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ANNALES DE L'ASSOCIATION BELGE DE RADIOPROTECTION

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Annales de l'Association belge de Radioprotection (BVSABR)

Annalen van de Belgische Vereniging voor Stralingsbescherming (BVSABR)

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SOMMAIRE **INHOUD**

STATUTS

approuvés en séance constitutive le 9 avril 1963, modifiés en Assemblées Générales Statutaires les 8 février 1975, 5 décembre 1981, 5 décembre 1986 et 3 décembre 2004

Article 1 – Buts de l'Association

L'ASSOCIATION BELGE DE RADIOPROTECTION
est une association scientifique ayant pour but:

1) de donner à ses membres une information objective et de qualité sur tous les aspects liés à la protection contre les rayonnements ionisants,
2) de contribuer à la connaissance de la radioprotection chez toutes les personnes et associations intéressées,
3) de promouvoir en permanence le développement de la radioprotection, par le regroupement de différentes disciplines scientifiques et par l'entretien de contacts au niveau international,
4) de donner un avis indépendant sur les aspects scientifiques, légaux ou organisationnels de la radioprotection, lorsque l'Association l'estime nécessaire ou sur demande.

Article 2 – Membres de l'Association

L'Association est composée de membres effectifs (de formation de niveau universitaire) et de membres associés (toute autre personne), qui s'intéressent à la protection contre les rayonnements ionisants.

STATUTEN

Goedgekeurd in de constitutieve zitting van 9 april 1963 gewijzigd door de Algemene Statutaire Vergaderingen van 8 februari 1975, 5 december 1981, 5 december 1986 en 3 december 2004

Artikel 1 – Doelstellingen van de Vereniging

De BELGISCHE VERENIGING VOOR STRALINGS-BESCHERMING
is een wetenschappelijke vereniging die tot doel heeft:

1) haar leden objectieve en hoogwaardige informatie te verschaffen over alle aspecten van de bescherming tegen ioniserende stralingen,
2) bij te dragen tot de kennis van de stralingsbescherming bij alle belanghebbende personen en verenigingen,
3) de ontwikkeling van de stralingsbescherming te blijven bevorderen door het samenbrengen van diverse wetenschappelijke disciplines en door contacten op internationaal niveau te onderhouden,
4) een onafhankelijk advies te verlenen over wetenschappelijke, wettelijke of organisatorische aspecten van de stralingsbescherming, telkens wanneer de Vereniging dit nodig acht of hierom verzocht wordt.

Artikel 2 – Leden van de Vereniging

De Vereniging is samengesteld uit effectieve leden (met een opleiding van universitair niveau) en geassocieerde leden (alle andere personen), die belang stellen in de bescherming tegen ioniserende straling.

Article 3 – Admission de nouveaux membres

Les membres effectifs et les membres associés sont admis par l'Assemblée Générale, à la majorité des membres effectifs présents.

Le vote sera secret chaque fois que demandé par un membre effectif présent.

Toute candidature de membre doit être présentée par deux membres effectifs, et doit être annoncée à l'agenda de l'Assemblée Générale suivante.

Avant d'être soumise au vote de l'Assemblée Générale, la candidature des membres doit être préalablement admise à l'unanimité par les membres du Bureau.

Artikel 3 – Aanvaarding nieuwe leden

De effectieve leden en de geassocieerde leden worden door de Algemene Vergadering aanvaard bij meerderheid van de aanwezige effectieve leden.

De stemming zal geheim zijn telkens dit door een aanwezig effectief lid wordt gevraagd.

De kandidatuur van ieder lid moet voorgedragen worden door twee effectieve leden en aangekondigd worden op de agenda van de volgende Algemene Vergadering.

Vooraleer aan de stemming van de Algemene Vergadering onderworpen te worden, moet de kandidatuur van de leden vooraf en bij eenparigheid aanvaard zijn door de leden van het Bureau.

Article 4 - Cotisation

La cotisation annuelle est fixée, chaque année, lors de l'Assemblée Générale, sur proposition du Bureau.

Artikel 4 - Bijdrage

De jaarlijkse bijdrage wordt ieder jaar tijdens de Algemene Vergadering vastgelegd, op voorstel van het Bureau.

Article 5 – Composition du Bureau

L'Association est dirigée par un Bureau composé des personnes suivantes: un président, un premier vice-président (futur président), un second vice-président (président sortant), un secrétaire général, un secrétaire général adjoint (futur secrétaire général), un trésorier et un secrétaire permanent.

Le Bureau compte en outre 12 membres au maximum. Il peut s'adjoindre des conseillers pour l'étude de problèmes particuliers. Les anciens présidents peuvent assister aux réunions du Bureau en tant que conseillers.

Artikel 5 – Samenstelling van het Bureau

De Vereniging wordt geleid door een Bureau samengesteld uit de volgende personen: een voorzitter, een eerste ondervoorzitter (toekomstig voorzitter), een tweede ondervoorzitter (uittredend voorzitter), een secretaris-generaal, een adjunct secretaris-generaal (toekomstig secretaris-generaal), een penningmeester, en een bestendige secretaris.

Het Bureau omvat daarenboven ten hoogste twaalf leden. Raadgevers kunnen toegevoegd worden om specifieke problemen te bestuderen. Gewezen voorzitters kunnen de vergaderingen van het Bureau bijwonen als raadgevers.

Article 6 – Nomination du Bureau
Le Bureau, composé de membres effectifs, est nommé par l'Assemblée Générale pour une période de deux ans, à l'exception du secrétaire général qui est nommé pour quatre ans.

A l'exception du président, les membres sortants sont immédiatement rééligibles à la même fonction.

Les élections ont lieu à la majorité absolue des voix des membres effectifs présents. Elles se feront au scrutin secret si la demande en est faite par deux membres effectifs au moins.

Le nombre de réunions du Bureau ne peut être inférieur à trois par an.

En cas de vacance de l'une des fonctions du Bureau, il est procédé lors de la plus prochaine réunion du Bureau à la désignation d'un remplaçant qui achève le mandat de son prédécesseur.

L'Assemblée Générale, sur proposition du Bureau, peut conférer les titres de Président d'honneur et de Membre d'honneur.

Artikel 6 – Aanstelling van het Bureau
Het Bureau, samengesteld uit effectieve leden, wordt voor een periode van twee jaar aangesteld door de Algemene Vergadering, behalve de secretaris-generaal die aangesteld wordt voor vier jaar.

De voorzitter uitgezonderd, zijn de uittredende leden onmiddellijk herkiesbaar in dezelfde functie.

De verkiezingen hebben plaats met absolute meerderheid van stemmen van de aanwezige effectieve leden. Zij zullen bij geheime stemming plaats grijpen zodra minstens twee effectieve leden hierom verzoeken.

Het aantal vergaderingen van het Bureau mag niet kleiner zijn dan drie per jaar.

In geval één der functies bij het Bureau vacant is, wordt tijdens de eerst volgende vergadering van het Bureau een vervanger aangesteld ter beëindiging van het mandaat van zijn voorganger.

De Algemene Vergadering kan, op voorstel van het Bureau, de titels van Erevoorzitter en Erelid toekennen.

Article 7 – Activités de l'Association
Le Bureau a pleins pouvoirs pour organiser les réunions scientifiques et pour constituer des groupes de travail sur un thème d'actualité.

Artikel 7 – Activiteiten van de Vereniging
Het Bureau heeft de volmacht om Wetenschappelijke Vergaderingen te organiseren en werkgroepen rond een actueel thema op te richten.

L'Assemblée générale est réunie au moins une fois par an, dans la première quinzaine de décembre. Tous les membres de l'Association sont convoqués à l'Assemblée Générale. Les comptes de l'Association sont clôturés au 30 novembre. Le secrétaire général et le trésorier présenteront un rapport sur l'exercice écoulé lors de l'Assemblée Générale.

De Algemene Vergadering wordt minstens éénmaal per jaar, in de loop van de eerste veertien dagen van december gehouden. Al de leden van de Vereniging worden op de Algemene Vergadering uitgenodigd. De rekeningen van de Vereniging worden afgesloten op 30 november. De secretaris-generaal en de penningmeester zullen een verslag over het afgelopen dienstjaar voorleggen op de Algemene Vergadering.

Article 8 – Publications de l'Association
Après approbation du Bureau, l'Association peut publier de l'information pour les membres, dans un ou plusieurs organes qu'elle juge appropriés. Ceci concerne en particulier, les travaux et communications présentés lors des réunions scientifiques.

Artikel 8 – Publicaties van de Vereniging
De Vereniging mag, na toestemming van het Bureau, in één of meerdere organen die zij als geschikt beschouwt, informatie voor de leden publiceren. Dit geldt in het bijzonder de bijdragen en mededelingen die in de Wetenschappelijke Vergaderingen werden voorgedragen.

Article 9 – Cas particuliers
Toutes les questions non prévues par les présents statuts sont tranchées par le Bureau qui soumettra sa décision à la ratification de l'Assemblée Générale.

Artikel 9 – Bijzondere gevallen
Al de aangelegenheden die in de onderhavige statuten niet voorzien zijn, worden door het Bureau afgehandeld, dat zijn beslissing zal onderwerpen aan de goedkeuring van de Algemene Vergadering.

Une Assemblée Générale Extraordinaire peut être convoquée dans les trente jours, à la demande écrite signée de dix membres effectifs au moins.

Een Buitengewone Algemene Vergadering wordt bijeengeroepen binnen dertig dagen nadat minstens 10 effectieve leden hier schriftelijk om verzoeken.

Article 10 – Modification des statuts
Les modifications aux présents statuts ne peuvent être décidées que par une Assemblée Générale, à la majorité des 2/3 des membres effectifs présents.

Artikel 10 – Wijziging van de statuten
Over de wijzigingen van de huidige statuten kan slechts worden beslist door een Algemene Vergadering met een tweederde meerderheid van de aanwezige effectieve leden.

La convocation à cette Assemblée Générale devra être accompagnée du texte des modifications proposées.

De uitnodiging voor deze Algemene Vergadering zal moeten vergezeld zijn van de tekst van de voorgestelde wijzigingen.

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FUKUSHIMA : CURRENT EVALUATIONS OF THE HEALTH RISKS AND POTENTIAL IMPLICATIONS FOR THE MEDICAL EMERGENCY PLANS IN BELGIUM

BVS/ABR scientific meeting
Brussels, 14 June 2013

Effects of radiation exposure on children: the new UNSCEAR report Highlights and critical review

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Chairman of the Research Implications on Health Safety Standards (RIHSS) Art 31 WG
Member of the Scientific Committee of MELODI
Alternate Belgian Representative in UNSCEAR

Abstract

Although it is recognized for long that organisms in development are particularly sensitive to exposure to ionizing radiation, it is the first time that UNSCEAR tries to carry out a synthesis of the accumulated knowledge in this field. Global scientific evaluations coming from international organizations, particularly from UNSCEAR, which presents itself as a "purely scientific committee", are usually considered as validated states of the art of the knowledge in the field of the effects of ionizing radiation on human health, for example for risk assessments after a nuclear accident.

Nevertheless the concept of "purely scientific" judgment is a kind of modern illusion, as science cannot avoid interferences with political, ethical and epistemological questions.

This is also the case with the 2013 UNSCEAR report regarding effects of radiation exposure of children that we will critically review in this article.

Besides the influence of conflicts of interest, discussions regarding important issues as the possible inadequacy of the equivalent/effective dose as risk indicator for all types of effects and the uncertainties concerning radiation-induced hereditary and transgenerational effects have been totally overlooked.

Moreover, the UNSCEAR Children report gives overwhelming importance to epidemiology alone and, within this, looks only to "strong epidemiological evidence", with an excessive highlighting of any possible bias and neglecting the possibility of unjustified dismissal of real health effects, while consistency of knowledge coming from all studies and from all concerned disciplines (including radiobiology) should be the basis of a balanced scientific judgment.

Health effects of ionizing radiation and related Safety Standards: place of UNSCEAR within the major international players

Although health effects of ionizing radiation have already been the subject of a huge amount of research, there are still numerous gaps in their knowledge, particularly in the low and moderate dose field and, perhaps surprisingly, regarding the effects of gender and age at exposure. Still recently, challenging discoveries have been made regarding radiation-induction of cataracts and circulatory diseases at levels of dose much lower than the previously presumed threshold doses. Regulation and policy in radiological protection of the population are regularly updated through a repetitive sequence of stages, beginning with the new results of scientific research, followed by global evaluations by international and national organizations and ending in identifying the potential regulatory implications and/or the new research needs. The organizations performing the periodical global evaluations of the state of the art are essentially the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Commission on Radiological Protection (ICRP) with its five standing committees, the BEIR (Biological Effects of Ionizing Radiation) Committee of the US National Academy of Sciences and, at the European level, the group of experts referred to in the Article 31 of the EURATOM Treaty. Generally these evaluations lead to recommendations by the main commission of the ICRP, up to now recognized as the leading group in the field of recommendations in radiological protection. Practically all the ICRP recommendations are then transposed into European directives, setting the mandatory safety objectives for the European Union (EU)

Member States, and into the international Basic Safety Standards, jointly sponsored by the International Atomic Energy Agency (IAEA), the International Labor Organization (ILO), the Nuclear Energy Agency of the Organization for Economic Co-operation and Development (OECD/NEA), the World Health Organization (WHO), the Food and Agriculture Organization (FAO) and the Pan American Health Organization (PAHO).

Apart from their role in the elaboration of regulations, the global scientific evaluations coming from the above-mentioned organizations, particularly from UNSCEAR, which presents itself as a "purely scientific committee", are usually considered as validated states of the art of the knowledge in the field of the effects of ionizing radiation on human health, for example for risk assessments after a nuclear accident.

Only recently, in fact since the disputes regarding the health effects of the Chernobyl accident, the World Health Organization (WHO) is producing its own health evaluations.

Although this international genesis gives some guarantees of validation and consolidation of the assessments, their centralization in a small number of committees, mainly within the UN "family", with specific mandates and a very limited number of members (for example 14 members in the ICRP Commission and 27 for UNSCEAR, representing only 27 countries in the world) entails risks of political influences, conflicts of interest and inbreeding, all the more so since the same experts are frequently members of several of these groups. In other words, this centralization entails a risk of a "club" effect, generating a kind of "pseudo-consensus".

The frequently evoked concept of "purely scientific" judgment is indeed a kind of modern illusion, as science cannot avoid interferences with ethical and epistemological questions. Is it simply possible to be « purely scientific »? Science cannot avoid ethical issues, some of them being deeply imbricated (and often not seen) within the area of the scientific work. There are many examples of value judgments within scientific assessments (management of epistemic uncertainty, just or sound character of assessments, selection of consonant sources, "importance" or "triviality" of a risk).

Science also cannot escape from some intrinsic subjectivity. In an attempt to control this, one often appeals to consensus as a guarantee for objectivity.

Doing so, one forgets that scientists, coming from the same melting pot, spontaneously favour cognitive consonance and share the same interpretative language, the same paradigm (a whole of reference presuppositions, which are often unconscious). On these grounds, interpretations of reality are not seen by them as subjective and have in their eyes an indisputable value.

For avoiding club thinking, allowing new views and perspectives to emerge, it is necessary to resist believing blindly all the statements coming from centralized international groups. Scientists and regulators should make their own judgments and should take their own responsibilities. Scientific vigilance and deontology and responsible decision-making, including unavoidable value judgments (scientific uncertainties; precautionary principle) are obviously necessary at all levels and neither scientific advisors nor regulators can allow themselves to «wait for instructions » from whatever international organizations.

Context of the 2013 UNSCEAR report regarding effects of radiation exposure of children (UNSCEAR Children report)

Although it is recognized for long that organisms in development are particularly sensitive to exposure to ionizing radiation, it is the first time that UNSCEAR tries to carry out a synthesis of the accumulated knowledge in this field (by the way, this is also true for the other above mentioned organizations).

The necessity of such a synthesis emerged after the Chernobyl accident and, particularly, some years ago after the disputes provoked by the 2005 UN_Chernobyl Forum Expert Group Report and by some declarations from prominent UN officials, claiming, regarding the health effects of Chernobyl, that it was (in 2005) « the end of the story ». In particular, there were disputes around the number of attributable deaths and cancers (at this moment and in the future), the existence (or not) of a radiation-related increase in the incidence of congenital malformations and other untoward pregnancy outcomes, the role of exposure to ionizing radiation in the observed increase in children's morbidity in the affected areas and, more globally, around the minimization by UN organizations of the health consequences of the Chernobyl accident.

The report published in 2011 by UNSCEAR (but in fact already approved in 2008) concerning the Chernobyl accident did not diverge from the 2005 UN Forum report, although several members and experts were in favor of a more balanced report.

In 2011, the European Commission published a report (Radiation Protection 170) called "Recent scientific findings and publications on the health effects of Chernobyl". This report had been asked by the EC to the group of experts referred to in the Article 31 of the EURATOM Treaty on the occasion of the 25th anniversary of the Chernobyl accident and has been prepared by the Working Party RIHSS (Research Implications on Health and Safety Standards). Although the aim was to review recent scientific findings and publications, the Article 31 experts referred, where necessary, to older publications with a view of producing a balanced state of the art and, if necessary, to complete or rectify some statements of the UNSCEAR report. It is worth mentioning that this EC report has not been taken into account and even not quoted in all subsequent UNSCEAR reports, including in the 2013 report regarding effects of radiation exposure of children, although it was explicitly asked by some experts.

More recently, a new UNSCEAR draft report (a report that was by the way insistently asked by some experts that were previously strongly involved in the 2005 UN Forum Report) was the subject of vigorous debates, in which Belgian delegates took an active part. This report, generally known as the "Attributability report", copes with the "attribution" of health effects to ionizing radiation exposure and with "inferring" of risks for the future. It is a somewhat tendentious report, because it is in fact partially aimed to "justify" a posteriori some disputed statements of the 2005 UN Forum Report and of the 2011 UNSCEAR Chernobyl report. But is also a dangerous report, because it tries to legitimate, at a very high level, the idea that no health effect can be «attributed » to ionizing radiation under 100 mSv and that even inference of risk for the future under this dose would be « non-scientific ». Today there is still no agreement on this report … and on the underlying 100 mSv issue.

Nevertheless, meanwhile, the UNSCEAR "Fukushima" report has been published, with a discussion of the health effects implying implicitly an adhesion to the controversial 100 mSv "threshold", without taking account of the disagreement expressed among others by the Belgian delegates.

The UNSCEAR Children report has also been published and, here again, without taking into account the issues that were highlighted on the occasion of the above-mentioned disputes.

The UNSCEAR Children report: structure, consultants and scope

The complete text of the UNSCEAR document called "Effects of radiation exposure of children" can be found in the Volume II (Scientific Annex B) of the "UNSCEAR 2013 Report". It is composed of a main text of about 44 pages (Sources of exposure; Anatomical development and physiology; Dosimetric aspects; Health effects; Future research), followed by three detailed documents called "Appendix A, B and C" (Dosimetry; Malignant neoplasms; Deterministic effects).

The key findings are contained in the so-called "Official Records of the General Assembly". This is the only text completely approved, word by word, by all members of UNSCEAR during the meeting in Vienna, and transmitted to the General Assembly of the UN.

There were 3 consultants for the "Children report": D. Nosske for the dosimetric aspects, L.S. Constine for the deterministic effects and R. Shore for neoplasms. F. Mettler provided the coordination, but was also in charge of the compilation of UNSCEAR already published data.

Noteworthy is the fact that a large part of the evidences regarding the effects of exposure of children to ionizing radiation are not dealt with in the report. So the part of L.S. Constine (pediatric oncologist) was focused to data coming from radiotherapy and the part of R. Shore to epidemiological data. All the radiobiological aspects are then practically absent in the report. Are also excluded from the scope of the report all the animal studies and the effects of prenatal exposures.

Regarding in utero exposures, the reason of the exclusion is that this topic had already been treated by UNSCEAR in the past. The problem with this approach is that new data in the field are then neglected. The same is true with all the topics that were not deepened and for which a simple compilation of old UNSCEAR statements were made, as for example the hereditary effects.

Among the limitations of the report we can also mention that the term "children", in contrast to "adults", included those exposed as infants,

children and adolescents under the age of 20. Although the studies on the consequences of the Chernobyl accident, among others studies, have clearly shown that there were important differences in risk of radiation-induced thyroid cancers between children below 3-5 years of age and older children or adolescents, the report distinguishes rarely the sub-categories of age and, above all, do not underline the potential importance of this factor, including for other diseases for which available data or dedicated studies are lacking.

The UNSCEAR Children report at a glance

The main parts of this summary are extracted from the official (and formally approved by all official representatives to UNSCEAR) report to the General Assembly after the 2013 session of UNSCEAR.

Dosimetric aspects:

Health effects and risks are dependent on a number of physical factors. Because children have smaller body diameters and there is less shielding by overlying tissues, the dose to their internal organs will be larger than for an adult for a given external exposure. Because they are also shorter than adults, children may receive a higher dose from radioactivity distributed in and deposited on the ground. Factors to correct for the difference between irradiation of children and adults from the ground are about 1.4 for infants and 1.1–1.2 for children.

These factors are important when considering doses to populations in some areas with high levels of radionuclides in and on the ground.

Regarding internal exposure, because of the smaller size of infants and children, and thus because their organs are closer together, radionuclides concentrated in one organ irradiate other organs of children's bodies more than occurs in adults. There are also many other age-related factors involving metabolism and physiology that make a substantial difference in dose at different ages.

Several radionuclides are of particular concern regarding internal exposure of children, with substantial differences with age in the dose per unit intake of radionuclides (iodine-131, strontium-90, radium-228, …)

Accidents involving releases of radioactive iodines (for example, in a nuclear power plant accident) can be significant sources of exposure of the

thyroid gland, and thus have the potential to induce thyroid cancer. For a given intake, the dose to the thyroid for infants is eight or nine as large as that for adults. For intakes of caesium-137, there is very little difference in dose between children and adults. Internal exposure of children also occurs in the medical use of radionuclides. The spectrum of procedures normally performed on children is different from that performed on adults. Potentially higher doses in children are offset in practice by the use of a lower amount of administered radioactive material.

Radiation-induced neoplasms

For a given radiation dose, children are generally at more risk of tumour induction than are adults. Cancers potentially induced by exposure to ionizing radiation at young ages may occur within a few years, but also decades later. In its report on its fifty-fourth session, the Committee stated that estimates of lifetime cancer risk for those exposed as children were uncertain and might be a factor of 2 to 3 times as high as estimates for a population exposed at all ages.

That conclusion was based on a lifetime risk projection model combining the risks of all tumour types together. The Committee has reviewed evolving scientific material and notes that radiogenic tumour incidence in children is more variable than in adults and depends on the tumour type, age and gender.

The Committee reviewed 23 different cancer types. Note that the term "radiation sensitivity" with regard to cancer induction refers to the rate of radiogenic tumour induction

Broadly, for about 25 per cent of these cancer types, including leukaemia and thyroid, skin, breast and brain cancer, children were clearly more radiosensitive. For some of these types, depending on the circumstances, the risks can be considerably higher for children than for adults.

UNSCEAR underlines that some of these cancer types are highly relevant for evaluating the radiological consequences of accidents and of some medical procedures.

For about 15 per cent of the cancer types (e.g. colon or bladder cancer), children appear to have about the same radiosensitivity as adults. For about 10 per cent of cancer types (e.g. lung cancer), children appear less sensitive

to external radiation exposure than adults. For about 20 per cent of cancer types (e.g. oesophagus cancer), the data are too weak to draw a conclusion regarding differences in risk. Finally, for about 30 per cent of cancer types (e.g. Hodgkin's lymphoma, prostate, rectum and uterus cancer), there is only a weak or no relationship between radiation exposure and risk at any age of exposure. At present, there are no statistically sufficient projections of lifetime risk for specific tumor sites following exposure at young ages. Estimates currently do not adequately capture the known variations, and additional studies are needed.

Deterministic effects:

For direct effects that occur after high (either acute or fractionated) doses (so-called deterministic health effects), the differences in outcome between exposure in childhood and in adulthood are complex and can be explained by the interaction of different tissues and mechanisms. These effects may be seen after radiation therapy or following high exposures in accidents. The difference between the radiation sensitivity of children and that of adults for deterministic effects in a specific organ is often not the same as the difference for cancer induction.

There are some instances in which childhood exposure poses more risk than adulthood exposure (e.g. risk of cognitive defects, cataracts and thyroid nodules). There are other instances where the risk appears to be about the same (e.g. risk of neuroendocrine abnormalities), and there are a few instances where children's tissues are more resistant (e.g. lungs and ovaries). Because of all the above considerations, the Committee recommends that generalizations on the risks of effects of radiation exposure during childhood should be avoided. Attention should be directed to specifics of the exposure, age at exposure, absorbed dose to certain tissues and the particular effects of interest.

Radiation-induced hereditary and transgenerational issues

"There have been many studies of possible heritable effects following radiation exposure; such studies were reviewed by the Committee in 2001. It has been generally concluded that no heritable effects in humans due to radiation exposure have been explicitly identified (specifically in studies of offspring of survivors of the atomic bombings). Over the past decade, there have been additional studies that have focused on survivors of childhood

and adolescent cancer following radiotherapy, where gonadal doses are often very high. There is essentially no evidence of an increase in chromosomal instability, minisatellite mutations, transgenerational genomic instability, change in sex ratio of offspring, congenital anomalies or increased cancer risk in the offspring of parents exposed to radiation. One reason for this is the large fluctuation in the spontaneous incidence of these effects."

Research

The Committee recognizes that continued research is needed to identify the full scope and expression of the differences in effects, mechanisms and risk from exposure to ionizing radiation for children and for adults. This is necessary because for a number of studies (such as of the atomic bombing survivors, children exposed to radioiodine after the Chernobyl accident and those who have had computed tomography scans), the lifetime results remain incomplete. Future long-term studies following childhood exposure will face significant difficulties owing to unlinked health records, administrative and political barriers and ethical and privacy considerations.

Important areas of future research and work also include evaluation of potential radiation effects for children: (a) in areas of high natural background exposure; (b) after high-dose medical procedures involving interventional fluoroscopy; and (c) after cancer radiotherapy (including evaluation of potential interactions with other therapies). The Committee has identified the following areas for future research as well: development of databases on radiation doses for children who can be tracked in the long term; and evaluation of effects following whole and partial irradiation of juvenile organs. Studies at the molecular, cellular, tissue and juvenile animal level are potentially informative.

Critical review of the UNSCEAR Children report

Dosimetric aspects: critical review, including possible inadequacy of the equivalent/effective dose as risk indicator for all types of health effects

A positive point in the report is the general agreement on the need to use organ/tissue doses (instead of effective dose) for evaluating health effects in children.

This being said there were a lot of important topics neglected in the document and there were few in-depth discussions, for example just a copy of ICRP documents without any critical evaluation.

In this respect a major issue is that consideration of radiotoxicological issues is lacking. The case of tritium and the issue of the children's morbidity in Chernobyl affected areas (this last topic being developed in the section regarding critical review of deterministic effects) may be seen as examples, illustrating that, for internal exposures, a major underlying issue could be the inadequacy of the equivalent/effective dose as risk indicator for *all types* of effects (not only for stochastic effects).

The case of tritium

Tritium is a low-energy beta emitter and is generally considered to be an element with low radiotoxicity. In the human body, it exists essentially in the form of tritiated water (HTO) or tritiated organic molecules (organically bound tritium or OBT), with two sub-fractions of exchangeable OBT (exchangeable with hydrogen in cell water) and non-exchangeable OBT (more specifically, tritium bound to carbon). Tritium ingested in organic form in food is considered approximately three times more radiotoxic than tritiated water (dose coefficient per unit of activity ingested is approximately three times higher). This is related to the biological (elimination) half-life.

Recently questions have been raised regarding health effects of beta radiation of low energy. Should the health effects from tritium be reassessed?

This issue is raised by the fact that the tritium isotope has some specific features. The electron path is very short (less than the diameter of a cell and even of a cell nucleus) and the ionization density is high, which can cause cluster damage to DNA if the tritiated molecules get into the cell nucleus. Two further phenomena contribute to locally enhance the effects of tritium – its in situ transmutation into helium and enrichment of water in the DNA hydration shell, converting it to tritiated water (referred to as "buried tritium" or the "isotope effect"). All these physico-chemical effects cause lesions, which can in turn lead to DNA mutations. Although the dose distribution is relatively homogenous when the tritium takes the form of tritiated water, it is heterogeneous when it is incorporated in DNA or

histones. The issue of the relevance of the mean organ dose concept as a risk indicator therefore arises. In other words, doses calculated according to the conventional method (using the ICRP's Sv/Bq conversion factors) could lead to an incorrect estimate of the risk.

Further research into the biological effectiveness of tritium is required in order to clear up these uncertainties and gaps in knowledge, focusing not only on aspects relating to carcinogenesis, but looking also at age at exposure and at differences between accident-related and chronic exposure.

This is particularly true for organisms in development and during the various stages of pregnancy, as shown by German experimental data on the effects of embryo exposure to tritiated thymidine and tritiated arginine (histone precursor) at the pre-implantation stage of pregnancy (in vitro experiments). Given the heterogeneous distribution and specific incorporation into DNA, tritiated thymidine is 1,000 to 5,000 times more effective than tritiated water in inducing harmful effects at the same level of applied activity. The effect is even more marked with tritiated arginine (factor of 10,000) and can be observed at lower levels of activity.

Given mechanisms at work, this observation could be relevant to other cell types and systems with regard to mutagenicity. In addition and in particular, although the above-mentioned studies describe the effects of embryonic exposure, the mechanisms involved are also relevant for later stages of organisms in development, including infants and children and in particular concerning the nervous central system.

Major underlying issue not addressed by the UNSCEAR Children report

It is important to realize that there are still major uncertainties regarding the assessments of risks induced by internal contaminations. The simple use of the concept of effective dose and its calculation through the dose conversion factors (Sv/Bq) may be misleading for risk assessment (cfr IRSN 2005, CERRIE 2004). The general assumption of an equivalence of risk for external and internal exposures may be wrong.

For (chronic) internal exposures, a major underlying issue could be the inadequacy of the equivalent/effective dose as risk indicator for all types of effects.

We should be more cautious before claiming that some results are not acceptable, just because they cannot be explained by the conventionally calculated doses.

Radiation-induced neoplasms: critical review

General flavour of the report: minimization or relativization of the risk for children

The general flavour of the UNSCEAR Children report and the most highlighted message is that the children sensitivity to tumor induction as compared to adults depends on the tumor type, and that it is higher for some tumor types, lower or equivalent for others, while it should be premature to say that the overall risk is higher for children than for adults.
This gives the false impression that there is no scientific reason for better protecting infants and children.

In fact, as shown in the last reviews of the atomic-bombing (Ozasa, 2012), both the excess relative risk (ERR) and the excess absolute risk (EAR) for all solid cancers were and still continue to be higher for younger ages at exposure, pointing to a lifetime risk for all solid cancers consistently higher for low ages at exposure (by a factor of 2 or 3 depending on the models and of the compared ages).

This should have been underlined and the first message to the General Assembly.

Other important aspects should have been underlined, as the fact that the average years of life lost per cancer case is greater for those exposed at young ages which, of course, is attributable to the fraction of excess deaths at early ages for those who were young at exposure. This fact, together with the very low latency times observed for some cancers, illustrates the importance of the age at apparition of the cancer, which can be particularly low, affecting young children. Near the quantitative aspect of the total number of cancers, this qualitative and humane aspect should have been highlighted.

As mentioned earlier, differences between age sub-categories, as illustrated by the higher sensitivity at ages at exposure below 5 y for radiation-induced thyroid cancers, are very important for health assessments and are not particularly highlighted.

The hidden underlying issue of the 100 mSv "threshold" value

Although the UNSCEAR Children report do not directly address the issue of the available data in the low dose area (the figure of 100 mSv has been arbitrarily chosen by international organizations as the upper limit of the so-called "low doses" of ionizing radiation), there is a clear and systematic approach in the document suggesting that there are no solid data in the low dose field for children exposures. In this respect there is an intention to assure a coherency between all the new UNSCEAR reports (Children report, Fukushima report, Chernobyl report and the still in discussion Attributability report), with a common claim that 100 mSv represents a kind of level of concern for radiation effects on human health, several experts maintaining that, under this level, the possibility of "any health effect" is "purely hypothetic" and even that exposures below this level have then to be considered as 'safe'. Although many experts still accept that the system of radiological protection may (or should) be based on the assumption that there is no threshold for radiation-induced stochastic effects (cancers and hereditary effects), this come-back of the magic number of a 100 mSv "practical threshold" can currently also be seen in other publications (or drafts) of international organizations.

In this respect the question of radiation-induced leukaemia's after exposure in childhood is quite representative. Although recognizing that, for leukaemia's, exposure in childhood appears to entail a three- to fivefold greater risk than exposure in adulthood, the UNSCEAR Children report concludes also that the risk at low doses is based on mathematical models since "the studies have not shown a statistically significant increase in leukaemia incidence at marrow doses of less than about 400 mSv."

It is important to remind here that there have been observable effects under 100 mSv, and consistent biological explanations.

Although prenatal period is not covered by the scope of the UNSCEAR Children report, data regarding radiation-induced childhood leukaemia's after in utero exposures are relevant for the discussion not only because they show effects at doses far below 100 mSv but also because there is probably no relevant biological discontinuity between a baby just before or just after birth.

The association between childhood cancer and childhood leukaemia and antenatal exposure to X-rays by obstetrical radiography has been demonstrated since many years (the first, and largest, case-control study was the Oxford Survey of Childhood Cancers, which started in UK in the early-1950s, and continued until 1981, including more than 15 000 case-control pairs), and, in spite of many discussions, is still considered as solid evidence. Indeed, the association has now been confirmed by many case-control studies carried out around the world and the association is now accepted as real, although some remain skeptical of a causal interpretation (Wakeford, 2013). This skepticism is mainly due to the finding that the relative risk of childhood leukaemia and that of all the other typical cancers of childhood are raised to a similar extent, unlike the pattern of risk when exposure occurs after birth, and to the absence of leukaemia cases among the A-bomb survivors irradiated in utero. However, only about 800 of these survivors received a dose of more than10 mGy while in utero (the average dose was 0.25 Gy), so only around 0.2 case of childhood leukaemia would be expected in the absence of exposure on the basis of mid-20th century Japanese national rates, and there is also the possibility that cases of childhood leukaemia incident during the 1940s, before systematic collection of data began in 1950, may have gone unrecorded or have been overlooked (e.g. because the involvement of leukaemia in an infectious disease death had not been recognized in the difficult years following the end of the war) (Wakeford 2013).

In addition, a study on A-bomb survivors exposed in utero suggests that the lymphoid cells at origin for childhood leukaemia could be particularly sensitive to cell-killing. Extensive cell-killing at moderate or high doses of these cells (as in A-bomb survivors) suppresses the risk of leukaemia, while the risk would still exist at lower doses (as after abdominal diagnostic x-ray examinations) (Ohtaki, 2004).

The last BEIR report (BEIR VII) concludes that « studies of prenatal exposure to diagnostic X-rays have, despite long-standing controversy, provided important information on the existence of a significantly increased risk of leukaemia and childhood cancer following diagnostic doses of 10-20 mGy in utero ».

Similarly, in a recent (December 2012) report on Childhood leukaemia and environmental factors, a joint group of the Health Council of the

Netherlands and the Superior Health Council of Belgium concluded that: "On the basis of epidemiological and laboratory research as reviewed by international and national experts, prenatal and postnatal exposure to ionizing radiation contribute to the incidence of childhood leukaemia. Because of this, the Committee considers a causal relation between exposures to ionizing radiation and childhood leukaemia as established. In addition, the Committee supports the view expressed by several multidisciplinary Committees of scientists that this holds for all types of ionizing radiation, and *that there is no exposure threshold below which an increase in leukaemia risk is absent*.

This case is particularly illustrative of the divergences between experts' approaches, some (as in UNSCEAR) claiming that a causal association is still not scientifically "proven" (and as a corollary refusing taking these studies into account for challenging the 100 mSv figure), others considering that accumulated multidisciplinary evidence is strong enough for drawing "science-based" conclusions.

The same approach can be found in the UNSCEAR Children report as regards important recent low dose studies. The Pearce study (2012) is a retrospective cohort study that included patients without previous cancer diagnoses who were first examined with CT in National Health Service (NHS) centers in Great Britain between 1985 and 2002, when they were younger than 22 years of age. Data for cancer incidence and mortality were also obtained from the NHS Central Registry. To avoid inclusion of CT scans related to cancer diagnosis, follow-up for leukaemia began 2 years after the first CT and for brain tumours 5 years after the first CT. A positive association was noted between radiation dose from CT scans and leukaemia (excess relative risk [ERR] per mGy 0•036, 95% CI 0•005–0•120; p=0•0097) and brain tumours (0•023, 0•010–0•049; p<0•0001). Compared with patients who received a dose of less than 5 mGy, the relative risk of leukaemia for patients who received a cumulative dose of at least 30 mGy (mean dose 51•13 mGy) was 3•18 (95% CI 1•46–6•94) and the relative risk of brain cancer for patients who received a cumulative dose of 50–74 mGy (mean dose 60•42 mGy) was 2•82 (1•33–6•03).

The authors consider their results support extrapolation of the dose-effect relation observed in the LSS to the doses from CT scans (tens of mGy).

Although good accepted by the scientific medical community and considered as important evidence supporting the efforts for optimization of the medical exposures, the Pearce study has not all been highlighted in the UNSCEAR Children report. On the contrary, lack of information about indications for the CT scans (e.g. head trauma may have conferred risk) and the lack of individual dosimetry were strongly underlined.

The same scenario occurred for the Kendall study (2012) and for the observations after Chernobyl. The Kendall study is a record-based case-control study of natural background radiation and the incidence of childhood leukaemia and other cancers in Great Britain during 1980–2006 (28 000 cases). They found an ERR of 12% (95% CI 3, 22) of childhood leukaemia per mSv of cumulative red-bone-marrow dose from gamma-radiation, supporting the extrapolation of high dose-rate risk models to protracted exposures at natural background exposure levels. Kendall's study is criticized in the UNSCEAR report because of the uncertainties associated with using an ecological measure of dose and a crude, ecological measure to adjust for socioeconomic status.

Following the Chernobyl nuclear reactor accident in 1986 a study found a notably raised risk (ERR per Gy 78.8; CI 22.1-213) of childhood leukaemia in the heavily contaminated districts of the Ukraine (but not in Belarus or Russia) (Davis et al 2006). As the results could be due to a sampling-derived bias in Ukraine, the authors concluded that this study provides no convincing evidence. In a later study in Ukraine (Noshchenko 2010), the risk of leukaemia was still significantly increased among those with radiation exposure doses higher than 10 mGy, but the risk estimate was substantially lower. Again the UNSCEAR children report drew the attention on possible bias and not on the possibility of the risk existing.

Overwhelming weight given to any possible bias.

These new studies have of course some limitations, as probably all studies. Nevertheless, they join a series of similar studies, giving *collective* findings that are comforting current assumptions lying at the basis of the radiation protection system (linear or linear quadratic relation in the low dose area). The important point is that this aspect is not all underlined, while overwhelming weight is given to any possible bias.

Low dose effects are biologically consistent

As we have seen, there is in fact compelling epidemiological evidence that there are observable effects (well below) under 100 mSv. There are also consistent biological explanations.
Tumorigenesis is currently viewed as multistage model, with mutations as a driving force.

It begins with damage to DNA and failure to correct this damage, which causes an initiating mutation (in a single target stem-like cell in most tumours). While cellular environment is crucial for promotional growth, further stages (conversion to malignant phenotype and tumour spread) are driven by further mutations.

Many genes are involved in the response to DNA-damage (DNA-repair genes, cell-cycle regulation genes) and the puzzle is not yet assembled. The important point is that some pathways for DNA-repair: are error-prone and that even the « error-free » pathway (homologous recombination) will unavoidably lead to mutations in some cases. Indeed this last pathway uses as reconstruction model the template of the other parental copy (homologous chromosome). Problem is that, in heterozygotes, if the good allele is damaged, the copy will be that of the bad allele (which is called "loss of heterozygoty")! And we are all carrying "bad" (recessive) alleles. It's the reason why you best not marry somebody of your close family!

As a consequence there will unavoidably be some losses of heterozygoty when a large number of individuals are irradiated, with a probability increasing with increasing dose.

Based on this "mutation paradigm", the major international organizations, including UNSCEAR, have recognized, sometimes recently, that there are serious biological reasons suggesting a cancer risk even at low doses.

Let's remember this important statement in the UNSCEAR 2000 report: "Par 541. Until the above uncertainties on low-dose response are resolved, the Committee believes that an increase in the risk of tumour induction proportionate to the radiation dose is consistent with developing knowledge and that it remains, accordingly, the *most scientifically defensible approximation* of low-dose response. However, a strictly linear dose response should not be expected in all circumstances". (UNSCEAR 2000, annex G)

Similarly the BEIR VII report concludes: “The committee concludes that *current scientific evidence* is *consistent with* the hypothesis that there is a linear, no threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans.”

Finally ICRP writes in its last recommendations: “64) Although there are recognized exceptions, for the purposes of radiological protection the Commission judges that the weight of evidence on fundamental cellular processes coupled with dose-response data supports the view that, in the low dose range, below about 100 mSv, it is scientifically plausible to assume that the incidence of cancer or heritable effects will rise in direct proportion to an increase in the equivalent dose in the relevant organs and tissues.”(ICRP 103)

The UNSCEAR Children report gives overwhelming importance to epidemiology alone and, within this, looks only to “strong epidemiological evidence”, with an excessive highlighting of any possible bias in the low dose studies, while consistency of knowledge coming from all studies and from all concerned disciplines (including radiobiology) should be the basis of a balanced scientific judgment.

Non-targeted effects of ionising radiation and their implications

Non targeted effects of ionizing radiation (NTE), including genomic instability, and a variety of bystander effects, is an important field of current research and could in the future challenge the current paradigm regarding the mechanisms at the base of the health impact of ionizing radiation. Important research programs are still conducted today, particularly at the level of the US Department of Energy (DOE) and in the framework of new European coordination structures as the Multidisciplinary European Low Dose Initiative (MELODI).

These new data have raised concerns about human risk at low doses. Some are even claiming that NTE studies, included in a “systems biology approach”, have now demonstrated that the risks at low doses are probably negligible or at least that the mutational paradigm should be abandoned, together with the linked linear no threshold hypothesis .

As good summarized by D. Goodhead in a recent review (2010), the conventional mutational paradigm for radiobiology is firmly established

and generally well validated by very many interlinked experimental and theoretical studies. It forms a logical basis for the standard paradigm for risk of cancer and heritable effects. From these paradigms has been developed the internationally applied system for radiation protection. It is now well-established that there are also a variety of additional radiobiological phenomena that do not conform to the standard paradigm for radiobiology. Several of these phenomena may well have implications for radiation risk, particularly at low doses where epidemiological data are weakest, and hence also for radiation protection. However, the current state of knowledge is unlikely to be sufficient for these phenomena, individually or collectively, to be formulated at this time into a new paradigm for radiobiology or to be incorporated as substantial modifications to the standard paradigm. At present there is also lack of direct evidence of their relevance to risk for human health, despite attractive hypotheses as to how they might be involved. Further research is essential to advance mechanistic understanding of processes such as induced genomic instability and bystander effects.

The same conclusions are to be found in a very recent review (Kadhim 2013) realized by several key experts involved in European projects. “Despite excellent research in this field by various groups, there are still gaps in our understanding of the likely mechanisms associated with non-DNA targeted effects, particularly with respect to systemic (human health) consequences at low and intermediate doses of ionizing radiation. Other outstanding questions include links between the different non-targeted responses and the variations in response observed between individuals and cell lines, possibly a function of genetic background. Furthermore, it is still not known what the initial target and early interactions in cells are that give rise to non-targeted responses in neighboring or descendant cells”.

Deterministic effects: critical review of the UNSCEAR Children report

A first issue that should have been more highlighted is that there are still many questions regarding radiation-induced non-cancer effects in general and the role of age at exposure in particular, including regarding the mechanisms and the role of epigenetic effects. Research is still on-going (circulatory diseases, cognitive effects, …).

Another important issue is that the large majority of data are coming from the field of radiotherapy, meaning high acute doses, while data are very scarce for chronic exposures, particularly for chronic *internal* exposures of children.

For such conditions, some unexpected (in general or at the doses considered) radiation-induced non-cancer effects cannot be a priori excluded and are suggested by some recent publications. It must be reminded here that effective doses are constructed on the base of the risks of stochastic effects and are uninformative for other endpoints, including radiotoxicological ones.

The issue of children's morbidity after Chernobyl and the contamination with Cesium

In this respect, it is worth mentioning the recent EC report on "Recent scientific findings and publications on the health effects of Chernobyl" (Radiation Protection No 170, 2011). By the way, let us remember that this report has not been quoted in the UNSCEAR Children report, although sent to consultants and asked for.

This EC report opens the discussion on the issue of the controverted reasons of children's morbidity in the most affected areas around Chernobyl.

There are many claims concerning the health of children in the contaminated territories around Chernobyl, which seem to suffer from multiple diseases and co-morbidities with repeated manifestations. The reports from international organizations did not give until now much interest in the multiple publications by Ukrainian, Russian and Byelorussian researchers on children's morbidity. This is partly due to the fact that many of these studies were not available in English but also to the fact that they often did not meet the scientific and editorial criteria generally required in the Western peer reviewed literature.

Anyway, all these health problems were collectively qualified as "psycho-social" by the UN agencies.

More or less recent studies brought again this issue into light, including the debated publications of Bandazhevsky, linking 137Caesium body loads with ECG alterations and cardiovascular symptoms in children such as

arterial hypertension, and the studies on neurobehavioral and cognitive performances in children of the contaminated areas.

To verify these observations, IRSN conducted series of animal studies (again not quoted although sent to consultants and asked for). Rats were exposed to 137Caesium contamination during several months (generally 3 months, sometimes 9) through drinking water containing 6500 Bq/L. Intake of 137Caesium was estimated to be 150 Bq/day/animal (500 Bq/kg of body weight), a figure that is considered by the authors to be comparable with a typical intake in the contaminated territories (based on Handl's evaluation in Ukraine: 100 Bq/day with variations, according to geographical location and diet, from 20 up to 2000 Bq/day as in the case of special dietary habits like excess consumption of mushrooms) .

Although the animals tested in these studies did not show induced clinical diseases, a number of important biological effects were observed on various systems: increase of CK and CK-MG, decrease of mean blood pressure and disappearance of its circadian rhythm; EEG modifications, perturbations of the sleep-wake cycle, neuro-inflammatory response, particularly in the hippocampus, etc.

It must be underlined that these somewhat unexpected results are obtained after relatively modest intakes of 137Caesium and that a fraction of the population in the contaminated territories has been shown to incorporate ten times more 137Caesium with their food.

On the ground of the fact that there is a currently a lack of analytical studies in which dose and risks on non-cancer diseases in children were estimated on an individual level, a series of longitudinal studies (again not quoted although sent to consultants and asked for…) have also been initiated recently in Ukraine in conjunction with the US University of South Carolina and were devoted to children's health, making use of the fact that all children in the studied territory had been obliged to participate in a yearly medical examination.

A first study investigated, for the years 1993 to 1998, the association between residential soil density of 137Caesium (used as exposure indicator) and blood cell concentrations in 1251 children. The data showed a statically significant reduction in red and white blood cell counts, platelet counts and haemoglobin with increasing residential soil contamination. Over the six-

year observation period, hematologic markers did improve. The authors draw the attention on the fact that similar effects and evolution were reported after the Techa River accident in 1957.

A second study investigated, for the same years 1993 to 1998, the association between residential soil density of 137Caesium and spirometry measures in 415 children. They found statistically significant evidence of both airway obstruction and restriction with increasing soil 137Caesium. The authors advance as possible explanation a radiation-induced modulation of the immune system leading to recurrent infections and finally to detrimental functional effects.

Series of other studies are announced. The authors of these studies conclude by saying that the current "optimism of the UN reports may be based on too few studies published in English, conducted too soon after the event to be conclusive").

In conclusion, UNSCEAR should have been more cautious in its statements regarding "deterministic" effects. Focusing on the fact that childhood exposure poses more risk than adult exposure for some effects, but not for others, gives the wrong impression that there is globally no reason for specially protecting infants and children. In addition, here also, qualitative human aspects related to the young age of apparition must not be forgotten.

Radiation-induced hereditary and transgenerational issues: critical review

Instead of highlighting the fact that up to now no heritable effects in humans due to radiation exposure have been explicitly identified, the report should have underlined that there remain many uncertainties, particularly on long term effects, as only a few human generations have been observed, and that, contrary to human beings, a large number of animal studies have demonstrated the existence of radiation-induced hereditary effects.

Radiation-induced genetic risk: concerns regarding international evolution

The way international committees currently deal with the radiation-induced genetic risks raises concerns. Since the last UNSCEAR report on this topic (2001), and particularly since the last ICRP recommendations, there is a tendency to more and more neglect the radiation-induced genetic risks. This issue is particularly relevant for exposures in childhood as possible effects

will have a" full" chance to arrive. Let us remember in this respect the old concept of "genetically significant doses".

New genetic risk coefficients recommended by ICRP consider exposure and genetic risk *for two generations only* - the equilibrium value used in ICRP 60 being judged to be of questionable scientific validity because of the unsupported assumptions necessary on selection coefficients, mutation component and population changes over hundreds of years . As a result, the risk associated with gonadal dose is now estimated to be around 20 cases per 10,000 people/Sv, rather than around 100 cases in ICRP 60 (previous recommendations).

But there are three fundamental issues: is the total radiation-induced genetic risk really lower than we thought in 1990? Is the genetic risk limited to the two first generations? Do we know enough to draw final conclusions?

Let us begin with the first point: is the (total) genetic risk lower than we thought 15 years ago?

Although this is not said explicitly in the above-mentioned ICRP documents, it is the message that everybody understands. The new risk coefficients for radiation-induced hereditary diseases are lower and they are presented as a global estimation of the genetic risk from radiation In fact they are lower because only two generations are now considered, but they are nevertheless compared with the previous risk coefficients that were estimated at equilibrium.

When evaluated on comparable bases (risk for the first generation, for 2 generations, …) , the genetic risk is not reduced, as obvious when comparing the UNSCEAR 2001 Report with the previous UNSCEAR Reports of 1988 and 1993.

The sharp decrease of the genetic risk coefficient recommended by ICRP is based only on its *choice* to take now the effect on the generations over the second as being zero.

Now the second question: can we say that the genetic risk is *practically limited* to the two first generations?

The above-mentioned ICRP documents strongly suggest this. They support this view by radiobiological data suggesting that a major contribution to the genetic risk comes from multigene deletions that are compatible with

viability and express themselves essentially in the two first generations by *multi-system developmental abnormalities* (in analogy with naturally-occurring microdeletion syndromes). This kind of radiation-induced effects can be seen as congenital abnormalities and will indeed rapidly disappear in the next generations due to selection effects. Besides these particular effects, ICRP incorporates also in its risk estimates the radiation-induction of autosomal dominant and X-linked diseases and of chronic multifactorial diseases, but it restricts here too its estimation to the two first generations. To justify this, ICRP underlines the numerous uncertainties involved in the estimation of the long term genetic risk. So the equilibrium value of ICRP 60 is now judged to be of questionable scientific value because of the "unsupported assumptions on selection coefficients, mutation components and population changes over hundreds of years".

In fact the "short term" hereditary effects are not limited to diseases in the two first generations. When the chronic multifactorial diseases are left aside (as it was the case in the UNSCEAR Reports of 1988 and 1993), the "equilibrium" risk coefficients are not significantly influenced by population changes over hundreds of years, but mostly by the selection effect for the most important component, i.e. the *autosomal dominant/X-linked diseases*, and this equilibrium is obtained after 5 to 6 generations (UNSCEAR Report 2001, figure V, p. 40). From a public health perspective, it would be by far more acceptable to take explicitly all the autosomal dominant/X-linked diseases into account, up to 5-6 generations, as it was done in the past.

Finally, do we know enough to draw final conclusions?

Considering the "*numerous uncertainties*" involved for not estimating the long term genetic risk, it seems paradoxical to recognize that considerable uncertainties still exist in this field, while concluding that enough is known as regards the mechanisms of radiation-induction of genetic effects to allow ignoring the possibility of significant long term risks.

In reality, the uncertainties regarding the radiobiological mechanisms are still important. Research teams are still struggling with things like non-targeted effects, transgenerational genomic instabilities, modifications in gene expression, etc, all playing possibly a role in the genetic risk.

Among the radiobiological issues having a potential impact on the evaluation of the radiation-induced genetic risk, there is the question of the mutations in tandemly repeated DNA loci (TRDLs such as minisatellites). Minisatellite mutations are generally considered as pure markers of exposure without health significance. Some of these mutations are nevertheless « associated » with various health disorders. Although this does not mean that they are the causative factor, it remains that the role of the minisatellites is still largely unknown.

Other issues related to the complexity of the genome machinery are new data regarding transgenerational mutagenesis. Transgenerational mutagenesis has up to now been observed only in animals but, using the expression of Bridges during a 2006 Seminar, « lack of human evidence does not mean evidence of lack of effect » and, if such effects would occur in human beings too, they would have wide implications.

Possible differences in genetic changes between external and (chronic) internal exposures are another important issue, for instance in situations like the post-Chernobyl contaminations. After all, the vast majority of human data are currently based on follow-up of populations after external exposures (Life Span Study, radiotherapy studies).

Concerns about the evaluation of radiation-induced genetic risk were also expressed during the EU Conference on 4 November 2004 dedicated to the critical review of the draft 2005 ICRP Recommendations. In the section devoted to biological issues, Prof. Dutrillaux explained that, in his opinion, the main problem is the radiation induction of deletions leading to *recessive* mutations and diseases of which the *phenotypes* might frequently *not be recognized* by the physicians. ”This probable strong underestimate of autosomal recessive diseases is related to their diagnostic difficulty. Their recessive condition prevents familial recurrence, especially in medically developed countries with small sibships. All are rare diseases and their rarity prevents paediatricians to repeatedly observe the same disease during their life”. Another key factor could be the radiation induction of multifactorial diseases, in which genetic contribution appears of prime importance. The genetic mechanisms involved are multiple, including genome instability, allelic expansions, microdeletions. Such cumulative small genetic disorders may propagate in the future generations with the risk of leading to more important pathological consequences. According to

Dutrillaux, "data on atomic bombing survivors and patient progeny have thus a major flaw: several generations are necessary for the passage to homozygoty of induced recessive mutations. There is not a sufficient delay to observe their expression today."

The basic question is whether we know enough about possible long term radiation-induced genetic effects to close this matter and to conclude now that the effect on the generations over the second is negligible.

Evidence relevant to untargeted and transgenerational effects in the offspring of irradiated parents

Little et al made recently (2013) a review of health effects in offspring of human populations exposed as a result of radiotherapy and some groups exposed to chemotherapy and also of the risks in offspring of other radiation-exposed groups, in particular those of the Japanese atomic bomb survivors and occupationally and environmentally exposed groups. Experimental findings are also briefly surveyed.

They conclude that animal and cellular studies tend to suggest that the irradiation of males, at least at high doses (mostly 1 Gy and above), can lead to observable effects (including both genetic and epigenetic) in the somatic cells of their offspring over several generations that are not attributable to the inheritance of a simple mutation through the parental germline.

They note that studies of disease in the offspring of irradiated humans have not identified until now any effects on health and that it is possible that transgenerational effects are restricted to relatively short times post-exposure. They underline that in humans conception at short times after exposure is likely to be rare.

Nevertheless optimism is premature and should preferably be avoided.

The role of internal and/or protracted exposures should be deepened: minisatellite DNA mutations in children are not seen in those exposed to external radiation sources, but they are repeatedly seen in populations of areas contaminated with internal emitters (Ukraine and Belarus, Techa river,…).

There is also an important lack of human studies, but there are some studies suggesting trangenerational induced sensitivity or chromosomal damage in children of liquidators (Aghajanyan). Although they show methodological

limitations, these studies should be deepened or verified instead of rejected, as it is currently the tendency.

Further research is needed, including in the offspring of persons exposed after Chernobyl, as underlined in the ARCH strategic long term research agenda. (2011 EC Radiation Protection 170; similar recommendation in Little 2013). Such research may help resolve the apparent discrepancies between cellular/animal studies and studies of human health.

Misleading messages to decision-makers

The current approach (initiated by ICRP but now practically generalized, including in the new UNSCEAR Children report) regarding radiation-induced genetic risk evokes ethical questions. Giving *authoritative* messages suggesting that the genetic risk is of lower or no concern, while minimizing possible long-term effects, is a position opposite to the application of the principle of precaution (understood here as recommending measures of precaution or prevention to avoid plausible but uncertain detrimental effects). Due to their scientific authority, organizations like ICRP or UNSCEAR influence the societal and regulatory actors that have actually to decide on the necessity to apply or not precaution or prevention measures.

The current evolution of UNSCEAR reports: threat for radiological protection

We have showed in a previous article (Smeesters 2013) that there exist some fundamental epistemological and ethical issues challenging the social credibility of the experts in (among others) radiological protection. These fundamental issues are conflicts of interest, the limits and misuses of the evidence-based approach (by focusing only on the avoidance of unjustified causal associations (false positives) and neglecting the possibility of unjustified dismissal of real health effects (false negatives), the interference with some value judgments often considered as "evident" in the scientific circles, facilitating self-censorship, due to the pressure of dominant paradigms and of the peers, the lack (or refusal) of precautionary attitude in scientific research and the scientific reductionism, all together causing an increasing gap with society.

UNSCEAR's work and approach are in fact challenged by the same issues, as we will see.

Political context and conflicts of interest (Chernobyl, Fukushima, ...): danger for credibility

In the nuclear field, potential conflicts of interest are unavoidable for many countries – as they have been responsible of major radioactive contaminations in the past (or could be in the future…) - and for many international institutions whose official mandate is to promote some practices (as the pacific use of nuclear energy).

These conflicts of interest are exacerbated by the potential consequences of the nuclear accidents of Chernobyl and Fukushima. A clear goal for several influent players within UNSCEAR is to reassure the Japanese population, particularly about the health of their children and thus to relativize or minimize as much as possible the possible radiation effects from exposure of children. By the way, the Belgian delegation tried, although with a very moderate success, to reach a more balanced view.

Misuse of the evidence-based approach: what is "being scientific"?

In current discussions in UNSCEAR (at stake among others in the attributability report), several experts state that "unequivocal attribution" (meaning: with 100 % certainty) of health effects to ionizing radiation is impossible under 100 mSv. They justify this statement by the fact that 100 mSv is currently the first statistically significant point in the dose-effect relation for all solid cancers together in the gender- and age-mixed population of the Japanese survivors to the atomic bombing (LSS) and that there are no other individual epidemiological studies where the evidence is strong enough to draw 100% certain conclusions. As a consequence no effect could be « attributed » to radiation under 100 mSv and even inference of risk for the future under this dose would be « non-scientific ».

These formulations give overwhelming importance only to epidemiology (and within this only to "strong epidemiological evidence"), while consistency of the corpus of knowledge coming from all epidemiological studies and from all concerned disciplines (including radiobiology) is an important part of a balanced scientific assessment. Another characteristic of these statements is that the epidemiological evidence concerning radiation-induced solid cancers in a mixed population is generalized to all types of health effects and populations.

Evidence-based approach is currently become a dominant scientific paradigm, particularly in the medical field, where it is the condition of agreement of any new drug and even of any treatment.

The basic concern is to avoid concluding that a causal relationship exists before it is strongly proved (hard evidence is required).

In other words, the main concern is avoiding the "false positives".

Current dominant pressure of this paradigm leads some experts or groups to consider that this way to proceed (to avoid carefully false positives) is the only way compatible with science, which is based on the possibility of testing and falsifying any hypothesis.

They use as an argument that the scientific method is based on the principle that there is an underlying order to the nature of things, and that by following certain rules and guidelines this nature can often be revealed. Ideas (hypotheses) are generated from observations and then tested by controlled experiments or observational studies, lending to better understanding (empirical science). Yet the problem is that, particularly in the current world, new things (or situations) are introduced rapidly but have possibly long term consequences, unknown by definition, asking for vigilance and responsiveness for early indications of health effects. Potential observations may be only possible after a long time, generating hypotheses at a late stage, whose testing (if feasible) may again take a long time. But decisions frequently are to be made about these new introduced things (or situations), while strong evidence or certainty is lacking. Such decisions must be based on available "evidence" (evidence, here not in the sense of "certainty", but in the sense of"indications" or "corpus of knowledge"), even if there persists uncertainties. Decision-makers need a sound basis for informed decision-making and are asking scientific experts (groups, committees …) for science-based balanced information, including science-based inferences.

These science-based inferences are sticking to scientific observations and are part of the scientific work. They are not "external to science" while decisions based on these inferences are "external to science".

This very fundamental conceptual issue is currently the object of animated discussions at the level of UNSCEAR, that, as a committee, tends these

last years to give overwhelming importance to the avoidance of false positives, by highlighting all possible bias for an association between effect and exposure, in comparison with the avoidance of false negatives, while possible dismissal of real health effect of radiation is a major concern for responsible decision-makers. This attitude lies at the basis of the minimized risk estimates of UNSCEAR regarding the health effects of Chernobyl and, recently, Fukushima: there is indeed no "100 % certainty" for many of these effects.

There were recently some important changes. The UNSCEAR's strategic objective for the period 2009-2013, endorsed by the General Assembly, in its resolution 63/89, is "to increase awareness and deepen understanding among authorities, the scientific community and civil society with regard to levels of ionizing radiation and the related health and environmental effects as a sound basis for informed decision-making on radiation related issues". Now, UNSCEAR underlined in its last report to the General Assembly (A/67/46, paragraph 23), that "this strategic objective highlighted the need for the Committee to provide information on the strengths and limitations of its evaluations, which are often no fully appreciated. This involves avoiding unjustified causal associations (false positives) as well as unjustified dismissal of real health effects (false negatives)." Formally it is an important step forward (by the way, suggested by the Belgian delegation). Unfortunately the culture is far to have changed in a large part of this committee.

Lack of precautionary attitude within scientific evaluation

Misunderstanding of the precautionary principle

Precaution is relatively largely accepted regarding decision-making processes in situations of uncertainty (although the definition of this concept may be very different).

The point here is that the precautionary approach is also relevant and appropriate in science! This is frequently misunderstood.

As underlined in the COMEST report from UNESCO, the precaution approach in science includes:

- a focus on risk plausibility rather than on hard evidence
- a responsiveness to the first signals ("early warnings")

- a systematic search for surprises ("thinking the unthinkable"), particularly for possible long term effects

The first point is linked with the previous discussions concerning misuses of the evidence-based approach.

For society the main concern of the experts is expected to be the protection of health. When there is scientific *plausibility* ("enough evidence") of the existence of a risk of serious harm, action is needed. Even if there is still uncertainty!

In other words, the main societal concern is avoiding the false negative

Precaution in science means in fact focusing on (or at least giving attention to) risk plausibility and not only to hard evidence.

The corollary is the need of being vigilant and responsive to the first signals of potential health problems ("early warnings"), as for example is the rule for vigilance about drugs.

Recent developments regarding the late recognized radiation effects of low to moderate doses on the lens of the eye and on the circulatory system are good illustrations of a lack of vigilance and responsiveness regarding early warnings that were described many years ago.

Systematic search for surprises ("thinking the unthinkable") is a more difficult challenge, because it means often challenging dominant paradigms or at least refusing to "follow fashion". It may seem strange or incredible but there are fashions in the scientific world. Example in the current radiation specialists' field is the quasi total lack of interest about hereditary effects, judged frequently as being practically inexistent or negligible just because nothing was seen until now (some tens of years …) in the survivors of the atomic bombing. Bad surprises may arrive in this field in the future. The same is true concerning non-cancer effects after in utero irradiation, where the dominant concept is currently that there is nothing to fear under 100 mGy, while the domain of internal exposures and of long term effects linked to epigenetic effects, as gene expression, is practically unexplored (with a few exceptions).

In this respect it is interesting to mention that the section on research needs was first absent in the UNSCEAR Children report. Then, in reaction to

several protests, a short list has been elaborated during the meeting. This illustrates a total lack of interest for possible false negatives or "surprises".

Conclusions

Although it is recognized for long that organisms in development are particularly sensitive to exposure to ionizing radiation, it is the first time that UNSCEAR tries to carry out a synthesis of the accumulated knowledge in this field. Global scientific evaluations coming from international organizations, particularly from UNSCEAR, which presents itself as a "purely scientific committee", are usually considered as validated states of the art of the knowledge in the field of the effects of ionizing radiation on human health, for example for risk assessments after a nuclear accident.
Nevertheless the concept of "purely scientific" judgment is a kind of modern illusion, as science cannot avoid interferences with political, ethical and epistemological questions. This is also the case with the 2013 UNSCEAR report regarding effects of radiation exposure of children, as we have shown in this article.

Besides the influence of conflicts of interest, discussions regarding important issues as the possible inadequacy of the equivalent/effective dose as risk indicator for all types of effects and the uncertainties concerning radiation-induced hereditary and transgenerational effects have been totally overlooked.

Moreover, the UNSCEAR Children report gives overwhelming importance to epidemiology alone and, within this, looks only to "strong epidemiological evidence", with an excessive highlighting of any possible bias and neglecting the possibility of unjustified dismissal of real health effects, while consistency of knowledge coming from all studies and from all concerned disciplines (including radiobiology) should be the basis of a balanced scientific judgment.

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