

Science and Values in Radiological Protection

Summary of the CRPPH Workshops
held in Helsinki (2008)
and Vaux-de-Cernay (2009)



Radiological Protection

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FOREWORD

Radiological protection was founded on and continues to be a combination of science and value judgments. As described by Lauriston S. Taylor,¹ radiological protection is “...*not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom*” (Taylor, 1957).

In the development of radiological protection policy and its practical application there is always a need for radiological protection policy makers, practitioners and other stakeholders to better understand the evolving interactions between science and values. At the same time, there is also a need for radiological protection scientists to better understand the broad processes of radiological protection decision-making and to better interact with these processes, particularly by providing input from their research. Rolf M. Sievert, the Swedish physicist who laid the foundations of modern radiation physics, clearly expressed the dynamic link between policy, research and application: “*The establishment of maximum permissible radiation levels is a non-scientific task, which must be based primarily on scientific knowledge and judgment*” (UN, 1958).

Achieving a mutual understanding among radiological protection policy makers, practitioners, researchers, industry and non-governmental organisations is expected to facilitate the prioritisation of research and the framing of decision-making in the future as well as to improve the quality and robustness of radiological protection.

The Committee on Radiation Protection and Public Health (CRPPH), a standing technical committee of the OECD Nuclear Energy Agency, has long been aware of the need to develop a shared understanding of emerging challenges for radiological protection among scientific and regulatory communities and other concerned stakeholders. The CRPPH Expert Group on the Implications of Radiological Protection Science (EGIS) published a report in 2007 on *Scientific Issues and Emerging Challenges for Radiological Protection* (OECD/NEA, 2007a). This report represents a broad summary of key scientific challenges that could arise from ongoing

1. Radiation physicist and pioneer in the field of radiation safety, Founding Member of both the International Commission on Radiation Units and Measurements (ICRU) and the International Commission on Radiological Protection (ICRP).

research on radiological protection. Additionally, the CRPPH Expert Group on the Collective Opinion (EGCO) published its report on *Radiation Protection in Today's World – Towards Sustainability* (OECD/NEA, 2007b). The report identifies key emerging challenges to the radiological protection system in order to assist decision makers at all levels to better address these within their relevant contexts.

In follow-up to these activities and in response to the existing need to foster mutual understanding among all stakeholders concerned, the CRPPH initiated a longer-term process of reflection on scientific and societal issues that might challenge radiological protection in the coming decade. The first step in this process was a workshop organised in collaboration with the Radiation and Nuclear Safety Authority of Finland (STUK) to address some of these issues. This first workshop entitled “Science and Values in Radiological Protection” took place on 15-17 January 2008 in Helsinki, Finland.² At this workshop more than 60 scientists, researchers, representatives of regulatory authorities and political decision makers from 22 countries (including countries not members of the OECD) met to discuss new trends in radiological protection.

A second workshop in the series was then organised in collaboration with France's IRSN (*Institut de radioprotection et de sûreté nucléaire*) and sponsored by the French Ministry of Ecology, Energy, Sustainable Development and Land-use Planning (MEEDDAT). This second science and values workshop took place on 30 November-2 December 2009 in Vaux-de-Cernay, France.³ Attending were more than 70 participants from 19 countries (European countries, Argentina, Canada, Chinese Taipei, Japan, Korea and the United States). The following types of institution were represented: public health authorities, regulatory bodies, international organisations, industry, hospitals, scientific expert organisations and universities.

At both workshops, selected key challenges to radiological protection were explored by plenary presentations.⁴ In-depth discussions then took place among participants in topical break-out sessions. The present report introduces the objectives, aims and topics of each workshop, and then summarises the findings and outcomes of the respective break-out sessions. The full programme of each workshop is provided in annex along with the lists of participants.

2. www.oecd-nea.org/rp/helsinki08/

3. www.oecd-nea.org/rp/vaulx_de_cernay09/

4. A subset of the plenary presentations from each workshop can be viewed online at the hyperlinks provided above. The remaining presentations were based on preliminary data, or on data awaiting journal publication elsewhere, and were thus unsuited to online publication.

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INTRODUCTION TO THE HELSINKI WORKSHOP (2008)

Objectives and aims

The first workshop entitled “Science and Values in Radiological Protection” took place on 15-17 January 2008 in Helsinki, Finland.¹ This workshop initiated a process of reflection and dialogue among the research community, policy makers and other stakeholders. The expectation was for this dialogue to contribute at term to organising and analysing scientific knowledge and values for managing radiological risk in such a way that a framework for action can emerge. In particular, the workshop was designed to help foster the following broad objectives in radiological protection:

- to improve the understanding by concerned parties of the science and the value judgments underlying the radiological protection system;
- to develop a methodological corpus for facilitating the transmission to the next generation of scientists, decision makers, etc.;
- to identify research needs in view of improving the robustness and quality of the system;
- to improve the transparency of the system so as to facilitate dialogue between all stakeholders;
- to anticipate and to analyse prospectively the potential implications of scientific and societal evolution.

In this way, the workshop aimed specifically:

- to be the first step in the identification of elements of a framework that is better suited for the integration of new scientific and technological developments and socio-political considerations in radiological protection;
- to identify the most appropriate next steps in this process.

1. www.nea.fr/html/rp/helsinki08/welcome.html.

Particular attention was paid to addressing the value issues and their potential impact on ethical evaluation of radiation risk and on the arising need for implementation of adequate radiological protective measures and regulations. Alongside novel scientific and academic phenomena, issues like consent, equity, control and responsibility are also very important for defining and imposing appropriate radiological protection measures and criteria. Thus the workshop was also intended:

- to discuss the incorporation of such values in radiological protection policy;
- to provide an adequate platform for open dialogue among scientists, decision makers and regulators.

To achieve the Helsinki workshop aims, and to progress the broader objectives, selected examples of emerging radiological protection issues, scientific phenomena and value issues were addressed in plenary presentations and break-out sessions.

Workshop format

The workshop lasted for two and one-half days and was structured around a number of invited plenary presentations addressing selected emerging challenges to radiological protection as viewed by different stakeholder groups.² These presentations were followed by facilitated break-out sessions that examined those challenges in greater detail, in particular their potential implications from the perspectives of science, values and interpretation. Participation in each break-out session was predetermined so as to achieve balance in terms of the spectrum of stakeholders participating in the workshop.

Three of the key scientific issues identified in the EGIS report (OECD/NEA, 2007a) were used as examples in the workshop, namely:

- non-targeted effects;
- individual sensitivity;
- circulatory diseases.

2. Plenary speakers included O. Niwa (for researchers' point of view); D. Drabova (regulators); Y. Marignac (NGOs); B. Le Guen (industry). Consult the workshop programme in annex; the plenary presentations can be obtained online: www.nea.fr/rp/helsinki08/programme.html.

Each topic was addressed initially in plenary and subsequently in the parallel break-out sessions which were moderated by designated experts. The intention of these discussions was two-fold. From a practical standpoint, detailed discussions of a given challenge assisted scientists and regulators to better understand the relevant implications to their work. From the process standpoint, this discussion was a test of a multi-stakeholder dialogue mechanism by which any variety of scientific issues with regulatory significance could perhaps be addressed in the goal of handling them efficiently and effectively.

The moderated discussions followed a *what if?* approach to determine the nature and significance of the potential implications of the various emerging issues or challenges. Where appropriate, participants identified the need for further research and/or analysis to aid in better understanding the challenge and how/if it may be accommodated. Discussion was facilitated by a set of proposed questions adapted to each “challenge” topic, reproduced below for the topic of “non-targeted effects”:

- Why are non-targeted effects a relevant topic?
- What do we know now about non-targeted effects?
- What do we not know now about non-targeted effects that we would like to know?
- What are the scientific issues?
- What are the regulatory issues?
- What approach(es) should be followed to address scientific issues raised above?
- What would we do differently if we knew now what we would like to know?
- What could or should we do now while we wait for the answers to these questions?

The findings of the break-out sessions were reported in plenary by the respective moderators and then freely discussed by the full set of participants. Those break-out sessions and subsequent discussions informed the summary³ of the Helsinki workshop provided in the following pages.

3. The summary report of each session is ordered according to the foregoing set of questions when possible, but it should be noted that not all break-out sessions gave equal consideration to the full range of questions.

NON-TARGETED EFFECTS

The opening presentation by William F. Morgan presented “Non-targeted effects and the DNA paradigm”. Non-targeted effects refer to those effects that occur in cells not directly hit by ionising radiation (for instance, by that delivered in a therapeutic intention). In particular, so-called “bystander effects” are those that occur in cells that were not traversed by radiation and are induced by signals from irradiated cells. Another significant not-targeted effect is that occurring in the genetic offspring of the irradiated cell, where an increased rate of genomic alterations is seen in the progeny of irradiated cells.

Currently there is much that is unknown with regard to these two aspects of non-targeted effects. For example, regarding bystander effects:

- What are the chemical messengers that result in damage being manifest in non-irradiated cells?
- Why does damage occur in only some cells in the vicinity of the irradiated cell?

Or, with regard to genomic instability:

- Why does this instability occur irregularly in the family of progeny cells?

More generally, it is not known whether these effects are linked to the later appearance of diseases, such as cancer, leukemia, or circulatory diseases, and thus it is not known how these effects may affect the shape of the dose/response curve or the overall model of radiation-induced damage.

Why are non-targeted effects a relevant topic?

The precise nature of radiation-induced damage and the mechanisms that lead to detrimental effects (i.e. cancer, leukemia, circulatory diseases, etc.) are not fully understood. However, we assume for radiological protection purposes that detriment is proportional to dose. If, however, effects in cells beyond those that are directly hit by ionising radiation do influence the genesis of radiation-induced diseases, this would suggest that amplification may be occurring and that, in fact, detriment is not as directly proportional to dose as we currently

suspect. While it is not clear that a future scientific demonstration of such amplification would necessarily affect the practical implementation of radiological protection, it is clear that it would be necessary to reconsider the dosimetric criteria on which we currently base protection decisions and decide whether new or additional criteria or approaches would better guide protection decisions.

Although non-targeted effects are still couched in uncertainty, the above discussion suggests that it is valid to consider possible implications for radiological protection even at this early stage.

What do we know now about non-targeted effects?

There is a substantial and growing body of knowledge in the area of non-targeted effects, and much research continues in this area.

It is known that bystander effects can be induced in non-irradiated cells by ionising radiation. This has been seen in many in-vivo experiments, using a human skin cell model, mice, or blood samples from irradiated humans. Bystander effects are thought to be mediated by cell-to-cell gap junction communication, and they are seen at low doses (on the order of a few mGy) in situations where there are no direct irradiation effects from significantly higher doses (on the order of a few tens of mGy). Many types of effects can be generated in bystander cells, including gene expression, mutation, transformation, micronuclei, cell killing, DNA double strand breaks, γ -H2AX foci, chromosomal aberrations, micronuclei, or cell apoptosis. Bystander effects have also been positive in some experiments; for example, delay of growth of implanted LLC cells in mice. The link between these bystander effects and tumor genesis has not, however, been established.

Genomic instability, another type of non-targeted effect, is also known to occur as a result of irradiation. In this case, progeny cells that have not been irradiated manifest an instability in their genomic makeup, which can include chromosomal rearrangements, micronuclei, aneuploidy, delayed mutation (spectrum different), gene amplification or even cell killing. These effects can occur in cells that may be several generations beyond the originally irradiated cell. Here again, however, no link between genomic instability and radiation-induced carcinogenesis has been established.

What do we not know now about non-targeted effects that we want to know?

As alluded to above, there are many aspects of non-targeted effects that remain unknown or very uncertain, and knowing more about these aspects

would facilitate taking better radiological protection decisions. Several aspects appear to be relevant for this purpose. Relevance to the low dose exposures of significance for radiological protection is clearly a very important area.

What are the scientific issues?

There are many scientific issues that remain insufficiently understood with respect to non-targeted effects, and much research is currently underway in this area.

Work is underway to understand the nature of the signal generating bystander effects, and the interaction of that signal with the bystander cell. In addition, there are studies to identify and understand the receptors for the signal, and to understand why all cells do not respond. Broadly, there is also work to understand the biological significance of bystander effects and how these may fit into a bigger picture of cell and tissue reactions to various external stimuli. Other more general observations are also being studied: for example, bystander effects seem to be dose-related only up to a certain low dose, and are primarily a low-dose phenomena, with higher doses not resulting in further effects. Bystander effects are mostly associated with low doses, and have been clearly demonstrated after low doses of high LET irradiation. However, in this context it is not clear that one α particle traversing a cell should be considered as a low dose to that cell. Nor is it clear what implications for other types of exposures might be found in these energy-deposition scenarios causing bystander effects. Experiments looking for bystander effects have been conducted with low-LET radiation; however, results have been ambiguous and sometimes eluded reproducibility. It is also not fully understood whether targeted and non-targeted cells respond differently.

Genomic instability is another area where much remains unknown, and where studies are ongoing. It is not known whether or how genomic instability may relate in a fundamental way to radiation carcinogenesis. More generally, it is not known whether these effects are linked to the later appearance of diseases, such as cancer, leukaemia, or circulatory diseases, and thus it is not known how these effects may affect the shape of the dose/response curve or the overall model of radiation-induced damage. Even if a relationship between genomic instability and detrimental health effects is at some point in the future, scientifically demonstrated, while it is not clear that this would necessarily affect the practical implementation of radiological protection, it is clear that it would be necessary to reconsider the dosimetric criteria on which we currently base protection decisions and decide whether or not new or additional criteria or approaches would better guide protection decisions.

What are the regulatory issues?

In addition to these scientific questions, the issue of non-targeted effects also raises a series of significant regulatory questions.

Broadly, at our current state of knowledge it is not clear whether these effects are biologically “good” or “bad”, making it difficult to understand how they might impact current radiological protection practices. For example, in medical treatments of patients, is the target area at risk in fact a greater volume than that actually irradiated? In general, do non-targeted effects amplify the detrimental effects of radiation, and if so how do we build non-targeted effects into radiation risk estimates?

What approach(es) should be followed to address scientific issues raised above?

In order to better understand the nature of non-targeted effects, it was agreed that mechanistic studies are essential, focusing on such things as DNA repair at low doses and low dose rates, on differences between the effects of high and low LET (linear energy transfer) radiation, and on the application of new technologies, for example regarding the significance of foci formation.

In addition, it was agreed that tissue and animal studies could bring important information, particularly on signalling pathways. Caution should however be taken in interpreting such results because animal inbreeding, diet and strain-specific reactions may influence experimental outcomes.

Finally, it was agreed that genetic susceptibility should be studied, using appropriate model systems, looking at genetic and epigenetic components, and studying individual differences.

What would we do differently if we knew now what we would like to know? What could or should we do now while we wait for the answers to these questions?

Although neither of these questions was addressed directly during this break-out session, their foundations were discussed in plenary. It was felt that better understanding of non-targeted effects would very likely not affect the overall level of risk, but rather would better explain the point of origin of the risk. Thus, based at least on our current, incomplete understanding, it would not be necessary because of non-targeted effects to change the approach that is currently taken to radiological protection in order to “better” protect people.

INDIVIDUAL SENSITIVITY

Michael Atkinson provided a plenary introduction to individual sensitivity in radiological protection. Individual sensitivity refers to the tendency of some individuals to be more or less sensitive than other individuals to radiation-induced damage. Such “hypersensitivity” or “hyposensitivity” can result from genetic differences, but can also be affected by living conditions (i.e. environmental exposure to other toxic substances) or lifestyle choices (i.e. smoking). The significance of this to the management of radiological protection is that the current system of protection is based on a broad, averaged approach that applies equally to all exposed or potentially exposed individuals. As such, decisions regarding justification, optimisation or limitation do not inherently account for variability in sensitivity, and thus may pose greater risks to some individuals than to others.

Currently, much scientific ignorance subsists in this area, regarding for example the size of the potentially hypersensitive population and the magnitude of their hypersensitivity, the range and types of exposures likely to trigger such hypersensitive reactions, the mechanisms that produce hypersensitivity that may be linked to other environmental factors, etc. However, the fact that such populations may exist can pose ethical and regulatory issues. These should be considered so as to avoid the need for hasty and perhaps insufficiently considered reactions by regulatory authorities should scientific discoveries arise confirming relevant hypotheses.

Why is individual sensitivity a relevant topic?

As touched on above, the fact that some fraction of the population could be more or less sensitive to detrimental effects from ionising radiation suggests that this is an issue that should be studied by governments and regulatory authorities. Individual sensitivity is plausible scientifically, and could result in significant risk differences.

It is known that, at the high doses to which radiation therapy patients are subject, about 5% of cancer therapy patients are hypersensitive to radiation, and express skin lesions much more frequently than other cancer therapy patients. Although it is unclear whether the cellular and tissue reaction mechanisms that

result in these deterministic, high-dose effects would be active at lower doses and result in stochastic effects, whether tissues and organs have similar sensitivities or not, or whether other mechanisms may be involved if stochastic effects do in fact occur, it is clear from animal studies that hypersensitivity can result in increased stochastic effects. In general, cell sensitivity is related to a deficiency in DNA repair, abnormal signalling pathways, abnormal genes, or other underlying phenomena all of which may be related to the development of cancer, and all of which may also be related to hypersensitivity. In this way, these cellular deficiencies may plausibly be linked in the case of hypersensitivity to the potential for stochastic effects from low levels of exposure.

In addition, however, it has been known for some time that, on average, women are twice as sensitive to radiation-induced stochastic effects (mostly breast cancer) than men, and that, again on average, young children (those of about 5 years and under) are about five times as sensitive to radiation-induced stochastic effects as are adults. Because of the relative lack of specific risk data on human populations, the UNSCEAR and the ICRP have judged that it is not appropriate to calculate age- and gender-dependent risk factors, but rather to use an androgynous, adult model as the basis for prospective exposure management. Using dose as the primary quantity for exposure management thus in effect avoids the necessity of taking age and gender risk differences into account. In general, it is also true that risk differences of less than an order of magnitude are generally well within the statistical uncertainty of our current level of knowledge, and so are often judged by risk management experts to be insignificant. However, stakeholders may not feel that differences of a factor of two or five should be dismissed as statistical noise.

Although individual sensitivity remains an effect still couched in uncertainty, the above discussion suggests that it is valid to consider possible implications for radiological protection even in the current state of knowledge.

What do we know now about individual sensitivity?

Individual sensitivity is known to be expressed at “high doses”, that is, at levels experienced by patients undergoing radiation therapy, and may be expressed at “low doses”, that is, at exposure levels experienced by occupationally exposed workers and by the public in general. With respect to radiation therapy patients, as previously stated 5% are hypersensitive to radiation, and of these, 5% (or 0.25% of all therapy patients) are very hypersensitive. Importantly, it is also suspected that there are some people who are hyposensitive to radiation, but the size of this group is not known.

In terms of cellular and animal studies, it is known that there are differences in cell sensitivity (e.g. epithelial cells are more sensitive than bone cells), and that cellular response is quantitatively and qualitatively different at high and low doses. It is also known that there are non-targeted effects at extremely low doses, but whether these have any detrimental consequences is not known. Dose fractionation results in less detrimental effect for low LET radiation, such that there is a need to consider the use of the DDREF (dose and dose-rate effectiveness factor), but from animal studies there is contradictory evidence concerning the benefit or detriment of low doses. There is, however, evidence for a genetic component to the effect of low dose-rate exposures in animal studies.

Focusing on studies of effects at low dose on humans, there is limited epidemiological evidence of stochastic effects below 100 mSv in adults, and below 50 mSv in children, but these are the exception rather than the rule. It is clear, however, that classical epidemiology has not and cannot provide any evidence of individual sensitivity, mainly due to the need for extremely large samples to obtain statistical resolution of these effects. Studies of high background areas have revealed chromosome aberrations (but no increase in cancer), but there is a need to better understand the effects of confounding factors (e.g. stress, smoking, lifestyle, etc.) in these studies. There is also evidence that there are environmental, lifestyle and other co-factors that affect how humans react to radiation exposure.

Again, although this knowledge base is rather incomplete, it does suggest that further study is necessary to better understand the magnitude and nature of these possible effects.

What do we not know now about individual sensitivity that we want to know?

As alluded to above, there are many aspects of individual sensitivity that remain unknown or very uncertain, and knowing more about these aspects would facilitate taking better radiological protection decisions. Aspects appearing to be the most relevant were highlighted in discussion.

What are the scientific issues?

High-dose hypersensitivities are particularly relevant to consider because they are known to exist in some radiation therapy patients. In particular, the link with specific genetic characteristics offers the possibility to develop predictive tests that would indicate whether or not an individual would be likely to be hypersensitive to radiation. However, for such tests to be truly useful in helping

to define an individual's treatment strategy it is important to better understand the mechanisms and consequences of effects caused by hypersensitivity, and their applicability, that is, at what range of exposures they might occur, what effect age at exposure may have, etc. Of course, any predictive tests would need to be suitably validated for accuracy and precision.

Beyond these high-dose effects, much remains unknown about possible low-dose effects due to hypersensitivity. For example, what fraction of the population is hypersensitive to low-dose radiation, and how can distribution(s) be characterised (i.e. in terms of gender, geographic location, age or habit data)? How much more radiosensitive is this group, and are there differences according to type of radiation or dose rate? Can the linear no-threshold (LNT) model reasonably be used to characterise risks to these individuals, and if so, how would the risk factor(s) be determined? Does an individual's hypersensitivity to high doses imply simultaneous hypersensitivity to low doses, and if so, how can this be experimentally studied? Do lifestyle choices affect individual sensitivity? Can radiation hypersensitivity cause effects other than cancer and heritable effects, i.e. circulatory diseases? Is there an interaction or relationship between hypersensitivity to radiation and cancer induction due to other "agents" (i.e. exposure to other carcinogenic substances)? Do different levels of natural background have different effects on cells, tissues or organisms?

What are the regulatory issues?

In addition to these scientific questions, the issue of individual sensitivity also raises a series of significant regulatory questions. For example, hypersensitive individuals are theoretically included in the exposed populations that have been used as the basis for the estimation of radiological risk, in particular the populations of Hiroshima and Nagasaki; does this basis thus sufficiently take into account the risks to hypersensitive individuals? In fact, is most of our current risk estimate actually due to risks in these individuals? If so, would it be appropriate to re-evaluate our current approach to radiological protection, either identifying a new dose limit to best protect hypersensitive individuals and another for "normal" individuals, or keeping a single dose limit but setting it as a function of risks to hypersensitive individuals? Additional regulatory issues arise if we accept that hypersensitivity may mean that some individuals are at two or more times the "normal" risk. These issues include the radiation protection of emergency response workers and perhaps also of the public (sensitive groups) in emergency situations, depending on the relevant level of exposure. These considerations have implications for the current approach to planning emergency response optimisation for women, pregnant

women and children, groups that while not being hypersensitive in the sense discussed here, are known to be more sensitive to radiation-induced detriment.

What approach(es) should be followed to address scientific issues raised above?

Given these types of scientific questions, can credible strategies be found to develop appropriate answers? Cellular research may certainly add to knowledge, but are single-cell models relevant with respect to effects at the level of the organism? Animal models may also add to our knowledge, but how relevant are animal models to human individual variation?⁴

The magnitude of these questions suggests that they are too large for a single national approach to successfully address them all. Needed is a broad common strategy and appropriate infrastructure that can focus efforts on the most relevant aspects of these questions. It must be recognised that these are facets of the broader question of whether or not low dose exposures (e.g. 10 mSv) do or do not cause any health effects. Clearly, these questions cannot be answered now and thus there is a need to live with uncertainty for some time yet.

However, research priorities can be developed today, through active dialogue between researchers and the regulatory and broader radiological protection community. From the scientific standpoint, four research approaches, each having advantages and disadvantages, are possible; these are shown in Table 1 below.

Future prioritisation of research will depend upon clarity in judging the likelihood of these studies to deliver answers. Other key aspects will be to consider whether risk-modifying factors (age, diet, lifestyle, etc.) influence sensitivity or not, and to reflect that test results must remain “up-to-date”, as parameters may change across lifetime.

Finally, the large remaining uncertainty implies that to discharge radiation protection duties to sensitive individuals, it will be important for society to maintain a high level of training and competence in relevant research.

4. In this context, the strong cross-national commitment to “reduce, replace and refine” animal testing is significant as well. This binding ethical obligation on researchers is broadly supported in today’s society.

Table 1. Research approaches to clarifying individual sensitivity, their advantages and disadvantages

Research approach	Advantages	Disadvantages
1. Using in-vitro models and experiments	Mechanistic studies possible	Limited capabilities
2. Using animal models and experiments	Controlled, low-dose experiments	Question of applicability to humans
		Societal commitment to limit animal testing
3. Using molecular epidemiological models	Link studies to other, ongoing cancer studies (e.g. Icelandic genetic study)	Need fingerprints of tumor causality
4. Using data from humans	Direct, genuine and non-approximated information	Need signature or pre-determined endpoint for such studies to be useful

What would we do differently if we knew now what we would like to know?

An important challenge is the need to assess what changes may need to be made in our current radiological protection approach when knowledge evolves. Adopting a prospective or *what if?* approach, several changed situations can be foreseen at once:

- A tool exists to prospectively identify or predict individual sensitivity.
- An understanding of the fraction of the population that is more sensitive is developed, and of their relevant distribution(s).
- An understanding has been developed of how much more sensitive the population is.
- Knowledge of the relationship between sensitivity to acute effects and to stochastic effects has been sufficiently developed.
- Knowledge of low-dose and dose-rate effects, whether negative, positive or neutral has been sufficiently developed.

Based on this level of understanding it is likely that radiological protection changes would be considered for both high- and low-dose situations.

High exposures

With regard to high exposures to therapy patients, there would be a need to review and perhaps update clinical guidelines and approaches to individual patients. This would most likely improve treatments by assuring that the appropriate dose (either lower or higher depending on the individual's sensitivity) would be administered.

For high doses resulting from an emergency exposure situation, triage of victims in terrorist events or large accidents, and identification of any victims susceptible to needing long-term follow-up may improve. Concerning the emergency workers themselves, it would be possible to pre-select particular individuals for their resistance to detrimental effects, or to identify those who would be the least suited to work that might involve high doses. It would also be possible to develop separate dose restriction approaches for both of these groups. However, in both cases, it would pose significant ethical and labor questions that would need to be addressed in an appropriately stakeholder involvement fashion in order to reach an accepted and sustainable resolution.

At low dose in the workplace

Effects of individual sensitivity at the workplace would most likely depend upon the magnitude of the individual sensitivity. If the increase (or decrease) in sensitivity is low (e.g. in the order of a factor of two but within the current range of RP uncertainty), there would be a need to assess the costs and benefits of change to the current radiological protection and labour management approach, and for this stakeholder involvement would be needed in the discussions.

If the increase (or decrease) in sensitivity is large (e.g. one or two orders of magnitude) the employer may have a duty to inform workers of the existence of a sensitivity test, to test workers, and inform them of the results and take relevant, agreeable actions. Guidance to what types of actions could be taken can be drawn from current approaches to known situations of heightened sensitivity. For example, the risk to the foetus is much higher than to an adult, but in the situation of a declared pregnant worker, the protection of the foetus is specifically addressed during pregnancy. Using a non-radiological example, workers suffering from asthma are in some cases not allowed to work in habitually dusty environments. However, several different types of issues would need to be discussed and resolved, including:

- Insurance coverage based on increased sensitivity would be a key question.
- Allowing the individual to work in an increased risk environment would be an employer, employee, regulator (and social?) issue.
- If there are individuals with no or little risk from radiation exposure, their management at work, perhaps in a fashion different from “normal” or hypersensitive workers, would need to be addressed.

For such situations, existing international text on genetic discrimination should at the very least be a starting point for worker/employer discussions.

At low dose to the public

Should individual sensitivity to radiation-induced injury be relevant at the low doses characterising typical exposures of the public, several types of issues would need to be addressed (through appropriate stakeholder processes). First and foremost, there would be a need to provide education and information to the public on this issue. This would be particularly important for people living in high-background areas.

Beyond the need for information, there would be a need to discuss the implications of increased or decreased individual sensitivity for insurance coverage, and for employment. In this context, the availability of genetic susceptibility test results would be a central issue, as would be the interpretation of test results.

Depending on the exposure level at which increased susceptibility becomes a significant question, it might become necessary to reassess medical diagnostic or screening campaigns, and approaches to medical-legal screening. There might also be a need to re-evaluate the single-criterion approach to public dose limitation, and approaches to optimisation of protection in the context of operational releases, accident situations, waste disposal and decisions regarding exclusion and exemption. It may also be necessary to consider the implications for protection approaches to other, possibly interrelated sensitivities, for example to UV exposures, or to other carcinogenic agents.

What could or should we do now while we wait for the answers to these questions?

Based on our current level of knowledge, and in particular on our understanding of the probable levels of increased risk should large populations of hypersensitive individuals exist, there appears to be no need to radically

modify the current approach to radiological protection. No specific changes are recommended for occupational protection, for protection of the general public, or for public screening programmes (i.e. medical screening or medico-legal screening).

This position reflects today's level of comfort with scientific uncertainty, and it does not exclude that the radiation protection community should be prepared to react in an appropriate fashion should new evidence arise. However, workshop participants suggested that significant public concern might arise should scientific studies indicate that large risk differentials exist, and that one possible approach to addressing such concern would be to involve stakeholders in discussion of the practical and ethical aspects of these issues as a preparation for decision-making.

In order to assure, on the one hand that necessary research is appropriately carried out, and on the other hand that the implications of research are understood and guidance and direction for research are provided, it will be essential to maintain competence in the regulatory, research and application (i.e. operational and medical) communities, and particularly to improve the radiological protection training and competence in the medical community.

In three exposure situations, however, it is suggested that some consideration should be given at this point to refocusing protective actions taking individual sensitivity into account. These are emergency exposure situations, medical diagnosis situations, and medical therapy situations.

Emergency exposure situations

Regarding emergency exposure situations, it is suggested that, emergency response planners and radiation protection decision makers consider specifically targeting optimisation of protection to "known" sensitive groups (e.g. children and pregnant women). This may already be a key focus in many countries, but given our current knowledge of the sensitivities of these groups, it could be prudent to highlight their protection in existing emergency response plans. In parallel with this, it could also be prudent to develop criteria and methods for the selection of emergency workers that are consistent with known risk differentials, and with other possible individual sensitivity issues. This should, of course, be done in consultation with workers and labour representatives so as not to infringe on worker rights.

Medical diagnostic situations

In the area of medical diagnosis, it was remarked that patient exposures tend to be low, and do not generally pose much concern in the mind of the consulting physician. While it is true that many diagnostic exposures are low, exposures from Computer Aided Tomography (CT) can be fairly high, and in any case protection in all exposures should be optimised (i.e. careful focus of the beam, proper machine calibration, avoid multiple exposures, etc.). To assist physicians in recalling the relative importance of radiological protection, more efficient display of patient exposures was recommended. As digital imaging becomes far more widespread, such a signal display can at least partially be accomplished by including dose assessment capabilities as implemented in Digital Imaging and Communications in Medicine (DICOM) headers of digital images. Broader reliance, as appropriate, on recent patient digital images, as opposed to systematically re-imaging each time a patient is transferred or seen by a new physician, would also assist in better management of patient diagnostic exposures.

Medical therapy situations

In the area of medical therapy, it is suggested that radiation protection specialists should seek to raise awareness within the medical community of individual sensitivity and of the possibility of heightened risk of secondary cancers. The opportunity presented by such a dialogue with the medical community should also be used to promote good practice in therapy, and to validate therapy standards. The possibility that reliable genetic testing to indicate individual sensitivity will be available in the near-term should also be discussed, and could lead to reflection on secondary cancer risks in sensitive populations, and on the ethical and practical aspects of “tailor-made” therapy approaches.

CIRCULATORY DISEASES

Circulatory diseases (CD) are one form of observed radiation-induced non-cancer diseases (circulatory, digestive, liver, and respiratory); they are defined as functional defects in the system of organs and tissues involved in circulating blood and lymph through the body. These effects have most frequently been observed during radiotherapy where high doses are usually applied. Therefore, indirect evidence on the magnitude of any risk is available where the tumour position can be linked to subsequent mortality related to vascular disease. As for the epidemiological studies, survivors of the atomic bombing of Japan who received single doses to the whole body of 0-4 Gy showed that the CD risk is dose-related and increases by about 14% per gray, although there is no clear indication of risk below about 0.5 Gy.

The keynote presentation by Dale Preston on circulatory disease, and Break-out Session 3, addressed these issues focussing particularly on:

- identification of key issues and elaboration of potential *what if?* scenarios;
- proposal of feasible solutions at various levels (science, recommendation, regulations, etc.);
- elucidation of possible mechanisms between chronic low-dose radiation and diseases of the circulatory system; e.g. radiation-induced increase of radical concentration thereby stimulating expression of specific genes;
- existing epidemiological evidence;
- dose-response relationship between ionising radiation and diseases of the circulatory system;
- extrapolation to low dose of high dose exposure risk for incidence of CD.

Abstract of the key note presentation

It has been generally accepted that high dose (several Gy) radiation exposure to the heart or other parts of the circulatory system results in long-term increases in circulatory disease risks. Over the past 10-15 years evidence has been emerging from the long-term follow-up of atomic bomb survivors and other populations to indicate that relatively low dose acute exposures (< 2 Gy) also are associated with increased circulatory disease risks. Although the estimated relative risks are smaller than for cancer at the doses normally of concern in practical radiological protection, it is clear that radiation-associated circulatory disease deaths will account for a substantial fraction of the total radiation impact on mortality in the atomic bomb survivors. However, those epidemiological data do not, and probably cannot, provide definitive evidence of increased circulatory disease risks following low dose (say 0.005 to 0.5 Gy) exposures. Despite this uncertainty, these findings have increased interest in efforts to identify mechanisms for long-term radiation effects on the circulatory system and prompted the re-examination of circulatory disease risks in other populations. The UNSCEAR report completed in 2006 (published as UNSCEAR, 2008) includes an annex on this topic. It seems inevitable that the ICRP and other groups involved in the formulation of regulatory guidelines will have to deal with the question of how to incorporate potential circulatory disease risks into the evolving system of radiological protection.

During the break-out session, the discussion identified the importance of the problem:

- existence of clear epidemiological evidence for radiation-induced CD above doses of 0.5 Gy; at lower doses the evidence is inconclusive;
- radiation-induced CD may have significant impact on morbidity and mortality;
- CD are currently not specifically addressed by the system;
- public and trade unions concerns are increasing;
- statistical evidence in exposed populations other than atomic bomb survivors seems to be increasing.

The ICRP position

The ICRP recognises (ICRP, 2007; § A191) the existence of CD risks at high doses, and the need to consider adjusting its overall risk coefficient as a result, however it notes that dose-associated effects are experimentally clearly observable only at high doses, around 1Sv. There are still uncertainties on the

shape of the dose-response curve at low doses and as to whether these effects have a threshold at around 0.5 Sv or whether there is no threshold. In general, ICRP accepts that available data do not allow for the inclusion of CD risks in the estimation of detriment following radiation doses of less than 100 mSv. This conclusion also agrees with the conclusion of the UNSCEAR 2006 Report (UNSCEAR, 2008) which found little evidence of any excess of risk below 1 Gy.

Below are summarising factors that support or deny a need for inclusion of this issue within radiological protection principles.

Supporting factors include:

- existing evidence of effects above 0.5 Gy;
- coherence with philosophy of radiological protection;
- ethical and moral aspects;
- public concern, the need to show that RP is aware of the problem and responding;
- incentive to improve some practices and technologies causing high exposure.

Opposing factors include:

- no effects are observed below 0.5 Gy;
- lack of knowledge regarding mechanisms (cellular, molecular...?);
- magnitude of radiation effects on CD is small compared to other causes considered in public health;
- inability to quantify cost/benefit associated with potential decrease of dose limits; the benefit may be nil if there is a threshold;
- lack of efficiency in specific area of practice concerned (CT);
- new epidemiological studies coming fairly soon;
- public concern: creation of potential distrust of RP for not having identified the problem earlier.

Potential mechanisms

Potential mechanisms of radiation-induced CD may be diverse: inflammatory, micro vascular, mutation-induced and other mechanisms. An

inflammatory mechanism, more consistent with deterministic effects, is the most plausible. Several questions need to be addressed in this respect:

- Are there different mechanisms at high and low doses?
- Are these mechanisms consistent with stochastic or deterministic dose response?
- What is the threshold? If the threshold is low, there may be a need for change in RP.
- Does the relative risk depend on type of CD?
- How does the spectrum of radiation-induced CD depend on dose?
- What is the link between CD and dose, dose-rate effect, and radiation quality?
- What are the age, gender, population and temporal effects?
- What is the importance of synergistic effects, i.e. interactive effects with other agents?
- What is the target tissue?

Break-out session conclusions

The break-out session on circulatory diseases concluded that if available Japanese risk estimates and LNT imply potential changes in radiological protection principles in relation to CD, there may be a significant need for revision of protection criteria. The radiological protection system is risk-informed, not risk-based, and the main emphasis is on constraints; as an indication, however, new risk estimates would suggest that current dose limits be lowered by 30-50%. It was noted that the application of the precautionary principle in judging whether or not to modify existing radiological protection criteria should include not only assessment of the change in detriment, but also assessment of the costs and other consequences that such a change would cause. The break-out session recognised that any potential change should be made in the light of evolving science and rigorous value judgments.

CONCLUSIONS OF THE HELSINKI WORKSHOP

The NEA Committee on Radiation Protection and Public Health (CRPPH) and the Radiation and Nuclear Safety Authority of Finland organised the workshop on “Science and Values in Radiological Protection”, which was held on 15-17 January 2008 in Helsinki. In this workshop more than 60 scientists, researchers, representatives of regulatory authorities, political decision makers and other experts from 22 countries gathered together to discuss new trends in radiological protection. They addressed selected emerging scientific phenomena, like non-targeted effects, individual sensitivity and circulatory diseases, which if taken into account may potentially induce modifications in existing radiological protection approaches and values. It was recognised that mutual understanding on the scientific evidence and on the radiological protection values and practice is important both for obtaining optimal protection and for identifying the gaps in knowledge that are most relevant for radiological protection. Most of the participants agreed that while there is no immediate need to change the current principles, extended dialogue among all concerned stakeholders is necessary in order to facilitate integration of challenging scientific phenomena into existing regulatory frameworks. This type of exchange forum between regulators and scientists was welcomed and could serve as a model way of moving forward. As a result of discussions of the three workshop topics, the following observations were reached.

Non-targeted effects

Non-targeted effects referred to those effects seen in cells not directly hit by radiation, such as the so-called bystander effects and genetic instability. These effects were characterised as being seen mostly at a cellular level, and as such having a somewhat uncertain effect on the overall detriment to the organism. It was felt that better understanding of non-targeted effects would very likely not affect the overall level of risk, but rather would better explain the point of origin of the risk.

Individual sensitivity

At this workshop the individual sensitivity that was discussed referred broadly to the sensitivity that may be caused by genetic imperfections, rather

than the sensitivity differences seen between men and women, or between children and adults. As a result of discussions, there seemed to be no need to radically modify the current RP approach. However, in emergency situations and in medical diagnostic and therapy situations, it was suggested that some consideration be given to refocusing protective actions taking individual sensitivity into account.

Cardiovascular disease

The discussion of cardiovascular disease at the 1st “Science and Values in Radiological Protection” workshop suggested that new epidemiological data, in particular from the Mayak workers, would be published not long after the workshop, and would broadly show agreement with data from the Hiroshima/Nagasaki Lifespan study, suggesting that cardiovascular diseases could be provoked by both acute and chronic exposures. Taking this detriment into account, at that point simply based on Lifespan Study (LSS) data, there could be a need to lower current dose limits by 30-50%, with strong emphasis on optimisation. However, the workshop concluded that the science is still evolving and there was no need at that point to recommend change to the system of radiological protection.

INTRODUCTION TO THE VAUX-DE-CERNAY WORKSHOP

The second in the series of NEA workshops on “Science and Values in Radiological Protection” was held in Vaux-de-Cernay, France on 30 November-2 December 2009.¹

Objectives and aims

During the first workshop (Helsinki, January 2008; reported above), a *What if?* approach was used to discuss the scientific aspects in some key areas of emerging radiological protection science. The results of the dialogue among the attending regulators, scientists and NGOs were seen as having very positively improved mutual understanding of issues, viewpoints and possible implications. The discussion was also seen as having begun to identify elements of a process and framework for the better integration of the social and scientific dimensions of radiological protection.

Re-emphasising that radiological protection is a combination of science and value judgments, the CRPPH agreed at its 66th annual meeting to continue the useful discussions begun in Helsinki by organising the second workshop. Here, however, the committee agreed to focus on radiological protection issues that are currently facing us, and that continue to pose challenges to our world today. As such, the second workshop in this series was designed to address a series of current radiological protection issues from the standpoint not of *What if?*, but rather, *What now?*

The second CRPPH “Science and Values in Radiological Protection” workshop thus organised reflection on three selected case study areas:

- radon as a public health issue;
- medical exposures in diagnostic and screening procedures;
- radiation-induced vascular effects.

1. www.nea.fr/html/rp/vaulx_de_cernay09/welcome.html.

Organisation and format

After a set of introductory presentations,² each of the case studies benefitted from a scene-setting presentation in plenary by a noted expert. These presentations were followed by break-out discussions over the course of two days. Participants chose their session of interest, and while many chose to stay in their chosen case study area for both break-out periods, others found it enriching to join a second group.

During the discussion participants presented and discussed their relevant national objectives and experience in the designated area, and brainstormed on approaches to better achieve their objectives when faced with emerging data. The break-out sessions engaged participants in addressing the following central questions.

1. Which issues need further elaboration before deciding whether it is necessary or appropriate to change the current approach?
 - Identification and discussion of science issues
 - What level of effect is being discussed?
 - What are the uncertainties involved and how well characterised are they?
 - Identification and discussion of practical issues
 - What would a change in regulation impact?
 - What would be the magnitude of such changes?
 - Identification and discussion of value issues
 - Balance of risks and benefits?
 - Precautionary judgment?
2. What aspects weigh on decisions regarding possible change?
 - Implications for regulation, industry and health care sectors
 - Practical implications for application
 - Resources needed

2. Jacques Lochard (progress towards a framework of understanding); Gilbert Eggermont (the public health perspective); Britt-Marie Drottz Sjöberg (civil society needs); see the full programme in annex.

- Adapting to a significant change in approach
- Education and training needs

In practice, wide-ranging conversations were held in the break-out sessions, touching on and returning to these questions at various times. For this reason, the following reports of break-out findings are structured “organically”, rather than organised by these questions taken as headings. The following accounts are developed from the summaries presented in plenary by each session rapporteur and ensuing discussion.

RADON AS A PUBLIC HEALTH ISSUE

The plenary presentation on radon as a public health issue was delivered by Margot Tirmarche (IRSN). She presented the new data, phenomena and observations that today stimulate the questions discussed across break-out groups at Vaux-de-Cernay: are current public health and regulatory approaches still adequate, or might they need revision?

The discussion on radon yielded a number of considerations, reported below: the conceptual shift from “intervention or action level” to “reference level”, and the scientific and value judgments this implies; the pertinence of the figure of 10 mSv/a; optimisation as a key focus in the context of radon protection; economic concerns, their impact on protective actions and on legal frameworks; information and communication; taking societal perceptions into account when assessing exposure situations and actions to be taken; children as a vulnerable group. Experience was shared and advice was formulated on several of these points.

From “intervention level” to “reference level”

The ICRP Publication 103 (ICRP, 2007) put forward a regulatory concept for the approach to mitigating radon exposure that could be described as a significant shift in moral or social value. The previous guidance, laid out in Publication 60 (ICRP, 1991), was based on the concept of “intervention level”: this corresponds to a binary approach, where exposure above a given benchmark should trigger action, and exposure below this benchmark would generally not justify intervention. To the extent that this benchmark is well and wisely chosen, individuals obtain the desired health protection benefit from the regulation. However, choosing the benchmark is not simple: new science and accumulated observation suggest that it may almost in fact be a moving mark. In the new approach, a “reference level” is set, and exposures above this mark – i.e., the individuals at highest risk – form an obvious primary target for regulatory intervention, but all exposures, *above or below* this mark are subject to optimised protection.

A level of exposure may be chosen at which protection is deemed to be optimised, and below which regulatory concern is less urgent or is felt to be

unwarranted – a level below which government chooses not to invest regulatory resources of action (this “optimisation” level may be selected according to a complex reckoning of national circumstances, whereas the upper “ceiling” constraint or reference level is based more typically on international scientific consensus). In the new approach there is a band of exposure situations lying between the reference level and the level where protection is deemed optimised; whatever its width (according to country), this band represents a new population of persons who receive a protective health benefit from radon regulation. This is a remarkable gain, when we consider that recent epidemiological studies suggest that radon is a key cause of lung-cancer deaths in both smokers and non-smokers, with statistical significance at exposure levels in the order of 150 Bq/m³, i.e. well within the range of exposures selected as reference levels in many countries.

From a binary approach the ICRP thus moves to recommend, with the WHO, an inclusive, continuous approach. The new ICRP recommendations call for this same optimisation approach in all circumstances. This is a value-laden choice: it can be attributed to values of systematic rigour, to a call for standardisation or harmonisation of approaches across more situations; it can be interpreted in the light of public health efficacy; but moreover, it can also be interpreted in the light of moral positions on benevolence and equity.

In each country represented at the workshop, current policy and practice reveal a deeply-rooted value of devoting resources to protecting those persons most exposed. The new approach embraces more generously a larger population, delivering care and protection (as before) to those who are the worst off, but now also to a set of those who formerly may not have been attended to. Considering that many national domestic radon management programmes have not been extremely successful in achieving the desired level of effective mitigation, it will be particularly interesting to observe whether this new approach results in the expected greater public health benefit (i.e. in avoiding a larger number of radon-related cancers, among the greater population who experience lower concentrations or doses of radon than those in the “high-end” populations who are consistently and traditionally protected).

How does each country set the width of the band of the population to be serviced in this way by regulation? How, in other words, can the reference and optimised protection levels be wisely set? Is the concept of “entry level” (in the occupational setting) still a good one? Which emphasis is given in national programmes to these differing concepts and levels and their action implications? What results in terms of public health outcomes can be hoped for? What are the actual interventions that contribute to optimising protection from radon exposure? Which criteria are employed to evaluate the success of national

regulation? Such were the questions examined by the “Radon as a Public Health Issue” break-out session of the Vaux-de-Cernay workshop, with a special focus on the first: *which* logic, which scientific facts and value choices, should be engaged in order to identify benchmark positions? In different national settings, what is the most adequate combination of science, values and regulatory outcomes?

Role of the 10 mSv/a figure

It is worth noting that both ICRP publications 60 and 103 (ICRP, 1991; 2007), although published 17 years apart, include the same “upper limit” but its role differs. In the former approach, 10 mSv/a in an existing domestic exposure situation was the benchmark level below which it was considered, quite simply, not justified to act. In the new approach, this same figure is the level which regulation plans not to exceed (i.e. exposure situations above this figure would most likely warrant remediation). The figure of 10 mSv/a focuses attention on situations to which most effort might be given (i.e. those lying above the reference level). Optimised protective action below that level is recommended as well.

In the occupational setting, the concept of reference level is expressed by an “entry point” (and in terms of indoor concentration rather than of dose): when radon concentrations cannot be reduced, in an occupational setting, below the value of 1 000 Bq/m³, workers “enter” the category of “occupationally exposed”, and a series of actions are engaged (dosimetry, record-keeping, medical monitoring, etc.) representing a certain cost for the employer.

How “good” is the figure of 10 mSv/a? Its functional value as a reference level was not condemned at the workshop. Many countries have national radon remediation programmes, and among workshop participants the consensus appeared to be that 10 mSv/a is a sufficiently good figure to work with in addressing existing residential situations. However, at the intersection of science and values it is interesting to note a number of facts associated with this benchmark, often related to the comparison between occupational and residential figures:

- The exposure conversion value has evolved; in 2009 the ICRP and UNSCEAR were close to agreement on relevant factors, and considered that the dosimetric benchmark of an effective dose of 10 mSv/a represents approximately 300-400 Bq/m³ of Rn-222 (at an equilibrium factor of 0.4). This contrasts with the values found by conversion using previous conventional factors, of 600 Bq/m³ for residential exposure and 1 500 Bq/m³ for occupational exposures.

- The average regulatory dose benchmark for occupationally exposed workers is 20 mSv/a (100 mSv in any 5 years), this with the monitoring and follow-up they receive; in comparison, 10 mSv/a over a lifetime in the case of an unprotected resident who may accumulate other risk factors (smoking for example) may seem high.

It has been suggested that the occupational “entry point” of 1 000 Bq/m³ could be left aside in regulation, and that a single concentration of 200 Bq/m³ could be retained across-the-board as the reference level to be used as the benchmark for optimisation efforts. After all, it could be argued, why drawing such a distinction between hours spent in the professional context and those spent at home? Should not a more holistic reasoning be applied? In view of the latest scientific data, the World Health Organization (WHO) proposes a reference level of 100 Bq/m³ to minimise health hazards due to indoor radon exposure (WHO, 2009) in residential settings.

Optimisation as the key issue

At higher exposure levels (those considered to deliver a dose of 10 mSv/a or higher) the course of action is clear in each country; regulation focuses attention and effort on mitigating those situations. However, epidemiological data now indicate that even nominally low concentrations of 100 Bq/m³ seem to represent a risk of inducing lung cancer in the population not only of smokers, but also non-smokers. This influences the change in conceptual regulatory approach; however, in deciding the degree of change (setting a reference level) and before effecting change, government should assess the supplementary effort to which it commits. For instance, when new policy indicates a lower optimised protection value, a greater number of dwellings will come under regulatory consideration. Such considerations of feasibility and defining the “reasonably achievable” in each context occupied proportionately more workshop time than did debate on the science lying behind risk estimations.

Indeed, detailing the scientific aspects of risk may not make a proportionately large contribution to optimising exposure situations.³ Of greater tangible importance here are decisions on which actions to take. Putting aside discussion of actual protective actions for identified residences in which radon concentrations are clearly above the reference level, other, broad-based actions – e.g. zoning laws, measurement or information campaigns – will touch and affect individuals across the board and regardless of their highly individual

3. An exception may be the case of childhood exposure: the need for more scientific understanding of the specific risk of radon exposure to children is discussed in a later section of this break-out session report.

exposure situation. Past a certain point, understanding their risk is not part of the solution for reducing that risk. We know that it is difficult to assess dose reductions as a result of precise actions. Radon exposure situations are known to be immensely complex and variable (seasonal variations, characteristics of an individual dwelling...) and the challenge for government is finding cost-effective actions that can result in mitigating the largest spectrum of those situations.

At the local level, optimisation is deciding “which management action(s) to apply”, which can be very diverse. At the national level, optimisation is deciding “which is the right optimised protection level”. Clearly, the national decisions subsume local ones, in that the feasibility and cost-effectiveness of implied (local, or case-by-case) actions will condition the optimisation calculation.

Economic concerns, their impact on actions and on legal frameworks

The break-out group discussed how to best assess the economic implications of modifying the regulatory approach. Today’s economic knowledge is generally tied to the traditional situation of acting on the most severe (highest) concentrations; the fact that cancers are found (and can potentially be avoided) in greater number at lower radon concentrations pushes government towards a new economic balance that must be assessed in all its complexity.

Legal frameworks exist on the national and international level for occupational exposure to radon. Legal frameworks for public exposure are generally not “stand alone”, but tied to a public health framework. The informal consensus was that probably no “international instrument” is needed for the regulation of public exposure, given that international recommendations and standards already exist.

The example of public buildings

The value-laden choices regarding professional exposure are thrown into light by the dilemma of “public buildings”. These are buildings through which a large number of citizens, seeking public services, pass for a relatively brief period of time. Within these buildings is found another population: that of the civil servants who staff them, persons who may find themselves significantly more exposed to radon should it exist. The case of Ireland, discussed during the Vaux-de-Cernay break-out sessions, highlights the types of issues that arise. Ireland assessed the radon status of every school in the country. (The outcome was a decision to intervene in some schools, but not in all.) Teachers and staff

spend more time within the walls of these buildings (across the week and across a lifetime); they serve children, who spend less time there, but who may be more sensitive. If the regulatory approach were to set standards – reference levels beyond which individuals’ protection should be optimised – social values would likely focus attention on children as the more vulnerable group. However, a standard that excludes children from a radon “hotspot” school might result in excluding the teachers and staff as well, unless policy foresaw a different standard for this group. An approach might be to see the staff not simply as less sensitive adults, but also, as professionally exposed workers, for whom a larger dose is admitted but for whom as well there is a need to set up better monitoring and health care programmes (both of which represent an economic cost) to take into account this radiological detriment.

This example poses several relevant questions. Whom, in fact, do we seek to protect? While children are known, in general, to be more sensitive than adults to radiation detriment, in the case of radon epidemiological studies refer to lifetime exposures rather than to exposures over more limited time periods, or as a function of age. As such, while children may in general be considered to be more at risk to radiation detriment than are adults, this is not, as yet, specifically supported by science. In the case of “public” and “occupational” exposure at schools, should the two school populations be treated in the same manner guided by the same figures, with attendant costs? Should radiation protection step outside the school and consider the 24-hour exposure of each group, and incorporate an “across-the-board” approach? Is it possible to have a “public dose limit” in the context of radon exposure – an existing situation – thus inducing other costs? What are the ensuing consequences not only in economic terms, but also in moral terms (societal values)? The overall response of the radiation protection community (and the decision of the Irish regarding schools) is to take a case-by-case approach within an overarching framework, i.e. by applying similar rules for different exposed populations.

“Socially affordable” mitigation

The break-out session discussed the fact that national programmes and expenditures are decided by political actors. Thus, the budget set for mitigation may be the “socially affordable” amount, and this amount (or more precisely, the ratio of effective budget to potential mitigation cost) will differ from country to country. What is “socially affordable” – i.e. where are trade-offs appropriate and acceptable in each context – is by nature a value-laden judgment call. A large number of factors enter into this judgment. Of central concern is keeping public health and safety factors foremost, and avoiding situations in which purely economic concerns – or rather, the economic interests of lobbies – would be given greater weight.

Advice on cost-effective procedures

Tying radon mitigation to other public health or economic programmes is seen to be a highly cost-effective move. Again, the programme with which radon reduction measures are best “harnessed” will differ according to context. In the Nordic countries, for example, radon mitigation is addressed through domestic energy saving policy. In the United States, indoor air quality programmes are seen as the most appropriate policy vehicle. Worldwide, smoking reduction campaigns are a special case. Smoking is by far the most significant contributor to public health detriment and therefore demands the greatest policy and resource effort. There is disagreement as to whether the cancer-prevention gains from coupling radon mitigation with other public-health programmes are marginal, or should be pursued (as the WHO indicates).

Concrete suggestions for relatively inexpensive and effective interventions were exchanged at the break-out sessions:

- A priority is to promote protective actions particularly for new buildings. Policy makers should impress upon authorisation boards and architects the need to apply cost-effective radon mitigation techniques for new buildings even in areas where average concentrations are below the reference level. Education and information efforts should include particularly the building trade.
- It would be desirable to develop tools for “quick” radon concentration assessment. More exchange of experience is needed in order to most effectively evaluate the idea of introducing a legal requirement to measure radon concentration before an owner can complete the sale of a building.
- The establishment and use of a national radon database should be promoted, so that the evolution of actual levels can be monitored over time. Data protection issues need to be considered in this instance.

Information and communication

It was agreed at Vaux-de-Cernay that communication is a central instrument in regulatory and government action to remediate radon exposure. Public players should continue to inform and to persuade even if science and framework are in flux. They should continue to build public and professional awareness of the radon health issue; it is appropriate to use the media for this purpose. Information on risks should be easily accessible to any interested party. Similarly, remediation services should be easily available; the open market is seen to be the appropriate forum. Indeed, there seems to be a shift

towards a “market economy” regarding risk information and remediation actions that can be undertaken by individuals: the supply should meet and even “push” the demand. Information provided by government should clearly lay out expectations and responsibilities for action. An individual reading a leaflet about radon risks should not conclude that these will necessarily be mitigated by government in his or her own case. Instead, the reader should learn about the actions that can be taken on an individual level, how to undertake those actions, and about what support can be expected and obtained from government (e.g. more detailed information and guidance, a tax break to recover material investment, etc.).

The important role of building professionals was emphasised during the break-out sessions, as they are often in an ideal position to inform homeowners about mitigation and prevention of radon in homes, and to help engage actions.

Societal perceptions in assessing exposure situations and the actions to be taken

The issue of domestic exposure is multi-faceted: that is, a dwelling is perceived not necessarily as a place of potential exposure, but primarily as a personal territory, a haven from danger, a place of family life and therefore, of family history. Older dwellings – and among them, the thick-walled granite constructions of an earlier age – may be imbued with cultural, aesthetic and sentimental value. Although they can produce among the highest radon concentrations, such ancient constructions benefit from a similarly high cultural esteem. There is a severe limit to the remediation that can be achieved in such traditional dwellings whose very walls may seep radon gas; their construction would certainly not be allowed by regulations today, but their destruction is equally out of the question, in cultural terms. The same terms apply, to some extent, in regard to public buildings: marble edifices of government are unlikely to be razed, for to do so would be to raze national symbol; the traditions of their use, however, can be altered.

With regard to components of “total dose”, societal perceptions make a significant distinction between “existing situations” and “planned situations”. It is widely apparent that “planned additions” to radiological burden must be controlled (examples include: construction of a new nuclear facility). “Existing situations” (e.g. the domestic residence), in contrast, are more readily tolerated. Of interest moreover is how these different categories are assigned. Indeed, members of the public do not appear to consider that “building a new house” is a possible example of a “planned addition” to their lifetime dose, and therefore do not consider that they need be attentive to reducing the potential addition.

(This attitude is in contradiction with the public health orientation of the authorities.)

The typical structured radiation protection approach (justification of activities/optimisation of protection/limitation of exposures) thus seems less directly applicable to radon exposure management. As mentioned above in the section on economic considerations, experience shows that it is more effective to “embed” radon risk mitigation in public health programmes or other extensive frameworks such as building codes or zoning regulations. Firstly, this could be effective from a behavioural point of view. The concrete actions in such frameworks are already “part of life” for the public; there is an established habit of remediating such hazards as lead-based paint or plumbing, or asbestos insulation, and radon remediation can be associated with these established gestures. The expertise of building professionals and their ability to give advice and intervene are important here, as mentioned above. Secondly, energy-saving features in construction in some cases may be directly linked to higher indoor radon exposures. It is thus meaningful to inform and guide homeowners about this risk, at the time when they are improving home energy efficiency.

It was noted, finally, that radiation may be unique in the public health setting in that it is readily measured and very well studied; thus radiation protection issues are in some ways more “precise” (identified) than are other public health issues; in turn, expectations for effective action may be proportionately high.

Children as a vulnerable group

In many areas of radiation protection there are clear gender and “age at exposure” effects. Regarding radon lung-cancer risk, there appears to be little (or no) gender difference. However, in contrast, age at exposure has not been sufficiently studied with respect to radon exposure to know if an age effect exists or not.

It is a reasonable conjecture that children are more at risk from radon exposure than their elders (while they are smaller and inhale a lesser volume of air, their developing lungs may be vulnerable). However, there is little epidemiological data to support or clarify that conjecture. Epidemiological studies are currently not carried out from childhood. The results of an exposure between the ages of 0-12 may be expressed many years later, and there is little basis then on which to differentiate such early exposures from documented (or documentable) later ones.

In the absence of firm information, for which population should optimisation then be designed? Should a “nominal” risk coefficient or a child-specific risk coefficient be selected? This is identified as an important societal and ethical question not just for radon. It is closely related also to the question of whether radon risk should be managed with reference to dose or to concentration. The nominal coefficient – a combination of well-grounded scientific demonstration and a little “best guess” – is developed from long-term studies of miners and from new domestic exposure epidemiological studies; in these settings, concentration is a reliable risk indicator. Conversion factors, already a delicate scientific problem, may be difficult to adjust to children; specific concentration/dose curves for individuals over the childhood years may exist, but are not today established.

The question of “whom do we choose to protect?” is another fundamentally important one, whose response is rooted in societal values, but which can be elucidated by better scientific knowledge. If we choose “children”, then we need to know better what precisely we are protecting them from (what are the specific mechanisms and pathways of effect in a developing organism). In the case of radon management, deciding to improve protection beyond the “average” (all ages) exposure can result in extending action to a significant degree – for example, to thousands more dwellings in a given region. The optimisation decision of how much more to spend to protect the childhood population group would be facilitated by finer knowledge of how much more protection is in fact provided by the extra resources.

Concluding thoughts

The “Radon as a Public Health Issue” break-out sessions at Vaux-de-Cernay terminated with the following reflections, each supported by a detailed discussion of “science and values”:

- Radiation protection of radon exposure should be integrated into the public health system.
- Remediation of radon in dwellings is a long-term process.
- Public authorities should continue to act (both to support research and to effect remediation), and should not forget that the desired results may be long in coming.

MEDICAL EXPOSURES IN DIAGNOSTIC AND SCREENING PROCEDURES

Plenary presentations by Charles R. Geard and by Gilbert Eggermont, and the evening “platform” discussions, were found by Vaux-de-Cernay break-out participants to provide an excellent basis for reflections on medical exposures in diagnostic and screening procedures. The group first framed the problem at hand, recognising it as a systemic one. The particular issue of “justification” was examined, building up a vision of the pressures and needs in hospitals and private medical practice. On this basis, advice was formulated in five areas ranging from the culture of primary training to governmental action.

A large and growing component of annual dose

In many NEA member countries there is an increasing use of ionising radiation for diagnosis and screening, forming a large component of annual dose for the population. New technologies are increasingly applied, notably because they can provide a much higher level of diagnostic detail, however they contribute disproportionately to the problem: for instance, CT scans are more frequently prescribed today, and deliver higher doses to the patient than conventional x-rays or than nuclear magnetic resonance (NMR) scans which deliver no dose. There is evidence that some diagnostic procedures are not justified at the individual level; in this regard there is special concern today for children as a group. Furthermore, there is evidence that some justified procedures are not optimised; this leads to unnecessary exposures and consequential cancer burden.

Framing the problem, it would seem that a crucial focus lies in the justification step in individual prescription of radiological diagnostic and screening procedures by practitioners. While better optimised administration of radiological procedures must be a target, it would appear that maximum dose reductions may be gained through enabling practitioners to weigh more carefully the original decision to refer patients for a scan. This is typically a decision shaped by both science (knowledge of risks and benefits of the procedure) and values (explicit or implicit priorities – those of the practitioner or moreover of the context in which he or she practices).

Currently, recommendations or guidance exist to foster better justification of procedures. On the international and national legal level, these instruments include Basic Safety Standards, directives, and national radiation protection regulations. In today's situation, however, these are not seen to be delivering effective dose management. Another set of recommendations is found on the international and national professional level: these include advice by expert groups such as protocols and appropriateness criteria for case-by-case justification. Today, however, such guidance appears to be insufficiently used by practitioners.

A systemic problem

The break-out group at Vaux-de-Cernay interpreted the situation as a systemic problem: it is multi-faceted and complex, involving many actors, actions, and interfaces. Thus the problem of incomplete justification and optimisation cannot be solved by actions at a single level. In other words, the whole system of radiological procedure delivery may need tuning in order to reduce unwarranted and unoptimised medical exposures. How to proceed? Because many levels and mechanisms are involved, workshop participants suggested that a transdisciplinary approach is essential. Further discussion in the break-out session focused on analysing the drivers of the problematic situation, before highlighting what can be done to change it.

With reference to Irish experience in analysing a systemic issue, the group first noted the actors, interfaces and key decision points in any justification. The length of the list of actors is itself an eloquent sign of complexity: patient, referring practitioner, radiologist, radiographer, other health professionals, including those with administrative roles in the health delivery system, radiation regulatory authority, health authority, professional bodies, scientific bodies, other international organisations, industry (designers, vendors of radiological diagnostic/screening equipment), educators, public at large. While obviously not each of these actors is implicated to the same degree in an individual justification, still each one exerts some pressure on these decisions.

Justification: what is “necessary”? Which “benefits” are weighed against risks?

It was recognised that over the past 20 years many demands, and blame as well, have been placed on the referring practitioner. Examples were brought of pressures on these actors within the system. Foremost may be patient demand, in what was labelled a “dash for diagnosis” – today the patient expects an immediate response from the health establishment. Practitioners point out that “you can sit an hour with the patient discussing headache and not have any

answer as to aetiology – but if you prescribe a CT scan you can diagnose or eliminate ‘tumour’ in a minute!” As another example, government, in formulating radiation protection policy in medicine, appears to expect that an increasing number of tests will be administered.

When a patient arrives with a prescription in hand, should the radiologist then take time to redo the justification? Break-out participants agreed that it is important to help physicians view themselves indeed as “referring” rather than “prescribing” – thereby explicitly including the radiologist in the chain of decision. However, they also recognised that time pressures as well as patient demand weigh upon both physicians and radiologists. Very likely, radiologists often are not taking the time that would be necessary to assess the pertinence of the suggested procedure. Finally, in terms of cultural relations between these two links in the chain, as verification by radiologists becomes generally rarer it simultaneously becomes an increasingly delicate task for the individual radiologist to challenge a colleague’s prescription.

More insight was brought by the Czech regulator during the stakeholders’ platform session. This authority has initiated consultation to discuss with physicians, and listen to the problems, concerns and fears encountered in the doctor’s office at the time when the justification is being worked up. The regulator pointed out that whereas justification relies on demonstrating that a procedure is “necessary”, the very meaning of “necessary” may differ widely according to the perceiver. An ex-post evaluation of justification is perhaps not always appropriate. The regulator recalled debriefing apparently ambiguous justifications, but for which “after two hours of discussion anyone would agree that it had been ‘necessary’ to do the scan”. (This argument excludes, of course, opportunistic scans, which by definition are offered without a pre-existing indication.) Typically, physicians report that they are aware of the dose added by procedures, but “other risks and consequences seem more important than the radiological risk”, and so they often end up writing the prescription. In some cases, the procedure may seem “necessary” as a pre-emptive defence against a possible accusation of malpractice. These observations led to the question of whether the diagnostic/referral system could not be set up in another way.

Guidance does exist to help the practitioner make the justification. However, it is not always easy to use during the doctor/patient encounter: manuals for instance may run to several hundreds of pages. Young practitioners consulted in France have expressed the need for quick access to information to reassure and reinforce a decision that often is already formed in their mind. This population claimed to know more or less what is justified and necessary in routine procedures, but described themselves as less at ease in the rarer cases when a weightier procedure may be indicated. At that time, they wish not only

for ready technical guidance, but also for answers to questions like these: “*Do we inform the patient of the added risk or not?*” And even in general, young practitioners ask themselves “*What to say to patients? Should we answer all questions about the risks and benefits of exposure, or, tell the patient to ask the radiologist?*” In these contexts, physicians would like to have a quick reference manual providing not only justification tips, but also a discourse for their patient relations. It was recognised during the break-out session that not only a manual, but moreover better primary training would be of help to these practitioners.

Japanese input to an evening platform session highlighted a related issue for reflection. The determination of “necessary” is to be made on the basis of the balance found between risk and benefit. With existing scientific knowledge, the risk of most medical radiological procedures can be estimated. But how to estimate benefit? It may be relatively easy to evaluate the costs of late therapy which are avoided by early detection of tumour. On the other hand, we can hardly quantify the value of reassurance when “negative” information (absence of disease) is obtained from a diagnostic procedure – the patient’s desire to obtain such intuitively “positive” information may be given high weight in the decision to proceed or not with an examination. How then to capture total benefit?

At the break-out session this reflection was completed by an example regarding the “market forces” at play. Independent radiologists who have made large capital investments in equipment may be likely to want to amortise this investment. However, this does not mean that all are initiating “opportunistic” procedures. Alongside the potential offer, there is a real demand among the public for fast, highly informative diagnostic procedures – part of the “total benefit” expected. Perhaps the only way to diminish the demand – to modulate the benefit perception – is to raise awareness among the public that they increase their risk by submitting to this exposure.

An important caveat recognised by workshop participants is that any efforts to redress the situation should not result in public *avoidance* of radiological procedures. While adjustments can and should be made regarding the justification and optimisation of individual exposures, public health detriment from a widespread avoidance of radiological procedures across the board would likely outweigh the gains in terms of collective dose.

Advice in five areas

Break-out session participants formulated advice for modifying the current systemic problem with five types of actions, detailed below. Generally this advice was formulated at the level of what government can foster (it was

considered that other groups outside an NEA workshop may have better resources to develop detailed advice for the remainder of levels or actors in the system).

Primary training and continuing education

Regarding the opportunity to take action at the level of primary training and continuing education, it was suggested that the individual licensing requirement should include appropriate training to medical students regarding the risks and benefits of radiological procedures. It should be an explicit objective in medical training to develop radiation protection culture. This may require a change in teaching methods, where it is advised to diminish reliance on peer transmission of medical “lore”; instead, schools should seek to develop evidence-based thinking about exposure. Teaching should foster practitioners’ later use of the full range of alternative clinical diagnostic tools. The practice of “defensive” medicine relying upon under-justified radiological procedures should be analysed and discouraged. Finally, it was advised that training to radiologists and radiographers should focus on the appropriate optimisation of procedures (including quality assurance on machine characteristics and settings).

Increasing professional and public awareness

It was seen that better awareness of risks and benefits could be fostered for the health care community through regulatory instruments and through the development of guidelines for better implementation. Regulatory tools could include e.g. a basic medical directive in Europe to emphasise the importance of justification in medical uses of ionising radiation, particularly for sensitive groups (i.e. children).

Public awareness of the risk/benefit balance of medical exposure could be increased through information campaigns and labelling or certification of practitioners. Experience could be drawn upon from other sectors, such as the successful antibiotics reduction campaign.

Development of practitioners’ guidance tools

Regarding guidelines, it is felt that good science is available to support justification – what is needed is to translate knowledge into action. Guidelines are already translated in all languages. Up-to-date appropriateness criteria exist but are not being used. Existing guidelines therefore should be adapted to the context of daily practice so as to improve their actual rate of implementation. To achieve this, the break-out session participants recommended dialogue between

those developing guidance and those expected to use it. Focused group interviews with young physicians could help to tailor information delivery to their needs. Moreover it would be useful to involve the range of stakeholders, including patients' organisations, who might be particularly fruitful sources of advice on how to communicate the risks associated with medical procedures.

Such consultation and development of practitioners' guidance tools should be carried out by sector and by country. Adaptation can rightly be performed on even the very local level, by hospital, where the management authorities can model radiation protection culture and make the adaptation projects into training actions. At the individual level, a certification or labelling approach can work: here the individual practitioner adapts his or her own practice to guidelines by becoming certified.

In terms of media, guidelines and criteria could be made accessible to practitioners via Internet. Alternatively, an authority could provide a desktop computerised application to make it easy for practitioners to search and access information in manuals. International bodies (such as the IAEA or the European Commission) could sponsor such initiatives on a global or regional basis.

Governmental prescription

Government prescription is seen to be perhaps most practicable on the level of optimisation, and of setting requirements for equipment manufacturers. These should be directed to improve equipment so that dose is optimised in a more automatic fashion. Apparatus should integrate feedback to the operator, using a comprehensive and understandable indicator of exposure (such an indicator could be developed with the involvement of operators). Governments should push to adopt a universal digital standard so as to foster the electronic transfer of images and therefore diminish duplicate tests for individuals. Finally, government should urge the development of audit tools for monitoring the effective application of the dose quality standard in public and private health delivery settings.

Improvement of the knowledge base

Finally, the break-out sessions formulated suggestions to research policy makers and funders so as to improve the knowledge base. A relatively easy and valuable action today would be to survey the level and evolution of medical diagnostic and screening practice: types of procedure applied, exposed populations, number of patients, where procedures are practiced (in private or public settings), and effective exposure. Research on radiation risk to the patient

due to medical exposure should be reinforced in the areas of epidemiology and modelling.

Concluding thoughts

The main conclusions in terms of advice and recommendation by the break-out group on medical exposures in diagnostic and screening procedures may be summarised as follows:

- It should be an explicit objective in primary medical training to develop radiation protection culture. Important components are evidence-based thinking about exposure, and both the principles and the practical aspects of justification and optimisation.
- Regulatory tools and public information campaigns can help raise awareness about the importance of justification in medical uses of ionising radiation particularly for sensitive groups (i.e. children).
- Stakeholder involvement will be useful in adapting existing guidelines so these can be more systematically applied by practitioners.
- Government can direct manufacturers to build better optimisation features into radiological equipment. Operators should be consulted on the development of a comprehensive exposure indicator which would be displayed on apparatus at the time of each act. Government can also foster audit tools to help monitor the effective application of the dose quality standard.
- The knowledge base should be improved by surveys of medical diagnostic and screening practice and effective exposure. Research on radiation risk to the patient due to medical exposure should be reinforced in the areas of epidemiology and modelling.

RADIATION-INDUCED VASCULAR EFFECTS

On the basis notably of the plenary presentation by Mike Atkinson, this break-out session examined issues arising as evidence accumulates of effects on the vascular system (i.e. heart disease and strokes) that may be attributable to radiation exposure. The state of knowledge in this area was addressed, including the biological and epidemiological evidence and risk assessment. The potential impacts upon radiation protection policy and practice were considered and recommendations made on a way forward.

Current knowledge

Epidemiology and risk estimates

A broad consensus has emerged on the risk of vascular disease from acute, moderate to high, peripheral exposures of the heart during radiotherapy of nearby target organs or tissues (Trott, 2009). Clinical practice is already being influenced by these findings.

There is increasing evidence of an enhanced risk of vascular disease in the A-bomb survivor population (Preston *et al.*, 2003; Wakeford and Little, 2009; Shimizu *et al.*, 2010)⁴ for acute exposures in excess of about 0.5 Gy and for chronically exposed workers at Mayak to accumulated doses of the same order of magnitude (Azizova and Muirhead, 2009; Azizova *et al.*, 2010; Azizova *et al.*, in press).⁵ For the Mayak cohort, there is a statistically significant increase in the risk of some, but not all, vascular diseases in the dose range of 0.1 to

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4. At the time of the workshop only Preston *et al.* (2003) and Wakeford and Little (2009) were available. Shimizu *et al.* was published in early 2010 but its main findings were known, having been disseminated in presentations in various fora (e.g. CRPPH, IAEA, etc.).
 5. At the time of the workshop only Azizova and Muirhead (2009) was available. This comprises a “non-peer reviewed” summary of the main findings of major studies of cardio- and cerebro-vascular disease in the Mayak cohort – the full studies (Azizova *et al.*, 2010; in press) were both in press at the time and are included here for completeness and ease of reference for the reader.

0.5 Gy. The statistical precision of the results from both cohorts is not yet sufficient to confirm or contradict either the existence of a threshold (at or around 0.5 Gy) for the occurrence of vascular diseases or the persistence of the risk (e.g. through a linear or other dose-effect relationship) to much lower doses. Concerns exist as to the effect of confounding factors (e.g. smoking) on the predicted risks in both studies, in particular in the former. Studies of both populations are ongoing and the risk estimates will be further refined with increasing follow up and, in the case of the Mayak cohort, through increasing the size of the cohort with workers exposed to lower accumulated doses.

In developing its revised recommendations, the ICRP (2007) reached the following views on radiation-induced cardio-vascular disease. Statistical evidence suggested that vascular effects may be induced at an acute exposure of about 1 Sv and is associated with dose. Uncertainties resided in determining the shape of the dose-response curve at low doses. Data in hand were compatible with the linear no-threshold (LNT) hypothesis, or, with a threshold situated at 0.5 Sv. ICRP judged that the available data were then too uncertain to be included in the estimation of detriment following radiation doses of less than 100 mSv. ICRP noted, however, that data from the 2006 UNSCEAR report (2008) which underpinned this judgment were mostly based on pre-2005/2006 knowledge which could require updating in light of new data from the Japanese A-bomb survivor cohort. ICRP 2007 judgments were also reached prior to the more recent epidemiological studies of the Mayak cohorts as referenced above.

Radiobiology and mechanisms

The radiobiological mechanisms for inducing vascular diseases following moderate to high acute exposures (e.g. of the heart as a peripheral organ in some radiotherapy treatments) are relatively well understood. In contrast, there is little if any understanding of the mechanisms following exposure to low and/or chronic exposure. Research in this area has only recently begun (e.g. Schultz-Hector and Hildebrandt, 2009, and references in footnote⁶) and a number of mechanisms and/or phenomena are being investigated; these include the following, some of which may be stochastic in nature:

- Inflammatory, stress and oxidative responses.
- Influence of telomere length.

6. See for example: NOTE, “Non-Targeted Effects of Ionising Radiation”, Euratom Research Project, 2006-2010 (www.note-ip.org) or CARDIORISK, “The Mechanism of Cardiovascular Risks after Low Radiation Doses”, Euratom Research Project, 2008-2011 (www.cardiorisk.eu).

- Abscopal effects.
- Role of bystander effects and cell to cell signalling.
- Influence of low doses on the progression of atherosclerosis, how it is influenced by genetic background and how it is mediated by stress and inflammatory responses.
- The pathogenesis of early and late alteration in the microcirculation of the heart and of atherosclerotic lesions in arteries (especially investigation of early molecular, pro-inflammatory and pro-thrombotic changes as well as perfusion alteration, cardiac cell integrity and immunologic influences).

Establishing soundly based evidence on biological mechanisms for inducing vascular disease following exposure to low and/or chronic levels of radiation will have a key role in decision-making on the implications of vascular disease for the system of radiation protection. Epidemiological studies will never have sufficient statistical power to directly resolve this issue at doses typically of interest in protection (as is the case when trying to assess the risk of cancer at low doses).

Potential implications

If the risks estimated in the A-bomb and Mayak cohorts were to be confirmed, and the existence of a threshold could not reasonably be refuted, the predicted incidence of radiation-induced vascular diseases would be comparable with that of radiation-induced cancer. Based solely on considerations of incidence, this would imply an increase in detriment of about 50 to 100%. The exact implications for detriment would require a more rigorous assessment, in particular reflecting value judgments on the morbidity and mortality from vascular diseases relative to those for cancer. Such an increase in detriment, were it to be confirmed, could have significant implications for the definition of effective dose and for dose limits and constraints.

The observations of statistically significant increases in the risk of some vascular diseases for dose accumulated chronically in the range of 0.1 to 0.5 Gy could have particular significance for occupational protection. Many workers have accumulated exposures within this range with some experiencing even larger doses in the past. While major improvements have been made in occupational exposures over the past two decades, many workers will continue to accumulate lifetime doses in a range where increased risks of vascular disease have been observed.

Issues arising during discussions

The following were identified as areas where further clarification and/or analysis was needed before sound, evidence-based judgments could be made on the implications of vascular diseases for radiation protection policy and practice:

- How the risk varies with dose and dose rate (e.g. acute versus chronic exposure, effect of fractionation, existence of a threshold, etc.).
- Realistic assessments of uncertainty in the estimated risks.
- Identification of the organs or tissues at risk – this is needed in order to assess relevant doses, both for epidemiological studies and subsequently, if necessary, for protection.
- How detriment may change should the observed risks of vascular disease be confirmed and a threshold for their occurrence could not be discounted (i.e. judgments on the relative weight to be assigned to morbidity and mortality for the various vascular diseases relative to cancer).
- Which vascular diseases should be analysed in epidemiological studies and/or what degree of aggregation (if any) between diseases should be used in the analyses.
- Whether greater attention be given to other non-cancer diseases (e.g. respiratory and digestive tracts) where increased risks were also observed in the Japanese A-bomb survivor cohort.
- The existence of plausible biological mechanisms for radiation-induced vascular disease following exposure to chronic and/or low levels of exposure typically encountered in radiation protection.
- The possible role of other factors in the aetiology of radiation-induced vascular disease (e.g. indications that digestive diseases associated with radiation may in fact be primarily cancer-related).
- The influence of confounding factors.
- The social and economic impact of any changes that may be suggested for dose limits and constraints as a result of possible increases in detriment from radiation-induced vascular disease.
- The role and application of the precautionary principle in light of current knowledge and prevailing uncertainties.

- Consistency with value judgments previously exercised in the evolution of radiological protection (i.e. adoption of the LNT approach in ICRP's recommendations in the 1950s when the risk of radiation-induced cancer was poorly quantified and the underlying mechanisms poorly understood – indeed, several decades later, the risk of cancer from exposure at low doses remains equivocal and a controversial issue in scientific and policy circles as well as the subject of major ongoing research programmes).

The way forward?

The conclusion proposed in the plenary report of the break-out sessions is this: *Recognising the strengthening evidence base from epidemiological studies and research on mechanisms, the policy implications of radiation-induced vascular effects should be given much more serious consideration – or if previously considered, these policy implications should be fully and appropriately acted upon.*

Further studies (on both mechanisms and epidemiology) are being undertaken on the potential link between radiation exposure and vascular disease, in particular for exposure to chronic and low exposures. More information is emerging and circulating, thereby increasing professional awareness of this issue. Critical reviews are being made of the existing data and literature and investigations made of plausible biological mechanisms. Regulators are increasingly becoming aware of the challenges raised by this new knowledge and are reflecting on its potential implications for the current protection system.

Notwithstanding the above, questions were raised as to whether enough was being done and sufficiently quickly given the apparent and increasing strength of the epidemiological evidence (in particular for chronic exposures where increased risks have been observed for accumulated exposures in the range of 0.1 to 0.5 Gy). Some felt that in the circumstances, a more pro-active response was needed from the radiation protection community; others argued for a more measured approach, pending the development of a stronger evidence base and, in particular, the establishment of a causal relationship, or plausible mechanism, for the induction of vascular diseases following chronic or low dose exposures. It was widely recognised by participants that value judgments would inevitably have a major role to play in the development of an evidence-based policy.

Pending further developments (in particular clarification of, or progress on, the various issues listed above) a number of actions were indentified that could,

in the interim, mitigate the impact of radiation-induced vascular disease (assuming its occurrence following exposure to low and/or chronic doses were to be confirmed). These included the following:⁷

- giving even more emphasis to optimisation;
- adopting dose constraints for organs (e.g. in the BSS);
- giving greater attention to doses accumulated over a lifetime.

The evidence base for the induction of vascular diseases from exposure to high acute doses of radiation is now well established and is already influencing clinical practice (e.g. in radiotherapy of the breast). This knowledge and changing clinical practice do, however, need to be more widely disseminated. It is necessary to foster greater awareness in medical personnel of the importance of minimising the exposure of the heart when it is in the vicinity of the organ of tissue being irradiated during radiotherapy.

7. See as well the Conclusions of the Article 31 Group of Experts following an EU Scientific Seminar on “Emerging evidence for radiation induced circulatory diseases” (EC, 2009). The Group of Experts, referred to under Article 31 of the EURATOM Treaty, provides the European Commission with an opinion on basic standards for health and safety.

CONCLUSIONS OF THE VAUX-DE-CERNAY WORKSHOP

The NEA held the second “Science and Values in Radiological Protection” workshop at Vaux-de-Cernay on 30 November-2 December 2009. This meeting was arranged as the sequel to the first meeting held in Helsinki in 2008, and it addressed three subject areas: “Radon as a public health issue”, “Medical exposures in diagnostic and screening procedures” and “Radiation-induced vascular effects”. These subjects were selected because each represents an issue for which new or emerging evidence or trends have incited regulatory authorities and practitioners to reconsider whether their current protection approach remains appropriate. The workshop re-emphasised that radiological protection is a combination of science and value judgments, and addressed the selected radiological protection issues from the standpoint of *What now?* The workshop was attended by 73 participants from 19 countries (European states, Argentina, Canada, Japan, Korea, United States, Taiwan) and proved that this kind of activity is welcome and needed in the developing of communication among scientists and regulators, and most probably, may help in formulation of future radiation protection policies.

The primary objectives of the second workshop were to go on developing a shared understanding between the various stakeholders, and to identify the elements of a framework more suited to the integration of new scientific and technological developments and socio-political considerations into radiological protection. In the three areas addressed, current approaches to radiological protection have not fully yielded the desired results (i.e. radon and medical exposures), or there is a perception that there is insufficient scientific evidence to warrant change in the current approach (i.e. radiation-induced vascular effects). Thus, while the objective of this workshop was not to develop detailed recommendations as to new approaches, discussions did delve into stakeholder experience, rational and justification for adopting new approaches, practical approaches to improving radiological protection, further research needs, and process and framework elements that could enhance radiological protection in these three areas by better integration of social and scientific aspects. As a result of the discussions of the three workshop topics, the following observations were reached.

Management of domestic radon exposure

In discussing this topic and exchanging experience regarding national approaches, it was noted that most countries focus actions on high-concentration homes. This suggests that the “values” aspect of the management decision has focused on protecting those most exposed. Epidemiology suggests, however, that most lung cancers occur in homes with lower concentrations, such that revisiting national protection strategies could be of value. Optimisation actions could include the promotion of protective actions for new buildings (e.g. building codes, pre-sale criteria), tying radon strategy to other programmes (e.g. smoking, energy efficiency, indoor-air quality), integrating radon exposure management into the public health system, rather than the other way around. It was noted, however, that remediation of radon in dwellings is a long-term process.

Management of diagnostic medical exposures

With the significant increase of patient exposures in many countries, the justification of diagnostic procedures, and the optimisation of protection were seen as key issues to discuss and improve. It was suggested that physicians tend to focus very strongly on the diagnosis and treatment of an individual’s health issues, suggesting that the driving value is to give priority to health risks today. There is evidence, however, that a significant fraction of diagnostic procedures are not justified at the individual level, and that protection is not optimised. Justification seems to be the critical step. Greater awareness and use of existing tools (e.g. diagnostic guidelines), and focus on sensitive populations (e.g. children) seem to be the areas of focus.

Cardiovascular disease

Because the scientific study of cardiovascular diseases seemed to be evolving rapidly, this topic was chosen to be revisited at the second science and values workshop. Radiation-induced cardiovascular disease is well known in high-dose radiation-therapy patients, however risks are broadly viewed as deterministic, without sufficient scientific knowledge to categorise otherwise. As such, the value driving decisions seems again to be to give priority to health risks today, in particular since these effects seem to be deterministic rather than stochastic. However, new epidemiological studies suggest that chronic, lifetime exposures may, at somewhat lower doses, cause cardiovascular diseases. Mechanisms of such damage, and identification of “target organ” are still topics of research. Again, it was judged that the science is still evolving and there was no need at that point to recommend change to the system of radiological protection. It was, however, noted that with the same level of knowledge

regarding stochastic effects of radiation in the 1950s, a precautionary approach was nonetheless adopted at that point, without the need for science to “prove” that a risk existed. As such, the workshop suggested that there is a need to increase awareness of this issue, and to reinforce scientific studies.

Conclusions

The CRPPH has recognised that mutual understanding on the scientific evidence and on the radiological protection values and practice is important both for obtaining optimal protection, and for identifying the gaps in knowledge that are most relevant for radiological protection. Most of the participants at both science and values workshops agreed that while there is no immediate need to change the current principles, extended dialogue among all concerned stakeholders is necessary in order to facilitate integration of challenging scientific phenomena into existing regulatory frameworks. This type of exchange forum between regulators and scientists was welcomed and could serve as a model way of moving forward. As such, the CRPPH has agreed to hold a third workshop on science and values, to take place in Japan in the latter half of 2011, hosted by the Japanese Government. Similar to the first two science and values workshops, this meeting will address scientific and value-related elements of decision-making relating to several important areas that will be agreed by the workshop’s scientific programme committee.

The science and values discussions have matured as a result of these workshops, and as such their subjects have evolved. The progression of topics in the first two workshops has been from addressing topics that are more scientifically uncertain, and thus putting less pressure to change radiological protection approaches, to those that are more currently relevant and present more incentive to change approaches. As such, it is felt that the third workshop should address areas that have been addressed for some time but without reaching radiological protection situations that are viewed as fully appropriate. The third science and values workshop should address these issues from the standpoint of *Where do we go from here?* In other words, what better understanding of scientific and value elements could assist in moving these situations forward in an accepted and sustainable direction.

REFERENCES

Azizova T.V. and C.R. Muirhead (2009), “Epidemiological Evidence for Circulatory Diseases – Occupational Exposure”, *Radiation Protection* No. 158, pp. 33-46.

Azizova, T.V. *et al.* (2010), “Cardiovascular Diseases in the Cohort of Workers First Employed at Mayak PA in 1948-1958”, *Radiat. Res.*, Vol. 174, Issue 2, pp. 155-168.

Azizova, T.V. *et al.* (in press), “Cerebrovascular Diseases in the Cohort of Workers First Employed at Mayak PA in 1948-1958”, *Radiat. Res.*

EBCTCG (Early Breast Cancer Trialists’ Collaborative Group) (2000), “Favourable and Unfavourable Effects on Longterm Survival of Radiotherapy for Early Breast Cancer: An Overview of the Randomised Trials”, *Lancet* 355, pp. 1757-1770.

EC (European Commission) (2009), EU Scientific Seminar (Working Party on Research Implications on Health and Safety Standards of the Article 31 Group of Experts), *Emerging Evidence for Radiation Induced Circulatory Diseases*, proceedings of a scientific seminar held in Luxembourg on 25 November 2008, Radiation Protection N° 158 (May be consulted online at: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/158.pdf [accessed March 2010]), EC, Luxembourg.

Hancock, S.L., M.A. Tucker and R.T. Hoppe (1993), *Factors Affecting Late Mortality from Heart Disease after Treatment of Hodgkin’s Disease*, *J. Am. Med. Assoc.* 270, pp. 1949-1955.

ICRP (International Commission on Radiological Protection) (1991), *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60. Ann. ICRP 21 (1-3).

ICRP (2007), *2007 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 103. Ann. ICRP 37 (2-4) (an extract containing ordering information may be consulted online at: www.icrp.org/docs/ICRP_Publication_103-Annals_of_the_ICRP_37%282-4%29-Free_extract.pdf [accessed September 2010]).

OECD/NEA (Nuclear Energy Agency of the Organisation for Economic Co-operation and Development) (2007a), *Scientific Issues and Emerging Challenges for Radiological Protection*, Report of the Expert Group on the

Implications of Radiological Protection Science (EGIS), NEA No. 6167, OECD, Paris.

OECD/NEA (2007b), *Radiation Protection in Today's World – Towards Sustainability*, Report of the CRPPH Expert Group on the Collective Opinion (EGCO), NEA No. 6165, OECD, Paris.

Preston, D.L. *et al.* (2003), “Studies of Mortality of Atomic Bomb Survivors Report 13: Solid Cancer and non-Cancer Disease Mortality: 1950-1997”, *Radiat. Res.* 160, pp. 381-407.

Schultz-Hector, S. and G. Hildebrandt (2009), Investigation of Biological Mechanisms of Radiation-induced Circulatory Diseases, in EC (2009).

Schultz-Hector, S. and K. Trott (2007), “Radiation-induced Cardiovascular Diseases: Is the Epidemiologic Evidence Compatible with the Radiobiologic data?” *International Journal of Radiation Oncology Biology Physics*, 67:1, pp. 10-18.

Shimizu, Y. *et al.* (2010), Radiation Exposure and Circulatory Disease Risk: Hiroshima and Nagasaki Atomic Bomb Survivor Data, 1950-2003, *BMJ* 340:b5349.

Taylor, L.S. (1957), Address of 7 Nov. 1956. *Am. J. Roent.* 77: 5, pp. 914-919.

Trott, K.R. (2009), “Evidence of Circulatory Diseases Among Patients Treated with Radiotherapy Emitters”, in EC (2009).

UN (United Nations) (1958), “United Nations International Conference on the Peaceful Uses of Atomic Energy”, Geneva, 1-13 September 1958, Vol. 21, Session 5a, pp. 3-7.

UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) (2008), “Effects of Ionizing Radiation”, *UNSCEAR 2006 Report*, Vol. 1, Report to the General Assembly with Scientific Annexes (issued on 25 July 2008; corrigendum on 7 July 2009; cf. www.unscear.org/unscear/en/publications/2006_1.html [accessed March 2010]).

Wakeford, R. and M.P. Little (2009), “Epidemiological Evidence for Circulatory Diseases – Non-occupational Exposure”, *Radiation Protection* No. 158, pp. 21-31.

WHO (World Health Organization) (2009), *Handbook on Indoor Radon: A Public Health Perspective*, World Health Organization, Geneva.

ANNEX 1
HELSINKI WORKSHOP PROGRAMME

15 January 2008

Welcome and forum opening

- 9:00-9:10 Welcome address from the host organisation (STUK)
Jukka Laaksonen
- 9:10-9:20 Welcome address from the OECD/NEA
Takanori Tanaka

Introduction

- 9:20-9:40 Science and values in radiological protection: historical
perspective and present challenges
Jacques Lochard
- 9:40-10:00 How is STUK responding to emerging challenges?
Sisko Salomaa
- 10:00-10:30 Break

Session 1:

**Views of Stakeholders on Emerging Scientific and Societal issues in
Radiological Protection**

Chair: *Mary Helen Barcellos-Hoff*, Plenary session

- 10:30-10:50 Views of researchers: *Otsura Niwa*
- 10:50-11:10 Views of regulators: *Dana Drabova*
- 11:10-11:30 Views of NGOs: *Yves Marignac*
- 11:30-11:50 Views of industry: *Bernard Le Guen*
- 11:50-12:30 Moderated discussion on presented views
- 12:30-14:00 Lunch

Session 2:

Case Studies – Presentations on Potential Implications Arising from What-if Scenarios

- Chair: *Sigurdur Magnusson*, Plenary session
- 14:00-14:45 Non-targeted effects and the DNA paradigm
William F. Morgan
- Scientific understanding and uncertainties
 - What if?
- 14:45-15:30 Circulatory diseases
Dale Preston
- Scientific understanding and uncertainties
 - What if?
- 15:30-16:00 Break
- 16:00-16:45 Individual sensitivity
Michael Atkinson
- Scientific understanding and uncertainties
 - What if?
- 16:45-17:30 Value issues, precautionary principle, equity and radiological protection
Presenter: *Sven Ove Hansson* (Full paper available at www.infra.kth.se/~soh/radeth.pdf)
- Scientific understanding and uncertainties
 - What if?
- 18:00~ Reception

16 January 2008

Session 3:

Understanding the Potential Implications for Radiological Protection

Parallel Break-out groups

Break-out session one: non-targeted effects

Moderators: *Mary Helen Barcellos-Hoff, William F. Morgan,
Otsura Niwa, Sisko Salomaa*

Break-out session two: individual sensitivity

Moderators: *Michael Atkinson, Yves Marignac, Kazuo Sakai,
Wolfgang Weiss*

Break-out session three: circulatory diseases

Moderators: *Guido Hildebrandt, Fred Mettler, Dale Preston,
Annie Sugier*

All break-out sessions will run on the following schedule:

9:00-10:30	Moderated discussion
10:30-11:00	Break
11:00-12:30	Continued moderated discussion
12:30-14:00	Lunch
9:00-10:30	Moderated discussion
14:00-16:00	Final moderated discussion, summary of issues
16:00-17:00	Chairs' meeting/preparation of summaries

Objectives of break-out sessions:

- Identify key risk and equity aspects, and discuss how the precautionary principle would be applied taking into account various value-judgments.
- Identify driving models, parameters and values structuring the radiological protection system of relevance for the issue at stake.
- Identify keys of *what-if* aspects, their significance and likelihood.
- Identify what judgments have led to different views of different stakeholders (e.g. different scientific views, different regulatory views, different NGO views, etc.).
- Identify what would be the implications for: regulatory work? research? industry?

- If these assumed challenges prove to be correct, identify how could the existing system adjust to this new situation?
- Identify what process would be necessary to adopt in order to arrive at these adjustments?

17 January 2008

Session 4:

Reports from Break-out groups

Chair: *Michel Bourguignon*

9:00-9:30	Summary report from break-out session one
9:30-10:00	Discussion
10:00-10:30	Summary report from break-out session two
10:30-11:00	Discussion
11:00-11:30	Break
11:30-12:00	Summary report from break-out session three
12:00-12:30	Discussion

Session 5:

The Way Forward

Chair: *Jacques Lochar*

12:30-12:50	Future steps in the process? <i>Ted Lazo, NEA</i>
12:50-13:00	Discussion

ANNEX 2
VAUX-DE-CERNAY WORKSHOP PROGRAMME

Programme – Day 1 (30 November 2009)

Opening (09:00-09:30)

Chair: **Shizuyo Kusumi**, Nuclear Safety Commission, Japan

Welcome Address from IRSN **Jacques Repussard**

Welcome Address from CEPN **Thierry Schneider**

Welcome Address from NEA **Uichiro Yoshimura**

Introduction (09:30-10:30)

Chair: **Shizuyo Kusumi**, Nuclear Safety Commission, Japan

- **Science and values in radiological protection: towards a framework** (9:30-9:50)
Jacques Lochard, Centre d'étude sur l'évaluation de la protection dans le domaine nucléaire (CEPN), France and Chair of ICRP Committee 4

This talk should make the link with the “Science and Values in Radiological Protection” workshop in Helsinki, and lay out the overall goals of the present workshop. It should explain the format of plenary/break-out sessions.

- **Public health perspective in radiological protection in challenging topical areas** (9:50-10:10)
Gilbert Eggermont, Policy reflexion group on radiation protection of the Belgian Health Council and Belgian Association of Radiation Protection, Belgium

This talk should give more detail on the choice of the three case topics and the linkage to public health concerns in radiological protection. It should make a specific link with Helsinki workshop findings and the CRPPH Expert Group on the Public Health Perspective in Radiological Protection work.

- **Civil society needs** (10:10-10:30)
Britt-Marie Drottz Sjöberg, Norwegian University of Science and Technology, Norway

This talk should briefly review the radiation protection concerns and communication needs of civil society. It will point out different categories of stakeholders and their understanding of radiation risks implied by the three case topics. It will address the question of how radiological protection professionals can better identify and respond to civil society concerns.

Coffee break (10:30-11:00)

Session 1: Setting the scene (11:00-15:30)

Chair: **Michel Bourguignon**, *Autorité de sûreté nucléaire (ASN)*, France
Holistic presentations of science, values, regulation and public health policy, NGO viewpoints... An informed view of “where we stand” on each case topic following the Helsinki workshop.

- **Radon as a public health issue** (11:00-12:00; 45 min. + 15 min. discussion)
Margot Tirmarche, Institut de radioprotection et de sûreté nucléaire (IRSN), France and ICRP Committee 1
- **Medical exposures in diagnostic and screening procedures** (12:00-13:00; 45 min. + 15 min. discussion)
Charles R. Geard, Center for Radiological Research of Columbia University, United States

Lunch (13:00-14:30)

-
- **Radiation-induced vascular effects** (14:30-15:30; 45 min. + 15 min. discussion)
Mike Atkinson, Institute of Radiation Biology, Helmholtz Zentrum Munich, Germany

Coffee break (15:30-16:00)

Break-out sessions 1st part: Issues surrounding current approaches

(16:00-18:00)

This session will deepen the discussion and widen the process begun at Helsinki, regarding the new data, phenomena and observations that stimulate us to ask whether current public health and regulatory approaches in each topical area are still adequate, or whether they may need revision. The focus of this session is thus on **scientific aspects** which may induce a need for paradigm change. See possible questions for break-out sessions.

- **Radon as a public health issue**
Moderator: **Christophe Murith**, Federal Office of Public Health, Switzerland
Facilitator: **Kathleen G. Grant**, RESOLVE, United States
- **Medical exposures in diagnostic and screening procedures**
Moderator: **Catherine Luccioni**, Conservatoire national des arts et métiers (CNAM), France
Facilitator: **Claire Mays**, NEA, France
- **Radiation-induced vascular effects**
Moderators: **Sisko Salomaa**, STUK, Finland and **Neale G. Kelly**, United Kingdom
Facilitator: **Deborah Oughton**, Norwegian University of Life Sciences, Norway

Break (18:00-18:30)

Evening session 1: Stakeholder platform opportunity (18:30-20:00)

Chair: **Ola Holmberg**, IAEA, Austria

One of the workshop objectives is to **foster dialogue** between radiological protection professionals, researchers, regulators... and other stakeholders from interested publics in order to deepen discussion on points of interest. In order to maximise stakeholders' benefit in attending the workshop, a platform for communicating and discussing relevant stakeholder views and concerns is offered in this evening context. The on-topic interventions are intended to cover relevant subjects that may not be directly addressed during the rest of the workshop (e.g. risk communication, etc.). It is intended that these discussions will take place in a relaxed and informal atmosphere.

This evening session will focus on aspects of dose regulations in radiodiagnostic and radiotherapeutic fields, ALARA in medicine and other issues related to medical exposures. Discussion is intended to be linked to

introductory talk in Session 1 on public health perspective in radiological protection in challenging topical areas.
(Presenter: Kazuko Ohno, Kyoto Medical College of Science)

Dinner (20:00-)

Programme – Day 2 (1 December 2009)

Break-out sessions 2nd part: Values underlying favoured approaches

(9:00-12:00)

Across countries or across stakeholders, we can observe that a single problem yields different solutions. What are the views, preferences and value judgments that are reflected in those solutions? This session will help understand the alternatives favoured by different actors, by identifying the factors each actor is weighting. The focus of the session is on **extra-scientific aspects (e.g. economic concerns; societal values...)** that influence the choices made in each context, and which potentially could be sources of friction among different societal actors or stakeholders. See possible questions for break-out sessions.

- **Radon as a public health issue**
Moderator: **Ferid Shannoun** WHO, Switzerland
Facilitator: **Kathleen G. Grant** RESOLVE, United States

- **Medical exposures in diagnostic and screening procedures**
Moderator: **John Cooper** Health Protection Agency, United Kingdom
Facilitator: **Claire Mays** NEA, France

- **Radiation-induced vascular effects**
Moderator: **Wolfgang Weiss** Bundesamt für Strahlenschutz, Germany
Facilitator: **Deborah Oughton**, Norwegian University of Life Sciences, Norway

Coffee break (10:30-11:00)

Lunch (12:00-13:30)

Session 2: Societal values and regulatory aspects: views from different perspectives (13:30-15:00)

Chair: **Simon Carroll**, Swedish Biodiversity Centre, University of Agricultural Sciences and Uppsala University, Sweden

- **Radiation protection policies: some public perceptions (13:30-14:05, 25 min. + 10 min. discussion),**
Jill Sutcliffe, Low Level Radiation and Health Conference, United Kingdom
- **Radiation protection policies: perceptions of regulator (14:05-14:40; 25 min. + 10 min. discussion)**
Karla Petrova, State Office for Nuclear Safety, Czech Republic
- **Radiation protection policies: global industry views (14:40-15:00; 15 min. + 5 min. discussion),**
Sylvain Saint-Pierre, World Nuclear Association, United Kingdom

Parallel rapporteurs meeting (13:30-15:00) (to prepare/harmonise summary presentations of break-out sessions)

Session 3: Summary reports of break-out sessions (15:00-18:30)

Chair: **Kazuo Sakai**, National Institute of Radiological Science, Japan

- **Radon as public health issue (15:00-16:00; 30 min. + 30 min. discussion)** Rapporteur (NEA)

Coffee break (16:00-16:30)

- **Medical exposures in diagnostic and screening procedures (16:30-17:30; 30 min. + 30 min. discussion)** Rapporteur (NEA)
- **Radiation-induced vascular effects (17:30-18:30; 30 min. + 30 min. discussion)** Rapporteur (NEA)

Break (18:30-19:00)

Evening session 2: Stakeholder platform opportunity (19:00-20:30)

Chair: **Simon Carroll**, Swedish Biodiversity Centre, University of Agricultural Sciences and Uppsala University, Sweden

Continuing discussions started during the Evening session 1 with focus on different aspects of NGO and society perceptions of the radiological protection regulatory framework, ways of communicating about novel scientific phenomena, and differing perceptions about the need for, and effectiveness of, regulatory actions, etc. Discussion is intended to be linked to introductory talk in Session 1 on civil society needs.

(Presenter: Abel Gonzales, Argentina)

Dinner (20:30-)

Programme – Day 3 (2 December 2009)

Session 4: Plenary panel discussion on topical issues from break-out sessions – exchange of views (9:00-12:00)

Chair and moderator: **Claire Cousins**, Addenbrooke's Hospital, United Kingdom and Chair of ICRP Main Commission

This session, arranged as a plenary panel discussion, will synthesise the main recommendations of the workshop and also provide an open platform for exchange of views. Audience members will be given the opportunity here to discuss openly radiation protection principles, regulatory approaches and perspectives in the context of emerging and identified scientific phenomena.

Panelists: moderators, speakers of Introduction and Sessions 1, 2 (moderators and selected speakers)

Coffee break (10:30-11:00)

Closing of the workshop (12:00-12:30)

Uichiro Yoshimura (NEA)

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Science and Values in Radiological Protection

Decisions regarding radiological protection are informed by science, including its uncertainties, influenced by stakeholder concerns, driven by prevailing circumstances, and broadly based on values and judgments. However, the processes by which protection decisions are taken do not always sufficiently articulate the scientific and value-judgment elements on which decisions are based. To assist decision makers at all levels to further clarify the various aspects of their decisions, and to assist scientists and regulators in better understanding each other's contributions to radiological protection decisions, the NEA Committee on Radiation Protection and Public Health (CRPPH) has held two workshops addressing science and values in radiological protection. This report summarises the discussions and conclusions of the first two workshops in this innovative series, and suggests the way forward in preparing the discussions at the third science and values workshop.

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