NUCLEAR ENERGY AGENCY
Committee on Radiation Protection & Public Health (CRPPH)

SURVEY ON RESPECTIVE PUBLIC HEALTH POLICIES IN RELATION TO RADIOLOGICAL PROTECTION WITHIN NEA COUNTRIES
Performed by the CRPPH Expert Group on Public Health Perspective in Radiological Protection in 2008

DISCLAIMER

This document was prepared using information from different countries collected through the expert network of the Committee on Radiation Protection and Public Health of the OECD Nuclear Energy Agency and as such it does not necessarily always represent official national positions.

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Cancels & replaces the same document of 17 September 2009
Public health approaches in radiation risk and radiological protection always need to include stakeholder involvement and value judgements. Stakeholder involvement is an important factor, including views from a broad variety of stakeholders and stakeholder groups representing all relevant aspects of public health issues; and value judgements are important in shaping an individual’s perception of a particular risk, or classes of risks. However, these value judgements can sometimes be hard to identify, and may, in fact be hidden and thus require detailed study.

This document comprises of results and analyses of interviews performed within NEA member countries through the expert network of the NEA Committee on Radiation Protection and Public Health (CRPPH) in four topical areas: (1) Radon; (2) Justification of medical exposure; (3) Public heath judgement in decision making based on new scientific evidence; and (4) Management of individual differences. In each area the set of specific questions was prepared by the CRPPH Expert Group on the Public Heath Perspective in Radiological Protection, received answers were summarised and further analysed aiming to provide a practical overview of radiological protection approaches used in different countries.

The document is also intended to be considered as a starting point for further elaboration and co-operation among radiological protection experts and/or regulatory or public health authorities, aiming to explore and influence value judgements in setting or modifying respective regulations.
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I BACKGROUND

Protecting public health is one of the key objectives of the radiological protection work of the Committee on Radiological Protection and Public Health (CRPPH), a standing technical committee of the OECD Nuclear Energy Agency (NEA). In order to address this objective more closely and to take a broad overview when considering public health risks, as objectives and priorities may be addressed differently when viewed from a social and public health perspective rather than from a radiological protection perspective, the CRPPH formed the Expert Group on the Public Health Perspective in Radiological Protection (EGPH).

The fundamental ideas of the EGPH work were described in three inter-related aspects:

- ionising radiation is identified as one risk among others;
- radiological protection can benefit from approaches to other public health risks and a unified approach can evolve;
- at least in some cases, management of radiation risk requires a broader perspective, and an appropriately coherent and co-ordinated approach.

In addition, there are two expected added value factors that should be further explored when considering the existing approaches regarding radiation risk and radiological protection from a public health perspective:

- stakeholder involvement as an important factor, including views from a broad variety of stakeholders representing all relevant aspects of public health issues;
- value judgement as an important factor in shaping an individual’s perception of a particular risk, or classes of risks.

II SCOPE OF THE EGPH

According to the resolution of the 65th CRPPH Annual meeting (30 May-1 June 2007), the work of the EGPH covers four subjects, that are identified and classified for further explorations into four Case studies:

- Radon: among the reasons for selecting this topic as a typical public health policy issue, there is the need to cope with global risk (radon vs. other indoor air pollution, smoking) and energy (insulation vs. ventilation) issues. In addition, there is a policy choice to be made between targeting only the (few) areas or houses with high radon concentrations, or enlarging the action plans to the (much larger) areas with moderate (or even low) radon concentrations. This choice implies socio-economical aspects, and ethical and juridical considerations;
• Justification of medical exposures: although justification is one of the basic principles of the radiological protection approach, its application in the typical field of medical exposures is still disappointing. New, and widely regarded as unjustified uses, such as opportunistic screenings, are rapidly developing in some countries. As such, there is a need to analyse the reasons for these mitigated results, and to discuss approaches to improve the situation;

• Public health judgement in decision making based on new scientific evidence: new scientific insights arise regularly in radiation risk (non cancer effects, radiation-induced circulatory diseases…), generally with associated scientific uncertainty. Current approaches and tools used to take new scientific evidence into account should be critically examined from a broad public health and interdisciplinary perspective, focusing on making judgments regarding when enough evidence exists to change the “current” regulatory approach. Such judgments should include input from a broad variety of stakeholders;

• Management of individual differences: appropriate approaches to the management of individual differences should be further explored. Differences in individual risks are increasingly highlighted in recent scientific results (genetic susceptibilities, age and gender differences, including embryos and foetus), in a way that a clear articulation of how these are taken into account in radiological protection decisions is needed.

III SURVEY

Following the 65th CRPPH meeting, the 2nd EGPH meeting (8-9 October 2007) prepared the background materials for each Case study and decided to undertake a targeted telephone survey on respective public health policies within NEA member countries.

The interviewed representatives were mostly members of regulatory bodies and public health authorities.

Questions asked in the survey were aimed to address key issues within each Case study. These questions were not meant to be comprehensive nor fixed and were operatively modified/complemented, in order to react as closely as possible to radiological protection policy issues in each interviewed country.

The surveys were performed in February-April 2008 time frame, with many countries opting for e-mail correspondence instead of an initially proposed telephone survey.

Of the 28 NEA member countries asked to participate through their CRPPH representatives, 14 responded and provided results (Australia, Austria, Canada, Czech Republic, Finland, France, Hungary, Iceland, Ireland, Korea, Slovakia, Switzerland, Turkey and USA).

The goal of this survey was to collect available information, enabling information exchange among countries, and to foster mutual understanding of radiological protection public health policy approaches in the areas addressed.
The results of this survey are to be considered as a starting point for further elaboration, in particular by searching for more input from stakeholders representing all relevant aspects of public health issues, and by further exploring the influence and role of value judgements.

IV RESULTS

For each of the topics, the results of the survey are presented, preceded by a summary of the background information that had been sent to the interviewed persons in order to set the scene.

1. Radon

Background information

Controlling radon exposure in buildings

Within radiological protection, control of exposure to radon is of great interest, since in radiological protection terms the exposures may be large, both at the individual and collective dose levels. Furthermore, there is often a perception that exposures to radon has not received enough attention given the risk, particularly in homes and public buildings, which form the focus of this work. Nevertheless, quantifying risk from radon at low levels (typical of domestic dwellings and most workplaces) is challenging and, until recently, was based on extrapolation from studies of uranium miners, who were exposed to relatively high levels of radon during discrete periods of time. However, recent works pooling several studies conclude that chronic exposure to radon in domestic dwellings can lead to statistically significant risks even at low levels (below 200 Bqm⁻³).

Regulatory standards and tools

A 1999 survey¹ investigated the control of radon in homes, workplaces, drinking water and building materials, particularly investigating the types and levels of regulatory standards in use and the organisations responsible for ensuring them. The survey found that, among other things, workplaces and schools were often subject to standards but that it was unusual for obligatory standards to be applied to homes, whether new or existing.

In all cases, the use of standards implied a targeted approach and in some cases a phased approach was in evidence (e.g. lower advisory level, higher obligatory standard). Moreover, the levels of support to assist home-owners varied, in some cases being capped at a financial level as well as being restricted to homes above a reference level and in some countries, very little or no support appeared to be offered. Standards – a large proportion of which were obligatory – were reasonably common for workplaces; in some cases standards identified a level at which radon was regarded as a source of ionising radiation for the purposes of national radiological protection law. In several countries, mapping was used to identify (and presumably target) areas of high radon. At least one country had made a large effort to a voluntary programme for control of radon in homes.

Variation in tools and targeting of resources

A number of approaches and instruments are adopted to tackle high (or the highest) radon areas; in most countries the bulk of the collective dose is due to radon levels that are below the national action/reference level. The reasons for variation in approaches to radon control are unclear; one reason – pointed out in the survey for the case of radon in drinking water – may be related to how large typical exposures are, with more stringent standard-setting in countries where radon levels are relatively high. A policy issue that this observation raises concerns the overall philosophy of national regulations, whether to target high individual risks (i.e. homes and buildings over the action level), or whether to target reductions in the overall collective dose, which would imply tackling radon in a large number of buildings at lower, or rather all, radon levels. In addition, although in terms of controllability and applicability, it seems to be easier to implement standards in new buildings than in older ones, relatively few countries have enforceable standards or obligatory measures in construction of new buildings.

Children and the foetus

Data on the effects of radiation in children are limited, and very little is known about the effects of radon exposure in this age group. As one example, cancer development in Japanese atomic bomb survivors suggests an increased susceptibility to radiation induced cancers in children compared to that in adults. Children also have different lung architecture, resulting in a somewhat larger dose of radiation to the respiratory tract, and children have a longer period of life in which to develop cancer. However, no conclusive data exist on whether children and the foetus are at a greater risk than adults from radon.

Schools are typical examples of public buildings with high occupancy by children, and generally were subject to regulatory standards (although not always obligatory). However, these are often grouped with workplaces, and the low number of countries setting standards for schools (as opposed to other workplaces or, say, day-care centres) does not imply particular concern over exposure of children. It is unclear how far the approach in these countries is based on evidence of potential elevated susceptibility of children to radon, or how far it is based on a perceived need by society to give a very high standard of care to children. A remaining issue is whether, and if yes, how exposure of the foetus is handled?

Questions and answers

How high a priority is radon in buildings in your country/institution? (13/14 answers)

<table>
<thead>
<tr>
<th>Priority</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>high or medium priority:</td>
<td>11</td>
</tr>
<tr>
<td>low priority</td>
<td>2</td>
</tr>
</tbody>
</table>

Do you think this is too much/too little/about right? (12/14 answers)

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>satisfactory</td>
<td>9</td>
</tr>
<tr>
<td>need more effort</td>
<td>2</td>
</tr>
<tr>
<td>unsatisfactory</td>
<td>1</td>
</tr>
</tbody>
</table>

2. See Annex 1.
3. The sum of numbers shown in the tables, in some cases, does not mathematically fit the number of participating countries, since some countries did not provide answers to all questions, or provided answers matching several criteria.
What effect are new, pooled studies on domestic radon exposure having on your approach to radon? (Darby et al.\(^4\), Krewski et al.\(^5\)) (10/14 answers)

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<tbody>
<tr>
<td>important</td>
<td>3</td>
</tr>
<tr>
<td>considered</td>
<td>5</td>
</tr>
<tr>
<td>not considered</td>
<td>2</td>
</tr>
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</table>

Do you think links between radon risk and other areas are appropriate/too little/too much in your country? (E.g. air pollution generally, building regulations, smoking policy) (12/14 answers)

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<thead>
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</thead>
<tbody>
<tr>
<td>appropriate</td>
<td>8</td>
</tr>
<tr>
<td>not considered</td>
<td>3</td>
</tr>
<tr>
<td>not appropriate</td>
<td>1</td>
</tr>
</tbody>
</table>

What tools other than action levels do you use for controlling radon exposure? (E.g. publicity campaigns, measurement services, building controls)

- communication in public media
- publishing and distributing guidance and explanatory materials
- education/licensing
- arranging measurements of radon in dwellings
- none

How are these targeted (if at all)?

- national monitoring programme
- communication with home owners
- organising measurements

Are these appropriate? (8/14 answers)

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<th></th>
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</thead>
<tbody>
<tr>
<td>appropriate</td>
<td>6</td>
</tr>
<tr>
<td>to be improved</td>
<td>2</td>
</tr>
</tbody>
</table>

How is exposure to younger age groups/pregnant women included?

Several countries undertake monitoring of indoor air for radon in public buildings (e.g. schools), however countries do not specifically discriminate the exposure for either younger age groups or pregnant women.

2. Justification of medical exposure

Background information

Increasing trend of medical exposures

In recent years, the use of ionising radiation has allowed great progress in many areas of medicine – both diagnosis and treatment, and medical exposure is the major component of doses from artificial sources of radiation. As an example, according to available data from Ireland, there are 598,000 X-ray examinations carried out annually, contributing significantly to the population’s exposure (Ireland’s population is 4.2 million, as of 2008). Major contributors are interventional radiology and CT scans. The average annual per-caput dose from these examinations is in some countries at the level of 800 µSv. In addition to radiology, there are practices in diagnostic nuclear medicine, accounting for 30,000 per annum in Ireland, and the corresponding per caput average annual dose is typically 40 µSv.6

Despite the fact that the majority of an individual’s average annual effective dose (~3 mSv) originates from natural background (~2.4 mSv), and the fact that medical examinations have undisputable positive aspects, the harmful effects of ionising radiation should be considered in medical applications.7 It is therefore essential that practices involving medical exposure are carried out in improved radiological protection conditions.

Medical ethics and radiological protection

In the medical area, radiological protection must be considered along with medical ethics. Medical ethics has a strong emphasis on the patient-physician relationship, according to which the physician is required to act in the interest of the individual patient. When it comes to radiological protection, the fundamental question to answer is whether an individual or collective risk weighting approach will be used. In general, both approaches are used, the individual approach in decisions on doses used in therapeutic and diagnostic procedures, the collective approach in assessments of collective doses from various types of medical practices as well as voluntary screening programmes. The application of both approaches requires a balance in the regulatory principles.

This study is not focusing on the entire principle of justification of medical exposure, rather on a survey of:

- applied practices used in justification of scans of asymptomatic individuals;
- medical radiological education (e.g. possible shortage of education in radiobiology and radiation risk-related subjects); and
- radiological protection during medical practices.

Justification of medical exposure

The most important principle for radiological protection in medical exposures is the one of justification. In most countries, all medical exposures to ionising radiation must be justified prior to the exposure being made. In the justification process, every medical exposure must show a sufficient net

6. Radiation Doses Received by the Irish Population, RPII 08/01, Radiological protection Institute of Ireland, 2008.
benefit compared with the individual detriment that the exposure might cause, taking into account the benefits and risks of available alternative techniques.

Four scenarios concerning the application of medical exposures are outlined below:

- Medical exposure is performed in an individual patient as part of his/her own medical diagnosis or treatment.
- Medical exposure is performed in volunteers as part of a biomedical research project.
- Medical exposures are performed in an asymptomatic population as part of an approved health screening programme for early detection of a disease.
- Medical exposure is performed in an asymptomatic individual as part of an opportunistic screening for early detection of disease (screening not offered by a doctor or health professional, see below).

In each of these scenarios, medical exposures must be justified in advance:

- The justification of medical exposure for an individual patient has to be carried out by the radiological medical practitioner, taking into account the specific objectives of the exposure and the characteristics of the individual involved. If the radiological medical practitioner is the same individual as the referring medical practitioner, special care has to be taken to ensure that the prerequisites for justification are duly fulfilled.
- Cases of medical exposure for biomedical and medical research must be subject to the approval of an ethics committee, set up in accordance with national regulations, and/or by the competent national and local authorities.
- Specific justification by the national health authorities – in conjunction with the regulatory bodies and other appropriate professional bodies – is necessary for radiological procedures to be performed as part of the organised health screening programme for asymptomatic individuals.
- Opportunistic screening must be carefully examined and individually justified, as further described below.

Organised health screening versus opportunistic screening

From both radiological protection and public health perspectives, organised health screening programmes, which include radiological procedures, are always of major concern, since asymptomatic individuals are exposed. Due to the typically low prevalence of serious diseases in an asymptomatic population, the vast majority of individuals undergoing screening are not affected by the disease for which the screening process has been implemented to detect. These individuals do not derive a direct health benefit, but can be harmed either by increased risk of radiation induced cancer or by undesired adverse health effects such as false-positive or false-negative findings and over-diagnosis.

In consequence, demanding prerequisites have to be fulfilled by a radiological health screening programme, such as a:

- clearly defined target population, based on a clearly defined risk profile;
well organised invitation system;

• demanding quality management assuring highest quality standards along the whole screening chain – including X-ray devices and technical performance as well as clinical reporting and work-up of suspicious findings; and

• regular evaluation of important performance parameters revealing the efficacy of the screening programme.

In addition, the justification for radiological screening programmes has to take into account the severity of disease and the potential of the screening procedure for detecting disease as well as the likelihood of effective treatment of detected cases. Furthermore, the expected benefits have to be weighed against both the adverse health effects and the radiation induced risks of the screening procedure.

Up to now, X-ray mammography is the only X-ray modality, which has been approved within a health screening programme. In this case, the justification was based on reliable data from several prospective, randomised clinical trials indicating a significant reduction in breast cancer mortality due to X-ray mammography screening.

Opportunistic screening has to be distinguished from the organised health screening programmes that are described above. Opportunistic screening is initiated by the patient themselves, or when a screening test is offered to “random patients” by a doctor or health professional. Unlike an organised health screening programme, opportunistic screening is not typically embedded in a screening algorithm, but resembles more or less an attempt at early case detection. So, the target population may not be clearly defined, the screening test may not be subject to a rigorous quality assurance programme, and an effective evaluation process may not be implemented. Despite the fact that the results of opportunistic screening may be considered as a part of a diagnosis, it is generally considered to be substantially less efficient than an organised health screening programme.

Driven by the fascinating new capabilities of multi-detector computer tomography (MDCT), CT-based opportunistic screening is becoming increasingly popular. In some countries this kind of screening is extensively advertised by providers, which may further support the acceptance by the public. The most prominent example is whole-body CT screening.

Another class of screening, distinct from both health screening programmes and opportunistic screenings, are those screenings of individuals who may have characteristics that would suggest that they might have a condition that is being looked for through imaging. Examples of such specific screenings would be as follows:

• lung CT for early detection of lung cancer, in particular in smokers and asbestos workers;

• CT quantification of coronary artery calcification, which is considered as a sensitive marker of arteriosclerosis; and

• virtual colonoscopy for early detection of intestinal polyps, which might be pre-cancerous lesions, and colorectal cancer.

These specific screenings focus on the diagnosis of a particular potential diseases and focus on pre-selected parts of the population. Questions at stake here may be, for example, what is the “best” frequency of such screenings, is there a need for advice from the referring practitioner, and others. These categories, however, were not specifically addressed in the survey performed here.
Questions and answers

Is the national Public health authority concerned of the growing medical exposure? (12/14 answers)

<table>
<thead>
<tr>
<th>Concern</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td>high concern – adoption of appropriate countermeasures</td>
<td>13</td>
</tr>
<tr>
<td>overall concern – monitoring situation, providing guidance</td>
<td>1</td>
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</tbody>
</table>

Is there a justification requested prior to medical exposure? (In most currently applied regulations the medical practices need to be justified to gain more benefit than risk while dose limits do not apply) (12/14 answers)

<table>
<thead>
<tr>
<th>Request</th>
<th>Number</th>
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<tr>
<td>yes</td>
<td>10</td>
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<tr>
<td>no</td>
<td>2</td>
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Is there any national recommendation (guidance) available for radiological practitioners describing the principles of justification? (12/14 answers)

<table>
<thead>
<tr>
<th>Recommendation</th>
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<tr>
<td>yes</td>
<td>8</td>
</tr>
<tr>
<td>no</td>
<td>4</td>
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Is there auditing of medical exposures? If not, what kind of retrospective control of medical exposures is used to evaluate justifications? (12/14 answers)

<table>
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<th>Audit</th>
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<tr>
<td>yes</td>
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<tr>
<td>no</td>
<td>6</td>
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Concerning the opportunistic screening, is this a recognised screening category? Is there any national follow-up of these practices? Is there any dosimetric data available? (10/14 answers)

<table>
<thead>
<tr>
<th>Recognised</th>
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<tbody>
<tr>
<td>yes</td>
<td>3</td>
</tr>
<tr>
<td>no</td>
<td>7</td>
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</table>

What is the practice in educating/licensing physicians and other practitioners?

- Specific training and re-training courses required and controlled by respective authority in charge
- Licensing and re-licensing
- Continuing education
- Control by the radiation regulatory authority (e.g. Australian Radiation Protection and Nuclear Safety Agency [ARPANSA])

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How is the oversight/regulation of health care facilities being carried out?

Mostly by the Ministries of Health and Welfare, (or Ministry of Education, Finland); in some cases in co-operation with regulatory authorities.

3. Public health judgement in decision making based on new scientific evidence

Background information

Situation

Radiological protection is always a combination of science and value judgements. There is a need for radiological protection policy makers, practitioners and other stakeholders to better understand the evolving interactions between science and values in the development of radiological protection policy and its practical application. 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 in terms of furnishing input coming from the research.

The policy judgement is expected to be based on the precautionary principle:

“The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU”\(^\text{10}\).

The purpose of the precautionary principle is to create an impetus to take a decision notwithstanding scientific uncertainty about the nature and extent of the risk. In the case of radiation, effects associated with radiation, and the absence of a scientifically supported threshold of exposure for mutations that may lead to cancer, the application of the precautionary principle is reflected in the linear-non-threshold LNT hypothesis (LNT) and therefore in a regime based on keeping exposure as low as reasonably achievable.

The aspects of new arising scientific phenomena in relation with pregnancy, genetic effects, and dose-and-dose-rate-effects were notable also in discussions of the ICRP Publ. 103\(^\text{11}\). In view of developing new scientific evidence, it could be worth asking whether or not the currently existing radiological protection (RP) criteria and regulations take these factors into account in light of the precautionary principle. This principle stipulates that for practices such as the release of radionuclides or radiation applications, extensive use in medical applications, or in other areas, the burden of proof lies with the policy or regulatory bodies. An important element of the precautionary principle is that its most meaningful applications pertain to those situations that have potentially irreversible effects.

Scientific phenomena potentially having an impact on radiological protection policies and criteria

Examples of new arising scientific phenomena that could influence the radiological protection principles and thus may be considered and elaborated further, include:

- non-targeted effects
- individual sensitivity

\(^{10}\) EU communication on the PP, (EU, 2000).
• radiation induced cardiovascular diseases
• LNT hypothesis for chemicals
• effects of in utero exposure
• synergistic effects
• radiation induced cataracts

Questions and answers

Does the Regulatory body follow up arising scientific issues that may eventually lead to modification of RP criteria in the future? (12/14 answers)

<table>
<thead>
<tr>
<th>yes or mostly yes</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>no</td>
<td>0</td>
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</table>

If not, is there an appointed (by Regulatory body) academic institution dealing with these issues and providing materials for considerations by RP authorities?

• In many countries regulatory bodies do not have appointed Academic institution(s) and either run their own research programme (e.g. Canada) or monitor recommendations issued by national or international institutions. However, regulatory bodies or respective PH institutions often cooperate with recognised academic institutions on these questions.

What is the process of accommodating novel scientific criteria? Does the process solely rely on knowledge and recommendations from international organisations (like UNSCEAR, ICRP, IAEA, etc.)?

• In general, countries rely on internationally adopted criteria and principles (typical for the EU countries), or observe internationally or nationally adopted principles (e.g. ICRP, UNSCEAR, etc.)

How is the precautionary principle being taken into account when establishing radiological protection criteria?

• The precautionary principle is either considered directly, through international recommendations (e.g. EU, ICRP), or indirectly anticipating the fact that as low as reasonably achievable (ALARA) and LNT principles satisfy a relevant level of protection.

4. Management of individual differences

Background information

Individual sensitivity and averaging approach

The issues arising from the consideration of individual sensitivities raise many moral and ethical questions that challenge the current functioning of the radiological protection system. While improved knowledge of an individual’s sensitivity offers an improved opportunity to understand their radiological...

12. See Annex 3.
risks, such knowledge would also suggest the need for individual risk management approaches (e.g. justification, optimisation, limitation) that would significantly complicate regulation and risk management. Because science seems to be moving in the direction of better understanding an individual’s risk, there is a need to discuss these issues and to be prepared to deal with them if they arrive.

Currently, radiological protection treats people as an average, to the point of not distinguishing between males and females. ‘Individual sensitivity’ refers to people who have particular traits (notably genetic) predisposing them to harmful effects of ionising radiation. Here the focus is on sub-populations that have generally not been distinguished, particularly where ability to readily distinguish is something that has only recently, or may soon, become possible (for example through some sort of genetic testing), or where information linking a particular trait with detriment from ionising radiation is new.

However, since one can define a group of such people by such traits, individual sensitivity is analogous to, and is sometimes taken to include, other groups in the population, such as women, pregnant women (sensitivity of foetus), or children.

**Level of protection**

Radiological protection uses various tools to restrict detriment from ionising radiation, principally: justification, optimisation of protection, and dose limitation. If it is clear that certain parts of the population are more sensitive than others, how should the system of protection take this into account? Given that justification and optimisation are essentially trade-offs between cost and benefit\(^\text{13}\), how should these take into account the existence of high-risk groups? Should, for example, separate dose constraints be set for people who are sensitive? Or should one dose constraint be set based on the most sensitive group? Whilst dose constraints, as part of optimisation, are tools applicable on a case by case basis, giving flexibility (e.g. if organisations were allowed to ‘screen-out’ sensitive workers from tasks), the same cannot be said for the public dose limit which, by its very nature, needs to apply to the whole population. If differentiation is made, the most obvious route is setting different numerical constraints or limits (transparent but complex) but are there other approaches that could be adopted allowing a single number to be maintained e.g. inclusion of a ‘sensitivity weighting factor’ in effective dose (this would avoid different limits, and minimise changes in legislation, but would not be very transparent)?

**Potential risk of discrimination?**

In many countries, people have various insurances related to various aspects of their well-being, including unemployment or disability insurance, life insurance, health or medical insurance and pensions. The provision of insurance has various forms, from fully private-commercial insurance to state ‘insurance’. Commercial insurance is based on risk sharing, so that premiums as a minimum cover payments plus expenses. Therefore, ability to identify and treat differently different risk groups gives an advantage to an insurance company but a disadvantage to higher risk groups, who may become uninsurable or pay higher premiums. Such people may thus potentially be restricted in their access to basic services. Issues may be expected to be different for state insurance and may for example include deciding whether to screen a population. There are several questions at stake, like: Is there a large, high risk population where early detection is of significant benefit? Is the evidence strong enough to support the expenditure in comparison with other demands? What are the ethical implications of discriminating/not discriminating?

Many employers perform general health checks on would-be employees and, given the ability to test for susceptibility to ionising radiation, may wish to do specific test(s) addressing this. Desire for such screening may be driven by an acknowledged duty of care and also in order to be more efficient (avoid loss

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\(^{13}\) In a very broad sense, not merely economically.
of working time and expenses such as insurance, sick pay). Such testing implies that those who have positive test results may be denied employment or may have their career paths in an organisation restricted. It may be argued that such screening is a good thing for the potential employee (reducing their risk) and the company (more efficient) but it may also be argued that it is for the employee to make this judgment and, indeed, to choose whether they want to know.

Questions and answers

The following questions were asked:

- Do you have any examples of situations where a key part of the situation was handling individual sensitivity?
- How did you handle this (particularly with respect to ALARA/optimisation)?
- What evidence did you have for judging the sensitivity and how did this affect your handling of the situation?
- To your knowledge, what level of individual radio-sensitivity testing is allowed and carried out by (potential) employers?
- Is this probabilistic in nature (identifies increased risk) or deterministic (factors currently affected a person’s capacity to do a job)?
- What is the legal situation?
- Do other organisations perform this type of testing? (for example, medical or life insurance, population health screening)
- What is the legal situation related to these tests?
- Does the medical sector adequately handle individual radio-sensitivity?
- If so, how?
- What further actions (if any) are needed?
- Do you feel this is an important issue for radiological protection?
- If not, why not?
- If so, how do you think it should be handled?
- How do you think the situation will change over time?

In general, answers to most questions indicated that:

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• With the exception of lower limits for minors and the embryo/foetus of declared pregnant women, individual sensitivity is not considered as a regulatory but academic and/or medical issue and thus countries do not have relevant regulatory nor legal mechanisms to address it.

• Regulatory authorities are aware of the problem but are waiting until sufficient scientific evidence is recognised which would justify potential changes in legislation.

• No testing nor screening of potential employees for individual sensitivity are performed nor legally allowed (tests currently performed do not include testing for individual sensitivity).

• Medical practitioners handle individual sensitivity on case-by-case and rely on their own experience and/or available medical guidelines.

• Individual sensitivity may be a future regulatory issue subject to scientific achievements and policy consensus.

V DISCUSSION

This summary report presents the results of a survey performed in fourteen OECD countries on radiological protection regulatory practices and approaches in four selected areas: 1) radon, 2) justification of medical exposure, 3) public health judgement in decision making based on new scientific evidence, and 4) management of individual differences.

For radon, results show there is a widely recognised need for enhanced control of radon in dwellings and public buildings, and many countries have already relevant regulations implemented in legislation. There are still further improvements in the regulatory control of radon and future policies for the control of radon risk. For example, there is a need to adopt approaches addressing differences in radon mitigation methods between new and existing buildings, including subsidies provided by governments as well as other measures (licensing of constructors, adopting regulatory control, etc.).

For the justification of medical exposure, the situation becomes more complicated, since the fundamental question to answer is whether individual or collective risk weighting approach will be used. In justification, both approaches are used: the individual approach for decisions on doses used in therapeutic and diagnostic procedures; the collective approach for assessments of collective doses from various types of medical practices as well as voluntary screening programmes. Several countries have adopted thorough auditing systems to control compliance with the optimisation of medical exposures, while in others the justification is fully under the jurisdiction and responsibility of the medical radiological practitioner.

Public health judgements in decision making based on new scientific evidence, use of the precautionary principle and management of individual differences are currently considered more academic than regulatory issues. However, there is among those who participated in the survey a belief that these issues should be considered in formulating future regulatory approaches. A close co-operation with academia is seen as a vital factor in satisfying the adoption of novel scientific phenomena into regulations. Most surveyed parties have active co-operation with academic institutions, both nationally and internationally, and if there is satisfactory scientific evidence for a need to change existing regulations, there are legal mechanisms in place for the adoption of such change. The question remains, however, how
is it decided that evidence is sufficiently robust to justify change. As far as differences in individual sensitivity are concerned, while such differences are acknowledged as existing, there is a fear that without proper legislation and further scientific evidence, the adoption of a legal regulation may easily lead to discrimination in the employment sector.

In general, surveyed parties considered that current radiological protection systems are well developed and adopted in existing regulatory legislation. This is particularly true for the regulation of radon and for the justification of medical exposure. As for the subject of new scientific evidence, most parties rely on relevant national and/or international academic institutions and do not perform their own research besides the evaluation of the implementation of available recommendations into respective regulations. Concerning the management of individual differences, there is almost unanimous consensus that this issue still requires scientific clarification before any regulation eventually can be proposed.

The summarised results provided here should be viewed as those provided by representatives of the radiological protection community, public health authorities and regulatory bodies. As such, they may be considered as a starting point for further elaboration. In particular it would be worth seeking input from stakeholders representing all relevant aspects of public health issues, for example, consumers, the general public, patients, and by further exploring the influence and role of value judgements.
Annex 1

RADON

1.1 How high a priority is radon in buildings in your country/institution?

- **Australia:** –

- **Austria:** Radon in buildings has been an issue in Austria over the past 20 years. In 1992 the Austrian Radiation Protection Commission made a recommendation including advisory levels. Since then systematic investigations have been undertaken resulting in an Austrian radon map, Austrian standards for prevention and mitigation measures in buildings, and information material for the public (booklet, CD; a specific radon website will be online soon). Thus, radon in buildings has a medium priority which led to a number of efforts as summarised above.

- **Canada:** Authorities: high priority; Public: relatively low perception of the radon risk.

- **Czech Rep.:** The exposure to radon in dwellings is supposed to be one of the priorities of radiological protection in our country. The reason is that radon concentration in buildings in the Czech Republic is heightened due to geological conditions and the annual effective dose of an individual is in average twofold in comparison with the world average value, but in some regions much more higher. As for new buildings, the knowledge of the radon risk level for a particular site is taken as priority. The measurement of the “radon index” is obligatory according to the Atomic law. The technical standard “Protection of buildings against radon from the soil” then gives appropriate measures for particular values. The description of the way of protection against radon for every new house must be submitted to the construction authority. The priority in case of old buildings (until 1991) is to find dwellings with high radon concentration (over 1000 Bq/m³) and to take remedial measures with financial support of the state there.

- **Finland:** At the national level the priority is rather high. There are clear health based regulations directed to citizens and health authorities as well as regulations in the building code. Given reference levels for existing buildings and new building play an important role in buying and selling transactions as well as in buying of new dwellings. At a municipal level there has been active mapping of indoor radon since 1986. Altogether 100,000 dwellings have been measured, the total number of dwellings in low rise residential buildings being 1.45 millions. In 2007 already several dozens of percent of single family houses in many municipalities were measured. Indoor radon concentrations at workplaces, schools, day care centres and public buildings have been regulated by the Radiation Act. The Radiation and Nuclear Safety Authority’s (STUK) research into indoor radon and co-operation with authorities aiming at exposure reduction is one of the focus areas.

- **France:** high.

- **Hungary:** The average radon concentration in Hungarian dwellings is slightly higher than the world-wide average (primarily due to geological reasons); therefore, radon is considered with priority.
Iceland: A low priority in Iceland since the bedrock is mainly of basaltic origin and not granite as in the other Nordic countries.

Ireland: High priority is given by the regulatory body (Radiological Protection Institute of Ireland [RPII]), which considers radon as an important radiological protection issue. Radon contributes approximately 56% of the collective dose from all sources in Ireland – the average annual dose is 2225 \( \mu \text{Sv} \), of which 180 \( \mu \text{Sv} \) is attributable to indoor workplaces such as offices. Several homes have been identified in which the average dose to occupants exceeds 100 mSv and in one extreme case the annual dose exceeded 1.2 Sv. To date the main focus has been on individual risk through targeted programmes in High Radon Areas but increasing attention is being given to reducing the collective dose through better construction practices.

Korea: The Ministry of Environment established the law of controlling indoor air quality in public buildings. In this law, radon is the last one of the 10 contaminants that should be controlled in indoor air, and the recommendation value is 4 pCi/l. However, there is no action level or recommendation level for dwellings.

Slovakia: The priority is high. Here are the activities performed in this area:

- mapping of radon in buildings (school, kindergarten and day nursery included)
- mapping areas of concentration to radon (radon maps of the territory and the territory with high density of population)
- mapping of the building materials
- supervising workplaces where an increased exposure to radon (natural radiation sources in general) may be expected (mines, caves and other underground workplaces, pumping stations, spa facilities, water treatment plants for ground water), and all workplaces where radon concentration is higher than 1000 Bq/m3.

Switzerland: In those regions of Switzerland where Radon is an issue, it has a high priority. There is a national Radon programme sustained by the Federal Office for Public Health. (http://www.ch-radon.ch).

Turkey: Due to the fact that the average radon concentration in dwellings is about 50 Bq/m\(^3\), which is well below the limit value (400 Bq/m\(^3\)) applied in Turkey; radon is not a high priority in buildings.

USA: The U.S. Environmental Protection Agency’s (EPA) radon programme remains a high priority voluntary programme. Emphasis on risk-reduction is targeted to homes and residences primarily and schools secondarily, since that is where the bulk of the exposure is thought to occur. The limited available information suggests radon is much less a problem in large office buildings. Another Federal agency, the Occupational Safety and Health Administration (OSHA) regulates radon in commercial workplaces. EPA’s most recent risk assessment estimated 21,100 radon-related lung cancer deaths annually in the U.S. Radon is also a priority for members of EPA’s partnership network, including the American Association of Radon Scientists and Technologists (AARST), the Conference of Radiation Control Program Directors (CRCPD), and others, e.g., the National Safety Council (NSC). To focus more attention and action on radon, EPA, AARST and CRCPD recently launched a web portal devoted to radon risk reduction (RadonLeaders.org). Another federal agency, the Agency for Toxic Substances and Disease
Registry (ATSDR) also identified radon as a priority hazardous substance for developing public health information. The ATSDR Toxicological Profile for Radon is currently undergoing a public comment review.

1.2 Do you think this is too much/too little/about right?

- **Australia:** –

- **Austria:** The priority given to radon in buildings is about right. However, the efforts have to continue in order to improve the radon map and to better inform the public with respect to their radon risk and how to reduce it.

- **Canada:** more attention needed.

- **Czech rep.:** The adequacy of the present way of regulation is continually evaluated. We suppose the extent of regulation to be satisfied but the level of public awareness of radon risk to be insufficient.

- **Finland:** Much has been done. However, there is need for strengthening the enforcement procedures of Finnish radon policies. Radon mitigation activities in existing dwellings should increase and radon preventive construction techniques in new dwellings should be more strictly applied. The focus should be on:
  - finding the dwellings containing high indoor radon concentrations;
  - reducing radon levels; and
  - giving priority to new dwellings and the latest Building Code 2004 requirements for indoor radon levels. Strengthening the importance of indoor radon regulations is part of the enforcement procedure.

- **France:** About right for public buildings, too little for dwellings.

- **Hungary:** The most urgent task about radon is the construction of the radon map of Hungary. There have been some steps taken but this task is far from being finished.

- **Iceland:** –

- **Ireland:** There is still a lot of work to be done but there is a consensus that all organisations need to work in a co-ordinated manner to effectively address the radon problem. The RPII has developed an Action Plan for radon and is working with the central Government to develop a national strategy. The RPII has ongoing close co-operation with relevant national agencies and commercial companies in the health, radon measurement and building construction sectors.

- **Korea:** It is appropriate. VOC (Volatile Organic Compound), asbestos, formaldehyde, etc. are more important in indoor quality control. However, an action level or a recommendation level for dwellings is necessary.

- **Slovakia:** satisfactory.

- **Switzerland:** appropriate.
• Turkey: about appropriate.

• USA: EPA spends about $10 Million annually for radon. About $8 Million of it is provided by Congress as a grant programme, known as the State Indoor Radon Grant (SIRG) programme. The states must match 40% of every Federal grant dollar they receive. Consequently, the national investment in the SIRG programme was ~ $13 Million in 2007.15.

1.3 What effect are new, pooled studies on domestic radon exposure having on your approach to radon? (Darby et al.16, Krewski et al.17)

• Australia: –

• Austria: The studies seem to confirm the Linear-Non-threshold-Theory which was the basis for the Austrian approach to the radon issue anyway. Therefore, currently there are no specific or additional actions planned in Austria. One effect in the future could be that the current advisory levels for radon will become legal limits.

• Canada: Similar epidemiological and academic studies are key factors in setting regulatory principles.

• Czech Rep.: These results confirm the assumption of radon risk and of necessity of its regulation. Regulation of the natural radiation (dwellings, water, building materials) has been in progress in the Czech Republic since 1991.

• Finland: The new EU-study has already changed our risk estimates. The estimated annual number of lung cancer cases due to indoor radon has been increased to 300 from the previous 200. The new estimate is based on calculations of Darby’s group. The new results have also strengthened the activities aiming at radon exposure reduction.

• France: None, just confirmed our point of view.

• Hungary: Up to now: none.

• Iceland: –

• Ireland: The existing guidance and reference levels in Ireland were already consistent with the most recent scientific findings and thus there is no need for change. We await the new ICRP recommendations on radon and plan to evaluate their implications for our radon programme.

• Korea: These studies seemed to affect the Ministry of Environment to make a plan of a nationwide radon survey, recently. Korea Institute of Nuclear Safety (KINS) is also screening available documents.

- **Slovakia**: Radon exposure from the radiological protection point of view is continuously being monitored. A comprehensive study is performed by respective specialised departments, *(e.g.* Dept. of the environment).*

- **Switzerland**: –

- **Turkey**: none.

- **USA**: The North American and European pooled studies give results consistent with the results of EPA’s 2003 risk assessment and its predecessor, the National Academy of Sciences’ (NAS) BEIR VI\(^\text{18}\) report. EPA anticipates that the findings of the ‘world’ pooling study will be consistent with these earlier analyses. EPA has also been a sponsor of the WHO international radon project (IRP).

1.4 **Do you think links between radon risk and other areas are appropriate/too little/too much in your country?** *(e.g. air pollution generally, building regulations, smoking policy)*

- **Australia**: –

- **Austria**: Radon is dealt with by the Indoor Air Pollution working group of the Ministry for Environment so the link between these two areas is given. There is no link to building regulations which is clearly inappropriate as implementation in the building regulations for new buildings would be an effective measure to reduce radon exposure in the long term. However, building regulations are within the responsibility of the federal state and therefore difficult to coordinate nationwide. There is no link to the smoking policy; however, it is not clear if a link would be beneficial to the radon issue or not.

- **Canada**: Radon regulations are currently not included in the Building code. Straightforward comparisons to other risks are not available. Further work is required.

- **Czech rep.**: These relations correspond to the public order.

- **Finland**: Smoking policy has become stricter in recent years. This has also resulted in a positive decreasing trend in smoking prevalence. Stopping smoking also decreases the risk of radon – due to the synergistic interaction. Generally the requirements in radon prevention in the Building Code are essential. Radon preventive construction techniques in new dwellings should be more strictly applied. The requirements of building authorities should be more uniform and strict in the whole country.

- **France**: Appropriate in general, but too little for the construction rules of new houses.

- **Hungary**: No links are given in regulations. However the comparison of two (or more) uncertain risk coefficients is always problematic.

- **Iceland**: –

- **Ireland**: Certainly these links are relevant, in particular those related to building codes and smoking habits. The RPII always emphasises the greater risk to smokers from radon as quantified in the most recent scientific literature. The importance of having appropriate building codes and

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\(\text{18. Health Effects of Exposure to Radon (BEIR VI), National Academy Press, Washington, DC 1999.}\)
their enforcement is also emphasised. For example, it is always stressed that compliance with building codes (that require a radon sump to be fitted in all new homes built since 1st July 1998 and, in addition, a radon barrier in homes in High Radon Areas) does not necessarily guarantee that there will be low radon concentrations present when the building is occupied – the owner should undertake a radon measurement and, if it exceeds the reference level, the radon sump should be activated.

- **Korea:** Links between radon risk and other areas in our country is too little.
- **Slovakia:** These links are appropriate.
- **Switzerland:** Compared to other risks, the risk from radon seems to have smaller impact. This probably comes from the regionally limited importance.
- **Turkey:** Appropriate.
- **USA:** EPA’s public risk communications and messages have always focused primarily on the radon lung cancer risk. That risk is often compared to other health hazards, *e.g.*, drunk driving deaths. With regard to smoking, EPA generally avoids using stop or anti-smoking messages out of a concern that doing so would lead non-smokers to think they are not at risk from exposure to radon. Rather EPA highlights radon as the leading risk factor for non-smokers and the second leading cause of lung cancer after smoking. EPA’s primary mitigation approach is the use of Active Soil Depressurisation (ASD) mitigation systems in existing buildings. These ASD systems are very effective in reducing indoor radon levels. They may also be effective in moderating indoor moisture levels, and in controlling other soil gases (*e.g.*, volatile organics) from entering buildings. ASD systems are often used to manage or control vapor intrusion into buildings that results from contaminated ground water and soils. Radon prevention is very compatible with building codes. Government at the city, county and state level are generally responsible for setting construction standards by adopting building codes. EPA encourages the use of ASTM E-1465 and the International Code Council’s Appendix F, in new home construction to minimise radon entry and facilitate remediation following construction or occupancy. EPA also encourages other Federal agencies and home builders to voluntarily include radon-resistant features in new homes. Also, a requirement for radon-reducing features in new construction is becoming more common in national and local green and healthy building programmes.

1.5 **What tools other than action levels do you use for controlling radon exposure? (E.g. publicity campaigns, measurement services, building controls)**

- **Australia:** –
- **Austria:** As mentioned above, information of the public (booklet, CD, website) is an important part of the Austrian radon policy and is to be continued. The Austrian radon map gives the citizen basic information on the radon potential in his community. The Austrian standards for radon lay down agreed procedures for the measurement of radon and for both preventive and mitigation measures and are therefore an essential tool for controlling radon in a home. In one province grants are given for the measurement of radon and for both preventive and mitigation measures. Finally, a national radon contact point has been established. Its tasks comprise the coordination of radon activities, the implementation of a radon data base, information of the public, training of professionals etc.
• **Canada:** Observance of action level (200Bq/m³) is controlled and published in regular and non-regular reports issued by respective governmental agencies.

• **Czech Rep.:** These may be in our country for example:
  - Obligatory measurement of the radon index of a site constituted by the Atomic law.
  - The way of protection against radon for every new house must be according to the law documented to the construction authority.
  - Only licensees of the State Office for Nuclear Safety (SUJB) are allowed to measure radon concentration in the soil and in dwellings.
  - The SUJB continuously supervises quality of their practice.
  - These measurements are performed according to standard methods.
  - Czech technical standards “Protection of buildings against radon from the soil” and “Protection of buildings against radon from the building materials”.
  - State programme for survey of indoor radon concentration in old buildings – free measurement and information for owners.
  - Information accessibility – web sites, printed information (Radon bulletin) for local authorities and for public, seven regional centres of the SUJB.

• **Finland: 1. Communication and campaigns:**
  - STUK:
    - press releases on measurements, mitigation and radon-safe building
    - leaflets, guide material
    - fairs, cooperation with organisations in the area of healthy indoor air
    - journal and newspaper articles
    - counselling by phone
    - training, partly in co-operation with the Ministry of Social Affairs and Health
    - Radon Bee, campaign in co-operation with Ministry of Social Affairs and Health. Today (2003-2010) local authorities work in co-operation with STUK in a radon campaign (Radontalkoot, Radon bee) in order to activate radon measurements and mitigation


work. The campaign also includes a programme for training companies for radon mitigation. Altogether 13,000 dwellings have been measured – 1900 of these exceeding the limit of 400 Bq/m². 167 municipalities out of 430 have already participated in the campaign. Training courses have increased the number of active radon mitigation companies.

- **Ministry of Social Affairs and Health:**
  - instructions and guidance booklets to health authorities
  - communication in fairs
  - training of health authorities
  - other distribution of radon information

- **Ministry of Environment:**
  - Building Codes
  - qualified guide book for radon mitigation (sub-slab-suction)
  - guide for radon prevention
  - other distribution of radon information

- **Finnish Society for Indoor Air Quality and Climate (FISIAQ) and other organisations in the area of healthy indoor air also distribute indoor radon information.**

- **2. Measurement service:**
  - STUK provides indoor radon measurements services, because the activity of private companies in this area is low.

- **3. Guidance material:**
  - Qualified basic guides for indoor radon mitigation are available through the activities of Ministry of environment, Ministry of Social Affairs and Health, Helsinki University of Technology and STUK. Fundings of ministries have been important. A detailed guide for the implementation of sub-slab-suction is fit for use of both professionals and house owners. A qualified basic guide for radon prevention in new building is available. The background research work has been funded by the Ministry of environment and Finnish Technology Agency TEKES and carried out by the Helsinki University of Technology, STUK and Building Information Ltd. The building Industry and building inspection authorities were also involved in the development work.

- **France:** Measurement campaigns by notified organisations.

- **Hungary:** There are no action levels regarding radon in Hungary. There is a draft of a ministerial decree that adopts the EU recommendations. We are doing radon measurements in the whole
country regularly due to public requests. We also have made a radon survey in homes and schools throughout the country with the aim of constructing the radon map.

- **Iceland:** –

- **Ireland:** Public campaigns (TV, radio, newspapers and road shows) stressing the importance of measuring radon and the associated health risks are carried out every year. There is no compulsory radon control for existing houses, but building codes apply to all homes built since 1st July 1998. This requires the pipe work for a radon sump to be installed in all new homes and, additionally, for radon barriers to be fitted to homes in specified High Radon Areas. Householders are advised to measure their home for radon once they move in and, if high concentrations are present, to activate the radon sump. There are several approved radon measurement services operating in Ireland. Some of these also offer a remediation/mitigation service.

- **Korea:** The country has not used any tool for controlling radon exposure. Some (very few) activities available (e.g. control of air in subway).

- **Slovakia:** Publicity campaigns (pamphlets, newspapers, on air information), measurement services (directly by Regulatory body or licensee), building control (national radon commission).

- **Switzerland:** There is an education to become a licensed radon specialist.

- **Turkey:** Monitoring of dwellings by using passive detectors and controlling the radioactivity of building materials.

- **USA:** Because the US/EPA radon programme is voluntary, the principal tools are: (1) using social marketing to raise public awareness that results in testing and mitigation, especially during residential real estate transactions, including (1.1) public service campaigns, e.g., National Radon Action Month (January); (1.2) partnerships, e.g., Conference of Radiation Control Program Directors (CRCPD) and the National Environmental Health Association (NEHA); (1.3) the World Wide Web\(^{21}\), (2) promoting the use of radon-reducing features in new home construction by builders; (3) promoting the adoption of radon-reducing features in local and state building codes; (4) including radon in healthy and green building programmes, e.g., Energy Star with AirPlus; and (5) financing radon activities at the state and local level through the SIRG programme (see also the answer to question 1.2). This is general (e.g. several public service announcements and advisories have been issued on radon) or targeted e.g. ‘social marketing’ to target groups thought to have most influence on take up of radon mitigation in private homes or the real estate sector. Focus group work is also undertaken. Other approaches include counting or estimating the number of homes with radon-mitigation measures e.g. number of homes with activated systems can be estimated from recorded installations and sales from component manufacturers. Radon mitigation measures in dwellings are regarded as a private cost; however in some states there are limited grant-aid programmes funded by levies on authorised radon service providers. The Agency for Toxic Substances and Disease Registry is updating its Toxicological Profile for Radon to inform the public, public health advisors, and decision makers of the risks from exposure to radon. The information provided in this document should help all communities to understand the risks from radon exposure and see the advantages for minimising exposure.

1.6 How are these targeted (if at all)?

- **Australia:** –
- **Austria:** Information of the public and through the Austrian standards for radon is basically not targeted. In order to receive a grant certain prerequisites are to be met and in this way it is targeted.
- **Canada:** –
- **Czech Rep.:** They are targeted both on the public, in general because everybody can be potentially exposed to an elevated level of natural radiation, and specially on the residents in “radon prone areas”, on occupants of the old houses with high radon concentration and on private developers of new buildings. Related groups are the local authority officers, first of all in the radon prone areas, construction authority officers, construction inspectors, designers, both remedial and preventive measure providers and licensees.
- **Finland:** Communication activities are targeted on general public and especially on local house owners in connection of local campaigns. Measurement services are targeted on all citizens and locally in campaign areas.
- **France:** Priority for schools, hospitals, public buildings in radon prone areas.
- **Hungary:** The survey in schools is targeting younger generations.
- **Iceland:** –
- **Ireland:** The focus is on previously identified High Radon Areas and media campaigns are often initiated after particularly high concentrations have been identified. The programme is supported by extensive literature that has been prepared by the RPII and advice and guidance is available on the website (www.rpii.ie).
- **Korea:** Not applicable.
- **Slovakia:** Targeted areas are general information to public, measurement activity for new buildings (comprehensive information for constructors) and for users of the buildings.
- **Switzerland:** –
- **Turkey:** Within a national monitoring programme.
- **USA:** The activities described in the answer to question 1.5 above are generally targeted to each specific audience, *e.g.*, efforts to have building codes amended to include radon target local and state building code officials, local home builder associations and other groups with an interest.

1.7 Are these appropriate?

- **Australia:** –
- **Austria:** They are appropriate insofar as they give the public the opportunity to inform themselves about radon and to control the radon exposure in their home (*what is radon?*, *what is...
the radon risk?, how to measure radon?, how to prevent/mitigate?). One missing item is – as mentioned above – the implementation of the radon issue in the building regulations.

- **Canada:** in general yes.
- **Czech Rep.:** We suppose them to be sufficient in case of active interest of the public and new building developers; the level of public awareness of radon risk and the interest of building developers and owners are insufficient.
- **Finland:** The activities are working and have resulted in the activation of indoor radon measurements and indoor radon mitigation. These efforts should be continued and strengthened.
- **France:** Yes.
- **Hungary:** There is still a lot to do (to continue the former studies, to start new ones).
- **Iceland:** –
- **Ireland:** There is a very significant increase in both the number of website hits and in the number of requests for measurements in the immediate aftermath of a media campaign. However, after a few weeks this returns to the normal ‘background’ level. Local media has been found to be a particularly successful way of communicating local issues to a local audience.
- **Korea:** Not applicable.
- **Slovakia:** Yes.
- **Switzerland:** –
- **Turkey:** –
- **USA:** EPA believes these are appropriate. These approaches appear to be moderately effective, given that an estimated 2.4 Million homes have reduced their annual average radon concentration; these 2.4 Million homes are 33% of the 7.3 Million homes estimated to have a radon level equal to or greater than the 4 pCi/L action level. The ATSDR toxicological profiles are considered to be one of the best references for schools of public health, and they enjoy a high hit rate on the Internet. It helps that the Toxicological Profile for Radon, its public health statement, and fact sheet are available as hard copy and on the Internet, in English and Spanish languages22.

1.8 How is exposure to younger age groups/pregnant women included?

- **Australia:** –
- **Austria:** Radon exposure to younger age groups/pregnant women is not treated in a specific manner in Austria. However, there have been rather extensive radon surveys in kindergartens and schools by some federal states of Austria.
- **Canada:** the programme addressing these issues is currently being developed.

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• **Czech Rep.**: This exposure is not separately regulated. Remedial measures in buildings with radon concentrations higher than 400 Bq/m$^3$ intended for long term stay of children are paid by the state.

• **Finland**: Exposure of children and pregnant women are handled as a part of long term exposure. There is no health based evidence on special action levels for them. Indoor radon concentrations in day care centres have been surveyed in a special study.

• **France**: Not taken into account specifically.

• **Hungary**: At school: see above. There have not been any studies performed on pregnant women.

• **Iceland**: –

• **Ireland**: Younger groups and pregnant women are not specifically targeted in media campaigns. Through an initiative of the Department of Education and Children, between 1998 and 2000 all schools have been surveyed for radon. These were subsequently remediated if radon concentrations exceeded the 200 Bq/m$^3$ reference level for schools. The policy adopted by the RPII is that, for schoolchildren, the time spent in school is an extension of the time spent at home and therefore the same reference level should apply.

• **Korea**: Not applicable.

• **Slovakia**: In radon case: it is considered not to be important.

• **Switzerland**: –

• **Turkey**: Since the average radon concentration in dwellings is significantly low, it is not necessary to estimate the exposure to younger age groups/pregnant women.

• **USA**: No explicit separate approach is taken for pregnant women; however as part of the focused social marketing approach, pregnant women and women with very young children have been target groups for health (radon) messages emphasising protection of the family. Separate data for children is not available. ATSDR includes separate messages for child and family health in the Toxicological Profile for Radon.
Annex 2

JUSTIFICATION OF MEDICAL EXPOSURE

2.1 Is the national Public health authority concerned of the growing medical exposure?

- **Australia:** In 2006-2007 an estimated 13.5 million radiological procedures (including about 2.4 million CT scans), and over 500,000 diagnostic nuclear medicine procedures were undertaken in Australia. ARPANSA monitors medical radiation doses to the Australian population by conducting national surveys, and is now in the process of conducting a national survey of CT doses.

- **Austria:** –

- **Canada:** Yes, it is a major concern.

- **Czech Rep.:** Yes, SUJB has monitored the numbers and structure of the medical examinations performed with the ionising radiation for several years. There is a very good co-operation with the General Health Insurance Company which covers the most of the population. The company provides the Office with valuable data that enable to analyse the trends in medical exposures – the sex and age distribution and the types of the procedures. The numbers of the procedures have not been increasing significantly during the past years; however, the structure is changing. Some methods were completely replaced by ultrasound (e.g. urological examinations, hip dysplasia, pelvimetry and others), whereas usage of others have rapidly increased (e.g. interventional radiology and CT scans). The recent challenges are new sophisticated technologies, which are more and more in use in modern medicine. From the radiological protection point of view the digitalisation is one of the important aspects. Although this new technology helps to improve the quality of the system itself, it could go against the radiological protection if not set up appropriately. The good quality image can be obtained despite the over or under exposure. This problem should be carefully evaluated and addressed appropriately by the regulator and licensees. The problem for the regulator is mainly the lack of knowledgeable staff/inspectors in this field.

- **Finland:** Yes. STUK is obliged by the decree of Ministry of Social Affairs and Health 423/2000 to make a summary of the number of examinations and of radiation doses on the basis of which national appraisals of the radiation exposure caused by the medical use of radiation and its development shall be prepared. STUK is reporting to the Ministry.

- **France:** Yes.

- **Hungary:** Council Directive 97/43 EURATOM has been transposed into Hungarian regulations by Ministerial Decree 31/2001 (X.3) EUM. According to the Decree the Hungarian national public health authority has to take steps to avoid unnecessary proliferation of radiological equipment and medical exposure.

- **Iceland:** Yes.
• **Ireland:** The Department of Health and Children is responsible for all medical facilities and associated exposures in the public health sector. However, with the exception of specific responsibilities assigned to it under S.I. No. 478 of 2002 which implements Council Directive 97/43/Euratom, generally it has no responsibility in relation to new developments in the private sector. The RPII is concerned with the huge increase in the number of new facilities being established in the private sector especially in the areas of DXA screening, PET/CT and radiotherapy. As the competent authority for the legislation implementing Council Directive 96/29/Euratom, the RPII is responsible for the regulation of facilities and equipment (workers and members of the public) but not patients or clinical procedures.

• **Korea:** The Ministry for Health, Welfare and Family affairs and Korea Food and Drug Administration (KFDA) are concerned of the growing medical exposure and have prepared a medical exposure reduction programme. KFDA has assessed patient dose in the medical field and prepared DRL (diagnostic reference level) in diagnostic radiology.

• **Slovakia:** The Public Health Authority performs supervision and participates in the education of medical doctors and health staff who are assisting medical exposure, performs QA and QC programmes and prepares legislation in this area. Legislation background: The Act No. 355 /2007 on protection, support and development of public health (Act on Public Health), Governmental order No. 340/2006 on health protection of individuals against the danger of ionising radiation in relation to medical exposure.

• **Switzerland:** Yes, there were publications noted on this topic. It is also included in the education of future radiologists.

• **Turkey:** Yes. Growing scientific evidence and concerns are also known by the Ministry of Health and there are plans to take actions related to this subject.

• **USA:** There is a general concern among some radiation protection professionals at the state and federal level. The U.S. Food and Drug Administration (FDA) collaborates with the states to administer the Nationwide Evaluation of X-ray Trends (NEXT) programme. FDA is working with the National Electrical Manufacturers Association (NEMA) to promote development of new imaging equipment with dose reducing features. The American College of Radiology has published Appropriateness Criteria to aid physicians in choosing when to prescribe CT and other procedures. EPA is working with other federal agencies to develop new radiation protection guidance on the use of diagnostic and interventional x-ray procedures in federal facilities.

2.2 **Is there a justification requested prior medical exposure? In most currently applied regulations the medical practices need to be justified to gain more benefit than risk while dose limits do not apply)**

• **Australia:** Yes. The radiation medical practitioner must justify and optimise the procedure involving the exposure of the patient to ionising radiation, either for each individual patient or by way of protocols specific for the procedure.

• **Austria:** –

• **Canada:** –

• **Czech Rep.:** Yes, all medical exposures must be justified. In most currently applied regulations, the medical practices need to be justified to gain more benefits than risks while dose limits do not
apply) – this is a principal requirement for the performance of the medical exposure. It is a basic requirement in the international standards – IAEA, EU Directives, which was also implemented in the Czech Atomic Law. There are three levels of justification in the case of medical exposures – the general justification of the use of ionising sources in the medicine – recently, this level is understood as generally agreed – we need these procedures for the adequate and precise diagnosis and the appropriate and effective treatment of a patient. The second level is the justification of certain procedures using the radiation – there of course is always some space for searching of alternative methods. The third level is the justification of the individual exposure – the examination.

- **Finland**: Yes. Justification is required in the Decree of the Ministry of Social Affairs and Health on the medical use of radiation 423/2000. Any new kind of method of examination or treatment causing exposure to radiation or mode of use of radiological equipment shall be shown in advance to be justified before it is introduced for general use. The general justification for an existing method of examination or treatment or mode of use of radiological equipment shall be separately evaluated as necessary when any new significant data are obtained on its efficacy or consequences, or a new alternative method causing lower exposure to radiation becomes available whereby the purpose of the practice may be achieved. Particular attention shall be paid to the justification of a practice involving exposure to radiation when development of a method of examination or treatment involving exposure to radiation is planned or when an alternative method involving lower exposure to radiation becomes available whereby an adequate outcome of examination or treatment may be achieved. If necessary the opinion of the competent ethical committees shall be sought. A physician issuing the referral shall assess the justification for a procedure causing exposure to radiation. For this purpose the physician shall as far as possible procure the necessary information on earlier examinations and treatment, and if necessary shall consult experts before issuing the referral. A physician issuing a referral shall submit the information pertaining to the assessment of justification to the unit responsible for performing the procedure and to a physician issuing a statement. A physician who is responsible pursuant to section 39 of the Radiation Act for a procedure involving exposure to radiation shall be required to verify the justification for the procedure. If, on the basis of his professional knowledge and experience, the said physician does not consider the procedure to be justified, then he or she shall negotiate as necessary with the physician who issued the referral with respect to the factors in the individual case pertaining to the assessment of justification before making a final assessment. If the physician responsible for the procedure involving exposure to radiation thereafter continues to consider that the procedure is unjustified, then the procedure shall not be performed.

- **France**: Yes. Elements of justification must be written down in the letter of demand of the test by the prescriber.

- **Hungary**: According to Decree 31/2001, justification is needed, in particular, prior to all new types of practices involving medical exposure.

- **Iceland**: Yes, there is a request for justification.

- **Ireland**: Yes; this is an explicit requirement of S.I. No. 478 of 2002.

- **Korea**: The justification of medical exposure for a patient has to be carried out by the radiological medical practitioners who are performing the specific objectives of the exposure. The justification of medical use of radiation in diagnostic radiology has to be applied by the radiological medical practitioner under the Medical Service Act and the Health, Welfare and Family affairs Enforcement Ordinance including the optimisation of Radiological Protection.
- **Slovakia:** Yes, justification is requested. We apply the Directive 43/1997/Euratom on health protection of individuals against the danger of ionising radiation in relation to medical exposure.

- **Switzerland:** According to the Swiss legislature justification is requested. In daily medical life however, fulfillment depends on the MD performing the exposure.

- **Turkey:** In general practice, only medical doctors can request for medical radiation exposure and practitioners generally ask for a justification. According to the legislation, medical exposures shall be permitted under the following conditions:
  
  - Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve medical exposure;
  
  - Any medical exposure for occupational, legal or health insurance purposes undertaken without reference to clinical indications is deemed to be not justified unless it is expected to provide useful information on the health of the individual examined or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies;
  
  - Public health screening involving radiological methods is only deemed to be justified if the expected advantages for the individuals examined are sufficient to compensate for the economic and social costs, including the radiation detriment;
  
  - Medical exposures for research purposes cannot be carried out without the suggestions and written approvals of the Ethical Review Committee of the health institutions, and the written consent of the individual on whom the research is to be carried out.
  
  - With the full implementation of EU Directives, justification will be based on legislation of the Ministry of Health and will be mandatory.

- **USA:** Justification is provided by the individual medical facility protocol or healthcare provider, except for mammography for which there is a national strategy. The standard of care in medicine is that any risk to the patient must be justified.

2.3 **Is there any national recommendation (guidance) available for radiological practitioners describing the principles of justification?**

- **Australia:** Yes there is national guidance available. The Code of Practice for Radiation Protection in the Medical Applications of Ionising Radiation is based on the radiological protection principles of justification, optimisation and dose limitation and will (when adopted into legislation) establish the regulatory requirements for the use of ionising radiation in medicine that will, in the context of good practice, ensure that the risks associated with radiation exposure to the patient are optimised and those to staff and other persons are ALARA. The Code will be supplemented by three modality specific Safety Guides (to be published in 2008) providing best guidance in Radiotherapy, Diagnostic and Interventional Radiology, and Nuclear Medicine.

- **Austria:** –

- **Canada:** Available guidance materials for calibration of devices, however not for procedures used in nuclear medicine.
• **Czech Rep.:** There are national standards for the medical procedures using the ionising radiation under the development as required by the legislation (based on the EU Directive no. 97/43 EURATOM). These standards are not specifically focused on the justification. It is always stressed, however, that before referring a patient for an X-ray or nuclear medicine examination alternative methods should be considered (see also EU RP Publication 118 “Referral Guideline for Imaging”\(^{23}\)). This message was also passed to medical practitioners many times in seminars and national conferences. Nevertheless, it is well known that there are still many examinations performed only for the confirmation of the already set up diagnosis. For example, this happens very often when an injury of the head appears. There was a study performed in the 90s in the Czech Republic and it was confirmed that in almost 90% of cases the physician determined the correct diagnosis without an X-ray check. However, the practice is that they want to have also this confirmation for their alibi if necessary.

• **Finland:** Yes. STUK has published guidance especially lately for paediatric examinations together with paediatric radiologists. For general radiology there are referring criteria and some guidance for “good practice” by radiologists. There are also tables of effective doses from most common examinations both on STUK’s web pages and also in hospitals for the use of referring physicians. Documents are available at the moment only in Finnish.

• **France:** Yes, referral criteria for an imaging guide have been established by the professionals (Radiologists and nuclear medicine practitioners).

• **Hungary:** There is no special guidance for practitioners how to justify individual exposures, where case-by-case justification might have been needed. Justification in general is the task of relevant professional societies.

• **Iceland:** No manuals available yet.

• **Ireland:** Yes; the Medical Council has issued a policy on the use of medical ionising radiation.

• **Korea:** The Ministry for Health, Welfare and Family affairs and the Korea Food and Drug Administration (KFDA) have prepared national recommendations of diagnostic reference levels in diagnostic radiology for the optimisation of radiological protection in medical exposure. The KFDA has assessed patient doses in the medical field and prepared guidance for patient dose assessment.

• **Slovakia:** Yes, there are national recommendations (guidance) for example: Guidelines No. 2822/2005 Ministry of Health “For preventive mammography examinations, Guidelines” and Ministry of Health “On radiological protection of patients in computed tomography”.

• **Switzerland:** –

• **Turkey:** There is no such guidance yet, but it will be available by the EU harmonisation.

• **USA:** The aforementioned Appropriateness Criteria issued by the ACR are one example. Since the practice of medicine is regulated by the individual states, there is some variance in the amount of attention given to the justification of procedures. For example, some states have banned opportunistic screening.

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2.4 **Is there auditing of medical exposures? If not, what kind of retrospective control of medical exposures is used to evaluate justifications?**

- **Australia:** Yes. ARPANSA and the States/Territories conduct surveys and oversight of the radiation doses from medical exposures.

- **Austria:** –

- **Canada:** –

- **Czech Rep.:** A regular clinical audit has not yet been performed in the Czech Republic. There is special legislation under preparation which will set up the rules for the clinical audit performance. Last year, there was a pilot programme organised by the Ministry of Health performed only in large state hospitals.

- **Finland:** Yes. Medical exposures are supervised by STUK. Also justification and optimisation of medical exposure is audited on clinical audits by independent auditors.

- **France:** Not so far.

- **Hungary:** Audit or retrospective control of medical exposure after the introduction of a practice has not yet been regulated. There is an estimation of expected medical exposure during the justification process, before the introduction of the practice.

- **Iceland:** No retrospective control to evaluate justification, physicians and other practitioners all have suitable education, including radiological protection.

- **Ireland:** The Health Services Executive has completed a clinical audit of diagnostic facilities throughout the country. Clinical audits will shortly be carried out for radiotherapy and dental facilities. This audit is in fulfilment of the requirements of the 97/49 EURATOM Directive and is being conducted through the use of a self assessment questionnaire.

- **Korea:** The KFDA have measured patient dose in the medical institutions and monitored patient dose in the medical institutions.

- **Slovakia:** Yes, there is. Methodical guidelines for accreditation of inspection bodies No. MSA – I/01/2006 (Slovak national accreditation service). Guidelines of Health ministry for:
  - Quality assurance in radiotherapy – linear accelerators
  - Quality assurance in radiotherapy – high energy photon beams
  - Quality assurance in radiotherapy – brachytherapy
  - Quality assurance in radiotherapy – X-Ray therapy
  - Quality assurance in radiotherapy – radiotherapy simulators
  - Quality assurance in radiotherapy – planning systems for radiotherapy
• **Switzerland**: The Federal Office for Public Health carries retrospective controls in order to limit collective doses.

• **Turkey**: No there isn’t. Also we don’t have a retrospective control but such mechanisms will be planned in the near future.

• **USA**: For mammography, the federal Mammography Quality Standards Act (MQSA) has resulted in regulations covering that procedure that require audits and accreditation of facilities. The NEXT programme described in section 2.1 is a voluntary programme to collect exposure data for specific procedures.

2.5 **Concerning the opportunistic screening, is this a recognised screening category? Is there any national follow-up of these practices? Is there any dosimetric data available?**

• **Australia**: The ARPANSA Radiation Health and Safety Advisory Council have issued a statement on The Use of Radiation in Preventative Medicine. In particular, the issues of un-referred whole body CT body scans and CT cardiac calcium scoring tests are considered.

• **Austria**: –

• **Canada**: –

• **Czech Rep.**: No, it is not recognised in the Czech Republic.

• **Finland**: All kind of screening with medical exposure is controlled by STUK. On regular site visits STUK is supervising medical use of radiation. Opportunistic screening is not allowed.

• **France**: Yes, there are some screenings at the national level (*e.g.*, for breast cancer). No follow up so far in terms of dose.

• **Hungary**: No, opportunistic screening is not a recognised screening category in Hungary.

• **Iceland**: –

• **Ireland**: S.I. No. 478 of 2002 states that health screening programmes shall only be undertaken with the prior consent of the Minister for Health & Children and in accordance with criteria that the Minister, or other nominated persons, may specify. The only authorised screening programme in Ireland is screening for breast cancer (mammography).

• **Korea**: The opportunistic screening such as CT scan has not to be performed often for reduction of medical exposure.

• **Slovakia**: The screening performs only by adopted legislation and the licence issued by Ministry of Health.

• **Switzerland**: –

• **Turkey**: No.
2.6 What are the practices in educating/licensing physicians and other practitioners?

- **USA**: There are no national restrictions on opportunistic screening, but some states have banned it. Some private providers still advertise the availability and cost of various screenings using emotional appeals.

- **Australia**: Physicians are licensed to administer ionising radiation by the relevant radiation regulatory authority. The role of ARPANSA in education in medical radiation issues is stated in the ARPANSA Radiation Health and Safety Advisory Council advice to the chief executive officer. Education activities are also conducted by professional organisations (e.g. Australia and New Zealand College of Radiology, Australia and New Zealand Society for Nuclear Medicine etc).

- **Austria**: –

- **Canada**: Yes, the extensive practice is in place.

- **Czech Rep.**: Only radiological medical practitioners (physicians) are obliged to attend a course in radiological protection and take a special exam organised by the Office. Referring medical physicians and non-radiological physicians (orthopaedic surgeons, cardiologists and others who use ionising radiation sources) will have to attend an e-learning course completed by a test.

- **Finland**: Physicians and other practitioners are educated in organisations supervised by the Ministry of Education. Their qualification is recognised by The National Authority for Medico-legal Affairs under the Ministry of Social Affairs and Health. STUK has given requirements for radiological protection training in ST-Guide 1.74. STUK is controlling supplementary training in radiological protection over a five year period.

- **France**: Initial medical training includes radiological protection. Continuing education training is mandatory with a renewal every 10 years.

- **Hungary**: –

- **Iceland**: Licensing on the basis of formal education and training, is carried out for the use of ionising radiation and inspections of such equipments in health care facilities.

- **Ireland**: The Medical Council and Dental Councils are responsible for the registration of prescribers and practitioners. They are responsible for approving specific training courses and maintaining registers of approved persons.

- **Korea**: Educating/licensing physicians and other practitioners in RP and medical ethics for reducing the patients’ dose of medical exposure. It is obligatory for all practitioners to go through training and additional education.

- **Slovakia**: The Authority shall issue the certificate of competency: for activities leading to irradiation and activities important from the viewpoint of radiological protection.

- **Switzerland**: –

• **Turkey**: In addition to some theoretical courses during their education, they also gain some experience at work before completing their basic or postgraduate training.

• **USA**: Individual practitioners are licensed by the states and there are state requirements for continuing education. Professional organisations can certify individuals. Professional organisations accredit facilities. MQSA programme accredits and certifies mammography facilities and recent law calls for accreditation of facilities providing high tech procedures.

2.7 How is the oversight/regulation of health care facilities being carried out?

• **Australia**: By the radiation regulatory authority for specific practices and State/Territory. The ARPANSA Radiation Health Committee, which includes the State/Territory regulators, deals with radiation issues on a national basis.

• **Austria**: –

• **Canada**: –

• **Czech Rep.**: As far as radiological protection is concerned, all health care facilities using ionising radiation sources must hold a licence issued by the Office and are regulated thereby. Routine/specific or ad hoc inspections are in the place and performed by SUJB inspectors in the frequency related to the potential risk (to patients/staff) concerning particular examination or treatment. These requirements are stipulated by the Atomic Law.

• **Finland**: STUK is the authority for oversight/regulation of health care facilities. STUK issues licences and inspects. Inspections are carried out on site visits. Inspection periods are: radiation therapy 2 y, nuclear medicine and demanding or large use of x-rays 3 y, ordinary or small use of x-rays and veterinary use of x-rays 5 y. Dental use of x-rays is under postal control that is done every 3 years in which also a patient dose is checked by TLD.

• **France**: They are carried out by French Nuclear Safety Authority (ASN) inspectors for radiological protection issues.

• **Hungary**: It is carried out during routine licensing and surveillance activities.

• **Iceland**: –

• **Ireland**: The RPII has responsibilities for the licensing and inspection of all facilities and equipment relating to medical uses of ionising radiation. It is responsible for ensuring that workers and members of the public are adequately protected in accordance with the provisions of Council Directive 96/29/Euratom. Currently the Minister for Health and Children is responsible for the protection of patients under Council Directive 97/43/Euratom, though this responsibility is expected to be transferred to another state agency shortly.

• **Korea**: We will carry out patient dose measurement in health care facilities and guide to apply DRL for patient dose reduction in medical exposure through periodic inspections.

• **Switzerland:** –

• **Turkey:** The Ministry of Health carries out the regulation of health care facilities. In addition, health care facilities using radiation sources are obliged to obtain the licence of the Turkish Atomic Energy Agency (TAEK).

• **USA:** Most health care facilities are required by the states to be accredited by a non-governmental independent accrediting body, known as the Joint Commission. Accreditation is also required by the federal government for health care facilities to be eligible for various national reimbursement programmes such as Medicare and Medicaid. However, for diagnostic x-rays, the accrediting process does not typically evaluate justification of procedures. In nuclear medicine, the administration of radiopharmaceuticals is regulated by the Nuclear Regulatory Commission.
Annex 3

PUBLIC HEALTH JUDGEMENT IN DECISION MAKING BASED ON NEW SCIENTIFIC EVIDENCE

3.1 Does the regulatory body follow up arising scientific issues that may eventually lead to modification of RP criteria in the future?

- **Australia**: ARPANSA, the national regulatory authority, maintains an active interest in the scientific evidence regarding the effects of ionising radiations on humans. A national committee of experts, the Radiation Health and Safety Advisory Council has a mandate to keep abreast of developing issues and report to the CEO of ARPANSA. This input flows into national standards, recommendations and codes of practice.

- **Austria**: Indeed, the Austrian Regulatory body follows such scientific issues in the framework of national and international meetings and conferences, discussions with national and international experts and by reading of new studies.

- **Canada**: Extensive programme covering research – epidemiological studies, contracted research, running own experimental laboratories, testing facilities, funding academic institutions, etc.

- **Finland**: –

- **France**: Yes, ASN is following the international literature.

- **Hungary**: Yes, it should.

- **Iceland**: To follow the international development in this field.

- **Ireland**: Yes.

- **Korea**: Yes. The Korean Regulatory body constantly follows up scientific results or issues that may lead to the modification of radiological protection criteria with consideration to the publications of the International organisation such as IAEA, OECD/NEA, and UNSCEAR, the proceedings to be presented at the international conference, etc.

- **Slovakia**: The regulatory body follows up information on scientific issues, but is relatively passive. We will accept the modification of RP criteria only in case that the EU will implement them.

- **Switzerland**: Yes, they do follow arising issues. The discussion about whether these issues have an impact on RP criteria are held by national (commissions) and international contacts.

- **Turkey**: Yes.

- **USA**: Yes, regulatory bodies follow closely the emerging science. The U.S. Department of Energy (DOE) is funding low dose radiation research at the cellular and sub-cellular levels. Several agencies assist DOE in funding epidemiological studies around the world (e.g., the
Radiological Effects Research Foundation studies in Japan and the Mayak/Techa River studies in Russia).

3.2 If not, is there an appointed (by Regulatory body) academic institution dealing with these issues and providing materials for considerations by RP authorities?

- Australia: –
- Austria: –
- Canada: No, rely on its own resources.
- Finland: –
- France: –
- Hungary: –
- Iceland: –
- Ireland: –
- Korea: There is no official appointed institute being able to provide technical materials for radiological protection by the Regulatory body, but there are several institutes (KINS, Korea Institute of Radiological & Medical Sciences [KIRAMS], Radiation Health Research Institute [RHRI]) which technically support research in the fields related to the radiological protection.
- Slovakia: The regulatory body has not appointed any academic institution.
- Switzerland: In Switzerland, there is the Federal Commission for Radiation Protection and Surveillance of Radioactivity which acts as such a link.
- Turkey: –
- USA: In addition, regulatory bodies rely on the advice of the National Academy of Sciences (NAS), the National Council on Radiation Protection and Measurements (NCRP), along with ICRP and UNSCEAR.

3.3 What is the process of accommodating novel scientific criteria? Does the process solely rely on knowledge and recommendations from international organisations (like UNSCEAR, ICRP, IAEA, etc.)?

- Australia: Officers from ARPANSA maintain an active interest in the work of UNSCEAR, ICRP and IAEA. In addition officers continually review the scientific literature for developments in these areas. However no research is conducted on the effects of radiation.
- Austria: Since Austria is a part of the European Community, it is also part of the Community’s decision-making procedure. Therefore, as soon as the European Community considers novel scientific findings in a Council Directive, this Council Directive will be implemented in the national regulation. In principle, in case of new findings being evident beyond any doubt and an acute need for action is necessary or desirable, the radiological protection authorities would
consider this new scientific evidence in the framework of the periodical inspections of the licensee by adding conditions and/or requirements to the license.

- **Canada:** Yes, particularly ICRP.
- **Finland:** –
- **France:** ASN also takes into account its own expertise or the expertise which can be obtained from Institut de Radioprotection et de Sûreté Nucléaire (IRSN) in learning societies and professionals.
- **Hungary:** The process is relied strictly on international recommendations (either on international organisations like IAEA, ICRP, or on official EU documents).
- **Iceland:** Rely mainly on recommendations from international organisations.
- **Ireland:** By observing recommendations of the ICRP, UNSCEAR as well as those of other academic institutions through relevant legislative processes.
- **Korea:** Based on the finalised recommendations and standards to be published from the international organisations, new scientific criteria are rationally accommodated through considering the situation of domestic regulations, the effect on the related industries, the public acceptance, etc.
- **Slovakia:** There is the obligatory to apply and implement recommendations of international organisations or EU directives as there is no renowned academic institution able to develop own criteria other than those internationally accepted.
- **Switzerland:** It mostly relies on those recommendations and interactions between the different regulatory bodies; basic radiobiological research does not exist in Switzerland anymore.
- **Turkey:** The process has relied on knowledge and recommendations from international organisations.
- **USA:** No, it is not limited to international recommendations. Recommendations from groups such as the NAS, NCRP, American National Standards Institute (ANSI), and the EPA’s Science Advisory Board (SAB) are considered in the process of revising regulations. Recent academic, literature and peer-reviewed publications are also considered during the extensive regulatory revision process.

### 3.4 How is the precautionary principle being taken into account when establishing radiological protection criteria?

- **Australia:** Radiological protection standards and recommendations are based on the LNT hypothesis. In addition the optimisation process for the minimisation of dose is applied to public and occupational exposures. In general radiation risks are managed to a level significantly below other risks to workers and the public.
- **Austria:** –
- **Canada**: RP criteria are adopted from the ICRP recommendations which provide limits and the ALARA principle. Precautionary principle would only be applied in rare circumstances.

- **Finland**: –

- **France**: ASN believes that the RP rules and the corresponding risk analysis already take into account the precautionary principle.

- **Hungary**: Since, according to the Hungarian legislation, there are several different authorities/ministries in charge of different areas and aspects of general RP activities, the very first stage is to agree and “harmonise” the viewpoints of these authorities.

- **Iceland**: As advised by international organisations.

- **Ireland**: It is taken into consideration based on relevant EC directives.

- **Korea**: In the case of RP criteria they are not to be established as such as current issues to require changes of RP criteria on the ongoing scientific controversy in the international organisation or to increase public request (e.g. Naturally Occurring Radioactive Material [NORM] and Technologically-Enhanced Naturally Occurring Radioactive Material [TENORM]) in domestic situations, the Regulatory body optionally legislates for some parts of the methodologies and the criteria restrictively agreed in the international societies. Thereafter, it is possible for the regulatory body to amend them after the new scientific facts are adapted to the international societies and new RP criteria are published to the world.

- **Slovakia**: The modification of RP criteria is accepted only in case that the EU implements them.

- **Switzerland**: –

- **Turkey**: Need further discussion.

- **USA**: LNT and ALARA are the basis for radiation protection programmes. They provide sufficient protection and already have the precautionary principle included.
MANAGEMENT OF INDIVIDUAL DIFFERENCES

4.1 Do you have any examples of situations where a key part of the situation was handling individual sensitivity?

- **Australia:** This issue has never been raised as a concern.

- **Austria:** General answer to “Individual sensitivity”: The question of “Individual radiosensitivity” has not yet been treated in the meaning of the context of this case study. If there are new scientific issues in connection with this question the Regulatory body will follow these new findings by a modification of the national radiological protection legislation. At present, the known risk groups such as children, pregnant women etc. are considered by the radiological protection legislation.

- **Canada:** Research in several related topical areas is being performed.

- **Finland:** General answer to “Individual sensitivity”: Public and work places are well protected according to current legislation and regulatory practices. Answer to 4.1: No. Based on information from radiation therapy, there are no observed effects that can be associated with the individual radio-sensitivity (no late effects, no mission reactions, no gene potentially associated).

- **France:** Yes; there are many patients who suffer from adverse effects after radiation therapy without overexposure.

- **Hungary:** No.

- **Iceland:** General answer to “Individual sensitivity”: We have no examples of such situations and the issue has not been discussed in Iceland. We follow work in this field on the international front.

- **Ireland:** General answer to “Individual sensitivity”: it is considered as an important issue, however there is no testing nor guidance available at the national level.

- **Korea:** General answer to “Individual sensitivity”: follow-up based on individual and voluntary approach. The individual radiation sensitivity is still at the stage of research except for gender (breast cancer of women) and age (high to cause cancer due to early exposure). Hereafter, if it is proceeded and proved to the research of SNP (Single Nucleotide Polymorphism) or epigenetic through epidemiology studies, it is going to be a hot issue. Sometimes one’s suitability for the job leads to the ethic controversy for individual radiation sensitivity. On the other hand, if we know the individual radiation sensitivity, it makes the risk of disease reduce and it is necessary to research. In my opinion it is necessary to evaluate appropriateness for their tasks based on the results confirmed through the epidemiology studies. However, if the situation is recognised by the authority, this approach may change.

- **Slovakia:** There are no examples up to date.
• **Switzerland**: Unfortunately in our field of regulatory responsibility – no. A different issue is of course the patient’s sensitivity in radiotherapy. See 4.9.

• **Turkey**: General answers: No sufficient research or practices on this matter.

• **USA**: For occupational settings, there are special limits for protecting the embryo/foetus of declared pregnant workers. Age dependent factors are included in environmental pathway assessments for emergency exposure scenarios. For example, following a release of radioiodine, regulators would assess whether ingestion of milk is safe for infants and children. At present, routine genetic screening is not used as a tool for radiation protection, in part because the science is not mature. If such tools become available, there are still ethical issues related to privacy rights that must be considered.

4.2 **How did you handle this (particularly with respect to ALARA/optimisation)?**

• **Australia**: In general risks are managed to a level at least an order of magnitude below what would apply to other risks and individual risks to sensitive individuals should be appropriately restricted.

• **Austria**: See 4.1.

• **Canada**: –

• **Finland**: No.

• **France**: So far we have done nothing precise.

• **Hungary**: –

• **Iceland**: See 4.1.

• **Ireland**: See 4.1.

• **Korea**: See 4.1.

• **Slovakia**: The individual sensitivity of any person has not been examined in this context up to date. Special sensitive groups (pregnant women, children) are considered with respect to optimisation in the case of public exposure assessment and public dose control, in medical exposure and in occupational exposure. But there are not any special limits or dose constraints, except of the limit for occupational exposure of pregnant women.

• **Switzerland**: –

• **Turkey**: –

• **USA**: Radiation Protection Professionals are generally trained to handle situations on a case-by-case basis. If a pregnant woman declares her pregnancy, she will likely receive counselling on possible health risks and the Radiation Protection Professional will work with her to optimise her work practices and monitor her exposure to assure she remains below the exposure limits.
4.3 What evidence did you have for judging the sensitivity and how did this affect your handling of the situation?

- **Australia:** Judgements are not based on individual sensitivity.
- **Austria:** See 4.1.
- **Canada:** –
- **Finland:** No evidence; promising field of study, particularly focusing on Ataxia telangiectasia mutated (ATM) heterozygote that shows individual dependency.
- **France:** There was no mistake in the treatment of these patients.
- **Hungary:** –
- **Iceland:** See 4.1.
- **Ireland:** See 4.1.
- **Korea:** See 4.1.
- **Slovakia:** We do not use any evidence on individual sensitivity up to date.
- **Switzerland:** –
- **Turkey:** –
- **USA:** Regulations are written so that it is the woman’s responsibility to inform her employer that she is pregnant. The employer cannot ask her if she is pregnant or treat her as though she is. Age is another individual sensitivity factor that is verified upon employment.

4.4 To your knowledge, what level of individual radio-sensitivity testing is allowed and carried out by (potential) employers?

- **Australia:** None.
- **Austria:** See 4.1.
- **Canada:** –
- **Finland:** No; general health checks are performed specifically for different categories of workers (A, etc.).
- **France:** None so far.
- **Hungary:** No preliminary tests are allowed. Employers do not test individual radio-sensitivity. However, if a person requests, it can be done using cytogenetic and cell biological tests like: in vitro testing of blood lymphocytes; serological testing of antioxidant capacity; in vitro testing of adaptive response capacity of lymphocytes.
Iceland: See 4.1.

Ireland: See 4.1.

Korea: See 4.1.

Slovakia: We do not have information on what level of individual radio-sensitivity testing by employer is allowed, but the individual health data are confidential in general. The employer is informed on medical classification as result of medical surveillance, not on results of examinations in detail.

Switzerland: There seems to be no testing of individual radio-sensitivity carried out by employers in nuclear installations in Switzerland (non-verified information). In the words of the radiological protection legislation any decision should be made according to the actual knowledge of science.

Turkey: –

USA: Not aware of any radio-sensitivity testing being conducted by employers. It is doubtful that this would be legally accepted at the present time. Current court ruling favors the employee’s right to work.

4.5 Is this probabilistic in nature (identifies increased risk) or deterministic (factors currently affected a person’s capacity to do a job)?

Australia: Probabilistic factors.

Austria: See 4.1.

Canada: –

Finland: Subject of scientific clarification.

France: Not known yet.

Hungary: Both, depending on the testing doses applied. Primarily probabilistic (it identifies the risk).

Iceland: See 4.1.

Ireland: See 4.1.

Korea: See 4.1.

Slovakia: –

Switzerland: Rather probabilistic.

Turkey: –

USA: Probabilistic.
4.6 What is the legal situation?

- **Australia**: There are no explicit legal requirements to consider individual sensitivity.
- **Austria**: See 4.1.
- **Canada**: –
- **Finland**: No legislation covering individual sensitivity.
- **France**: So far genetic discrimination is forbidden in France.
- **Hungary**: This issue has not yet been legally regulated in Hungary.
- **Iceland**: See 4.1.
- **Ireland**: See 4.1.
- **Korea**: See 4.1.
- **Slovakia**: There is not any provision on radio-sensitivity testing, in our legislation.
- **Switzerland**: Any situation where radiological protection is concerned, it is mandatory to take actions according to the most up to date scientific knowledge (as reasonably possible).
- **Turkey**: –
- **USA**: Same as comment on 4.4.

4.7 Do other organisations perform this type of testing? (For example, medical or life insurance, population health screening)

- **Australia**: None to our knowledge.
- **Austria**: See 4.1.
- **Canada**: –
- **Finland**: No.
- **France**: To our knowledge, this is not done in France.
- **Hungary**: Tests are used exclusively for medical (preventive or therapeutic) purposes, not for insurance or screening purposes.
- **Iceland**: See 4.1.
- **Ireland**: See 4.1.
- **Korea**: See 4.1.
Slovakia: No they did not, as far as we are informed.

Switzerland: No.

Turkey: –

USA: –

4.8 What is the legal situation related to these test?

Australia: –

Austria: See 4.1.

Canada: –

Finland: Non-existing; the only potential testing can cover general predisposition to carcinogenesis; In Finland there are individual studies addressing families having predisposition to cancer (general, not radiation induced).

France: They can be performed by doctors but not by employers.

Hungary: People working in workplaces with increased levels of radiation must be routinely (annually) subject to medical examinations, that include qualitative and quantitative analysis of blood cells. However, these examinations are not suitable to detect variations in individual radio-sensitivity and thus to screen individuals with an increased risk. Currently, if a person requests a predictive test, the consent of the Ethical Board must be obtained.

Iceland: See 4.1.

Ireland: See 4.1.

Korea: See 4.1.

Slovakia: There is not any provision on radio-sensitivity testing, in our legislation.

Switzerland: –

Turkey: –

USA: –

4.9 Does the medical sector adequately handle individual radio-sensitivity?

Australia: No.

Austria: See 4.1.

Canada: –

Finland: Not focusing on this problem.
• **France:** No.

• **Hungary:** Not at the moment, neither in preventive nor in therapeutic medicine.

• **Iceland:** See 4.1.

• **Ireland:** See 4.1.

• **Korea:** See 4.1.

• **Slovakia:** Individual radio-sensitivity is not handled with special attention currently.

• **Switzerland:** To my knowledge only as far as the patient’s radio-sensitivity is concerned. There are different predictive assays available to improve the effect of radiotherapy while sparing the healthy tissue.

• **Turkey:** –

• **USA:** Somewhat. Women are asked if they are pregnant before receiving an x-ray or radiopharmaceutical. Children are also imaged with different imaging techniques to reduce the amount of exposure, while optimising the image.

### 4.10 If so, how?

• **Australia:** –

• **Austria:** See 4.1.

• **Canada:** –

• **Finland:** –

• **France:** –

• **Hungary:** –

• **Iceland:** See 4.1.

• **Ireland:** See 4.1.

• **Korea:** See 4.1.

• **Slovakia:** –

• **Switzerland:** Cultivate biopsy tissue and define certain cornerstone values like SF₂ (surviving fraction at 2 Gy) or tₚ₀ (potential doubling time). Eventually the testing of gene activities with chips could come into focus.

• **Turkey:** –

• **USA:** See comment in 4.9.
4.11 What further actions (if any) are needed?

- Australia: –
- Austria: See 4.1.
- Canada: –
- Finland: –
- France: –
- Hungary: –
- Iceland: See 4.1.
- Ireland: See 4.1.
- Korea: See 4.1.
- Slovakia: –
- Switzerland: Define the legal boundaries and develop simpler, less time consuming and more inexpensive tests.
- Turkey: –
- USA: –

4.12 Do you feel this is an important issue for radiological protection?

- Australia: No.
- Austria: See 4.1.
- Canada: –
- Finland: It is an important academic issue; once it is scientifically solved, it might become a regulatory issue and then also a public health issue.
- France: Yes.
- Hungary: Not in the range of usual occupational and public doses. It may be an issue in the cases of patients subject to radiotherapy. Radiological side effects could be minimised in that way.
- Iceland: See 4.1.
- Ireland: See 4.1.
- Korea: See 4.1.
• **Slovakia:** Radiological protection based on individual radio-sensitivity will cause some ethical, technical and legal problems. The categorisation of individual radio-sensitivity and their integration into the system of radiological protection will make the system more complicated. One of the proclaimed reasons for the development of the new recommendations has been their complexity. Occupational and public doses are relatively low at present, on a level of a few tenths of the limit in general. It seems that there is still capacity to reduce the doses. If there is a necessity to protect more sensitive groups or individuals, maybe it would be simpler or more effective to reduce the dose limits in general or to establish special limits or dose constraints for well defined (large) groups.

• **Switzerland:** Yes, employers could identify and thereby protect members of sensitive subpopulations before an actual irradiation takes place. Risks could be reduced. There would still be an ethical problem of occupationally “stigmatising” radiosensitive people and excluding them from certain types of work.

• **Turkey:** –

• **USA:** Currently, progress in science/data supporting quantification of individual sensitivities (on a prospective basis) is not developed enough for this to be an issue at the present time. Resolution of any issue relating to individual sensitivity would almost certainly be complex and warrant a major policy debate (notably, beyond RP professionals). Note that in public health terms, regulation tends to be directed to the individual level (as is the system of radiological protection) whereas public health is rather orientated towards the population level.

4.13 If not, why not?

• **Australia:** Present restrictions are very conservative and should adequately protect more sensitive individuals.

• **Austria:** See 4.1.

• **Canada:** –

• **Finland:** –

• **France:** –

• **Hungary:** –

• **Iceland:** See 4.1.

• **Ireland:** See 4.1.

• **Korea:** See 4.1.

• **Slovakia:** –

• **Switzerland:** –

• **Turkey:** –
USA: –

4.14 If so, how do you think it should be handled?

Australia: –
Austria: See 4.1.
Canada: –
Finland: –
France: An international recognition of the reality of hyper sensitivity is needed, especially in radiation therapy.
Hungary: Further research is needed to reveal the limits of essays. Then the essays should be standardised and a quality control mechanism should be introduced.
Iceland: See 4.1.
Ireland: See 4.1.
Korea: See 4.1.
Slovakia: –
Switzerland: Discreetly, but there already are certain tests (e.g. HIV) which have to be handled extremely carefully.
Turkey: –
USA: –

4.15 How do you think the situation will change over time?

Australia: There will be little change in this area in the near future.
Austria: See 4.1.
Canada: –
Finland: Subject of scientific findings.
France: It will change when convincing data are available.
Hungary: Hopefully, in the future the application of predictive tests for patients will become a routine.
Iceland: See 4.1.
Ireland: See 4.1.
• Korea: See 4.1.

• Slovakia: –

• Switzerland: –

• Turkey: While the price for this was in the billions some 10 years ago, it now costs less than half a million. So, in the near future such tests could really become affordable. Improved science and technique could also help. The legal part falls under the protection of personal data, which already is an issue for example with insurances.

• USA: Unclear and will depend on evidence that becomes available. Currently, the evidence base (particularly epidemiological studies) suggests that any effect will be relatively small, certainly at the population level. The implication is that clear findings from low-dose response research will be important. The system of radiological protection/ALARA appears effective in adequately protecting the population at large on an individual basis but results from investigating individual sensitivity might question the protection given by the system for a given individual. As another example, the Clean Air Act gives protection to a certain level for the average individual rather than for each individual. US DOE has an extensive low-dose research programme that includes examination of inter-individual variation in genetics and epigenetics.
Annex 5

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