ICRP Newsletter n°14

May 2007

During its meeting held in Essen (Germany) in March 2007, the International Commission on Radiological Protection (ICRP) unanimously approved the final version of the draft on new general recommendations for the protection of mankind and the environment against ionizing radiation. These general recommendations will supersede the previous version published in 1991, i.e. more than 15 years ago (Publication 60).

An open process

This decision is the ultimate step of a process initiated 9 years earlier. For the first time, ICRP has opened a dialogue with radioprotection professionals This process was marked out with multiple meetings, seminars and conferences organized by various national and international bodies. In particular, the part played by NEA and the European Commission should be highlighted. Furthermore, the project was twice opened to a wide consultation via Internet. As a total, more than 700 pages of comments were received.

The reasons for change

The reasons are of three types: integrate scientific progresses, incorporate the feedback from the current system application, and meet the Society expectations with regard to environmental protection.

ICRP conducted an in-depth review of the scientific knowledge acquired during the past fifteen years. The following main consequences were recorded with regard to the management of the radiological hazard:

(1) The assumption on the linear-non-threshold dose-effect relationship was confirmed; (2) the overall risk coefficient for stochastic effects (cancers and hereditary effects) of about 5% per Sievert is still appropriate; finally (3), the dose and dose rate effectiveness factor (DDREF) is kept at a value of 2. The DDREF allows changing from the risk coefficient assessed from the studied groups of populations (typically exposed to high doses and high dose rates) to the coefficient applied for commonly exposed people (low doses and low dose rates).

The feedback on the application of the radiological protection system derived from ICRP 60 demonstrated that it correctly operated in the conventional area of practices where sources are controlled from the very beginning, but appeared more difficult to apply in certain situations involving intervention, whether in case of radiological emergency or in chronic exposure situations (exposure to natural sources, management of contaminated territories, etc.).

Since the publication of ICRP 60, the Society changes were characterized by the requirement for a sustainable development and consequently, an increased demand for quality of the environment. In this context, the assertion stating that the environmental protection was ensured through the mankind protection was reviewed and appeared to be not demonstrated. ICRP created a dedicated committee in order to define the bases of a radiological protection system for non-human species (fauna and flora). The revision of the ICRP recommendations was the occasion to integrate the forerunners of this consideration, with still modest extent provisions.

The main innovation

The main innovation is the end of a ***two-speed protection system***, which stipulated in one case (practices, e.g. operation of industrial sources) the setting of a maximum dose value followed by a reduction of exposures as low as reasonably achievable and, in the other case (interventions, e.g. contaminated sites or territories) the setting of a minimum dose – sometimes high – and the obligation to take action ***only*** when the dose was exceeded. From now, the first approach applies, regardless of the exposure situation type (planned, emergency, or existing situation), with reference values selected in accordance with the situation characteristics and initiation of an individual dose reduction process until an optimized level is obtained.

These reference values apply to the exposure of an individual to a ***single source***. They are named “dose constraint” in planned situations, and “reference level” in other situations. This is in fact the same concept. In order to provide a guidance to the national decision makers for selecting appropriate values, ICRP defined a

dose scale (Table 1) reflecting the fact that, within a continuum of risk (linearity without threshold), the risk that everyone is ready to accept depends on the exposure context. This scale is divided into three bands depending as the action is more or less necessary, in accordance with the characteristics of the exposure situation (more or less easy control of the source, individual or societal benefit from the situation, requirements with regard to information, training and dosimetric or medical surveillance). The numerical values defining these bands already existed in the previous recommendations: <1 mSv/year, 1-20 mSv/year and 20-100 mSv/ year.

Therefore, in the core of the new system, the optimization principle appears to be the guideline to keep the doses to exposed individuals as low as reasonably achievable, regardless of the exposure situation. Both other principles are kept, but "softened":

– the justification applicable to decisions resulting in a modification of exposures due to a single source, while acknowledging that radiological protection is only one element being considered;

– the individual dose limits, applicable to the exposure resulting from ***all sources*** to which the individual is exposed, even if it is often difficult to identify all of them. The limits apply only to planned exposure situations, which are the only ones for which it is possible to control in advance the extent of individual exposures. The ICRP 60 values remain unchanged.

The exposure categories (occupational, public and medical) are also kept with, in particular, different numerical values and an accounting separate from doses, even when an individual is at the same time a worker, a member of the public and a patient.

Practical consequences for the management of emergency and existing exposure situations

The ICRP purpose was to simplify the system without upsetting it, in order to incorporate the request for stability expressed by professionals and especially by regulatory bodies. However, the new recommendations will result in inflections in the management of emergency and existing exposure situations.

These changes basically concern the reference values and their application.

Until now, the management of emergency situations involved the implementation of individual protection measures (ingestion of iodine tablets, sheltering, evacuation, relocation), which were initiated in accordance with intervention levels associated with each measure, without really considering the resulting individual dose (residual dose). From now, ICRP stipulates a criterion expressed in terms of residual dose and recommends a maximum value of 100 mSv, regardless of circumstances, except for saving human lives. In order to meet this level of ambition, a strategy combining all the protection measures should be defined.

In existing situations (natural or post-accident exposures), the current practice consists in implementing protective actions only when action levels are exceeded. Furthermore, based on the idea that such situations are more difficult to control, the recommended values are relatively high (action almost always justified above 100 mSv/year, almost never justified below 10 mSv/year, and justified on a case-by-case basis between both values). The experience demonstrated that it was possible – and desired for equity and ethical reasons – to go further. ICRP now recommends to implement gradual strategies aiming at finally obtaining exposure levels similar to the levels in normal situations (about 1 mSv/year), even if this involves a long term vigilance, including by exposed individuals.

However, the new recommendations remain general. ICRP created two working groups in charge of progressing on the application of the new system in emergency and existing exposure situations. The relevant reports are planned for 2009. In the meantime, these changes will probably be applied by other international bodies that started revising their own Basic Safety Standards (IAEA and Euratom).

Constraints and reference levels (projected effective dose[1], in mSv)	**Characteristics of the exposure situation**	**Requirements to be met**	**Examples**
20 to 100[2]	Situations when individuals are exposed to non controllable sources. Dose reducing actions highly disturbing. Exposures are usually controlled through actions on the exposure pathways and not on the source itself.	Try and reduce doses, especially if they are close to 100 mSv. Obligation to inform individual on the risks and on dose reducing actions. Obligation to assess individual doses.	Reference level defined for the dose (projected or residual) in case of **radiological emergency**.
1 to 20	Exposed individuals usually benefit from the exposure situation, but not necessarily by the exposure itself. Exposures may be controlled from the sources or by an action on the exposure pathways.	If possible, a general information should be available in order to allow individuals to reduce their doses. For planned situations, obligation for individual surveillance and training.	Constraints for exposure of **workers in planned situations**. Constraints for **companions of patients** treated with radiopharmaceuticals. Reference level for **radon in dwellings**.
less than 1	Individuals exposed to a source obtain no benefit or a little benefit from the exposure situation which, on the contrary, is beneficial to the Society as a whole. Exposures are usually controlled by actions taken directly on the source, for which protection requirements can be planned in advance.	A general information on the exposure level should be made available. Periodic checks should be conducted on the exposure pathways and levels.	Constraints for the **public in planned situations**.

[1] Acute or annual dose.
[2] In exceptional situations, informed volunteer workers may receive doses exceeding the specified maximum value to save lives, prevent severe radiation-induced effects, or prevent the development of conditions that may be catastrophic.

Table 1. Scale of constraints and reference levels with regard to a dominant source. Examples of values applied for protection of workers and members of the public and valid for all exposure situations that can be controlled.

APPENDIX to ICRP Newsletter n°14

SCIENTIFIC BASES FOR 2007 RECOMMENDATIONS PRACTICAL CONSEQUENCES

The ICRP recommendations for 2007 rely on a set of scientific knowledge, updated via studies conducted during the past fifteen years and listed in three documents complementing the recommendations, and also subject to review by national and international bodies:

- *Low dose extrapolation of radiation-related cancer risk* (ICRP Publication 99, 2006),
- *Biological and epidemiological information on health risks attributable to ionizing radiation: a summary of judgments for the purposes of radiological protection of humans* (Appendix A to 2007 Recommendations),
- *Quantities used in radiological protection* (Appendix B).

ICRP derived the following consequences for management of radiological hazards.

RISK TO RADIATION-INDUCED CANCER

Form of the dose-effect relationship. The statistical power of epidemiological surveys increases with the follow-up duration of exposed populations. The increasing number of cancers observed thus contributes to a better understanding and accuracy of the resulting dose-effect relationships. The data derived from the survey of the Hiroshima and Nagasaki Japanese survivors, who represent the largest population being carefully studied in long term, and associated with a realistic assessment of individual doses, is compatible, for a wide range of doses, with a linear or linear-quadratic relationship. The results from numerous other surveys are also compatible with a linear relationship. UNSCEAR[1], like the United States National Academies[2] and National Council on Radiation Protection and Measurements[3], concludes that the linear extrapolation of the estimated risk for acute doses of approximately 1 Sv, may be applied when estimating the risk at low doses. From this basis of results, ICRP estimates that, for low doses, i.e. within a dose range less than 100 mSv, it is *scientifically reasonable* to assume that cancer increase is directly proportional to the dose increase (linear relationship).

Threshold question. Although the minimum dose required to assess an excessive risk tends to decrease when the statistical power increases, UNSCEAR believes that epidemiology alone cannot demonstrate the existence or not of a dose threshold below which radiation would not induce cancers; but, UNSCEAR adds that the disability of epidemiological surveys to detect an increased risk for very low doses does not imply that the risk for cancer does not exist for such dose levels. ICRP has adopted these conclusions and considers that its protection system can remain based on a linear-non-threshold relationship.

Effectiveness reduction of radiation at low doses and low dose rates. It was not possible to refine, on the basis of epidemiological surveys only, the value of the dose and dose rate effectiveness factor (DDREF), set to 2 by ICRP in 1990. The comparison, by the United States National Academies[2], between experimental exposures and the combination of epidemiological, animal and cellular data, resulted in values ranging from 1.1 to 2.3, with a recommended value of 1.5. However, a value of 2 is compatible with the basic data and the US report recognizes that the selection involves subjective and probabilistic uncertainties. The report adds that the DDREF value ranges from 2 to 4 for inducing genetic or chromosomal mutations, and from 2 to 3 for inducing cancers and for shortening animal lifetime. Consequently, ICRP keeps a DDREF equal to 2 for solid organ cancers (for leukemia, a linear-quadratic relationship is more likely). However, it recognizes that different values may exist for specific organs and tissues.

Cancer risk quantification. Since 1990, new information were gathered, especially with regard to the risk for specific organs. Most of it was obtained from the survey of Hiroshima and Nagasaki Japanese survivors, with a 47-year follow-up for lethal cancer, and 41-year follow-up for cancer incidence. Furthermore, as the cancer diagnosis is better than in the past, it is now possible to attribute a greater importance to data about incidence. For certain cancers and certain cancer sites, the survey results are reasonably compatible with the results obtained from epidemiological surveys on patients and workers,

[1] UNSCEAR: United Nations Scientific Committee on the Effect of Atomic Radiation. 2000 and 2006 Reports.
[2] NAS/NRC, National Research Council of the National Academies. BEIR VII Report, phase 2, 2005.
[3] NCRP, Report 36, 2001.

as well as ecological surveys. However, most of the latter surveys are faulty due to a lack of data about doses and about tumors attributable to radiation. The current ICRP calculation method, weighted on both sexes, implies estimating nominal cancer risks for various organs and tissues, adjusted in accordance with the DDREF, lethality and quality of life. On these bases, ICRP proposes a risk coefficient equal to 5.5 10^{-2} Sv^{-1} for the population as a whole, and 4.1 10^{-2} Sv^{-1} for adults, i.e. a risk level similar to that recommended in 1990.

RISK OF RADIATION-INDUCED HEREDITARY DISEASE

Like radiation-induced cancers, radiation-induced hereditary diseases have no specific character, are discovered late, and have no difference as compared with current genetic diseases. Although the existence of radiation-induced hereditary effects is not proven for mankind, ICRP estimates that a sufficient number of concordant experimental evidences exist with regard to the presence of mutations in animal germinal cells for the requirement to continue including the risk for hereditary effects in its protection system. Since 1990, new data were gathered with regard to the quantitative aspect of genetic mutations expressed in successive generations, and to the fundamental knowledge of genetic diseases as a whole and radiation-induced diseases in particular. UNSCEAR notes that the results of the Hiroshima and Nagasaki survivors monitoring and of studies on mice, demonstrate an overestimate of the risk in the past. ICRP is now applying the same approach when estimating the risk, as UNSCEAR and United States National Academies, by comparing the rate of spontaneous genetic mutations in human genes and the rate of radiation-induced mutations in mouse genes, while previously the estimate was based on mice only. ICRP also considers that the previous expression of the genetic risk, which resulted from a theoretical balance between mutation and selection, is no longer valid. The assessment now concerns the risk for hereditary diseases up to the second generation, which is estimated as 0.2 10^{-2} Sv^{-1} for the population as a whole. This value corresponds to long-term exposures at low dose rate over two generations (exposure of grandparents and parents and effects observed on children and grandchildren).

OVERALL DETRIMENT FROM RADIATION-INDUCED CANCERS AND HEREDITARY EFFECTS

Table 1 provides comparative values for stochastic effect risks selected by ICRP 2007 against the values recommended in 1990. The comparison is not directly possible because (1) the nominal rate for cancers corresponded in 1990 to the lethal cancer risks weighted by parameters different from those considered in 2007 (risk for non-fatal cancer, life time lost from fatal cancers and health alterations due to non-fatal cancers) and (2) the calculation for hereditary diseases is based on another method. The 1990 and 2007 values are not very different for cancers, while a 6 to 8 reduction coefficient exists for hereditary effects. ICRP recommends an approaching value of 5% per Sv for the overall detriment to be applied when defining international radioprotection standards.

Exposed population	**Cancers**		**Hereditary effects**		**Total**	
	2007	1990	**2007**	1990	**2007**	1990
Global	**5.5**	6.0	**0.2**	1.3	**5.7 ≈ 6.0**	7.3
Adult	**4.1**	4.8	**0.1**	0.8	**4.2 ≈4.0**	5.6

Table 1. Comparison between 1990 (ICRP Publication 60) and 2007 values of nominal risk coefficients for stochastic effects, expressed in % per Sv.

RADIATION-INDUCED EFFECT RISK TO EMBRYO AND FETUS

Mortality during the pre-implantation phase may be ignored under usual situations, as it is unlikely for doses less than 100 mGy.

Malformations are difficult to estimate, both in quality and quantity. Based on a real threshold around 100 mSv, ICRP considers that its system may ignore this risk, under current conditions.

Severe mental retardations may appear between the 8th and 15th week of pregnancy, with a threshold above 300 mGy; the IQ decrease by 25 points per Sv is difficult to interpret and the relation to the dose is very uncertain. Even with no threshold, but considering the low importance of IQ decrease for doses less than 100 mSv, ICRP considers

that this effect is not to be considered for dose levels usually met.

Cancer risk following *in utero* exposures is of the same order of magnitude than the risk due to exposure of very young children; as a maximum, it is equal to several time the risk for the population as a whole.

GENETIC SUSCEPTIBILITY TO CANCER

Since 1990, knowledge about genetic susceptibility to cancer experienced a dramatic progress. On these new bases, summarized in Publication 79 in 1999, UNSCEAR reports in 2000 and 2001, and United States Academy reports in 2005, ICRP considers that strongly expressing, high penetrance, cancer genes are too rare to justify a significant modification to the risk estimate for low doses, as estimated based on population observations. But, for certain individuals, consequences may be severe, for example for irradiated patients with specific genes, who would then show an increased probability to develop a second cancer. This is the only case when genetic susceptibility should be considered.

RADIATION-INDUCED DISEASES OTHER THAN CANCER

Radiation-induced diseases other than cancer have been identified and studied since 1990. The risk for cardiovascular, digestive and respiratory diseases is significantly increased for the Hiroshima and Nagasaki Japanese survivors after doses of around 1 Sv. Uncertainties remain about the possible forms of the dose-effect relationships and the question about the existence of a threshold around 500 mSv remains open. The same observations exist for groups of patients being irradiated in the thoracic area. Although acknowledging the potential importance of such effects, ICRP concludes that the current data is still too inaccurate to be considered when estimating the radiological detriment resulting from doses less than about 100 Sv.

OTHER TYPES OF EFFECTS

Other effects are still more difficult to interpret and quantify. This is the case for **genomic instability**[4], **bystander effect**[5], and **adaptive response**[6].

ICRP considers that these effects may be ignored with regard to protection, either because the effect is already implicitly considered in the risk assessment, or because no tangible evidences of an adverse effect exist.

[4] Genomic instability: increase, following radiation exposure, in genome modifications, which may correspond to the first critical step in cancer development.

[5] Bystander effect: capability for cells affected by an external agent to transmit information to other cells that are not direct target cells for the agent, but may express a damage.

[6] Adaptive response: stimulation of cell repair process by small radiation doses, for which it s difficult to say whether the effects are beneficial or adverse.

APPLICATION OF DOSIMETRIC QUANTITIES

The *absorbed dose*, which expresses the amount of energy deposited by radiation, remains the basic physical parameter that allows determining the resulting biological damages. This is the only value that may be applied when assessing harmful tissue reactions (deterministic effects) resulting from high doses. The *equivalent dose* and the *effective dose* keep the same definitions and application as before, but their values undergo modifications, associated with changed values of weighting factors w_T and w_R. The effective dose is used when assessing exposures and controlling the risk of stochastic effects at low doses currently met during the everyday life. It provides the instrument used to demonstrate the compliance with limits for workers and for the public, incorporating internal and external exposures. With regard to occupational exposures, the results from dosimeters are expressed in terms of equivalent dose, with the implicit assumption that the organism exposure is homogeneous. The *collective dose* is designed as a protection optimizing tool, which allows comparing protection techniques and methods. Using the collective effective dose is not appropriate when assessing the risk from epidemiological surveys. Furthermore, doses can be aggregated only when they fall within consistent ranges of levels and rates, and when they concern contemporaneous individuals living in comparable environments.

WEIGHTING FACTORS

Radiation weighting factors (w_R)

Their re-assessment by UNSCEAR resulted in a simplification, applied by ICRP:

- w_R = 1: photons, electrons, muons;
- w_R = 2: protons, charged pions;
- w_R = 20: alpha particles, fission fragments, heavy ions;
- w_R = continuous function of neutron energy.

As compared with Publication 60 in 1990, the values for protons and neutrons are modified. A single value of 2 is recommended for protons (instead of 5), and a continuous relationship depending on the energy is specified for neutrons (instead of predetermined values, scaled depending on the energy).

Tissue weighting factors (w_T)

Due to new epidemiological data, the risk for radiation-induced cancer is quantified for eight additional organs and tissues. In order to incorporate the uncertainties and simplify calculations, ICRP now groups the w_T into four families:

- w_T = 0.12: bone marrow, colon, lung, stomach, breast, and remainder tissues (adrenals, extra-thoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus, and uterus/ cervix), for which the w_T applies to the arithmetic mean of these fourteen other tissues. (total = 0.72);
- w_T = 0,08: gonads;
- w_T = 0,04: bladder, oesophagus, liver and thyroid (total = 0.16);
- w_T = 0,01: bone surface, brain, salivary glands and skin (total = 0.04).

As compared with Publication 60 in 1990, the relative risk for breast was increased (from 0.05 to 0.12), while the risk for gonads was decreased (from 0.20 to 0.08). Other pre-existing weighting factors are little modified (changed from 0.05 to 0.04 for bladder, liver, oesophagus and thyroid) or not modified at all. By definition, the sum of the w_T values is equal to 1.