recommendation, sources and exposures that are not excluded are within the scope of the systems of protection, recommendations or authorisation. There is a question as to whether cosmic rays and natural background exposures, which are not authorised, are out of the system of radiological protection even if they could be out of the system of radiological control. The radiological protection system should include all exposures and sources.

The aim of the EGRA terms of reference is to develop a more detailed understanding of the regulatory concept of authorisation, from a conceptual and practical standpoint, to clarify for radiological protection regulatory authorities and practitioners how such a concept could be applied, and to help to assure a harmony between ICRP recommendations and their practical application.
Terminology

The EGRA recognised the difficulties of selecting “the best” terminology to express its ideas, because:

- Certain words have specific meanings in other international and national contexts
  - but many such words already have different meanings in different texts
- Certain words are difficult to translate into languages other than English
  - but concepts can be more easily translated into appropriate national terminology

There is a problem regarding terminology. The EGRA recognised the difficulties of selecting “the best” terminology to express its ideas, as certain words have specific meanings in various international and national contexts, and are difficult to translate into languages other than English. However concepts can be more easily translated into appropriate national terminology.

On the other hand, the BSS uses the word “Authorisation” in a narrow sense to mean permission granted in a document by the regulatory authority to a legal person who has submitted an application. The authorisation can take the form of a registration or a license.

The EGRA specifically wishes to avoid the proliferation of common words used in a narrowly-defined sense, thus it uses terms in their broad, general sense. The main focus points are that the regulatory process of authorisation is taken to indicate a broad path through which governments and regulatory organisations decide what regulatory controls, if any, should be applied. Regulatory control is taken to indicate the full range of possible regulatory actions.

On the other hand, the BSS uses the word “Authorisation” in a narrow sense to mean permission granted in a document by the regulatory authority to a legal person who has submitted an application. The authorisation can take the form of a registration or a license.
**Conceptual Approach**

CRPPH reports are **CONCEPTUAL** in nature, not **STATUTORY**

- It is not intended that this text be taken as direct input to national regulations or international statutes
- The key concept of this report is the **REGULATORY PROCESS OF AUTHORISATION**

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**The Regulatory Process of Authorisation: Key Aspects**

Concerning the key aspects, the government or regulatory authority addresses all sources and exposure situations, which gives a positive and proactive message. One approach and rationale for all sources and exposure situations seems to be simplification.

- The government / regulatory authority addresses **ALL Sources and Exposure Situations**: Positive, proactive message
- One approach and rationale for **ALL Sources and Exposure Situations**: Simplification
  - Planned
  - Accidental
  - De facto

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**The Regulatory Process of Authorisation: Key Aspects**

Although this does not imply that all sources and exposures situations will be subject to regulatory controls, it does imply that some level of regulatory judgment is applied to all known sources and exposure situations.

- Although this does not imply that all sources and exposures situations will be subject to regulatory controls, it does imply that some level of regulatory judgement is applied to all known sources and exposure situations.

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The Regulatory Process of Authorisation: Universality

- This umbrella process would be consistent with approaches to risk management in other areas. Common mechanisms simplify actions and facilitate resource allocation.

The Regulatory Process of Authorisation: Method

- Constrained optimisation is used in all situations: Easy to explain.
- Optimisation is stopped when the optimum protection is identified: No need for de facto, generic endpoints; but can establish numerical criteria to facilitate a graded approach.
- Residual doses from optimisation are agreed to be ALARA: Engages stakeholders as appropriate.

The Regulatory Process of Authorisation: Advantages

- Simplicity
  - No need for complex, specifically-defined terms (practice, intervention, exclusion, exemption, clearance)
- Coherence
  - Single framework and rationale (optimise below constraint)
- Transparency
  - Clear process, facilitates stakeholder involvement

Constrained optimisation is used in all situations, and is easy to explain. Optimisation is stopped when the optimum protection is identified. There is no need for de facto, generic endpoints; but numerical criteria can be established to facilitate a graded approach. Residual doses from optimisation are agreed to be ALARA. It engages stakeholders as appropriate.

There are the following advantages in this general approach: Simplicity, since there is no need for complex, specifically-defined terms; Coherence, since a single framework and rationale is used; and transparency, since it is a clear process that facilitates stakeholder involvement.
This is a general scheme of the regulatory process of authorisation. At the end, a certain source or exposure belongs to one of the following three classes: <Not justified>, <Subject to regulatory controls> or <Not subject to regulatory controls>.

All sources and exposure situations that could potentially come to the attention of the government and/or regulatory authorities are taken into consideration.

Sources or exposures known by authorities must be classified and screened, according to appropriate judgment. Basic screening questions include:

- Is this clearly not justified? If yes, it will be not justified.
- If not, is it controllable or worth while controlling? If not, it will not be subject to regulatory controls.
- Otherwise, a full analysis is needed.
This is a classification of source characteristics by Osborne-Turvey based on the request of EGRA. Source characteristics are classified into five levels. Each characteristic is scored according to how it affects the source and the exposure. Groups marked with an asterisk are double counted in the stakeholder calculation.

<table>
<thead>
<tr>
<th>Group</th>
<th>Possible Options</th>
<th>Option Value Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation</td>
<td>Low = 1, High = 4</td>
<td></td>
</tr>
<tr>
<td>Security</td>
<td>Public = 4, Other = 1</td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td>Natural = 1, Artificial = 4, Other = 1</td>
<td></td>
</tr>
<tr>
<td>Application</td>
<td>Method = 0, Industrial = 3, Research = 3, Other = 3</td>
<td></td>
</tr>
<tr>
<td>Contaminated</td>
<td>Sealed = 1, Unsealed = 3, Nochance = 1</td>
<td></td>
</tr>
</tbody>
</table>

*To be double counted in stakeholder calculation.
Source Character Score = Source expressed as percentage of maximum (31) =

This is a table of classification for exposure characteristics. This classification is similar to the classification for sources.

<table>
<thead>
<tr>
<th>Group</th>
<th>Options</th>
<th>Option Value Selected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary</td>
<td>Required = 4, Involuntary = 4, Other = 1</td>
<td></td>
</tr>
<tr>
<td>Exposed</td>
<td>External = 1, Internal = 4</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>Normal = 1, Poisson = 4</td>
<td></td>
</tr>
<tr>
<td>Beneficiary</td>
<td>Poor = 4, Reasonable = 1, Good = 0</td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td>Chronic = 4, Other = 1</td>
<td></td>
</tr>
<tr>
<td>Risk</td>
<td>High = 4, Medium = 3, Low = 0</td>
<td></td>
</tr>
<tr>
<td>Receptor</td>
<td>Worker = 1, Patien = 4, Public = 5, Other = 0</td>
<td></td>
</tr>
<tr>
<td>Number Exposed</td>
<td>&gt; 10000, 1000-10000, 100-1000, 1-100, Other = 1</td>
<td></td>
</tr>
</tbody>
</table>

*To be double counted in stakeholder calculation.
Exposure Character Score = Score expressed as percentage of maximum (31) =

In constrained optimisation, technical and social input to the decision-framing and decision-making processes is used. This is the normal optimisation process according to the ICRP scheme.
Decisions on sources not justified are based on social considerations with technical input after simple screening, or more detailed analysis. Social and/or technical change may provoke the re-analysis of sources or exposures previously judged not justified.

After analysis, the optimum protection solution will generally involve regulatory controls, graded to address safety concerns. Social and/or technical change may provoke the re-analysis of regulatory controls previously judged to be necessary. After a couple of procedures, it will be sent back for further analysis.

The optimum protection solution may be to not impose regulatory controls. Regulatory controls and/or conditions may be imposed, up to the release point, on processes creating radioactive materials for release. Materials so released will not be "forgotten", but cannot be recovered.
The World of Sources and Exposures

Sources and exposure situations not subject to regulatory control can re-enter the process if justified concern arises.

As for the process of regulatory authorisation, current concepts can be identified in this process, although they are not necessary or explicitly named.

This is a chart which is commonly called exclusion. Exclusion is based on controllability or on practical radioactivity. If the sources or the exposures don’t have “practical” radioactivity, they are not subject to regulatory controls.
Exemption is based on optimisation. In this case, it is necessary to be authorised by a full analysis at first; however it cannot be subject to regulatory controls after the analysis.

Clearance is also subject to regulatory control. After the analysis, some sources may not be subject to regulatory controls.

In conclusion, the key point is that regulatory authorisation is simply to describe the process details that regulatory authorities follow to carry out their mandate to judge, either specifically or generically, all radiation sources and radiation exposure situations of which they are aware. All is within the regulatory system of radiological protection, even if the majority of the cases are out of the system of radiological control.

Conclusion
- The key point: Regulatory Authorization is simply to describe the process details that regulatory authorities follow to carry out their mandate to judge, either specifically or generically, all radiation sources and radiation exposure situations of which they are aware.
- All is within the regulatory system of radiological protection, even if the majority of the cases can be instead out of the system of radiological control.
Conclusions

- The EGRA will continue to work on its report taking now into account the ICRPR draft.
- Clarifications needed in several parts but the general scheme seems to be solid. Examples to be added.
- Hopefully this approach of a different field of regulatory application of radiological protection and radiological control will be reflected in ICRP Recommendations.
SESSION 2

Regional Views on the New System of Radiological Protection

Chairs: Salvatore Frullani and Tomoko Kusama
Views from the Japanese Regulatory Authority

These are the views from one of the Japanese regulatory authorities. There are several ministries which are concerned with the regulation of radioactivity.

Views from Regulatory Authority 1

Regulatory authorities usually face the question “How do we introduce a new concept for regulation?” when a new guideline is published.
This is the process of radiation protection policy making alongside the international standards. After the recommendations or basic standards are published by international agencies, the radiation council starts discussions on how the recommendations and the guidelines are applied to the Japanese system. Reports are made after the discussions. After these processes, the regulatory authority can start the new regulation.

The radiation council defines the values which should be made into law. The purpose of the council is to unify and harmonise technical standards for radiation protection from various regulations. The radiation council consists of a chair and 18 members, and a general administrative group.

This is the relationship between the radiation council and other regulatory authorities. The radiation council has some consultant function for technical matters. The Nuclear Safety Commission makes some political decisions. When the regulatory authority tries to apply the technical standards, they must consult with the radiation council. The council may then give advice to regulatory authorities.
It is most important for the regulator to have accountability to the public and operators.

Regulatory authorities need to answer three kinds of questions: How do we apply new concepts for regulation; why do we need to introduce new concepts for regulation; and is it feasible and/or acceptable for everybody to apply new concepts for regulation? We need to persuade them.

The ICRP’s new recommendations include the consolidation of 11 former recommendations, a paradigm shift for radiation protection, dose constraints, exclusion levels, and others.
Outline of ICRP New Recommendation

- Summing up of former 11 recommendations
- Paradigm shift(?) for radiation protection
  - From: Justification → Optimization → Dose Limit
  - To: Justification → Numerical Values → Optimization
- Dose constraints
- Exclusion levels
- Others
  - Change of terminology, Environment etc.

11 Reports and 30 numerical values

This table shows the consolidation of 11 reports and 30 numerical values, to make them into only 4 values of dose constraints.

<table>
<thead>
<tr>
<th>Maximum constraint</th>
<th>Situation to which it applies</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>In emergency situations, for workers, other than for saving life or preventing serious injury or preventing catastrophic circumstances, and for public evacuation and relocation, and for high levels of controllable existing exposures. There is neither individual nor societal benefit from levels of individual exposure above this constraint.</td>
</tr>
<tr>
<td>20</td>
<td>For situations where there is direct or indirect benefit for exposed individuals, who receive information and training, and monitoring or assessment. It applies into occupational exposure, for countermeasures such as sheltering, iodine prophylaxis in accidents, and for controllable existing exposures such as cadmium, and for comforters and carers to patients undergoing therapy with radionuclides.</td>
</tr>
<tr>
<td>1</td>
<td>For situations having societal benefit, but without individual direct benefit, and there is no information, no training, and no individual assessment for the exposed individual in normal situations.</td>
</tr>
<tr>
<td>0.01</td>
<td>Minimum value of any constraint</td>
</tr>
</tbody>
</table>

Even though the current ICRP recommendations have few explanations on the maximum constraints, the regulator must explain this concept of radiation protection to public.
Outline of ICRP New Recommendation

- Summing up of former 11 recommendations
- Paradigm shift(?) for radiation protection
  - From: Justification → Optimization → Dose Limit
  - To: Justification → Numerical Values → Optimization
- Dose constraints
- Exclusion levels
- Others
  - Change of terminology, Environment etc.

Paradigm Shift for Radiation Protection?

There seems to be a paradigm shift in the system of radiation protection. Current recommendations start from justification, move through optimization, and end with dose limitation. The proposed recommendations start from justification, through consideration of numerical values and end with optimization.

Under new paradigm – worse prediction -

The responsibility for judging the justification of practices usually falls on government. However, in the worse case, the government may hesitate or be more careful to introduce new radiation technologies. Numerical values such as maximum constraints, exclusion levels, etc. are already defined without sufficient explanation. There is a tendency to make decisions on the values without considering its real meaning or background. Operators and the appropriate national authority have responsibilities for optimizations. However, it may cause unconscious violations and high cost for excessive protective preparations, due to a lack of practical application models.
Outline of ICRP New Recommendation

- Summing up of former 11 recommendations
- Paradigm shift(?) for radiation protection
  - From: Justification → Optimization → Dose Limit
  - To: Justification → Numerical Values → Optimization
- Dose constraints
- Exclusion levels
- Others
  - Change of terminology, Environment etc.

About dose constraints

- We need concrete explanation and evidence to our nations and stakeholders:
  - Why can we set 100 mSv as the maximum constraint for emergency case?
  - Why can we set 20 mSv to maximum constraint for worker?
  - Why can we set 1/few mSv of NORM as the maximum constraint for public?
  - Why can we ignore under 0.01 mSv?
  - How can we calculate maximum constraint for radon from 10 mSv/y?

Concrete explanations and evidence are needed. Why can we set 100 mSv as the maximum constraint for emergency cases, and 20 mSv for workers? Why can we set 1/few mSv of NORM as the maximum constraint for the public? Why can we ignore doses under 0.01 mSv? How can we calculate a maximum constraint for radon from 10 mSv/y? Detailed but simple explanations are required.

About dose constraints

- It is needed to make clear the relationship between dose limit and dose constraint in new concept.
  - How do we distinguish to apply dose limit and dose constraint for public?
  - How can we define and distinguish "single source" from many chaotic practical cases?
  - How do we recognize the difference of basic philosophy between dose limit and dose constraint.

The relationship between the dose limit and dose constraint in the new recommendations needs to be clarified. Specifically, how do we distinguish the dose limit from the dose constraint for the public? How can we define and distinguish a "single source" from many chaotic practical cases? How do we recognise the difference in basic philosophy between dose limits and dose constraints? Those kinds of questions should be clearly explained by ICRP experts.
Outline of ICRP New Recommendation

- Summing up of former 11 recommendations
- Paradigm shift(?) for radiation protection
  - From: Justification → Optimization → Dose Limit
  - To: Justification → Numerical Values → Optimization
- Dose constraints
- Exclusion levels
- Others
  - Change of terminology, Environment etc.

Exclusion level

<table>
<thead>
<tr>
<th>Nuclides</th>
<th>Exclusion activity concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artificial alpha emitters</td>
<td>0.01Bq/g</td>
</tr>
<tr>
<td>Artificial beta/gamma emitters</td>
<td>0.1Bq/g</td>
</tr>
<tr>
<td>Head of chain activity level, $^{238}$U,$^{232}$Th</td>
<td>1.0Bq/g</td>
</tr>
<tr>
<td>$^{40}$K</td>
<td>10Bq/g</td>
</tr>
</tbody>
</table>

According to the draft report, the definitions for each exclusion level seem to be clear.

Exclusion level

-How do we think about NORM ?-

<table>
<thead>
<tr>
<th>Nuclides</th>
<th>Activity (Bq/g)</th>
<th>Industrial use</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{40}$K</td>
<td>0.0117%</td>
<td>$^{187}$Re: KOH(21Bq/g), KCl(15.9Bq/g) Huge amount of its compounds are widely used without conscious</td>
</tr>
<tr>
<td>$^{87}$Rb</td>
<td>27.83%</td>
<td>$^{176}$Lu: Not so used</td>
</tr>
<tr>
<td>$^{147}$Sm</td>
<td>14.99%</td>
<td>$^{147}$Sm: Broadly used for electric material</td>
</tr>
<tr>
<td>$^{134}$La</td>
<td>2.59%</td>
<td>$^{134}$La: Not so used</td>
</tr>
<tr>
<td>$^{187}$Re</td>
<td>62.6%</td>
<td>$^{187}$Re: Small used for catalyst etc.</td>
</tr>
</tbody>
</table>

However, what do we think about NORM? These isotopes exist naturally, but they are also used for industrial purposes. There is no solution or answer for this question in the draft report.
Conclusion

- Regulatory Authority has Accountability and ICRP member has Responsibility for new concept.
- Following more detailed guidance need to be prepared (by ICRP members) in order to introduce new concept to regulation in near future.
  - Dose constraint
  - Usage of dose matrix on optimization process
  - Potential exposure
  - Stakeholder involvement
  - Protection of the environment

In conclusion, regulatory authorities have accountability and the ICRP has responsibility for the new concepts. More detailed guidance needs to be prepared by ICRP members in order to introduce new concepts like dose constraint, etc. into regulations in near future.
Here, I will give a presentation focusing on dose constraint.

Though ICRP advocates that its new recommendations are not a revolution, but evolution, it seems to be a drastic change in the radiological protection system. In Publication 60, the meaning of dose constraint is rather weakly expressed. However in the new recommendations, justification is almost out of the protection system, whereas constraints become more fundamental than dose limits. Optimisation of protection from a source comes in the end, complementing the constraints and limits. Exceeding a constraint may be a statutory offence.
Different situations are included in these maximum constraints, which may cause confusion for us.

There are differences in normal, emergency and controllable exposure situations. Maximum constraints are defined by ICRP. Constraints are to be defined by the national authority, taking feasibility into account. In normal situations, optimisation will be applied below the dose constraints and as low as reasonably achievable. However in emergency and controllable exposure situations, optimisation will be applied below action and intervention levels, where no further reduction is required.

It is strange that the minimum constraint of 0.01 mSv/y, below which no more action for reduction is required, appears in the table of maximum constraints.
Dose limits have been a primary target not to be exceeded, with optimisation performed below the dose limits as low as reasonably achievable considering the effect of several sources and. Now it is proposed that a certain maximum constraint set for each single source should be optimised as low as reasonably achievable, with optimisation limited to a single source.

The maximum constraint is proposed to be 1 mSv/y, therefore the actual constraint must be below 1 mSv/y, which is stricter than current one. Accordingly, it will require additional cost to meet the new requirement in many facilities.

Another problem is the double control by constraints and dose limits. There will be two kinds of controls. The first is constraints; the second is dose limits.
Though ICRP places emphasis on individual control, dose limits rather than constraints are the quantity used for individual protection. In addition, ICRP should leave detailed procedures to the national authority, as is mentioned in Summary 21 that ICRP advice has to be of a general and international nature. The commission cannot provide direct regulatory or managerial texts. Accordingly dose constraints should not be targets but just means to secure the dose limits.
ICRP recommendations are the fundamental view when we carry out radiation protection in nuclear power plants, and we have respected the recommendations so far. The Man-Sv/unit of Japanese LWRs has been sharply reduced to present levels by various measures based on the principle of ALARA. However, in order to decrease levels further, longer operation periods and reduction of periodical inspection items, etc. are the most effective measures. Traditional measures also should be adopted as appropriate.
Number of workers exceeded 20mSv/year

This graph shows the number of workers whose dose exceeded 20 mSv/y. Publication 60 was introduced into Japanese regulations in April 2001. Following this, 20 mSv/y averaged over five years became a management target. Although the number of workers who exceeded 20 mSv/y decreased, the managing effort was not an easy job in the plant where large-scale modification works, such as primary system piping replacement (SG replacement, and shroud replacement) were performed.

In the new recommendations, it is said that the public and worker dose limits will remain as it is in Publication 60. We welcome ICRP’s decision on this. We hope these dose limits should be taken in the new recommendations, as well as maintaining the radiation protection system based on dose limits. Specifically, 50 mSv/y is an important limit to allow excellent work with flexibility in the plants.

Dose limits should be maintained as the main system

■ ICRP’s decision to maintain dose limits in the new recommendations is welcome,
■ Best of all, the dose limit of 50mSv/y is essential to perform effective work with having flexibility in the plants.

As for the worker, individual dose monitoring is carried out using a dosimeter, unlike the public, and the data is totalled nation wide in Japan. Therefore there is no necessity to introduce the dose constraint in order to respect the dose limit of 50 mSv/y. Moreover, if 20 mSv/y is introduced into Japanese regulation, about 15-18 mSv/y will be set as a management target in the facilities, and plant operation will become very difficult.

About dose constraint for workers(1)

■ Every worker has dosimeter.
  But…Why dose constraint?
■ What are the merits of introducing that?
■ Dose constraint of 20mSv/y will cause many difficulties for plant operation.
About dose constraint for workers(2)

■ In what case dose constraint for workers should be applied, and in what case not?
■ The clear criterion for usage of dose constraint is needed for better understanding.
■ Dose constraint for workers, if necessary, must be 50 mSv/y in accordance with dose limit.

Although we think it’s appropriate to continue to use the conventional dose limits of 50 mSv/y and 100 mSv over 5 years for workers, we would like to confirm the following point: in what case should dose constraints for workers be applied, and in what case should they not be applied? A clear criterion for usage of the dose constraint is needed for better understanding. The meaning of the single source is also ambiguous for a nuclear power station consisting of two or more plants.

About dose constraint for public(1)

■ In Japan, target dose 0.05 mSv/y, like dose constraint, has been applied to the periphery of nuclear power station by NSC for about three decades,
■ So even if multi stations, It is certain <1 mSv/y.
■ And the problem has not occurred by the management based on dose limit until now.
■ Do we need to apply new system in Japan?

In accordance with ALARA principles, the public dose is far less than 1 mSv/y. In the case of close location of multiple stations, we can carry out dose evaluation individually and check that the 1 mSv/y dose limit is respected. It is not appropriate to apply the dose constraint of, for example, 0.3 mSv/y to stations in Japan. The target dose of 0.05 mSv/y has been applied at the periphery of the nuclear power station by the Nuclear Safety Commission for about three decades. It has served as a substantial dose constraint on the plant design until now.

About dose constraint for public(2)

■ People might think “Radiation risk has increased because dose limit value was reviewed smaller” It’s misunderstanding but possible.
■ So enough explanation to the public will be needed to avoid them having mistakes.
■ In what case dose constraint for public should be…? Same Q as workers(2)

When a dose constraint value of one or less is recommended, people might think that radiation risk has increased because the dose limit value has been decreased. Sufficient explanation to the public will be needed to avoid misunderstandings. I think it is appropriate for us to continue to use the conventional dose limit of 1 mSv/y. However, with regards to the dose constraint for the public, it is not clear how the new values should be applied.
LNT and radiation risk

- By applying the LNT hypothesis strictly, the very small quantity of exposure also gives the public an unnecessary feeling of fear towards radiation.
- As suggested by research of HRBA, certain exposure level (several mSv/y) in which no radiation influences are observed is not important as a matter of radiation protection.
- Paying attention to the results of comprehensive researches, we expect to reflect these to the ICRP recommendations.

Environmental radiation protection

- Realistic parameters and assumptions should be adopted to the study to avoid overestimation.
- The fact that no radiation influences on fauna and flora are observed in the HBRA might be valuable data for the study.
- A balanced discussion concerning radiation and other materials (e.g., chemicals) as environment effect factors is expected.

Summary

- No needs for dose constraints in Japan.
- The clear criteria for usage of constraints.
- The main system= dose limits. It’s practical.
- What’s the single source?
- Paying more attention to the results of comprehensive researches is expected.
- A well-balanced discussion is expected for the study of environmental radiation protection.

By strictly applying the LNT hypothesis, a very small quantity of exposure also gives the public an unnecessary feeling of fear towards radiation. As suggested by the research of high background radiation areas (HBRA), exposure levels of a few mSv/y in which no radiation effects are observed are not an important radiation protection matter. ICRP recommendations should reflect the results of comprehensive research such as epidemiology investigations, animal experiments, cell experiments etc.

Concerning environmental protection, we hope that realistic parameters and assumptions should be adopted. The fact that no radiation influences on fauna and flora are observed in the HBRA might be valuable data for the study. Furthermore, a well-balanced discussion is expected. Nuclear power is the most environment-friendly generation system today. ICRP says that “the primary aim of radiological protection is to provide an appropriate standard of protection for man without unduly limiting the beneficial actions giving rise to radiation exposure”.

To summarise:

- It is unnecessary to introduce the dose constraint in Japan.
- Clear criteria for usage of dose constraints are needed.
- The dose limits should be adopted in the final recommendations as the main system of protection.
- The meaning of a single source should be clarified.
- More attention should be given to the results of comprehensive research.
- A well-balanced discussion is expected for the study of environmental radiation protection.
Note: Since there is not enough discussion in Korea internally, the following comments are from a personal standpoint.

2005 Recommendations of the ICRP: Korean View

Jaiki Lee

Prof. in Nuclear Engineering
Hanyang University, Seoul, Korea
Chairman, Radiation Protection Committee of the Nuclear Safety Commission, Korea

Background

- Para.6 argues transition of sense of value from utilitarian approach to individual centered thinking as one of reasons for the change

- Not timely. Individual centered thinking has been overwhelming as early as 1970s.
- Periodic updating is an enough reason.
Scope

Exclusion
- Combination of dose level and difficulty of control constitute ground of exclusion.
- Para.210 simply borrows the conclusion of an IAEA report.

- No clear reason for the different exclusion levels (10 times) between artificial and natural sources.
- More elaboration is needed for justification.

Quantities

Effective dose
- Para.54 stresses: effective dose is intended for prospective use, not for use in assessment of stochastic risk in retrospective way.

- Personal monitoring of external exposure is retrospective in nature and relates H10 to effective dose.
- Cautions are needed in use of effective dose, but para.54 seems overstressing the issue.

Quantities (2)

Tissue weighting factors
Kind explanation of 'connective tissues' may be necessary.

Control of stochastic effects
- Para.88 points out needs of investigation if doses approach the dose constraints.

- May call for over-reactions. Such actions are needed at deterministic effect regime.
- The dose level should be 'the highest dose constraint' (0.1 Sv).

As exclusion is decided based on a combination of dose level and difficulty of control, there could be differences in the exclusion levels between artificial and natural sources. Meanwhile paragraph 210 of the draft recommendations simply borrows the conclusion of an IAEA report, and it is not clear why the exclusion levels for artificial nuclides should be 1/10th of the corresponding levels for natural nuclides (i.e. uranium, thorium and K-40). More elaboration is needed to justify the exclusion levels.

ICRP stresses that the effective dose is for prospective use and not for retrospective use in the assessment of stochastic risk, because the effective dose incorporates weighting factors derived from nominal risk and total detriment. The effective dose may be incorrectly interpreted. However, dose limits prescribed in terms of effective dose are understood in terms of retrospective applications. Measuring external dose with personal dosimeters is retrospective. Cautions are needed in using effective dose but it seems inappropriate to stress that the effective dose is only for prospective purposes.

In terms of language for tissue weighting factors, the definition of connective tissues is not clear. A clear explanation on this, including their location and status in the body would be helpful.

Paragraph 88 states that an investigation may be undertaken if a dose approaches the dose constraints. Considering the different size of dose constraints, this statement may lead to over-reactions; such actions are needed if doses approach the deterministic effects regime. The statement could be modified to mean the highest maximum dose constraint (0.1 Sv) or it could simply be deleted.
Biological Aspects

- Para.99 states no tissues show clinically relevant radiosensitivity in the range of a few mGy up to a few tens of mGy. 

  • Prudent. But it could be translated as if there are deterministic effects at dose level of a few mGy.
  • Better if the dose range can be 'several tens of mGy'.

Biological Aspects (2)

- Para.115: embryonic lethal effects are infrequent at dose of a few tens of mGy.
- Para.116: similar statement on malformations.

  • Ambiguous and too cautious on such a sensitive issue.
  • Firm position and definite dose value are needed to prevent unjustifiable abortion.

Biological Aspects (3)

- Similar expression on non-cancer diseases: no evidence in the dose range up to a few tens of mSv.

  What happens to a worker who has been exposed 100 mSv in 10 years?

The statement in paragraph 99 could be misunderstood to mean that there are chances of deterministic effects in the dose range of a few mGy. It may be better if the dose range is expressed as “several tens of mGy”.

Paragraph 115 states that embryonic lethal effects will be very infrequent at doses of a few tens of mGy. It seems ambiguous and too cautious for such a sensitive issue. To prevent or reduce unjustifiable abortions, the Commission should set a firm position with a definite value of dose. A similar problem is noted in paragraph 116 describing malformations.

For non-cancer effects, the Commission argues that the data available at present do not allow for their inclusion in the estimation of detriment in the dose range up to a few tens of mSv.
System of Radiation Protection

Justification

- Not clear if justification is an element of system of protection
- Justification is important but responsibility of regulatory authority.

Responsibility is one thing and being an element of system of protection is another.

System of Radiation Protection (2)

Occupational Exposure

- Workers other than in controlled area are members of the public.

Ambiguity in classification of radiation worker.
- Occasional workers in Korea (also in Japan)
- Professional patient helper?

Individual Dose Restriction

- Take natural exposure (1 mSv a year) as reference level
  - 100 times: high need for action
  - 1/100 times: low need for action.

What the scale 100 means?
- Might be related with risk level anyhow.

Unlike the clear definition of the system of protection in Publication 60, which comprises justification, optimisation and individual dose/risk limits, it is not clear in the draft what constitutes the new system. A more explicit definition of the system of protection is needed.

The definition of an occupational worker is unclear. Paragraph 143 defines occupational exposure as "exposures incurred at work as a result of situations that can be reasonably regarded as being the responsibility of the operating management". In paragraph 169, workers outside of a controlled area are classified as member of the public. Does this mean that a worker who enters controlled areas for work is an occupational worker? In Korea and Japan, the concept of "occasional worker" has been applied. Differentiating occasional workers from radiation workers is not easy. Should this be based on the expected dose level or status of being informed and trained?

The Commission takes the average annual effective dose from natural radiation excluding radon as the reference dose level for protection of the individual. There is no plausible reason for the exclusion of radon. Furthermore, the Commission takes 100 times the reference level as an indication of a high need for action, while a level corresponding to 1/100th of the reference level as indication of a low need for action. This approach stands on weak ground because the scale of 100 has no meaning without the support of judgment. Furthermore, the demarcation should be based on the size of risk.
Individual Dose Restriction (2)

Table 7
- Being informed and trained are condition of applying 20 mSv constraint
- Being informed and trained is only a necessary condition to be an occupational worker.
- Individual-related attributes vs. source-related constraints

Individual Dose Restriction (3)
- Minimum value of constraints: 0.01 mSv a year
- Unsatisfactory.
  - Reduced reference level to 1 mSv by set aside radon exposure and took 1/100 of the reference level and the minimum.
  - To the contrary, the maximum constraint for domestic radon is equivalent to 10 mSv/y.
- A higher value might be considered.

Individual Dose Restriction (4)
- Setting specific constraints for single sources, emergency and controllable existing exposure situations
- Still a complicated problem.
  - Ambiguity remains in definition of single source.
  - International guideline may be helpful.
  - Starts from major sources and well-defined situations.

Table 7 in the draft suggests 4 numerical values of annual effective doses. As the value of 0.01 mSv is not a maximum constraint but a minimum, this value should be removed separately. The next two constraints, 20 mSv and 1 mSv in a year, are intended to apply to occupational and public exposure, respectively. Since the individual-related dose limits of Publication 60 remain effective, the maximum constraints might be set at these levels. However, Table 7 and paragraph 164 state that being informed and being trained are conditions for applying the 20 mSv constraint.

The minimum dose constraint of 0.01 mSv/y seems unsatisfactory. This constraint is the cause of debates over the last 5 years. It looks as if efforts are focused on staying at the old consensus. The average background radiation dose was adjusted to 1 mSv/y by cutting off the contribution of radon, and an ungrounded scale factor of 100 was applied to deduce 0.01 mSv/y. The maximum constraint for domestic radon to which anybody could be exposed is equivalent to 10 mSv/y. Although radon is of natural origin and a case of controllable existing exposure, the minimum constraint value is not coherent with that constraint.

ICRP pointed out since that too many constraints are defined in the present system, it intends to simplify them. The draft gives only three maximum dose constraints. However, if we consider all the constraints to be set by the regulatory body of a country for different situations, it may still be complicated. As ICRP pointed out, there is ambiguity in the definition of single sources. Although socio-economic status is different from country to country, guidelines from appropriate international bodies, OECD/NEA for instance if ICRP has no intention, might be very helpful.
Dose Constraints vs. Dose Limits

- New concept of source related constraints: basic requirement and deviation regarded as a failure
- Dose limits: the same but individual related and for normal situation
  - Specific source constraints may be somewhat lower than dose limit: e.g., 1.6 mSv a year.
  - Constraints play a limited role for dominant single sources.
    - Problematic in case of industrial radiographers.

Dose Constraints vs. Dose Limits (2)

- No constraints for emergency workers in term of radiation weighted dose
- Pub. 60: 5 Gy of equivalent dose limit to skin
  - Does the Commission believe the effective dose constraint adequately protect extremity and skin? Clarification is needed.

Optimization of Protection

- Encourage use of the best available technology
- Use of Dose Matrix instead of collective dose
  - Is the best available technology the best technology?
  - Dose matrix: more comprehensive and flexible
    - Some elements of matrix may need simplification: e.g., age and gender dependencies, inequity aspects

In Publication 60, the constraints were regarded as a guideline in optimisation, and for prospective purposes. On the contrary, the individual dose constraints in the draft are obligatory. In both cases, the dose limits are an upper bound. The maximum constraints in the draft are equal to the effective dose limits. Since persons may be exposed to multiple sources, certain allowances might be left when the regulator sets the constraints, even though individuals are, in reality, only exposed to a single source or a few sources. Occupational workers are usually exposed to a single source but the established dose constraint will be at a lower level than the maximum dose constraint.

Incidentally, it is not clear if the maximum effective dose constraint for an emergency could be applied to highly localised exposure conditions. While no radiation weighted dose constraints are given in the draft, equivalent dose limits of 5 Gy to the skin for emergency workers was given Publication 60. If the Commission believes that extremities or skin is protected adequately by the effective dose constraint, clarification of this point may be needed.

The best available technology may not be the best technology. The dose matrix seems more comprehensive and flexible than the aggregated collective dose but it causes complications due to multi-element aspects. Those aspects are given explicitly in paragraph 202. Age- or gender-dependent risks and equity considerations are likely to make optimisation complicated. Differences in risk based on age and gender may not be significant. Inequity is reasonably well restricted by the dose limits and dose constraints.
Medical Exposure

- Emphasizes importance of radiation protection training of physicians
- Justification of a procedure for individual patient

- Training of physician: problems of extremely tight curricula and quality of instructors
- Justification at individual patient level is ambitious but subject to restrictions

Potential Exposure

- Uncertain nature prohibits application of dose constraints: Application of risk limits
- Generic risk limits (Pub. 76)
  - $2 \times 10^{-4} \text{ y}$ for occupational
  - $5 \times 10^{-6} \text{ y}$ for member of the public

- Looks coherent with the regulatory practice for accidents at nuclear power plants

Protection of the Environment

- A special report, Publication 91, on this subject has been published

- Scientific data in these areas increase gradually but are not sufficient yet to set applicable protection standards based on them.
- Adequate to include only the very essence in the basic Recommendations

The key question in the protection of the environment is if there is any evidence showing that a significant number of lives are endangered or suffer genetic damage due to ionising radiation exposure. Scientific data increases gradually but are currently not sufficient to answer this. Promoting a stewardship policy may look nice but means little unless it is supported by specific actions. If the ICRP believes its judgement on protection of non-human species given in Publication 60 is still valid, this belief should be kept in mind when deploying policies on environmental protection. However, it seems adequate to include only the very essence in the basic recommendations.
After the 9/11 catastrophe, concerns about radiation dispersion devices or dirty bombs rose up to forefront, and international activities to minimise such threats were launched. Key points of the code of conduct established by the IAEA relate to security of important radioactive sources. The Commission also prepared a document on the protection of people in the aftermath of a radiological attack. Although measures against such an episode do not belong to a traditional radiological protection regime, it might be considered in the framework of radiation protection.

If a worker who had been occupationally exposed to ionising radiation developed a cancer, he or she may argue that the cancer was caused by the occupational radiation exposure. Such a problem would be resolved by a pre-planned compensation scheme or by settlement through litigation. So-called probability of causation (POC) is sometimes applied to aid decision making in either case. However, there are considerable uncertainties in the estimate of POC. Although policy on this matter may depend on the situation of a country, it might be very helpful if the Commission could provide certain principles.

**Issues to Consider**

**Security of Radioactive Sources**
- Orphan source problems may be controlled by assuring accountability of medium or large radioactive sources
- The 9/11 terror called for strengthening of source security
- Inclusion of physical protection framework in the recommendations may be considered

**Issues to Consider (2)**

**Probability of Causation (POC)**
- POCs aid decision-making in compensation issues for a developed cancers of radiation workers
- Problem of over-conservatism
  - NOISH(USA) program admits claims if chance of POC exceeding 50% is greater than 1%.
  - In Korea, a worker developed leukemia got compensation, whose cumulative dose is less than 20mSv (POC<5%)
- Certain principle of the Commission may be helpful

**Regretful Aspects**

- No significant changes of the framework of protection
  - LNTH is maintained
  - Risk coefficient changes are insignificant
  - No evidence of failure of the present protection system
- Outcome away from the anticipated
- Is this the best we can achieve after all the hot discussions made for many years?
Format of the Recommendations

- The Pub. providing the Recommendations stands on the top tier and it might be a standing-alone document as far as possible.
- Informative things from documents of lower tiers may appear in footnotes than in the main text.
- Pub. 60 may be referred as ‘the 1990 Recommendations’ because it will be superseded by the new one.

Terminology

Practice
- Use of very common term to mean special situation. ‘radiological practice’ may be considered.

Existing controllable exposure situation
- ‘controllable existing exposure situation’ is preferred.

Terminology (2)

Radiation weighted dose
- Confusing. ‘equivalent dose’ may be tolerable. Otherwise, ‘radiation quality weighted dose’ or ‘radiation importance weighted dose’ may be considered.

Tissue reactions
- This term may include positive effects. ‘tissue damage’ or ‘tissue impairment’ would be less confusing.
Terminology(3)

Dose matrix

➢ Theoretically good but hard to understand. Easier term like ‘dose pattern’ is of worth to consider.

All the comments are preliminary. Successive reviews and discussions will be made later this year through both the regulatory body and the Korean Association for Radiation Protection. The results will be fed back to the ICRP.

Final Question

Have we done all that we reasonably can to reduce undue costs incurred due to over-concerns on radiation?

Thanks!
Concerning radiation facilities in Australia, an existing research reactor (HIFAR) is to be replaced by a 20 MW research reactor that is planned to come into operation in 2006. The HIFAR will then enter a process of decommissioning. Although Australia does not have nuclear power, there are operating U mines for export markets, in addition to some legacy mines. Issues relating to the management of NORM arise in industry, mostly in the mineral sands industries, but also in the petroleum and gas industries, which are also a user of radioactive sources. Australia has a sophisticated medical sector employing applications of radiation.
Taking into account the background above, this presentation concentrates on issues in the ICRP 2005 draft Recommendations that may affect the regulation of radiation in the environment – in mining and minerals processing, the management of NORM, remediation of sites, and the development of waste disposal facilities. The Recommendations give greater prominence to optimisation as a process underlying all applications of the radiation protection system. Finally, I want to explore whether there needs to remain a place in the system for the principle of justification.

National authorities are able to set specific constraints, expected to be lower than the Commission’s recommended values though I assume not ever lower than the minimum constraint of 10 µSv. This could present difficulties for traded commodities containing some levels of radioactive material and it would be helpful if at least the maximum constraints were defined. The definition of the situations in which the different maximum constraints apply would benefit from further clarification. Table 7 is likely to have a life of its own and would therefore benefit from further drafting.

The rationale for the 1 Bq g⁻¹ for U and Th series is reasonable. Consistency with the value adopted by the IAEA in “DS 161” is welcome. The new specific recommendations for exclusion are sensible; the Recommendations simply touch upon the idea of exemption from the radiation protection framework. This implies that regulators need a full schema for exemption, which leads to authorised exemption, agreement on the graded approach to regulation of materials and practices above exemption levels. Australia is to develop a protocol for exemption.
I congratulate the Commission for the work it has put into developing a framework for the protection of non-human species. I think nearly everyone in radiation protection accepts the ICRP 60 position that protection of humans generally protects the environment, at least at the population level. But it is also the case that nowadays such an assertion needs to be demonstrated – and there is legislation that requires the protection of individuals and environments in which humans are not present.

The development of reference animals and plants, particularly to allow estimates of dose from knowledge of exposure, allows the system to cut through a great deal of potential complexity. Developing the “derived consideration levels” for the reference animals and plants that take into account the natural backgrounds experienced in each case build in a relationship to the human protection system. Finally, the whole assessment feeds into a decision-making process that will involve judgement.

Obviously, there is an infinite variety of species and the science is immensely complicated and data sparse – but I think it is evident that the Commission is working with pragmatism and empiricism and is aiming to produce a system of environmental radiation protection that is fundamentally quite simple.
It is clear that the Commission is going beyond optimisation as a purely mechanical process where an operator or a regulator deems a certain dose to be the ALARA target and the operator moves toward that target using a cost-benefit approach. The Commission sees optimisation as fostering a safety culture in the operator so that everybody responsible for control of exposures asks the question on reasonable reduction of doses. It is consistent with modern thinking in occupational health and safety. It does require, however, a certain degree of sophistication about radiation protection in the operating and regulatory organisations.

The recommendations also advocate the involvement of stakeholders in the optimisation process. There will be questions of who the stakeholders are and how they might involved. Related to optimisation is the issue of the distribution of doses in space and time. The Commission sees a more limited role for the notion of collective dose. They recommend the use of a dose matrix. There are many questions about just how such weighting will be done, and whose views about the weight to be given to particular elements of the matrix will prevail in any circumstance.

The issue of justification is one that intrigues all regulators. It is right to say that justification is carried out by Governments when you are thinking of major decisions. However, there may be a separate issue of the justification of a certain nuclear power plant on a certain site and that form of justification should be a part of the radiation protection system applied by the regulator. At the other end of the scale, no government is going to bother with possible trivial uses of radiation. Having the principle of justification embedded in the radiation protection system is a useful approach.
The presentation includes three main aspects. First is a discussion of the direction and progress achieved. Second are points which require further clarification. Third is the impact of the increasing concern of radiation protection in China.
1. Right direction and good progress

• Many years efforts:

lots of discussion, seminar, lively and open debate within and with the radiation protection community, the proposed recommendations of ICRP has become more and more completed.

• We are happy to see we are going on the right direction to the final goal:

more coherent, simpler, but continuous system.

• Good Indications of New system are:

◆ Simplified and consolidated.
Situation of confusion and difficulties in application of old system, especially from “double track” concepts of practice and intervention will be improved.

The draft recommendation explained by Dr. Clark is in the right direction. There have been many discussions, seminars, and lively and open debates within and with the radiation protection community. The proposed ICRP recommendations have become more and more complete.

The new ICRP recommendations are simplified and consolidated. The situation of confusion and difficulties in application of the old system, especially from “double track” concepts of practice and intervention will be improved.
Regarding Section 1, the concepts of dose limits and collective dose have been retained. Optimisation of protection still plays an important role and a more pragmatic view of optimisation will be introduced.

There is also a widening of the radiation protection field. There is more concern about natural exposure. In addition, the protection of non-human species will be incorporated. Exclusion levels for artificial and natural materials have been provided, which will help in saving regulatory resources.

Some points need further clarification. Dose limits are for multiple sources, whereas constraints are source specific. In China, we regard the dose limits as the center of regulatory assessment. It has regulatory significance for retrospective assessment.

2. Points which needs more clarification

- Dose limits and constraints
  Dose limits is for multi-sources, and constraints is source specific, in Asia, we used to regard the dose limits as the center of regulatory assessment, it has regulatory significance for retrospective assessment.

- Widening the radiation protection field:
  natural exposure more concerned, protection of non-human species will be incorporated.

- Exclusion levels for artificial and natural materials provided, helpful to save regulatory resources.
Now, in new system, is it intended to move the center from dose limits to the constraints? Which one is of regulatory significance now: constraints? dose limits? or both? Which one is the foundation of national regulatory system? Dose limits or constraints?

• Application of “matrix method”.

The method’s application into optimization can prevent from misuse of collective dose, but we’d better more clearly clarify that the collective dose is still one of important elements, and is necessary to provide more guidance for this.

3. Radiation Protection of more concern in China

• Recently, China BSS issued some problems of more concern:
  Occupational exposure from natural sources
  Underground coal miners: \( \sim 6 \times 10^6 \)
  Total number of underground workers: \( \sim 10^7 \)
  Young girls of aircrew: large team in china

Recently, the China BSS company identified some problems of concern, namely occupational exposures from natural sources. The number of underground coal miners is around 6 million, and the total number of underground workers is 7 million. There are also a large number of young girls amongst aircrews.
Occupational exposure levels from natural sources in China

<table>
<thead>
<tr>
<th>Type of occupation</th>
<th>Individual dose (mSv yr⁻¹)</th>
<th>Collective dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial</td>
<td>Range</td>
</tr>
<tr>
<td>Underground mine</td>
<td>4.8</td>
<td>0.36-18</td>
</tr>
<tr>
<td>Non-ferrous underground mine</td>
<td>1.2</td>
<td>1-2.0</td>
</tr>
<tr>
<td>Underground ferrous mine</td>
<td>12.8</td>
<td>2.3-5.6</td>
</tr>
<tr>
<td>Other underground mine</td>
<td></td>
<td>0.18-160</td>
</tr>
</tbody>
</table>

This is data on occupational exposure levels from natural sources in China. From this table, it can be shown that the values for underground workers are relatively high.

Occupational exposure levels from natural sources in China

<table>
<thead>
<tr>
<th>Type of occupation</th>
<th>Individual dose (mSv yr⁻¹)</th>
<th>Collective dose (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial</td>
<td>Range</td>
</tr>
<tr>
<td>Underground mine</td>
<td>6</td>
<td>0.2-31</td>
</tr>
<tr>
<td>Case</td>
<td>8</td>
<td>0.41-46</td>
</tr>
<tr>
<td>Tunnel construction</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Nuclear or radiation technology application</td>
<td>2</td>
<td>2.2*10²</td>
</tr>
<tr>
<td>Underground uranium mine</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Nuclear Industry</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

This is data for the other underground workers. From these data, we understand that the underground mine worker receives more dose.

The concentration of Thoron in dwellings in part area of china

<table>
<thead>
<tr>
<th>Site &amp; Time</th>
<th>Sampling methods</th>
<th>Count of sampling</th>
<th>Concentration of Thoron (mSv)</th>
<th>Equilibrium factor of Thoron (mSv)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beijing 0000</td>
<td>Cumulative</td>
<td>121</td>
<td>0.1-0.6 (4.07-30.2)</td>
<td>0.1-0.6 (4.07-30.2)</td>
</tr>
<tr>
<td>Shanghai 0000</td>
<td>Cumulative</td>
<td>121</td>
<td>0.1-0.6 (4.07-30.2)</td>
<td>0.1-0.6 (4.07-30.2)</td>
</tr>
<tr>
<td>Hangzhou 0000</td>
<td>Cumulative</td>
<td>121</td>
<td>0.1-0.6 (4.07-30.2)</td>
<td>0.1-0.6 (4.07-30.2)</td>
</tr>
<tr>
<td>Hangzhou 0000</td>
<td>Cumulative</td>
<td>121</td>
<td>0.1-0.6 (4.07-30.2)</td>
<td>0.1-0.6 (4.07-30.2)</td>
</tr>
<tr>
<td>World</td>
<td></td>
<td>121</td>
<td>0.1-0.6 (4.07-30.2)</td>
<td>0.1-0.6 (4.07-30.2)</td>
</tr>
</tbody>
</table>

This is the concentration of Thoron in dwellings in part of China. It is clear that the data for China are higher than the global average.
### Internal radiation levels due to radon and thoron in dwellings built with soil-woody structure, mSv·h⁻¹

<table>
<thead>
<tr>
<th>Location</th>
<th>Radon</th>
<th>Thoron</th>
<th>Total</th>
<th>Radon/Thoron</th>
</tr>
</thead>
<tbody>
<tr>
<td>GanSu Cave-house</td>
<td>0.69</td>
<td>7.18</td>
<td>7.87</td>
<td>10.4</td>
</tr>
<tr>
<td>Soil-wood</td>
<td>0.89</td>
<td>2.62</td>
<td>3.51</td>
<td>2.9</td>
</tr>
<tr>
<td>Heng Yang Earth-wood</td>
<td>0.36</td>
<td>5.3</td>
<td>5.66</td>
<td>14.7</td>
</tr>
</tbody>
</table>

This data indicates that the concentration of Thoron is higher than that for Radon in this kind of building. The reason is that in China, soil is used to make houses.

### The content of $^{232}$Th in China, America and world (Bq·Kg⁻¹)

<table>
<thead>
<tr>
<th>Country</th>
<th>Average</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>China mainland</td>
<td>49</td>
<td>1.0–438</td>
</tr>
<tr>
<td>Fujian</td>
<td>96.3</td>
<td>19.5–260</td>
</tr>
<tr>
<td>Zhangzhou</td>
<td>109</td>
<td>17.8–190</td>
</tr>
<tr>
<td>Xiamen</td>
<td>93.5</td>
<td>66.1–125</td>
</tr>
<tr>
<td>Zhuhai</td>
<td>146</td>
<td></td>
</tr>
<tr>
<td>Hong Kong</td>
<td>193</td>
<td>11–345</td>
</tr>
<tr>
<td>America</td>
<td>35</td>
<td>4–180</td>
</tr>
<tr>
<td>World</td>
<td>30</td>
<td>11–34</td>
</tr>
</tbody>
</table>

### Non-human species protection

- a) Some studies carried out, for example, estimation of dose to marine biota from release of NPP.
- b) A program of non-human species protection is prepared.
- c) A seminar will be held this August.

In China, some studies have been carried out, for example, on estimates of dose to marine biota from NPP releases. A programme of non-human species protection has also been prepared. Another seminar programme will be held this August.
• Dealing with the regulation of residual radioactivity and waste deposition from decommissioning.

In addition, there are the other problems like dealing with the regulation of residual radioactivity and waste deposition from decommissioning in China.
SESSION 3

Processes for Stakeholder Involvement in Radiological Protection Decision Making

Chairs: Jacques Lochard and Sadayoshi Kobayashi
The first part of this presentation provides an overview of the 3rd Villigen Workshop. The NEA organised three workshops in Villigen, Switzerland, looking into stakeholder involvement in radiological protection aspects. The 3rd workshop was held last year to provide an opportunity to examine in detail some case studies on stakeholder involvement. This presentation includes a summary of all the case studies.

Case study 1 concerns the proposed opening of new Canadian uranium mines.
The highest concerns for the local community are health risks, environmental degradation, and socio-economic impacts, particularly for Aboriginal people living in the mining district. Approximately 75% of the people living in the uranium mining region are Aboriginal and native to the region. Although they are traditionally hunter-gatherers, uranium mining has become their primary source of employment. So expansion of the mining area could have a negative effect in terms of worker health and safety.
In the early 1990s, six major new uranium mines were proposed for northern Saskatchewan. In 1991, a public hearing process was initiated. This was led by an Advisory Panel that was to report to the Federal and Provincial governments for the licensing of the mines. After that, the panel reviewed six mining projects and produced four reports for government including findings and recommendations.

Clear roles were established within the stakeholder framework: stakeholders participated through public meetings; the Panel reported its recommendations to governments; and federal and provincial authorities decided whether to proceed to licensing and are responsible for licensing. The Advisory Panel issued guidelines for Environmental Impact Statements (EIS), which were submitted to the panel for review. The public, NGOs, and governments reviewed the EIS reports. The Government funded public and NGO participation. The EIS was issued after Panel review and public hearings, the results of which were submitted to governments.

The Government responded in writing to every issue addressed in the Panel reports, including answers to specific questions. Licenses were eventually granted for all sites. Many panel recommendations were incorporated into the project licenses and/or other vehicles. Governments, the mining companies and the local inhabitants all agreed on the process and its results. However, as there is a requirement of long-term monitoring of the area, stakeholder involvement is continuing.
Case Study 2: This is the case of public participation in the review of discharges from an operating facility in France.

Local Concerns over Operational Discharges: Cape de la Hague, France
Local issues:
• Concerns over emissions and possible accidents, and their consequences on health
• Feeling of exclusion from the system of regulation and control system, feeling of anger and powerlessness
• Feeling that elected officials and administration officials were on the side of the operators

In this difficult context, COGEMA applied for license modification to increase discharges.

Framework
• 1997: Epidemiological study suggests excess leukaemia
• August 1998: COGEMA submits a draft modification file
• September 1998: The safety authority creates a pluralist group of experts and local groups (GRNC) to examine the file “admissibility”
• October 1998: The first analysis ends in a refusal of the file
• Early 1999: After additional documents were provided by COGEMA, and collaborative work undertaken with the GRNC, a favourable recommendation was given, while expressing criticism
• February 2000 - May 2000: "Traditional" Public Inquiry
• Recommendation on admissibility sent to the government

In 1997, an epidemiological study suggested excess leukaemia. In the following year, COGEMA submitted a draft modification to increase discharges. The safety authority recognised the conflict and created a pluralist group of experts and local groups (GRNC) to examine the file “admissibility”. The first analysis ended in a refusal of the file. After additional documents were provided by COGEMA, and collaborative work undertaken with the GRNC, a favourable recommendation was given, while expressing criticism of the situation. The recommendation on admissibility was sent to the government.
Key Elements of Stakeholder Involvement

- File admissibility considered by public experts, but also by a pluralist group of experts.
- Consideration of remarks and comments from pluralist group.
- Pluralist group able to produce its own assessment of impacts and dangers, participate in analysis, and interact directly with the operator.
- Critical exchanges between the operator, experts, ministries, safety authority, and local associations.
- Very strong participation of local associations in the analysis of details and the acceptability of the final solution.

The process resulted in the approval of the license modification. New levels of allowable releases were agreed to by COGEMA, the public and the government. As in the Canadian case, local groups continue to participate in discussions and environmental monitoring.
Case 3 concerns decontamination of the Rocky Flats site in the US.

**Case Study 3:**
Radiological Release of the Rocky Flats Contaminated Site

**Government Wishes to Release Rocky Flats Site from Radiological Controls**

Local Issues
- Weapons production facility located 26 km from Denver, Colorado.
- Acceptance was based on secrecy and self-interest during the Cold War...
- ...but this acceptance was increasingly eroded by public concerns.
  - Safety: 1969 fire reveals threat to Denver area
  - Changing social and political climate
    - 1979 protest by 9,000, with 300 arrested; counter protest by 16,000
    - 1986 struggle between DOE and EPA
    - 1988 Chernobyl accident

**The Rocky Flats Site**

This slide gives you the place and the scale of the site.

This is a weapons production facility located 26 km from Denver, Colorado. Acceptance of the facility was based on secrecy and self-interest during the Cold War. However, this acceptance was increasingly eroded by public concerns. In 1969, a fire revealed the threat to the Denver area. In addition, the changing social and political climates lead to an increasing number of protests year after year. There was also a struggle between DOE and EPA. Safety concerns increased after the Chernobyl accident.
Key Elements of Stakeholder Involvement

- The independent assessment had a clear and limited mandate - Assess the DOE-developed clean-up levels
- The review panel was made up of community representatives
- The review process established trust by focusing on community input to the analysis process:
  - Assessing clean-up levels at other sites
  - Reviewing computer models
  - Determining inputs and assumptions
  - Identifying relevant exposure scenarios for possible future site uses - Contextualising science

Results

- The review panel agreed on new soil clean-up levels
- The DOE took this recommendation into account, and modified its clean-up order to reflect the panel’s recommendation.
- The site is now in the process of being cleaned up.

As a result, the review panel agreed on new soil clean-up levels. The DOE took this recommendation into account, and modified its clean-up order to reflect the panel’s recommendation. The site is now in the process of being cleaned up. Again the situation became normal after stakeholder involvement.

The independent assessment had a clear and limited mandate to simply assess the DOE-developed clean-up levels. The review panel was made up of community representatives. The review process established trust by focusing on community input to the analysis process, like assessing clean-up levels at other sites, reviewing computer models, determining inputs and assumptions and identifying relevant exposure scenarios for possible future site uses, which might be considered as contextualising the science.
The next case study concentrates on post-accident rehabilitation in Belarus.

Case Study 4:
Post-accident Rehabilitation in the Chernobyl-contaminated Territories

As a result of the Chernobyl accident, there are large rural populations living in significantly contaminated areas. The problem is that the “Top-down” approach taken by the government and international organisations resulted in loss of trust, and contributed to general feelings of hopelessness.
Between the 1986 Chernobyl accident and the present, the extensive national effort to characterise contamination levels, rehabilitation techniques, and affected population health has had some negative effects. It is within this context that, in the mid-1990s, the European “Ethos project” was founded. Phase 1 was a small test approach in Olmany, district of Stolyn, Belarus. In phase 2, the approach was extended to 5 localities inside the district of Stolyn.
Key Elements of Stakeholder Involvement
- Involvement of the local population, previously largely excluded
- Inter-disciplinary approach aimed at coping with the complexity that previous methods had missed
- Aim to promote and develop radiological safety as an integral part of the overall improvement of the quality of life
- Working Groups established in consultation with local people, based on their concerns:
  - Radiological protection of children
  - Production of clean milk
  - Marketing of privately produced food
  - Radiological culture through education
  - Involvement of young people in rehabilitation
  - Management of domestic radioactive waste
- Working Groups employed collective learning approach, characterized local problems, and developed solutions based on local resources

From the outset, the Ethos team sought to involve the local population, previously largely excluded. The team adopted an inter-disciplinary approach. The complexity of the problems that confront the local people cannot be got rid of easily. The aim was to promote and develop radiological safety as an integral part of the overall improvement of the quality of life. Working Groups were established in consultation with local people, based on their concerns like the radiological protection of children, production of clean milk, etc. Working Groups employed collective learning approaches rather than expert level approaches with the collaboration of local people and the Ethos team.

This is one example of round table meetings with local people and the Ethos team.

Cooperation was established where previously none had existed. The effectiveness of rehabilitation was improved. The quality of life, e.g. contamination level of children, had been improved. Trust was built between the local populations and the Ethos team. There are some indications that confidence has been restored.
Conclusions from these Case Studies

- The resolution of many different situations can be assisted through stakeholder involvement in the decision-making process.
- There are many different approaches to stakeholder involvement.
- Stakeholder involvement can be carried out at a variety of different levels.

In conclusion, the resolution of many different situations can be assisted through stakeholder involvement in the decision-making process. There are many different approaches to stakeholder involvement. It can be carried out at a variety of different levels, and it is clear that all people are able to be involved in this process and make positive contributions. Regarding the ICRP recommendations, it is natural for us to have concerns because we are the stakeholders of the ICRP. The question is if we are listening to our own stakeholders.
AN ASIAN VIEW OF STAKEHOLDER INVOLVEMENT

Sadayoshi Kobayashi
Technical Advisor, Nuclear Safety Commission, Japan

2nd Asian Regional Conference
Evolution of the System of Radiological Protection
27-28 July 2004, Tokyo

An Asian View of Stakeholder Involvement:

Sadayoshi KOBAYASHI
Honorary Researcher
National Institute of Radiological Sciences
Technical Counselor,
Secretariat of Nuclear Safety Commission

This presentation is a Japanese view, rather than an Asian view, of stakeholder involvement.

A Japanese View of Stakeholder Involvement:

Sadayoshi KOBAYASHI
Honorary Researcher
National Institute of Radiological Sciences
Technical Counselor,
Secretariat of Nuclear Safety Commission
Contents
1. Who are “Stakeholders”
2. Social and Cultural Background of Japanese: Harmony, “Nemawashi” and “Ringi” for consensus
3. Perception of “Stakeholders” by NSC Members and the Public and Their Behavior
4. Some Examples Activities of Government Departments involving Stakeholder Participation
5. Subjects of Public Interest: Asian High School Students
6. Requirements for Effective Stakeholder Involvement
7. Conclusion

The presentation includes the meaning of “Stakeholders”, the social and cultural background of Japanese governmental activities involving stakeholder participation, the subject of public interest, etc.

1. Stakeholders in ICRP Draft Recommendation
(S11) Stakeholders: Parties who have interests in and concern about a situation
Involvement of Stakeholders: A proven means to achieve
(1) incorporation of values into decisions,
(2) improvement of the substantive quality of decisions,
(3) resolution of conflicts among competing interests,
(4) building of trust in institutions,
(5) education and information of the workers and the public,
(6) reinforces safety culture, and
(7) introduces necessary flexibility in the management of radiological risk

According to the definition, “stakeholder” means parties who have interests in and concern about a situation. Accordingly “Involvement of Stakeholders” should be a proven means to achieve the incorporation of values into decisions and the improvement of the substantive quality of decisions, etc.

Who are stakeholders?

NEA/CRPPH Expert Group on the Process of Stakeholder Involvement, EGPSI

However, we must make it clear who are stakeholders.
A “Stakeholder” is not someone who holds cooked beef but rather a holder of a stake.

There is a dispute about the interpretation of a “Stakeholder” in Japanese. Here are three candidates which might suit an interpretation of a “Stakeholder”.

2. Interpretation of a “Stakeholder” in Japanese
   (1) 利害関係者: Persons who gain or lose by an event or a situation (more or less monetary value).
   (2) 有権者:Persons who have right (stake) and a will to say for an event or a situation.
   (3) 当事者: Persons who are directly involved in, or, have qualification or responsibility to deal with an event or a situation.

3. OECD/NEA/EGPSI:
   Interpretation of “Stakeholder Involvement”
   Participation of a civil society

4. In radiation protection area:
   ★Persons who are (likely to be) exposed to radiation, or
   ★Persons who are afraid of being exposed to radiation,
   ★Persons who have interests and concern about radiation exposure, and etc.

According to the OECD/NEA definition, “Stakeholder Involvement” is the participation of a civil society. However in the area of radiation protection, stakeholders would be persons who are (or likely to be) exposed to radiation, or persons who are afraid of being exposed to radiation, or persons who have interests and concern about radiation exposure, etc.
Some Consideration on the Japanese Cultural and Social Background:

Harmony, “Nemawashi” and “Ringi” for consensus

Referring to the Japanese cultural and social background, it seems that consensus is regarded as importance.

The First Constitution of Japan, AD 604

17 Articles of Prince SHOTOKU

一日。以和為貴。無忤為宗。

Article 1.

Harmony is to be valued, and an avoidance of wanton opposition to be honored.

In Article 1 of the First Constitution of Japan, enacted in AD 604, harmony is to be valued.

The results of a stakeholder dialogue on the implications of the ICRP proposals can be found in the summary report of the meeting held in Lanzarote, Spain on 2-4 April 2003.
17 Articles of Prince SHOTOKU

Article 10. —— and though we alone may be in the right, let us follow the multitude and act like men.

In addition, the idea of the majority is prioritised higher than that of a person in the constitution.

Characteristics of Japanese ‘stake’
An outstanding stake gets struck.
(A tall tree gets stronger winds. )
Stand out from the crowd, and you just invite trouble for your self.

In Japan, they say “An outstanding stake gets struck” or “A tall tree gets stronger winds”.

What are the characteristics of Japanese “Stake”? 
Japanese “Stake”
- Harmonization
- Follow others, be inconspicuous
- Let others do it, don’t do it myself

The characteristics of the Japanese “Stake” are “Harmonisation”, “Follow others, be inconspicuous”, and “Let others do it, don’t do it myself”. 
**Nemawashi 根回し**

**Original meaning:**
Root binding. In preparation for transplantation of a tree, digging around a tree to be transplanted, cut off the roots around so as to allow new, fine and dense roots grow that enables easy and successful transplantation some months later.

We often use *Nemawashi* in order to proceed with something in Japan.

**Nemawashi 根回し**

**Derived meaning:**
An activity to obtain consensus of the stakeholders beforehand by maneuvering negotiations behind the curtain.

The derived meaning of *Nemawashi* is an activity to obtain consensus of the stakeholders beforehand by maneuvering negotiations behind the curtain.

Most common and the ‘Must’ procedure in political, business and social transactions in Japan.

**10. Ringi 根議**

- The process of obtaining sanction (from senior executives) for a plan by circulating a draft proposal prepared lower down in the organization among the relevant parties.

One of the procedures used in *Nemawashi* is *Ringi*: the process of obtaining sanction for a plan prepared lower down in the organisation by circulating a draft among the relevant parties.
Characteristics of Japanese Way of Decision-Making

Typically:
1. Bottom-up, not Top-Down
2. Nemawashi, and Ringi for Consensus, Harmonization
3. Slow and Unnecessarily Time-consuming

The Japanese way of decision making is typically bottom-up: it needs consensus procedures and is unnecessarily time-consuming.

As they say, a top-down approach is the western style, whereas bottom-up is the Japanese style.

This is a summary of the questionnaire of the participants of this conference.

Public Response to Public Involvement
1. Should the public be involved?
2. Do you personally participate?

This is a summary of the questionnaire of the participants of this conference.
Program Activities of NSC and Some Other Government Agencies involving Participation of the Public as Stakeholders

We are trying:

1. Meetings with Public Participation
   - Public Hearings

2. Public Comments System
   - Draft Reports and Public Comments

Outcome:
- Some are successful, but mostly very limited results

Japanese governmental organisations also have their own programme activities involving participation of the public as stakeholders.

Typical stakeholder involvement -1
Local referendum on the proposed merger of towns and villages

Consolidation of smaller municipalities to form larger ones is currently promoted by the central government, which has become a subject of heated conflict in many cases.
- In some cases it has been solved through the poll of local residents.
- The poll itself needs to be validated first by municipal ordinance.

Currently the central government is promoting consolidation of smaller municipalities to form larger ones.

In some cases it has been solved through the poll of local residents.

Typical stakeholder involvement -2
Introduction of Jury system

Additionally, a jury system will be introduced in some kinds of trials in the near future in Japan.
Radiation-related Subjects of Interest by High School Students in 7 Asian Countries — Subjects of Interest

Question No. 12:
What do you want to know about “radiation”?

1. Amount of radiation that does not affect human health (Safe dose)
2. Safety measures in managing radiation exposure
3. Emergency preparedness in radiation accidents
4. Facilities that are using radiation
5. Application in food
6. Mutation breeding of crops
7. Industrial application
8. Medical applications
9. Regulation by the government
10. Frontier fields of research
11. None in particular

This slide shows the results of answers made by high school students in seven Asian countries concerning interest in radiation.

There are some differences in their interest in radiation-related subjects.

Emergency preparedness is the most interesting subject in Japan. Safe dose is the most important in five countries.

There is a classification of stakeholders, depending on the subject in question.
Some criticisms on stakeholder involvement

- Abandonment of responsibility on the part of administration.
- Unnecessary expenditure of resources.
- Time consuming.
- No guarantees for positive results.

- Too many captains bring your boat to the mountain-top. (Too many cooks spoil the broth.)

But the benefits outweighs 1

Requirements for Effective Involvement of Stakeholders - 1

For the Government/Administration:

1. Open commitment to respect/incorporate in the decision making the results of stakeholder involvement.
2. Provision of financial/physical support esp., “Facilitators” with regard to dialogue/communication, to stakeholders.
3. Continuity and consistency of the policy to involve stakeholders in decision framing/making.

The government and administration require an open commitment to respect and incorporate the results of stakeholder involvement in the decision-making process, and provision of financial and physical support with regard to dialogue/communication, and to stakeholders. Additionally they require continuity and consistency of the policy to involve stakeholders in decision framing/making.

16. Requirements for Effective Involvement of Stakeholders – 2

For the Stakeholders:

1. Commitment for consistent involvement, recognition of their right and responsibility.
2. Acceptance of “Facilitators” as an effective aid leading to a productive goal.
3. Recognition of their “rank” and role.

(Diversity in knowledge, understanding, etc.)

On the other hand, the stakeholders require commitment for consistent involvement, recognition of their right and responsibility, acceptance of facilitators as an effective aid leading to a productive goal, and recognition of their rank and role.
Conclusion

The concept of “Stakeholder Involvement” is not yet fully understood nor accepted in Japan, especially when the public is involved as stakeholders. It is still at the infantile stage.

Greater efforts are needed on the side of national and local administration to fully understand its necessity and usefulness.

The first step is “communication/dialogue”. On-going systems of “Public comments”, “Open Panel Discussion” etc. need to be made more functional and effective for this purpose.

As a conclusion, the concept of “stakeholder involvement” is not yet fully understood nor accepted in Japan. Accordingly greater efforts are needed on the side of national and local administration. On going systems of “Public comments”, “Open Panel Discussion”, etc., need to be made more functional and effective for this purpose.
THE STAKEHOLDER INVOLVEMENT PROCESS:
LESSONS LEARNED FROM CRPPH ACTIVITIES

Jacques Lochard
CRPPH Vice-Chair, CEPN, France

This presentation provides an overview of the stakeholder involvement process undertaken within CRPPH over the last five years.

The background of this activity is clear. Social evolution during the last decade has resulted in a strong shift in public expectation toward greater and more direct involvement of stakeholders in decision-making processes. This is reflected in the 2005 draft ICRP recommendations. Progress in this area has also been seen over the last five years. The CRPPH has followed a pathway of national views and experiences to understand the benefits, challenges and implications of greater stakeholder involvement in radiation protection decision-making processes.
In 1994, the CRPPH collective opinion *Radiation Protection Today and Tomorrow* recognised an increased role for the social dimension in radiation protection, a concept already introduced in recent ICRP publications. This was followed by the First and Second Villigen workshops on the societal aspects of decision making in complex radiation situations, and the better integration of radiation protection in modern society, respectively. The Third Villigen Workshop concerned the implications of stakeholder involvement in radiation protection decision making, and will be elaborated here.

Three points are selected as conclusions. The challenge is not to integrate society into radiation protection but rather to adapt radiation protection to meet the needs of society. Next is the importance of fostering mutual trust between the radiation protection community and society. The key word is “Acceptance” through the development of context specific approaches based on openness, inclusiveness and agreed procedures. The third is that practical lessons, at the national and international levels, can be drawn from case studies illustrating how stakeholder involvement is working in specific contexts.

Here are of the benefits of stakeholder involvement: it responds to shifts in societal attitudes towards science, industry and government; it offers the possibility of resolving tensions between economic and social concerns; it helps to prevent disputes and conflicts where it is deployed *ex-ante*, and resolve disputes and conflicts where it is deployed *ex-post*; it increases the substantive quality and sustainability of decisions; it builds trust in institutions; and it educates and informs the public.
What is different about stakeholder involvement?

- Partnership rather than consultation
- Dialogue rather than informing
- Mutually acceptable outcomes rather than unsatisfying compromises with “winners” and “losers”.
- Long term stable decisions rather than short-term fixes
- Focus on both decision-making processes and outcomes rather than just outcomes
- Mutual learning rather than convincing

Implications of stakeholder involvement

- Potential impacts at every stage of the policy process
- Implies long term commitment and dedication of resources
- Cannot be left to one part of an organisation
- Organisational and training implications
- Does not imply diversion from core objectives
- Balance must be found between stakeholder demands and ability of processes to meet them

Conclusion (1)

- Past experience shows that to be successful the stakeholder involvement processes must rely on sound science and be transparent and inclusive i.e. bring to the table all interested parties as long as their approach is evidence-oriented.
- Recent findings (TRUSTNET 2 Project) emphasises the key distinction that must be made between decision-framing (the preparation of the decision) and decision-taking. Responsibility for taking decisions must remain in the hands of operators, regulators...

Another way to present the key results is to characterise what is different about stakeholder involvement. It is partnership rather than consultation, and dialogue rather than informing. It leads to mutually acceptable outcomes rather than unsatisfying compromises with “winners” and “losers”, and long term stable decisions rather than short-term fixes. This is why stakeholder involvement takes time, and mutual learning rather than convincing.

Concerning the implications of stakeholder involvement, we can see the potential impacts at every stage of the policy process. It implies long term commitment and dedication of resources, which means that it takes time. It cannot be left to one part of an organisation. Of course, there are organisational and training implications. It is difficult to balance stakeholder demands and the ability of processes to meet them. An open mechanism has to be found.

Past experience shows that to be successful, stakeholder involvement processes must rely on sound science and be transparent and inclusive i.e. bring to the table all interested parties, as long as their approach is evidence-oriented. Recent findings, e.g. in the TRUSTNET 2 Project, emphasises the key distinction that must be made between decision framing and decision taking. Responsibility for taking decisions must remain in the hands of operators, regulators, etc.
Stakeholder involvement represents an opportunity to improve relations with society and to enhance the quality and effectiveness of the decision-making processes related to radiation protection. The Villigen Workshops have demonstrated that radiation protection has already responded to the increasing demand for stakeholder involvement in many domains. CRPPH will maintain its commitment in the coming years to accompany and improve this trend.

We are now in the preparation of a new collective opinion, which was last published in 1994. A topical session on the key challenges for the next five years or next decades was held at the 62nd CRPPH meeting last March. Last June, a brainstorming meeting with stakeholders was held. Though NGOs were invited to that meeting, they were not able to attend. The Expert Group on the CRPPH Collective Opinion (EGCO) will meet in September 2005. Their draft report will be discussed at the 63rd CRPPH meeting in March 2005. In the second half of 2005, the final report may be adopted.

All agreed that the radiation protection system needs to respond to people and public, and that radiation risk governance needs to be addressed in an inclusive and pluralist fashion. The role of the public and other stakeholders in risk identification and assessment was identified. For example, NGOs usually want to participate in environmental monitoring. There is the evolving role of experts concerning accountability, ethics, etc, and a shift from decision support systems to tools for informing dialogues, debates and deliberations.
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On behalf of all the colleagues who took an active role in the CRPPH programme of work on stakeholder involvement, the author wishes to thank the **Japanese Government** for its generous contributions over the past years in support of this programme.

He also wishes to express special thanks to **Sadayoshi Kobayashi** and **Masahiro Doi** for their personal contributions to the advancements of the Committee’s reflections on stakeholder involvement and to the success of its actions to diffuse them.
SESSION 4

Where Do we Go from Here?

Chairs: Yasuhiro Yamaguchi
SUMMARY OF THE CONFERENCE

Hans Riotte
Head, Radiation Protection and Radioactive Waste Management,
OECD Nuclear Energy Agency

The 2nd Asian Regional Conference on the Evolution of the System of Radiological Protection

Summary of the Conference

Hans Riotte, NEA
Head, Radiation Protection and Waste Management
Tokyo, 28 - 29 July 2004

During the three workshop sessions, we have tried to address the following objectives.

Objectives

- Final draft ICRP recommendations
  - Ready for delivery, in the view of the NEA Pacific Region & China?
- NEA/CRPPH work on the Process of Regulatory Authorisation
  - A useful framework for the application of the new recommendations?
- NEA’s work on stakeholder involvement in radiological protection decision making
  - Helpful experience in the Far East socio-political context?
In Session 1, we set the view of the draft ICRP recommendation. In Session 2 we explained the NEA work on the process of regulatory authorisation with stakeholder involvement. In Session 3, we explained the NEA work on stakeholder involvement in radiological decision making.

After these sessions, the question appeared: “How much change makes an evolution?” I think some changes are due to new sciences. It is important to keep in mind that these changes confirm that what we have done is right.

There are some changes to consolidate, clarify, and simplify the ideas in the draft recommendation.
There are also some developed aspects which have already been described before. These concepts seem to lead towards better understanding to facilitate implementation.

One instrument which has been discussed for use in the process of regulatory authorisation is the umbrella approach for regulatory frameworks. We should keep in mind that this approach is conceptual rather than statutory.

Discussions on stakeholder views on the authorisation concept showed that there are some concerns which still need to be addressed.
Other issues raised are the protection of the environment, the regulation of natural sources and NORM, etc. Another issue is the problem of defending national justification or non-justification schemes in an international, globalised world.

The CRPPH authorisation framework is seen as a useful common approach, though more road-testing and development is necessary. The framework could be helpful in decision making on exclusion and exemption questions, etc.

The NEA experience over the last five years with respect to the Villigen workshops on stakeholder involvement and decision making have shown that stakeholder involvement will help to prevent and resolve disputes, and increase quality and sustainability of decisions.
NEA lessons (cont’d)

- Implications for organisations
  - Long-term commitment needed
  - Cross-cutting issue
  - Organisational & training implications
  - NOT to divert from core objectives
- Finally, responsibility for decision stays with organisation/authority

There are also implications for the organisations involved in these processes. Finally, it is also clear that responsibility for decision making stays with responsible organisation or authority.

Personal Japanese (Asian?) view:

- Socio-cultural background “harmony”, “consensus”
  - Role in Western approaches?
- Criticism/requirements
  - As in Western countries?
- SH involvement based on “civil society” not fully understood; but evolving
  - Authority’s report for public comment
  - Referendum (merger of municipalities)

With respect to the Japanese/Asian approach, it appears to focus on socio-cultural background harmony and consensus. At the same time, the number of people who regard stakeholder involvement as important is similar to that in Western countries.

I would like to add some personal observations. The two main concepts of “consensus” and “civil society” can lead to some misunderstanding, and so should be looked into in detail. Another interesting observation is the result of the questionnaire showing that 80% of respondents acknowledge the relevance of stakeholder involvement, but 30% have no specific examples. There was also a discrepancy in one histogram for the role of stakeholders. I believe that the result of the histogram will differ if the question is changed.
In order to build common understanding, there are two areas of dialogue. One is to continue these types of workshops and meetings. On the other hand, we will have a similar process in the dialogue on the ICRP recommendations for RP of non-human species. The role of the NEA should be to further the development of the regulatory process for authorisation in order to support governments.
There might be some confusion over dose constraints and dose limit. At the regulatory scene, many kinds of constraints are used for controlled areas, shielding or dose control at the periphery of a source. In addition, individual dose limits are also applied for workers and public.
Premises

- ‘LNT’ and ‘ALARA’ are supported
- Dose Limits for individual are introduced
- Minimum Constraint is 0.01mSv

We regard three items as initial conditions for regulation. The first is support for “LNT” and “ALARA”. The second is the introduction in the regulatory framework of dose limits for individuals. Third is the minimum dose constraint of 0.01mSv. In Japan, the BSS is introduced to set exemption levels. Details for its regulation will be enforced next April.

What does Regulatory Authority do?

- Authorize, supervise and control the use of radiation
- Set up and optimize regulatory framework
- Harmonize the framework internationally

Based on these premises, the regulatory body authorises, supervises and controls the use of radiation. They also set up and optimise the regulatory framework while referring to the results of recent research. It is also important for them to be harmonised with the international framework. Accordingly, ICRP recommendations are one of the most important references, so the government tries to understand and evaluate them. But since there are huge assignments for the regulatory body in the new draft recommendations, we must thoroughly review our regulatory system.

What can be introduced, then?

Items for Consideration

- NORM, TENORM, and Natural Radiation
- Protection of the Environment
- Dose Matrix

Regarding the individual items for consideration, we have the same problems with respect to NORM, TENORM and Natural Radiation as in the other Asian countries. The concept of environmental protection is a new topic for the Japanese government. The dose matrix is an interesting item, and will be very helpful for the regulation and evaluation of radiation protection. I’m looking forward to seeing some examples. I’d also like to continue contact with ICRP and NEA to improve our regulatory system.
I am enormously grateful for the opportunity given to me and ICRP to engage with this stakeholder group in order to ensure that we can go forward profitably with the desired new recommendations. As mentioned yesterday we will be asking you all send your comments to ICRP. They will be posted on the ICRP website. All the received comments will be available for you to see.

It’s not my intention to reply to each comment individually giving all of the reasons why we accept or do not accept. We will take everything into account. However, I have about four particular issues to mention.

The first is what we will do in the Beijing meeting in October. One of the principal tasks is to approve the foundation documents for the building blocks that support the recommendations and will go some way towards answering questions that you have put to me over the last day and half. Committee 1 on radiation effects is producing a report on the effects of radiation at low doses, summarising the results of cellular information that can be derived from animal experiments. We can also learn from epidemiologic work that tells us how we should move forward with regard to the effect of low doses of radiation. That report is from the task group chaired by Charles Land. The last draft is about two hundred pages so it’s a fairly comprehensive review of all the scientific information regarding dose effects. Committee 1 is also producing a second report. This task group, chaired by Roger Cox, who is also the chairman of Committee 1, is focusing on biological risk factors for use in radiation protection, and covers the issues involved in deciding upon nominal probability coefficients for fatal cancer and for cancer incidence. Committee 2 is producing the third of the foundation documents on dosimetric quantities for protection. This will be a thorough review of all the quantities, including the clarification of quantities such as radiation weighted dose or RBE weighted dose, and the use of special names for various units. The basic unit is always J/kg, but we use a series of modified dimensionless factors, so it is useful to have a series of separate names to avoid confusion.

The fourth and fifth foundation documents are being prepared by Committee 4, chaired by Annie Sugier, on the application of the Commission’s recommendations. The first of these foundation documents and fourth in my list is that on optimisation. This includes advice on how to move forward with a process that we now see as much more an attitude of mind rather than mathematical equations. But we are very conscious, as John Paterson said this morning, that it absolutely reflects the Commission’s view that the social system differs in different areas of the world and we cannot have a single system which will encompass all of the different values of societies in various regions of the world. So our advice has to be at the highest level and adaptable to the different regions of the world.

The fifth foundation document is on the definition of the individual. Something which we have not spoken about at all is to whom we apply these criteria. What is an individual member of the public? The ICRP has not visited the critical group concept for more than 20 years. It was not mentioned in Publication 60. So the time is right for us to help regulatory authorities by giving guidance on how to decide on the use of relevant habit data, and how those data may be incorporated.
with the vast number of dose coefficients generated by Committee 2. We are now about to add doses to the infant from the consumption of mothers milk. How are we to use these many numbers?

These foundation documents will be posted on the ICRP website to allow us all to be able to look at the comments, and I hope this will assist in the comprehension of our recommendations. The next point that I think you may be interested in begins to talk more broadly about what is happening within ICRP. Publications that are very shortly to appear include those on dose coefficients for infants consuming mother’s milk, as well as a final report, to be published shortly, on radiological protection criteria in the event of radiological attack, in other words, terrorism. Another document that will shortly appear concerns protection issues relating to the release of patients with unsealed radioactive sources, principally iodine 131, and the public health issues associated with these mobile radioactive sources. Another report that will be coming soon is the release of patients with sealed radioactive sources. This principally concerns prostate implants, which theoretically should stay in the prostate, but in practice can be found elsewhere in patient’s body. These are some of things which are of direct practical relevance, as well as documents supporting the new recommendations.

The next topic to be mentioned is sad for me because I think this visit will be my last visit as chairman of ICRP. I relinquish the chair of ICRP next June. The new chair of ICRP will be Dr. Lars-Erik Holm, Director-General of the Swedish Radiation Protection Authority – a medical doctor with a background in epidemiological research.

So I really want to finalise the new recommendations in the spring of next year following a review of comments by June when the present Commission ends its current term. The new members of the commission will be elected this October; however, one or two decisions have already been made. Serving under Lars-Erik Holm as vice-chairman will be Roger Cox who is my successor at the NRPB, United Kingdom, and is now chairman of Committee 1, which will be taken by Julian Preston from the EPA, United States. Christian Streffer will be handing over the chair of Committee 2 to a member of that Committee. Fred A. Mettler and Annie Sugier continue to chair Committee 3 and 4, respectively. The new environment committee, Committee 5, is chaired by John Hembury, former chief scientist of the Environment Protection Agency of the United Kingdom. The first meeting of the new Commission and committees will take place at the beginning of September next year. Their job will be to progress the tasks that flow from the new recommendations. Committee 2 will certainly produce new dose coefficients on the basis of the new tissue radiation weighting factors for both intakes of radionuclides and exposure to external fields. In the long-term they will be reviewing biokinetic data for developing the new model of the human alimentary tract to give us a completely new set of dose conversion coefficients. Committee 4 will certainly have to do a certain amount of interpretation of the recommendations in the areas of emergency response, contaminated ground and enhanced natural radionuclides. Committee 5 will be establishing their reference on environmental derived concentration levels based on multiples of natural background which will help regulators, designers and operators to implement the philosophy for protection of non-human species.

Thank you very much to the Japanese government, to the ministry, to NEA, and to all my dear friends here in Japan who have supported my chairmanship.
I’d like to explain the activities of the NEA in the near future regarding the ICRP recommendations.

Where the NEA will go from here

Agreed and/or Personal views

Salvatore Frullani

CRPPH Expert Groups at work

- During the past several years, the CRPPH has been working to contribute its ideas and needs to the international dialogue regarding the development of the new ICRP general recommendations. At present, two Groups are at work on matters related to ICRP draft:
  1. EGIR (Expert Group on the Implications of ICRP Recommendations) focus on the possible regulatory and application-related implications that would arise should ICRP draft recommendations be implemented in national regulations.
CRPPH Expert Groups at work

2. EGRA (Expert Group on Regulatory Application of the Authorisation) develops concepts and ideas raised in the EGRP (Expert Group on the Evolution of Radiological Protection) report to enlarge the "Authorization" meaning to become an umbrella concept that provides a logical framework for all regulatory decision making. This concept could provide a practical regulatory interpretation of the concepts that are developed by ICRP.

EGIR members

EGIR membership is large and includes Japanese members, although there are no other Asian members.

Time Line for EGIR

2004
- June: Release of ICRP Draft Recommendations
- 1 November: NEA (CRPPH & other Committees) Comments Received
- 15 November: Draft Summary of Comments
- 22-24 November: 1st EGIR Meeting (R. Clarke on 23rd afternoon)
- 15 December: Rev 1 Sent to EGIR & CRPPH

2005
- 17 - 18 January: 2nd EGIR Meeting
- 19 January: Bureau Meeting: Release Rev 2 to ICRP
- 8 - 10 March: CRPPH Discussion and Approval
- Fall: Final Publication

In June, the ICRP Draft Recommendations were released. On 15 November, the NEA will send a draft summary of comments to all EGIR members. On 22-24 November, the first EGIR Meeting will be held, which Dr. Clarke will attend in part. In mid-December, Rev. 1 of the comments and results of discussions will be sent to the EGIR and CRPPH. On 19 January, Rev. 2 of the comments will be sent to ICRP.
The work for EGIR includes the preparation of its own comments on the draft, review of all comments sent by CRPPH members and other NEA standing technical committees, preparation of suggestions for specific wording changes to the draft, each accompanied by a clear rationale for the proposed change, and presentation of this work to the CRPPH Bureau and, through it, submission to the ICRP.

Rev. 2 of the EGRA report was sent to EGRA Members last July. On 21-23 September, the 2nd EGRA Meeting will be held. On 11 October, NEA will present EGRA concepts to the ICRP in China. In January, EGRA will review and incorporate comments, which will be sent to the CRPPH.
Work for EGRA

- Discussion of Classification and Screening process.
- Judgement of an unjustified practice and/or intervention.
- Examples of application of the concept of Regulatory Authorization to specific cases covering planned, emergency and de facto situations.
- Preparing comments for EGIR work, paying special attention to the wording of radiological protection and radiological control aspects.
- CRPPH Meeting and final editing.

29.07.2004

2nd Tokyo Workshop

The work of EGRA includes discussion of the classification and screening process, judgment of an unjustified practice and/or intervention, examples of authorisation in specific cases covering planned, emergency and de facto situations, preparation of comments for EGIR work, etc.

All of you are invited to join the work of EGIR, EGRA and CRPPH through its Japanese members and other members of the Expert Groups and Committee. Any comments and suggestions are more than welcome. You can all help us finalise our reports.

Any comment and suggestion is more than welcome.

29.07.2004

2nd Tokyo Workshop
Annex 1

PRESENTATIONS FROM THE PANEL DISCUSSION ON STAKEHOLDER INVOLVEMENT IN RADIOLOGICAL PROTECTION DECISION MAKING

1. Result of the Questionnaire to the Participants of the Conference on Stakeholder Involvement

**For whom are you working?**

- Operator/Utility, 26
- Regulatory Body, 21
- RP Research Institute or Organisation, 30
- Others, 9

**How old are you?**

- <30, 4
- 30-39, 15
- 40-49, 20
- 50-59, 25
- >60, 21

**What is your field of occupation?**

- Nuclear Power, 39
- Medical Application, 11
- Others, 36
- Industrial Application, 2

**Q1. Have you ever heard of specific activities or examples of Stakeholder Involvement in government/authority decision making?**

- NO, 33%
- YES, 67%
Q8. How you feel about the following statement: Stakeholder Involvement is very time-consuming and expensive, and will not result in better decisions than can be made without consulting stakeholders.

- Strongly Agree: 4%
- Agree: 12%
- Somewhat Agree: 23%
- Disagree: 46%
- Strongly Disagree: 15%

Q2-2: Which would you consider to be stakeholders?

- Non-governmental organizations (NGOs)
- The private industry associations
- Public interest advocacy groups
- The government agencies responsible for making the decision
- Regulatory bodies
- Other government departments not directly involved for the decision

Number of responses:

- Through the publicity of the concerned stakeholder
- Non-governmental organizations (NGOs)
- The private industry associations
- Public interest advocacy groups
- The government agencies responsible for making the decision
- Regulatory bodies
- Other government departments not directly involved for the decision

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2. Presentation by Chie Takada, Japan Nuclear Cycle Development Institute

**Some Comments**

*as a certain stakeholder*

*and at the closer position than the other stakeholders*

Chie TAKADA
Japan Nuclear Cycle Development Institute

**Background**

- In Tokai-mura and the around area, A lot of nuclear operators are there. So many radiation workers lives their life. (⇒ Many local people have any relationship with the radiation workers.) and Public peoples remember the experience of the JCO Criticality Accident.

The senses for the "radiation" of workers and of the public are very close.

**In case of supplying of guidance and advice to workers**

Available "radiation protection" needs realization by people on the both position of to manage and to be managed.

The key matters to the realization of most workers are,

- No significant change of numerical values (e.g. Dose Limits)
- Simplification of numerical values (e.g. Dose Constraints)

**What's the most interesting matter of workers and the local people?**

What dose the numerical numbers set in bottom? The dose limits leads them enough comfort?

⇒ "Using" the natural radiation level to the explanation is definitely. "Using" the natural radiation level is not carry much conviction. Because, The recent cognition level of the local people of the natural level existing and changing with areas is high.

We would like to give more explanation by more "intelligible" expression about NNL.

**To Achieve the "down-to-earth (the location)" radiation protection**

- Stakeholder involvement needs a large cost?
- Is it difficult to convince all of the stakeholders?

The answers may be "yes", but...

"Protection culture" needs the stakeholders' sense of being members of stakeholder. So...
3. Presentation by Jun Kuwabara, Japan Atomic Energy Research Institute

日本の放射線防護分野における「ステークホルダー関与」

Scientific considerations

Who are Stakeholders?

Border of stakeholders and non-stakeholders

Can I bring a suit, if the decided thing is bad for me.

Build “Stakeholder Involvement” into the Process to Decide Standards

In particular, for local issue

“Stakeholder Involvement” as adjustment stage for acceptance from stakeholders
Annex 2

LIST OF PARTICIPANTS

AUSTRALIA
LOY, John                                        Tel: +61 2 9541 8300
Australian Radiation Protection                   Fax: +61 2 9541 8303
and Nuclear Safety Agency                          Eml: john.loy@arpansa.gov.au
38-40 Urunga Parade
Miranda NSW 2228

CHINESE TAIPEI
KAO, Hsi Mei                          Tel: +886 2 22322199
Section Chief                             Fax: +886 2 82317829
Atomic Energy Council Radiation Protection  Eml: hmkao@aec.gov.tw
5F NO80 Sec 1, Cheng Kung Rd. Yung-Ho city
Taipei, Taiwan 234

FRANCE
LOCHARD, Jacques                                   Tel: +33 01 58 35 86 65
Directeur, CEPN                                     Fax: +33 01 40 84 90 34
Route du Panorama                                    Eml: lochard@cepn.asso.fr
B.P. 48
F-92263 Fontenay-aux-Roses Cedex

ITALY
FRULLANI, Salvatore                               Tel: +39 06 49 90 2 234
Physics Laboratory                      Fax: +39 06 49 38 70 75
Istituto Superiore di Sanita                         Eml: salvatore.frullani@iss.infn.it
299 Viale Regina Elena
I-00161 Rome

JAPAN
AKAHANE, Keiichi                           Tel: +81 43 206 3064
Medical Exposure Assessment Section        Fax: +81 43 284 0918
Research of Medical Physics                   Eml: akahane@nirs.go.jp
Research Center for Charged Particles
National Institute of Radiological Science
4-9-1 Anagawa, Inage-ku
Chiba-shi 263-8555
ANDO, Hideki  
Director of Health & Safety Division  
Tel: +81 29 267 4141  
Fax: +81 29 267 7174  
O-arai Engineering Center  
Eml: ando@oec.jnc.go.jp  
Japan Nuclear Cycle Development Institute  
4002, Narita-Cho, Oarai-machi  
Higashi Ibaraki-gun  
Ibaraki-ken 311-1393

AOKI, Hideto  
Advisor  
Tel: +81 3 4511 1908  
Fax: +81 3 4511 1998  
Technical Counsellor  
Eml: aoki-hideto@jnes.go.jp  
Japan Nuclear Energy Safety Organization  
17-1, 3-chome, Toranomon Minato-ku  
Tokyo 105-0001

AOKI, Yoshiro  
Chairman  
Tel: +81 3 5295 1481  
Fax: +81 3 5295 1486  
Radiation Effects Association  
Eml: aoki@rea.or.jp  
Maruishi-DAI2 Bldg  
1-9-16 Kajicho, Chiyoda-ku  
Tokyo 101-0044

AOYAMA, Shin  
Director, Nuclear Safety Division,  
Ministry of Education, Culture, Sports,  
Science and Technology (MEXT)  
Tel: +81 3 5253 4111 ext.7110  
Fax: +81 3 5253 4027  
Eml: saoyama@mext.go.jp  
1-3-2 Kasumigaseki, Chiyoda-ku  
Tokyo 100-8966

ASO, Takayuki  
Ministry of Education, Culture, Sports,  
Science and Technology (MEXT)  
Tel: +81 3 6734 3902  
Fax: +81 3 6734 4027  
Eml: taso@mext.go.jp  
2-5-1 Marunouchi, Chiyoda-ku  
Tokyo 100-8959

CHIBA, Yoshinori  
Manager, Radiation Protection Center  
Hitachi Ltd.  
Tel: +81 294 55 4919  
Fax: +81 294 55 9891  
Eml: yoshinori_chiba@pis.hitachi.co.jp  
Nuclear Power Systems Division  
1-1, Saiwai-cho 3-chome, Hitachi-shi  
Ibaraki-ken 317-8511

DOI, Masahiro  
Head, Methodology Development Section  
Sciences Research Group  
National Institute of Radiological Science  
Tel: +81 43 206 3150  
Fax: +81 43 251 4853  
Eml: masa_doi@nirs.go.jp  
4-9-1 Anagawa, Inage  
Chiba 263-8555

FUCHIGAMI, Keiko  
Biotechnology Safety Division  
Ministry of Agriculture  
Forestry and Fisheries  
Tel: +81 3 3501 3780  
Fax: +81 3 3502 4028  
Eml: keiko_tagawa@nm.maff.go.jp  
1-2-1 Kasumigaseki, Chiyoda-ku  
Tokyo 100-8950
FUJIHARA, Hiroshi
Tokyo Electric Power Company
1-1-3 Uchisaiwai-Cho, 1-chome, Chiyoda-ku
Tokyo 100-0011
Tel: +81 3-4216-1111 Ext.: 4973
Fax: +81 3-4216-4949
Eml: fujihara.hiroshi@tepco.co.jp

FUJIMORI, Akihiro
Unit Chief, Office for Radiation Regulation
Nuclear Safety Division,
Science and Technology Policy Bureau (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959
Tel: +81 3-5253-4043
Fax: +81 3-5253-4048
Eml: fujimori@mext.go.jp

FUJIMOTO, Kenzo
Director, Environmental Radiation Protection Research Group (NIRS)
4-9-1 Anagawa, Inage-ku
Chiba 263-8555
Tel: +81 43 206 3103
Fax: +81 43 284 1769
Eml: kenzofuj@nirs.go.jp

FUJIWARA, Saeko
Dept. Chief
Radiation Effects Research Foundation
5-2 Hijiymama Park, Minami-ku
Hiroshima 732-0815
Tel: +81 82 261 9122
Fax: +81 82 261 3259
Eml: fujiwara@rerf.or.jp

FURUTA, Sadaaki
Safety Co-ordination Section
Japan Nuclear Cycle Development Institute
4-49 Muramatsu, Tokai-mura, Naka-gun
Ibaraki 319-1184
Tel: +81 29282 0513
Fax: +81 29282 4921
Eml: furuta.sadaaki@jnc.go.jp

HAKATA, Tadakuni
Technical Counselor
Secretariat of Nuclear Safety Commission
Cabinet Office
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 9841
Fax: +81 3 3581 9836
Eml: thakata@op.cao.go.jp

HAMADA, Tatsuji
Advisor
Japan Radioisotope Association
2-28-45 Honkomagome, Bunkyo-ku
Tokyo 113-8941
Tel: +81 3 5395-8021
Fax: +81 3 5395-8051
Eml: hamada-tatsuji@jrias.or.jp

HARA, Shintaro
Unit Chief for International Cooperation
Atomic Energy Div.,
Research and Dev. Bureau (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959
Tel: +81 3 673 4161
Fax: +81 3 6734 4162
Eml: shara@mext.go.jp

HASHIMOTO, Makoto
Japan Nuclear Cycle Development Institute
4002, Narita, O-arai
Ibaraki 311-1393
Tel: +81 29 267 4141
Fax: +81 29 267 1674
Eml: shu@oec.jnc.go.jp
HASHIMOTO, Michio
Director
International Affairs Office
Nuclear and Industrial Safety Agency
Ministry of Economy, Trade and Industry
1-3-1, Kasumigaseki, Chiyoda-ku
Tokyo 100-8986
Tel: +81 3 3501 1087
Fax: +81 3 3580 5971
Eml: hashimoto-michio@meti.go.jp

HATTORI, Takatoshi
Senior Research Scientist
Central Research Institute of Electric Power Industry
2-1-1, Iwado-kita, Komae-shi
Tokyo 201-8511
Tel: +81 3 3480 2111 ext: 1449
Fax: +81 3 3480 2493
Eml: thattori@criepi.denken.or.jp

HIGASHI, Kunio
Commissioner
Nuclear Safety Commission
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 3470
Fax: +81 3 3581 3475
Eml: khigash@op.cao.go.jp

HIGUCHI, Hideo
Secretariat of Nuclear Safety Commission
Bldg. No.4, 6th fl.
3-1-1, Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 9259
Fax: +81 3 3581 9839
Eml: hideo.higuchi@op.cao.go.jp

HIROSE, Katsumi
Research Head
Meteorological Research Institute
1-1 Nagamine, Tsukuba-shi
Ibaraki-ken 305-0052
Tel: +81298538725
Fax: +81 29 853 8728
Eml: khirose@mri-jma.go.jp

HOMMA, Toshimitsu
Principal Researcher
Japan Atomic Energy Research Institute
2-4 Shirakata Shirane
Tokai-Mura, Naka-Gun
Ibaraki-ken 319-1195
Tel: +81 29 282 6862
Fax: +81 29 282 6147
Eml: homma@popsvr.tokai.jaeri.go.jp

HORIKAWA, Yoshihiko
General Manager
Radio Waste Management and Decom. Group
The Kansai Electric Power Co. Inc.
3-3-22 Nakanoshima, Kita-ku
Osaka 530-8270
Tel: +81 6 7501 0161
Fax: +81 6 6444 8588
Eml: k581682@kepco.co.jp

HOSONO, Makoto
Department of Radiology
Kinki University School of Medicine
377-2 Ohno-Higashi, Osaka-sayama
Osaka 589-8511
Tel: +81 72 366 0221 ext: 3132
Fax: +81 72 368 2388
Eml: hosono@med.kindai.ac.jp
ICHII, Takeshi  
Research Scientist  
Central Research Institute of  
Electric Power Industry  
Nuclear Technology Research Laboratory  
2-11-1 Iwadokita, Komae-shi  
Tokyo 201-8511  
Tel: +81 334802111 ext: 1925  
Fax: +81 334802493  
Eml: ichiji@criepi.denken.or.jp  

ICHIKAWA, Ryushi  
Honorary Scientist  
National Institute of Radiation Sciences  
4-9-1 Anagawa  
Chiba 263-8555  
Tel: +81 43-251-1984  
Fax: +81 43-251-1984  
Eml: hsato@nsra.or.jp  

IIMOTO, Takeshi  
Research Center for Nuclear Science & Technology  
The University of Tokyo  
2-11-6, Yayoi, Bunkyo-ku  
Tokyo 113-0032  
Tel: +81 3 5841 2915  
Fax: +81 3 3813 2010  
Eml: iimoto@rcnst.u-tokyo.ac.jp  

IIUZKA, Teruyoshi  
Field Safety & Radiation Control Group  
Nuclear Energy Filed dept.  
Toshiba Corporation  
8 Shinsugita-cho, Isogo-ku  
Yokohama 235-8523  
Tel: +81 45 770 2213  
Fax: +81 45 770 2174  
Eml: teruyoshi.iizuka@toshiba.co.jp  

IKEUCHI, Yoshihiro  
Deputy Director  
Office of Planning & Coordination  
Japan Chemical Analysis Center  
295-3, Sanno-cho, Inage-ku  
Chiba-City 263-0002  
Tel: +81-43-424-8661  
Fax: +81-43-423-5326  
Eml: y-ikeuchi@jcac.or.jp  

INOMATA, Katsumi  
Secretariat of Nuclear Safety Commission  
Bldg. No.4, 6th fl.  
3-1-1, Kasumigaseki, Chiyoda-ku  
Tokyo 100-8970  
Tel: +81 3 3581 9256  
Fax: +81 3 3581 9839  
Eml: katsumi.inomata@op.cao.go.jp  

ISHIDA, Jun-ichiro  
Director, Total Quality Management Division  
Japan Nuclear Cycle Development Institute  
4-49 Murumatsu, Tokai-Mura, Naka-gun  
Ibaraki 319-1184  
Tel: +81 29 282 1122  
Fax: +81-29-282-4932  
Eml: jishida@hq.jnc.go.jp  

ISHIDA, Kenji  
Senior Research Scientist  
Low Dose Radiation Research Center  
Central Research Institute of  
Electric Power Industry  
2-11-1 Iwado-kita, Komae  
Tokyo 201-8511  
Tel: +81 3 3480 2111 ext. 2572  
Fax: +81 3 3480 3113  
Eml: ishida@criepi.denken.or.jp
ISHIDA, Masaharu                                   Tel: +81 (3) 5253 4043
Office of Radiation Regulation,                  Fax: +81 (3) 5253 4048
Nuclear Safety Division                           Eml: mishida@mext.go.jp
Ministry of Education, Culture, Sports,         
Science and Technology (MEXT)                     
2-5-1 Marunouchi, Chiyoda-ku                     
Tokyo 100-8959                                    

ISHIGURE, Nobuhito                                  Tel: +81 43 206 3110
Group Leader                                       Fax: +81 43 284 1769
Environmental Radiation Protection Research       Eml: ishigure@nirs.go.jp
Research Center for Radiation Safety              
National Institute of Radiological Science         
4-9-1 Anagawa, Inage                               
Chiba 263-8555                                    

IWAI, Satoshi                                      Tel: +81 3 3277 4505
Senior Research Advisor                           Fax: +81 3 3277 4505
Mitsubishi Research Institute Inc.                Eml: iwai@mri.co.jp
3-6 Otemach, 2-Chome, Chiyoda-ku                  
Tokyo 100-8141                                    

IWASAKI, Tamiko                                     Tel: +81 43 251 2111
Senior Research Advisor                           Fax: +81 43 251 2111
National Institute of Radiological Science         
4-9-1 Anagawa, Inage                               
Chiba 263-8555                                    

KAI, Michiaki                                       Tel: +81 97 586 4435
Lab. Environmental Health Science                 Fax: +81 97 586 4387
Dept. of Health Sciences                           Eml: kai@oita-nhs.ac.jp
Oita University of Nursing and Health Science     
2944-9 Megusuno, Notsuharu                        
Oita-ken 870-1201                                  

KANEKO, Masahito                                    Tel: +81 3 5295 1781
Managing Director                                  Fax: +81 3 5295 1486
Radiation Effects Association                     Eml: mkaneko@rea.or.jp
Maruishi-Daini Building, 5th floor                 
1-9-16 Kajicho, Chiyoda-ku                        
Tokyo 101-0044                                    

KATAOKA, Joe                                        Tel: +81 3 35 95 21 94
Section Chief                                      Fax: +81 3 35 03 85 62
Guidance of Medical Service                       Eml: kataoka-jou@mhlw.go.jp
Health Policy Bureau                               
Ministry of Health, Labour and Welfare            
1-2-2, Kasumigaseki, Chiyoda-ku                   
Tokyo 100-8916                                    

KATO, Masami                                        Tel: +81 3 4511 13 90
Japan Nuclear Energy Safety Organization          Fax: +81 3 4511 18 98
Safety Standard Division                          Eml: kato-masami@jnes.go.jp
Fujita Kanko Toranomon Bldg 7F                    
3-17-1 Toranomon, Minato-ku                       
Tokyo 105-0001
KATOH, Kazuaki                             Tel: +81 29 850 8088
Professor Emeritus of KEK                 Fax: +81 29 866 1552
AIM Corporation                            Eml: aim@leo.nifty.jp
1318-1 Tsukuba
Tsukuba 300-4352

KAWAGOSHI, Hiroshi                           Tel: +81 3 6734 4024
Director, Office of International Relations  Fax: +81 3 6734 4027
Ministry of Education, Culture, Sports, Science  Eml: kawagosi@mext.go.jp
and Technology (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959

KAWAKAMI, Hiroto                             Tel: +81 3 4511 1800
Japan Nuclear Energy Safety Division       Fax: +81 3 4511 1898
Fujita Kanko Toranomon Bldg.               Eml: kawakami-hiroto@jnes.go.jp
3-17-1 Toranomon, Minato-ku
Tokyo 105-0001

KAWAMURA, Hisao                          Tel: +81 175 22 9111
Dept. Mass Analysis                        Fax: +81 175 22 9112
Japan Marine Science Foundation            Eml: kawamura@jmsfmml.or.jp
4-24, Minato-machi, Mutsu-shi
Aomori 035-0064

KAWATA, Yosuke                             Tel: +81 3 3504 1081
Mitsubishi Materials Corporation           Fax: +81 3 3504 1297
Radioactive Wastes Management Dept.        Eml: kawata@mmc.co.jp
1-297, Kitabukaro-tyo, Ohmiya-ku
Saitama-shi, Saitama-ken, 330-8508

KIKUCHI, Toru                             Tel: +81 285 58 7062
Jichi Medical School Radioisotope Center   Fax: +81 285 40 8481
3311-1, Yakushiji, Minamikawachi-machi,    Eml: tkikuchi@jichi.ac.jp
Kawauchi-gun, Tochigi-ken 329-0498

KOBAYASHI, Hirohide                     Tel: +81 29 282 1111
General Manager                          Fax: +81-29 282 9966
Japan Nuclear Cycle Development Institute Eml: koba@tokai.jnc.go.jp
4-33 Muramatsu, Tokai-mura, Naka-gun
Ibaraki-ken 319-1194

KOBAYASHI, Sadayoshi                    Tel: +81 3 3581 9259
Technical Counsellor                     Fax: +81 3 3581 9839
Secretariat of the Nuclear Safety Commission Eml: skobaya@op.cao.go.jp
Cabinet Office                           3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970

KOBAYASHI, Toshikazu                    Tel: +81 3 3581 9948
Technical Counsellor                     Fax: +81 3 3581 9837
Secretariat of Nuclear Safety Commission  Eml: toshikazu.kobayashi@op.cao.go.jp
Bldg. No. 4, 6th fl.
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
KOMORI, Kazuhiro
Senior Researcher
Safety Information and Data Acquisition Division
Japan Nuclear Energy Safety Organization (JNES)
Fujita-kanko, Toranomon Bldg. 8th Floor
17-1 Toranomon 3-chome, Minato-ku
Tokyo 105-0001
Tel: +81(3) 4511 1941
Fax: +81(3) 4511 1998
Eml: komori-kazuhiro@jnes.go.jp

KONDO, Ryohei
Special Staff, Int. Nuclear Co-operation
Atomic Energy Division
Research & Development Bureau (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959
Tel: +81(3)6734 4161
Fax: +81(3)6734 4162
Eml: rkondo@mext.go.jp

KONISHI, Emiko
Nagano College of Nursing
1694 Akaho, Komagane
Nagano 399-4117
Tel: +81 265 81 5159
Eml: konishi@nagano-nurs.ac.jp

KOSAKO, Toshiso
Research Center for Nuclear Science & Technology
The University of Tokyo
Yayoi 2-11-16, Bunkyo-ku
Tokyo 113-0032
Tel: +81 3 58 41 29 22
Fax: +81 3 38 18 86 25
Eml: kosako@rcnst.u-tokyo.ac.jp

KOSHIMIZU, Hiroki
Nuclear Safety Regulatory Standard Division
Nuclear and Industrial Safety Agency (NISA)
Ministry of Economy, Trade and Industry
1-3-1, Kasumigaseki, Chiyoda-ku
Tokyo 100-8986
Tel: +81-3-3501-0621
Fax: +81-3-3580-5971
Eml: koshimizu-hiroki@meti.go.jp

KUMAZAWA, Shigeru
Senior Staff
Fuel Cycle Facility Safety Analysis Group
Safety Analysis and Evaluation Division
Japan Nuclear Energy Safety Organization (JNES)
3-20, Toranomon 4-chome, Minato-ku
Tokyo 105-0001
Tel: +81-3-4511-1515
Fax: +81-3-4511-1598
Eml: kumazawa-shigeru@jnes.go.jp

KUNIYOSHI, Hiroshi
Director of Radiation and Accident Management Division
Secretariat of Nuclear Safety Commission
Bldg. No. 4, 6th fl,
3-1-1, Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 3478
Fax: +81 3 3581 9839
Eml: hiroshi.kuniyoshi@op.cao.go.jp

KUROTAKI, Katsumi
Radiation Effects Association
Maruishi-Daini Bldg. 5F
1-9-16 Kajicho, Chiyoda-ku
Tokyo 101-0044
Tel: +81 3 5295 1484
Fax: +81 3 5295 1485
Eml: kurotaki@rea.or.jp
KUSAMA, Keiji
Manager, Radiation Protection Section,
Division of General Affairs,
Japan Isotope Association
28-45, Honkomagome 2-chome, Bunkyo-ku
Tokyo 113-8941
Tel: +81 3-5395-8084
Fax: +81 3 5395 8052
Eml: kusama@jrias.or.jp

KUSAMA, Tomoko
Oita University of Nursing and Health Sciences
2944-9 Notsuharu
Oita-ken 870-1201
Tel: +81 97 586 4445
Fax: +81 97 586 4389
Eml: kusama@oita-nhs.ac.jp

KUSUMI, Shizuyo
Commissioner
Nuclear Safety Commission
Bldg. No. 4, 6th fl,
3-1-1, Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 3470
Fax: +81 3 3581 3475
Eml: shizuyo.kusumi@op.cao.go.jp

KUWABARA, Jun
Shirane 2-4, Shirakata
Tokai-mura, Naka-gun
Ibaraki-ken 319-1195
Tel: +813 29 282 5201
Fax: +813 29 282 5201
Eml: quabara@popsvr.tokai.jaeri.go.jp

MASUI, Hideki
Deputy Manager
Tokyo Electric Power Corporation
1-1-3 Uchisaiwai-cho, 1-chome, Chiyoda-ku
Tokyo 100-0011
Tel: +81 3-4216-5983
Fax: +81 3 4216 4649
Eml: masui.hideki@tepco.co.jp

MATSUBARA, Junko
Radiation Effect Association
Maruishi-Daini Bldg. 5F
1-9-16 Kajichou, Chiyoda-ku
Tokyo 101-0044
Tel: +81-3-5295-1583
Fax: +81-3-5295-1486
Eml: jmatsub@rea.or.jp

MATSUDAIRA, Hiromichi
5-387 Heiwadai,
Nagareyamashi 270-0157
Eml: koshoji@ka2.koalanet.ne.jp

MATSUO, Kazumori
Supervising Director
Dept. of Emergency Preparedness Operation
Nuclear Safety Technology Center (NUSTEC)
Tokyo Toyama Kaikan Bldg. 5
1-3-101 Hakusan, Bunkyo-ku
Tokyo 112-8604
Tel: +81 3 3816 4730
Fax: +81 3 3816 4735
Eml: matsuo@nustec.or.jp

MIKAJIRI, Motohiko
Radiation Effects Association
Institute of Radiation Epidemiology
Maruishi-Daini Bldg. 5f
1-9-16 Kajicho, Chiyoda-ku
Tokyo 101-0044
Tel: +81 3 5295 1558
Fax: +81 3 5295 1485
Eml: mikajiri@rea.or.jp
MISUMI, Takashi
Managing Director
Radiation Effects Association
Maruishi-Daini Bldg. 5f
1-9-16 Kajicho, Chiyodaku
Tokyo 101-0044
Tel: +81 03 5295 1783
Fax: +81 03 5295 1485
Eml: tsumu@rea.or.jp

MITANI, Shinji
Senior Staff
Japan Nuclear Energy Safety Organization, (JNES)
3-17-1 Toranomon, Minato-ku
Tokyo 105-0001
Tel: +81 3 4511 1805
Fax: +81 3 4511 1898
Eml: mitani-shinji@jnes.go.jp

MIYABE, Kenjiro
Radiation Protection Division
Tokai Works
Japan Nuclear Cycle Development Institute
4-33 Muramatsu, Tokai-mura, Naka-gun
Ibaraki-ken 319-1194
Tel: +81 029-282-1861
Eml: miyabe@tokai.jnc.go.jp

MIYAMARU, Kunio
General Manager
Radiation Safety Nuclear Power Division
Tokyo Electric Power Company
1-3 Uchisaiwai-cho 1-chome, Chiyoda-ku
Tokyo 100-0011
Tel: +81 3 3501 8111
Fax: +81 3 3596 8547
Eml: miyamaru.kunio@tepco.co.jp

MIYAMOTO, Dai
Ministry of Education, Culture, Sports, Science and Technology (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959
Tel: +81 3 6734 4045
Fax: +81 3 6734 4048
Eml: d-miya@mext.go.jp

MIYAMOTO, Kiriko
Examiner for Nuclear Safety,
Secretariat of the Nuclear Safety Commission
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81-(0)-3-3581-9256
Fax: +81-(0)-3-3581-9839
Eml: kiriko.miyamoto@op.cao.go.jp

MIYAUCHI, Hideaki
Ministry of Education, Culture, Sports, Science and Technology (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959
Tel: +81 3 6734 4045
Fax: +81 3 6734 4048
Eml: miyahide@mext.go.jp

MIYAZAKI, Shinichiro
Kansai Electric Power CO., Inc.
3-3-22 Nakanoshima, Kita-ku
Osaka 530-8270
Tel: +81 6 75 01 01 51
Fax: +81 6 6441 4277
Eml: k576619@kepco.co.jp

MIZUMACHI, Wataru
JNES
Fujita Kanko Toranomon Bldg., 7F
17-1, 3-chome, Toranomon, Minato-ku
Tokyo 105-0001
Tel: +81 (3) 4511 1901
Fax: +81 (3) 4511 1998
Eml: mizumachi-wataru@jnes.go.jp
MOCHZUKI, Yasushi
Director, Health and Safety Measures Promotion Office, Working Hours and Welfare Division
National Personnel Authority, Japanese Gov.
1-2-3 Kasumigaseki, Chiyoda-ku
Tokyo 100-8913
Tel: +81-3-3581-5311
Fax: +81-3-3597-9527
Eml: mochizukiy@jinji.go.jp

MORIGAKI, Takashi
Animal Health and Animal Products Safety
Food Safety and Consumer Affairs Bureau,
Ministry of Agriculture, Forestry and Fisheries
2-1 Kasumigaseki 1-Chome, Chiyoda-ku
Tokyo 100-8950
Tel: +81 3 3502 8111
Fax: +81 3 3502 8206
Eml: takashi_morigaki@nm.maff.go.jp

MORIOKA, Hisayoshi
Safety Examiner, Secretariat of Nuclear Safety Commission
Bldg. No. 4, 6th fl.
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 9256
Fax: +81 3 3581 9839
Eml: hmoriok@op.cao.go.jp

MUKAIDA, Naoki
Tokyo Electric Power Company
1-3 Uchisaiwai-cho, 1-chome, Chiyoda-ku
Tokyo 100-8560
Tel: +81 3 4216 1111
Fax: +81 3 3596 8547
Eml: mukaida.naoki@tepco.co.jp

MURATA, Takashi
Director of General Affairs Division
Secretariat of Nuclear Safety Commission
Bldg. No. 4, 6th fl.
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 3476
Fax: +81 3 3581 9835
Eml: tmurata1@op.cao.go.jp

NAGATAKI, Shigenobu
Executive Director
Japan Radioisotope Association
2-28-45 Honkomagome, Bunkyo-ku
Tokyo 113-8941
Tel: +81 3 5395 8021
Fax: +81 3 5395 8051
Eml: nagataki@jrias.or.jp

NAKAGAMI, Motonori
Manager
Operations & Maintenance Group
Toshin-cho, Hogashi-ku
Nagoya 461-8680
Tel: +81 70 5970 3776
Fax: +81 52 973 3176
Eml: nakagami.motonori@chuden.co.jp

NAKAMURA, Seiichi
Health Research Foundation
Pasteur Bldg. 5F
103-5 Tanaka-Monzen-chou, Sakyu-ku
Kyoto 606-8225
Tel: +81-75-702-1141
Fax: +81-75-702-2141
Eml: sinakamu@taishitsu.or.jp

NAKAMURA, Takashi
Cyclotron and Radiosotope Center
Tohoku University
Aramaki, Aoba-ku, Sendai-Shi
Miyagi-ken 980-8579
Tel: +81 (22) 217 7805
Fax: +81 (22) 217 7805/7809
Eml: nakamura@cyric.tohoku.ac.jp
NAKAMURA, Yasushi
Japanese Atomic Power Company
1-1 Kanda Mitoshiro-cho, Chiyoda-ku
Tokyo 101-0053
Tel: +81 3 4415 6080 ext: 6128
Eml: yasushi-nakamura@japc.co.jp

NAKANISHI, Seiji
General Manager
Office of International Affairs
Radiation Effects Association
Maruishi-Daini Bldg. 5F
1-9-16 Kajicho, Chiyoda-ku
Tokyo 101-0044
Tel: +81 3 5295 1497
Fax: +81 3 5295 1485
Eml: seiji@rea.or.jp

NISHIHORI, Toshio
Chief Specialist, EHS
Global Nuclear Fuel
2-3-1 Uchikawa, Yokosuka
Tokyo 101-0044
Tel: +81 46 833 2304
Fax: +81 46 833 2395
Eml: toshio.nishihori@gnf.com

NITTA, Koshi
Deputy Director of Radiation Protection
Secretariat of Nuclear Safety Commission
Bldg. No. 4, 6th fl.
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
Tel: +81 3 3581 9256
Fax: +81 3 3581 9839
Eml: koshi.nitta@op.cao.go.jp

NIWA, Ohtsura
Director, Radiation Biology Center
Kyoto University
Yoshida Konoe-cho, Sakyo-ku
Kyoto 606-8501
Tel: +81 75-753-7563
Fax: +81 75 753 7564
Eml: oniwa@house.rbc.kyoto-u.ac.jp

NOGUCHI, Hiroshi
Head Internal Dosimetry Lab.
Japan Atomic Energy Research Institute
Tokai-mura Naka-gun
Ibaraki-ken 319-1195
Tel: +81 29 282 5242
Fax: +81 29 282 6063
Eml: noguh@popsvr.tokai.jaeri.go.jp

NUMAKUNAI, Takao
General Advisor
Institute of Radiation Measurements
2-4 Shirane Shirakata, Naka-gun
Ibaraki-ken 319-1106
Tel: +81 29 282 5546
Fax: +81 29 283 2157
Eml: t.numakunai@irm.or.jp

ODA, Kimihiko
Senior Deputy Director-General
Executive Director for Nuclear Safety
Ministry of Education, Culture, Sports, Science and Technology (MEXT)
2-5-1 Marunouchi, Chiyoda-ku
Tokyo 100-8959
Tel: +81-3-6734-4002
Fax: +81-3-6734-3835
Eml: koda@mext.go.jp
OGATA, Akiko  
Safety Intelligence Division,  
Incorporated Administrative Agency  
Japan Nuclear Energy Safety Org. (JNES)  
Fujitakanko-Toranomon Bldg. 8th Floor  
3-17-1 Toranomon, Minato-ku  
Tokyo 105-0001

Tel: +81(3) 4511 1946  
Fax: +81(3) 4511 1998  
Eml: ogata-akiko@jnes.go.jp

OGIU, Toshiaki  
Head, Special Research  
Research Centre for Radiation Safety,  
National Institute of Radiological Science  
4-9-1 Anagawa, Inage-ku  
Chiba 263-8555

Tel: +81-43-206-3200  
Fax: +81-43-206-4138  
Eml: ogiu@nirs.go.jp

OHMOMO, Yoichiro  
President  
Institute for Environmental Sciences  
1-7 Ienomae, Obuchi, Rokkasho-mura, Kamikita  
Aomori-ken 039-3212

Tel: +81 175 71 1203  
Fax: +81 175 72 3690  
Eml: momo@ies.or.jp

OISHI, Tetsuya  
Examiner  
Secretariat of the Nuclear Safety Commission  
3-1-1 Kasumigaseki, Chiyoda-ku  
Tokyo 100-8970

Tel: +81 3 3581 9256  
Fax: +81 3 3581 9839  
Eml: tetsuya.oishi@op.cao.go.jp

OKAMURA, Yasuharu  
Japan Nuclear Fuel Limited  
4-108 aza Okitsuke, Oaza Obuchi  
Rokkasho-mura, Kamikita-gun  
Aomori 039-3212

Tel: +81 175-71-2014  
Fax: +81 175 71 2061  
Eml: yasuharu.okamura@jnfl.co.jp

OKUYAMA, Shigeru  
Manager for Safety Affairs  
Nuclear Waste Management Organization (NUMO)  
Mita NN Bldg.  
1-23 Shiba 4-chome, Minato-ku  
Tokyo 108-0014

Tel: +81 3 4513-1573  
Fax: +81 3 4513 1599  
Eml: sokuyama@numo.or.jp

OOYAMA, Kazuhisa  
Senior Staff, Radiological Equip. Sec.  
Japan Nuclear Fuel Ltd.  
Reprocessing Business Div.  
4-108 aza Okitsuke, Oaza Obuchi  
Rokkasho-mura, Kamikita-gun  
Aomori 039-3212

Tel: +81 175 71 2015  
Fax: +81 175 71 2161  
Eml: kazuhisa.ooyama@jnfl.co.jp

SAKAGUCHI, Shoichira  
Deputy Director of General Affairs Division  
Secretariat of Nuclear Safety Commission  
Bldg. No. 4, 6th fl.  
3-1-1 Kasumigaseki, Chiyoda-ku  
Tokyo 100-8970

Tel: +81 3 3581 9918  
Fax: +81 3 3581 9835  
Eml: ssakagu@op.cao.go.jp

151
SAKAI, Kazuo  Tel: +81 3 3480 2111
Senior Research Scientist  Fax: +81 3 3480 3113
Low Dose Radiation Research Center  Eml: kzsakai@criepi.denken.or.jp
2-11-1 Iwado-kita, Komae
Tokyo 201-8511

SASAKI, Masao  Tel: +81 75 955 8943
Professor Emeritus  Fax: +81 75 955 8943
Radiation Biology Centre, Kyoto University  Eml: msasaki@emp.mbox.media.kyoto-u.ac.jp
Yoshida, Konoe-cho, Sakyo-ku
Kyoto 606-8501

SASAKI, Yashuhito  Tel: +81 43 206 3000
President  Fax: +81 43 206 3721
National Institution of Radiological Science  Eml: y_sasaki@nirs.go.jp
4-9-1 Anagawa, Inage-ku
Chiba-shi 263 8555

SATO, Hideharu  Tel: +81 3-5470-1986
General Manager, Research and Planning Dev.  Fax: +81 3 5470 1991
Nuclear Safety Research Association  Eml: hsato@nsra.or.jp
5-18-7 Shimibashi, Minato-ku
Tokyo 105-0004

SHIGEMATSU, Itsuzo  Tel: +81 3 5729 1855
Consultant Emeritus  Fax: +81 3 5729 1855
Radiation Effects Research Foundation  Eml: kurotaki@rea.or.jp
4-8-8 Yakumo, Meguro-ku
Tokyo 152-0023

SHIMADA, Yoshiya  Tel: +81 43 206 3221
Low Dose Radiation Effect Project  Fax: +81 43 251 4268
National Institute to Radiological Science  Eml: y_shimad@nirs.go.jp
4-9-1 Anagawa, Inage-ku
Chiba 263-8555

SHIOTSUKI, Keiko  Tel: +81 35395 8084
Radiation Protection Section Div.  Fax: +81 35395 8054
of General Affairs Institution  Eml: shiotsuki@jrias.or.jp
28-45 Honkomagome-2, Bunkyo-ku
Tokyo 113-8941

SHUTO, Yuki  Tel: +81 3 3260 9414
Research Institute for Social Safety (RISS)  Fax: +81 3 3260 9492
Human Factors Lab.  Eml: shuto@e-riss.co.jp
Tsukudo-Okamoto Bldg.
3-12 Tsukudo-cho, Shinjuku-ku
Tokyo 162-0821

SODA, Kunihisa  Tel: +81 (3) 3581 3470
Commissioner  Fax: +81 (3) 3581 3475
Nuclear Safety Commission  Eml: kunihsia.soda@op.cao.go.jp
3-1-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8970
TAKASHIMA, Fusao                           Tel: +81 175 71 2014
Japan Nuclear Fuel Ltd.                    Fax: +81 175 71 2161
Reprocessing Business Div.                 Eml: fusao2.takashima@jnfl.co.jp
4-108 aza Okitsuke, Oaza Obuchi
Rokkasyo-mura, Kamikita-gun
Aomori-ken 039-3212

TAKEDA, Koutaro                            Tel: +81 11 251 1111 (ext: 5731)
Manager                                    Fax: +81 11 222 4838
Nuclear Engineering Group                  Eml: k-takeda@epmail.hepco.co.jp
Hokkaido Electric Power Company, Inc.      
2 Higashi 1-Chome, Ohdori, Chuo-ku
Sapporo, Hokkaido 060-8677

TANABE, Hiroshi                            Tel: +81 175 71 2392
Japan Nuclear Fuel Limited                 Fax: +81 175 71 2071
4-108 aza Okitsuke, Oaza Obudi             Eml: hiroshi.tanabe@jnfl.co.jp
Rokkasyo-mura, Kamikita-gun
Aomori-ken 039-3212

TATSUMI, Kouichi                           Tel: +81 3 5295 1491
Director, Institute of Radiation Epidemiology Fax: +81 3 5295 1485
Radiation Effects Association               Eml: tatsumi@rea.or.jp
Maruishi-Daini Bldg. 5th Fl.
1-9-16 Kajicho, Chiyoda-ku
Tokyo 101-0044

TEZUKA, Masayuki                           Tel: +81 3 5295 1483
Director                                    Eml: tezuka@rea.or.jp
Planning Division, Maruishi-Daini Bldg. 5    
1-9-16 Kajicho, Chiyoda-ku
Tokyo 101-0044

TOYOSHIMA, Naoyuki                         Tel: +81 92 761 3031
Safety Analysis and Radiation Protection     Fax: +81 92 726 1559
Nuclear Power Operation Dept.               Eml: naoyuki_toyoshima@kyuden.co.jp
Kyushu Electric Power Co., Inc              
2-1-82 Watanabe-dori, chuou-ku             
Fukuoka 810-8720

UMEZAWA, Hirokazu                          Tel: +81 3 3581 9259
Technical Counsellor                       Fax: +81 3 3581 9839
Secretariat of Nuclear Safety Commission    Eml: humezaw@op.cao.go.jp
Bldg. No. 4, 6th fl.                       
3-1-1 Kasumigaseki, Chiyoda-ku             
Tokyo 100-8970

YAMADA, Masatsugu                           Tel: +81 3 6734 4024
Ministry of Education, Culture, Sports, Sciences Fax: +81 3 6734 4027
and Technology (MEXT)                      Eml: mayamada@mext.go.jp
2-5-1 Marunouchi, Chiyoda-ku               
Tokyo 100-8959
YAMAGUCHI, Ichiro  
National Institute of Public Health  
4-6-1, Shirokane-dai, Minato-ku  
Tokyo 132-8638  
Tel: +81(3)3441 7196  
Fax: +81(3)3446 6468  
Eml: drhyama@niph.go.jp

YAMAGUCHI, Yasuhiro  
Japan Atomic Energy Research Institute (JAERI)  
Department of Health Physics  
Tokai-mura, Naka-gun  
Ibaraki 319-1195  
Tel: +81 29 282 6067  
Fax: +81 29 282 6063  
Eml: yachan@popsvr.tokai.jaeri.go.jp

YAMAMOTO, Masafumi  
Project Manager  
No. 15 Mori Bldg.  
2-8-10, Toranomon, Minato-ku  
Tokyo 105-0001  
Tel: +81 3504 1537  
Fax: +81 3504 1297  
Eml: m_yama@rwmc.or.jp

YAMANAKA, Takeshi  
Safety Standard Division,  
Japan Nuclear Energy Safety Org. (JNES)  
Fujita Kanko Toranomon Bldg 7F  
3-17-1 Toranomon, Minato-ku  
Tokyo 105-0001  
Tel: +81-(0)-3-4511-1804  
Fax: +81-(0)-3-4511-1898  
Eml: yamanaka-takeshi@jnes.go.jp

YODA, Norihiko  
Ministry of Education, Culture, Sports, Science and Technology (MEXT)  
2-5-1 Marunouchi, Chiyoda-ku  
Tokyo 100-8959  
Tel: +81 3 6734 4045  
Fax: +81 3 6734 4048  
Eml: drppstpb@mext.go.jp

YOKOYAMA, Sumi  
Department of Health Physics, (JAERI)  
Tokai-mura, Naka-gun  
Ibaraki-ken 319-1195  
Tel: +81 29 282 5195  
Fax: +81 29 282 6063  
Eml: sumi@popsvr.tokai.jaeri.go.jp

YONEHARA, Hidenori  
Radon Research Group  
Research Center for Radiation Safety  
National Institute of Radiation Sciences  
4-9-1 Anagawa  
Chiba 263-8555  
Tel: +81-43-206-3099  
Fax: +81-43-206-4097  
Eml: Yonehara@nirs.go.jp

YOSHIKAWA, Susumu  
Director, Nuclear Power Division  
Tokyo Electric Power Environmental Engineering  
6-14-6 Chome Shibura, Minato-ku  
Tokyo 108-8537  
Tel: +81 (3)  4511 7610  
Fax: +81 (3) 3452 4730  
Eml: yoshikawa-susumu@mail.tee-kk.co.jp

YOSHIZAWA, Michio  
Japan Atomic Energy Research Institute  
2-4 Shirakata-Shirane, Tokai, Naka-gun  
Ibaraki 319-1195  
Tel: +81 29 282 6066  
Fax: +81 29 282 6063  
Eml: m-yoshi@popsvr.tokai.jaeri.go.jp
KOREA (REPUBLIC OF)
LEE, Jaiki                                         Tel: +82 2 290 0466
Hanyang University                                   Fax: +82 2 290 0533
Nuclear Engineering Department                       Eml: jklee@rrl.hanyang.ac.kr
17 Haengdang-dong, Seongdong-gu
Seoul 133-791

CHANG, Si Young                            Tel: +82 (42) 868 3205
Manager, Health Physics Dept.              Fax: +82 (42) 868 8609
Technical Support & Administration         Eml: sychang@kaeri.re.kr
Korea Atomic Energy Research institute
105 P.O. Box Yusong
Taejon 305-600

P.R. OF CHINA
GUO, Qiuju                                 Tel: +8610 62755403
Associate Professor                        Fax: +8610 62751615
Department of Technical Physics            Eml: qjguo@pku.edu.cn
Peking University                            Peking 100871
Peking 100822

PAN, Zi Qiang                                   Tel: +86 10 685 10 370
Science and Technology Commission              Fax: +86 10 685 39 375
China Atomic Energy Authority                        Eml: zqpan@a-1.net.cn
P.O. Box 2102-14
Beijing 100222

XIA, Yihua                                       Tel: +86 (1069) 357 584
Dept of Health Physics                               Fax: +86 (1069) 357 008
China Institute of Atomic Energy (CIAE)              Eml: xiayh@iris.ciae.ac.cn
P.O. Box 275(24)
Beijing 102413

UNITED KINGDOM
CLARKE, Roger H.                                Tel: +44 1635 253957
Corner Cottage,                                      Fax: +44 1235 82 26 19
Woolton Hill,                                        Eml: clarke.rogerh@btopenworld.com
Newbury
Berkshire RG20 9XJ

PATerson, John                                      Tel: +44 20 7911 5000 Ext 2514
Reader                                               Fax: +4420 7911 5821
School of Law                                        Eml: J.Paterson@westminster.ac.uk
University of Westminster
4 Little Titchfield Street
London W1W 7UW

International Organisations
LAZO, Edward                              Tel: +3 (0)1 45 24 10 42
Deputy Head                                    Fax: +33 (0)1 45 24 11 10
Radiation Protection and Waste
Management Division                           Eml: lazo@nea.fr
OKAMURA, Katsuyoshi  
Radiation Protection and Waste Management Division  
Tel: + 33 (0) 1 45 25 11 41  
Fax: + 33 (0) 1 45 24 11 45  
Eml: katsuyoshi.okamura@oecd.org

RIOTTE, Hans  
Head  
Radiation Protection and Waste Management Division  
Tel: +33(1) 45 24 10 40  
Fax: +33(1) 45 24 11 10  
Eml: hans.riotte@oecd.org

SHIMOMURA, Kazuo  
Deputy Director  
Safety and Regulation  
Tel: +33 01 45 24 10 04  
Fax: +33 01 45 24 11 06  
Eml: kazuo.shimomura@oecd.org

OECD Nuclear Energy Agency  
Le Seine St. Germain  
12, boulevard des Iles  
92130 Issy-les-Moulineaux