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# Global Initiative on Radiation Safety in Healthcare Settings

## Technical Meeting Report

15<sup>th</sup> to 17<sup>th</sup> December, 2008  
WHO Headquarters  
Geneva



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**Delegates at the WHO HQ, Geneva during 15<sup>th</sup> to 17<sup>th</sup> December 2008 for the Technical Meeting on the WHO Global Initiative on Radiation Safety in Healthcare Settings**

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## Global Initiative on Radiation Safety in Healthcare Settings Technical Meeting

WHO Headquarters, Geneva  
15 - 17 December 2008

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## Abbreviations

AAPM	American Association of Physicists in Medicine
ACR	American College of Radiology
ACS	American cancer Society
AEC	Automatic Exposure Control
ALATRO	Asociación Latinoamericana de Terapia Radiante Oncológica
AMRO	WHO Regional Office for the Americas
AOSR	Asian & Oceanian Society of Radiology
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ASN	Autorité de Sureté Nucléaire (France)
ASTRO	American Society for Therapeutic Radiology and Oncology
BEIR	Biological Effects of Ionizing Radiation
BfS	Bundesamt für Strahlenschutz (Federal Radiation Protection Agency, Germany)
BIMP	International Bureau of Weights and Measures
BSS	Basic Safety Standards
CCP	Cancer Control Program
CIRSE	Cardiovascular and Interventional Radiological Society of Europe
CRPPH	Committee on Radiation Protection and Public Health
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DIM	Diagnostic Imaging & Medical Devices
DIRAC	Directory of Radiotherapy Centers
DR	Digital Radiology
DR TREN	Directorate General for Energy and Transport
DRLs	Diagnostic Reference Levels
EANM	European Association of Nuclear Medicine
EBM	Evidence Based Medicine
EC	European Commission
EFOMP	European Federation of Organisations for Medical Physics
EFRS	European Federation of Radiographer Societies
EGPH	Expert Group on Radiation Protection in the context of Public Health
EHT	Essential Health Technologies
EMAN	European Medical ALARA Network
EPA	Environmental Protection Agency (US)
ESR	European Society of Radiology
ESRO	ESTRO School of Radiology and Oncology
ESTRO	European Society of Therapeutic Radiology and Oncology
EU	European Union
Euratom	European Atomic Energy Community
FANC	Federal Agency for Nuclear Control (Belgium)
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration (US)
FDI	World Dental Federation
FIP	International Pharmaceutical Federation
FORO	Ibero-American Forum of Radiological and Nuclear Regulatory Agencies

GAEC	Greek Atomic Energy Commission
GHWA	Global Health Workforce Alliance
GMP	Good Medical Practice
GI	Global Initiative
GP	General Practitioner
HIS	Hospital Information System
HPA	Health Protection Agency (United Kingdom)
HQ	Head Quarters
HSE	Human Security and Environment
HSS	Health Systems & Services
IAEA	International Atomic Energy Agency
IAP	International Action Plan
IARC	International Agency for Research on Cancer
ICRE	International Commission on Radiological Education
ICRP	International Commission on Radiation Protection
ICRU	International Commission on Radiation Units and Measurements
ICSU	International Council for Science
IEC	International Electrotechnical Commission
IHE	Interventions for Healthy Environments
ILO	International Labour Office
IMRT	Intensity-Modulated Radiation Therapy
INCTR	International Network for Cancer Treatment and Research
INES	International Nuclear Event Scale
IOMP	International Organization of Medical Physicists
IR	Ionizing Radiation
IRA	Institut universitaire de radiophysique appliquée (Switzerland)
IRPA	International Radiation Protection Association
IRQN	International Radiology Quality Network
IRSN	Institut de Radioprotection et Sureté Nucléaire (France)
ISO	International Organization for Standardization
ISOE	Information System on Occupational Exposure
ISR	International Society of Radiology
ISRRT	International Society of Radiographers and Radiological Technologists
IUPESM	International Union for Physical and Engineering Sciences in Medicine
JASTRO	Japanese Society of Therapeutic Radiology and Oncology
KM	Knowledge Management
MDCT	Multi-Detector Computed Tomography
MoH	Ministry of Health
MRI	Magnetic Resonance Imaging
MS	Member States
NAHU	Division of Human Health, IAEA
NCI	National Cancer Society
NCRP	National Council on Radiation Protection & Measurements (US)
NEA	Nuclear Energy Agency
NGOs	Non-Governmental Organizations
NIRS	National Institute of Radiological Sciences (Japan)
NM	Nuclear Medicine
NRC	Nuclear Regulatory Council (US)
NRPA	Norwegian Radiation Protection Authority



NSRW	Division of Radiation, Transport and Waste Safety, IAEA
PACS	Picture Archiving and Communication Systems
PACT	Program of Action for Cancer Therapy
PAHO	Pan American Health Organization
PET	Positron Emission Tomography
PHC	Primary Health Care
PHE	Public Health and Environment
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QM	Quality Management
QUANUM	Quality Assurance for Nuclear Medicine
QUATRO	Quality Assurance Team for Radiation Oncology
RCR	Royal College of Radiology
RIHSS	Research Implications on Health Safety Standards
RIS	Radiology Information System
ROSIS	Radiation Oncology Safety Information System
RP	Radiation Protection
RPoP	Radiological Protection of Patients
RSHCS	Radiation Safety in Health Care Settings
RSM	Radiation Safety & Monitoring
RSNA	Radiological Society of North America
RT	Radiotherapy
SFPM	French Society of Medical Physics
SFRO	French Society of Oncologic Radiotherapy
SIR	Society of Interventional Radiology
SOLACI	Latin American Society of Interventional Cardiology
SPECT	Single Photon Emission Computed Tomography
SSI	Swedish Radiation Protection Authority
STUK	Radiation and Nuclear Safety Authority (Finland)
TECDOCs	Technical Documents
UK	United Kingdom
UN	United Nations
UN/DESA	United Nations Department of Economic and Social Affairs
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
US	United States
WAPS	World Alliance for Patient Safety
WFME	World Federation of Medical Education
WFNMB	World Federation of Nuclear Medicine and Biology
WFPHA	World Federation of Public Health Associations
WG	Working Groups
WHA	World Health Assembly
WHO	World Health Organization
WP	Working Party

# 1. Executive Summary

The last two decades has seen a significant increase in the demand for medical radiation services following the introduction of new techniques and technologies that has led to major improvements in the diagnosis and treatment of human diseases. Inappropriate or unskilled use of these technologies can result in potential health hazards for patients and staff. There is a need to control and minimize these health risks and to maximize the benefits of radiation in medicine.

WHO proposes a **Global Initiative on Radiation Safety in Health Care Settings** to mobilize the health sector towards a safer and effective use of radiation in health care. This initiative aspires to bring together health authorities, international organizations, professional bodies, scientific societies, academic institutions, NGOs and experts in concerted actions to improve the implementation of radiation safety measures in medical settings.

The present report details the discussions, conclusions and recommendations derived from a Technical Meeting on the **Global Initiative on Radiation Safety in Health Care Settings** convened by WHO on 15-17 December 2008. The 67 participants, including experts from 25 MS and representatives from 15 international organizations, professional associations and scientific societies<sup>1</sup>, have agreed to collaborate in this initiative. The global strategy was discussed; main activities were identified under three areas of work: risk assessment, risk management and risk communication; ways for enhancing collaboration and engaging key stakeholders were proposed; and a roadmap was outlined.

The WHO will work with the stakeholders to develop and implement this **Global Initiative on Radiation Safety in Healthcare Settings**, which aligns with the WHO agenda to:

- promote development;
- foster health security;
- strengthen health systems;
- harness research, information and evidence;
- enhance partnerships; and
- improve performance.

## 2. Background

### 2.1 Population exposure and demand for procedures

The medical use of ionizing radiation is by far the largest single contributor to population exposure from artificial sources. Annually worldwide, there are more than 3,600 million X-ray examinations, around 10% of these occur in children, 37 million nuclear medicine and 7.5 million radiotherapy procedures.

Each year about 7 million health workers incur radiation doses attributable to their occupation across the world. Although there is a downward trend in exposure for several groups of workers, the occupational exposure is affecting an increasingly larger number of people, particularly in the medical uses of radiation.

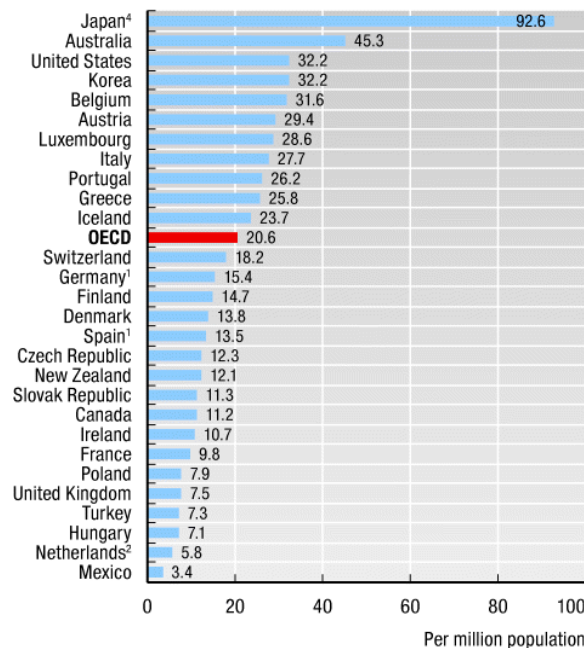
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<sup>1</sup> See list of participants page 81

The use of radiation in medicine has resulted in major improvements in the diagnosis and treatment of diseases. The benefits to patients are enormous. Although the individual cancer risk associated with diagnostic exposures is low, the overall medical exposure is becoming a public health concern due to the widespread use of radiation in healthcare. While new technologies bring in new benefits and modern medical equipment are safer, their inappropriate or unskilled use can lead to health hazards for patients and staff. There is therefore a need to control and minimize the health risks and maximize the benefits of radiation in medicine.

Associated with the introduction of new technologies and the deployment of more resources into healthcare, the access to and the use of radiological medical procedures have increased significantly in industrialized countries and emerging economies. The global expenditure on medical equipment and devices rose from US\$ 145 billion in 1998 to US\$ 220 billion in 2006. These rapid technological advances are providing many new opportunities to improve healthcare. However, considerable inequalities still exist between and within countries. Although the global resource base for health is growing, the health sector remains under-resourced in many countries.

According to the UNSCEAR data, there is much variation between countries in the installation of CT scanners and the number of CT examinations performed each year. For example, the number of CT scanners / million people differs significantly within the OECD countries (Figure 1). The mean frequency of CT examinations in countries with Level 1 healthcare<sup>2</sup> (i.e. > 1 physician / 1,000 people) was 57/1,000 in the 90's and is now over 127/1,000. There is also variation in the number of examinations between these countries which do not correlate well with equipment availability. With the increasing use of multi-detector CT, there is a corresponding increase in the population dose, which could be further compounded by inappropriate use and / or inappropriate exposure settings.



**Figure 1. UNSCEAR survey: number of CT scanner / per million people in OECD countries.** In countries with more than 1 physician / 1,000 people there are 32 CT scanners / million people, while in countries with 1 physician / 1,000 to 3,000 people there are only 3 CT scanners / million people. (Data from 2005 or latest year available).

<sup>2</sup> UNSCEAR: Level I healthcare countries (24% of total) = > 1 physician / 1000; Level II healthcare countries (49% of total) = 1 physician / 1,000 to 3,000; Level III healthcare countries (16% of total) = 1 physician / 3,000 to 10,000; Level IV healthcare countries (11% of total) = < 1 physician / 10,000.

Although radiotherapy is essential for cancer treatment, it is still not widely available for cancer patients in many parts of the world (Figure 2).

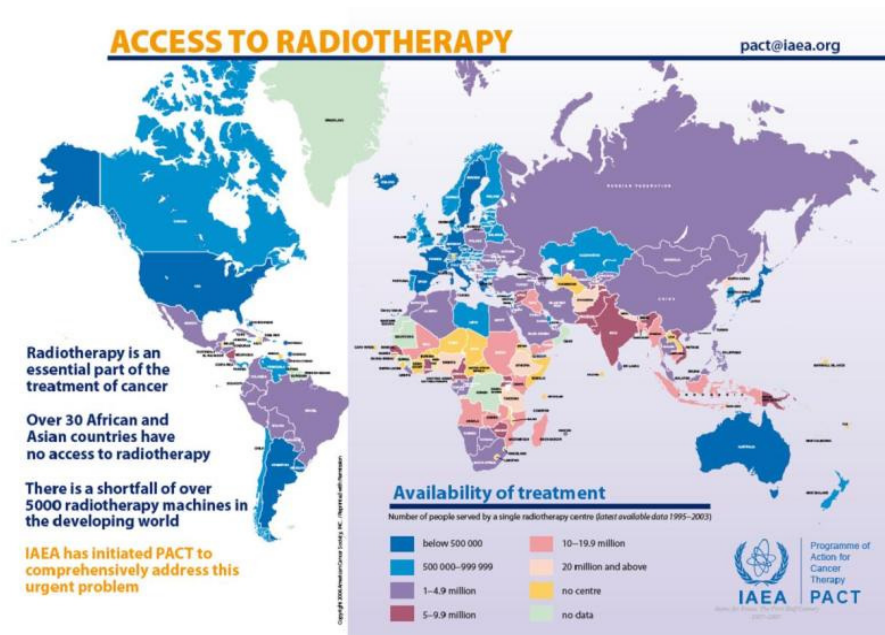


Figure 2. IAEA/PACT data: access to radiotherapy world-wide

## 2.2 Need for united action and collaboration

The increase in demand for and the provision of more radiological medical procedures have resulted in higher population exposure to radiation. In recent years, the world leaders in diagnostic imaging, interventional radiology, radiotherapy and nuclear medicine, international organizations, UN agencies, specialized institutions, professional bodies, academic institutions, scientific societies, experts, and Member States health authorities have developed various initiatives to improve healthcare, patient safety and system sustainability.

Global health is receiving unprecedented attention. There is an increasing interest in united action with emerging signs of willingness from the stakeholders to improve and make the healthcare systems more sustainable. Therefore, this initiative comes at a timely moment to build global partnership towards a safer and appropriate use of radiation in health care.

From time to time, health authorities have to tackle cross cutting issues and develop policies with potential economic and social implications, which could be beyond their competence. There should be a better communication and collaboration between health and non-health sectors (e.g. economics, education, environment and industry) to improve awareness; achieve coordinated actions and better outcomes. This could be achieved by informing each other about the health impacts of their plans and taking appropriate pro-active steps to avoid un-intended consequences when developing these policies. This integrated multi sectorial approach by engaging stakeholders from other non-health sectors is particularly relevant to address radiation safety issues in health care.

The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) are the culmination of enormous efforts over the past decades towards an

international harmonization of norms and standards for radiation protection. The uptake of BSS by the health sector is weak and the engagement of health authorities in BSS applications is still inadequate and insufficient. This is a challenge that requires cooperation between relevant competent authorities at national level (e.g. ministries of health, nuclear regulatory bodies) and concerted efforts at regional and global level (e.g. international organizations, UN agencies, professional bodies, scientific societies).

## **2.3 Issues and Challenges**

There is a range of issues and challenges which impacts on the safe use of radiation in medicine. Some examples of these include: limited data on population exposures, needs of vulnerable groups, fragmented care, unnecessary exposures (inappropriate procedures and/or inappropriate techniques), unintended exposures (errors, incidents, accidents); occupational radiation protection issues; workforce and workload issues (shortage of radiation medicine workers, escalating demand and increasing complexity of care); and restricted healthcare budgets.

### **2.3.1. Population exposures data**

Medical exposures are unevenly distributed in the population, with marked differences between industrialized and developing countries as well as between rural and urban settings. The report from UNSCEAR is the most comprehensive source of compiled information on radiation doses and levels worldwide. However, the data of population exposures from the medical uses of ionizing radiation is mainly available from industrialized countries, while in developing countries this information is scarce. WHO can assist its Member States to conduct appropriate national surveys on the frequency of procedures and patient doses by mobilizing the health sector. This action will improve the available data on dose and risk assessment, by a broader and more effective participation of Member States in these international surveys.

### **2.3.2. Vulnerable groups**

In terms of health risks, medical exposures impact more heavily on certain groups of the population. Children are especially vulnerable due to a higher sensitivity and a longer life-span to develop and manifest long term radiation induced health effects, i.e. cancer. Prevention of unnecessary radiation exposure is therefore critical in paediatric patients by justification of procedures and optimization of doses. Children, young adults and pregnant women should be particularly considered when developing policies to improve radiation safety in healthcare settings. Research focusing in the evaluation of possible health effects following medical exposures early in life should be encouraged.

### **2.3.3. Fragmentation of care**

There is an increasing concern about the fragmentation and over-specialization of healthcare and concerted efforts are needed to maintain and strengthen an informational, relational and managerial continuity of care. Unregulated commercialization of healthcare could: be inefficient and expensive, exacerbate inequality, compromise quality of care and contribute to the perception that health authorities are becoming less capable in protecting the public.

Patients may consult an ever-expanding range of healthcare professionals from a variety of clinics, agencies, practices and organizations, even abroad by telemedicine and health tourism. This is especially the case for those patients with chronic illnesses. They may be referred to frequent or repeat radiological procedures by the different providers involved in their care who are not aware of previous

records. The availability of confidential medical records to the providers with the findings of previous investigations will reduce the number of unnecessary procedures and exposure. This is one of the challenges which need to be addressed.

#### **2.3.4. Justification to tackle inappropriate use**

Countries are increasingly focused in primary healthcare which puts general practitioners (GPs) at the entry point of the healthcare system. It was shown that ambulatory care provided by GPs is: more patient-oriented, more responsive and far cheaper by consuming less resource, than those provided by specialists working from hospitals<sup>1</sup>. It was estimated that a reduction of unnecessary radiological procedures by up to 30% could be achieved by applying referral criteria. This will reduce healthcare cost, population radiation dose, workload, errors and waiting lists.

Referral guidelines and appropriateness criteria are the key tools for justification of radiological medical procedures. Although these guidelines are available in some countries, they are not used by all practitioners. Furthermore, referral guidelines are unknown in many countries around the world. A concerted action is required to provide a common platform to harmonize and disseminate these to the Member States, to promote their adoption/adaptation and to monitor their use. In the preparation of these guidelines, special attention is required to provide recommendations for certain patient groups, e.g. children; as well as to cover opportunistic screening and self-referral issues.

The current environment is conducive to advocate a wider use of these guidelines in healthcare and to emphasize their impact in reducing individual and population radiation dose. Concrete efforts are needed to bridge the gap between guideline publication and their integration into day-to-day practice by developing user-friendly implementation tools in collaboration with the end-users. Although evidence-based medicine cannot by itself ensure effective and safe healthcare, it will assist practitioners in making decisions based on scientific evidence as well as patient values and preferences. Patients should be better informed to provide consent and to share decision making with their doctors, thus requiring the development of suitable communication strategies on radiation risks and benefits.

#### **2.3.5. Optimization to reduce inappropriate techniques**

New technologies acquire images quickly and easily. This could potentially increase patient exposures, if optimization measures are not applied. There is a need to introduce quality assurance programs to improve the quality, safety and effectiveness for the increasingly complex diagnostic and therapeutic procedures. By applying the principle of optimization, the radiation dose to the patient commensurate with the medical purpose. The use of diagnostic reference levels (DRLs) and the minimization of exposures to the non-target volumes in radiotherapy contribute to reduce unnecessary patient exposures.

Computed tomography (CT) is the single most important source of radiation exposures in diagnostic imaging. New technology such as multi-detector CT provides shorter scan times but could result in a larger volume being scanned if optimization technique was not applied. This will lead to a higher patient dose which is critical in children. CT should only be performed in children unless absolutely indicated and be supported by appropriate low dose protocols.

Computed Radiography (CR), Digital Radiography (DR), Picture Archiving and Communication Systems (PACS) and teleradiology are new technologies for diagnostic imaging and their application has significantly increased world-wide in recent years. These new technologies have allowed practices to eliminate x-ray films, to archive and transfer images electronically. Their application has removed some of the traditional

parameters used to monitor exposures: optical density, number of images, collimation etc. They could also significantly increase the patient dose if inappropriately used. Providing guidelines to the Member States addressing a range of subjects including staff training, QA programs etc. will support the introduction of these new technologies and ensure their safer use in radiation medicine.

### **2.3.6. Error reporting systems**

The number of fluoroscopically or CT guided percutaneous interventional procedures has increased significantly world-wide and the range of applications continues to expand. Interventional radiology procedures have significantly improved the management and care of many patients with lower morbidity and fewer complications if appropriately performed. If inappropriate techniques were employed, the skin radiation doses could be so high as to lead to local radiation injuries e.g. burns or more serious health consequences. However, no formal reporting system for these adverse events is in place.

A number of unintended exposures have occurred in patients receiving radiotherapy. Some of these exposures have resulted in severe health consequences and even death. There is a need to harmonize the reporting criteria and event classifications. By providing a blame free environment, error reporting systems can enhance patient safety by informing and educating the stakeholders the reasons for past failures and the control measures for the prevention of future risks. International collaboration in the development and maintenance of incidents and accidents databases should be encouraged. These systems should lead to a constructive response based on an analysis of risk profiles and an assimilation of the lessons learnt.

### **2.3.7. Improve performance by clinical audits**

Internal audits by self-assessment and external comprehensive clinical audits are essential to promote good practice in radiation medicine. For example, clinical audits are useful tools to monitor compliance to the use of justification referral guidelines. Comprehensive clinical audits will improve the quality of radiological services, and minimize future errors and adverse events. Guidance on clinical audits should be developed and provided to the Member States. The health authorities should promote clinical audits to evaluate clinical performance and radiation safety. Means to strengthen the co-operation and coordination between the Ministries of Health and other relevant competent authorities should be explored.

### **2.3.8. Occupational radiation protection**

The radiation dose to radiation medicine workers could be high in some applications, and could even result in deterministic effects if appropriate measures for occupational radiation protection are not implemented. Fluoroscopically guided interventional procedures are used by an increasing number of medical specialities. During their working life, these interventionists could have received radiation doses at which cataracts could develop. New data on the radiosensitivity of the eye with regard to lens opacities and cataract induction are expected. Despite this uncertainty, the focus should be on optimization to protect the workers and to reduce eye exposure.

Molecular imaging technologies, e.g. PET and SPECT could lead to higher exposures to the radiation medicine workers. The concept of biological target volume is used in radiotherapy multimodal planning, involving fused technology (SPECT/CT or PET/CT). The therapeutic applications of radiopharmaceuticals have expanded and new tumor targeting methods have been developed. Despite these benefits, the use of

new technologies in nuclear medicine poses new challenges for radiation protection to both patients and workers.

### 2.3.9. Workforce issues

The health workforce is inequitably distributed throughout the world, between industrialized and developing countries, and between rural and urban settings. There is a global shortage of radiation medicine workers, particularly in low-income countries. There is an increasing migration of experienced healthcare workers into industrialized countries, implying one country's human resources policies will inevitably impact on other countries' healthcare systems.

Significant investment is needed to empower healthcare workers with the required skills, attitudes and professional recognition to ensure safe and effective healthcare. This is particularly critical for workers dealing with radiation. A concerted effort is required to mobilize the responsible institutional players within and across countries, i.e. academic institutions, international societies and health authorities to create new education and training opportunities. These include on-the-job learning through mentoring, coaching and continuing education and changes to the medical and paramedical curricula to enable workers to achieve professional recognition and certification.

There is a need to raise awareness among policy and decision-makers of the need to scale-up the roles of medical physicists, radiographers, radiological technologists and radio-pharmacists, in healthcare. More efforts are required to incorporate, radiation protection topics in medical and public health curricula. Education and training programs will be strengthened by making the best use of the available materials and by developing, adapting and translating training packages as necessary.

## 2.4 WHO response: the Global Initiative in Radiation safety in health Care Settings

The World Health Organization is the coordinating authority for health within the United Nations (UN), with specific mandate on public health. In addition to its headquarters in Geneva, WHO has six Regional Offices and 147 country offices in 159 Member States. This decentralized structure provides WHO with a large network, many opportunities and optimal conditions to work with the health authorities of its 193 Member States.

WHO is responsible for the development of evidence-based public health policy recommendations and for the provision of technical support and capacity building to its Member States in topics related to radiation protection and human health. The promotion of radiation safety culture in the medical community is in keeping with this responsibility.

WHO's vision is the safer and more effective use of radiation in healthcare through good practice promotion and prevention of unnecessary radiation exposures. To achieve this vision, WHO proposes the **WHO Global Initiative (GI) on Radiation Safety in Healthcare Settings (RSHCS)**. This initiative aspires to bring together health authorities, international organizations, UN agencies, specialized institutions, professional bodies, scientific societies, academic institutions, NGOs and individual experts in concerted action to improve implementation of radiation safety standards in medical settings.

WHO convened an Expert Consultancy on 26-27 June 2008 to identify Member States (MS) needs for improving RSHCS and to determine the expected role of WHO to assist countries in meeting those needs.



A panel of experts from 20 countries<sup>3</sup>, FORO<sup>4</sup> and IAEA mapped out MS capacities and needs, identified priorities, and defined key players and roles. There were fruitful discussions focused on how the GI could complement the IAEA International Action Plan for the Radiological Protection of Patients and other international, regional and national actions.

The present report details the discussions, conclusions and recommendations derived from a Technical Meeting on the GI on RSHCS convened by WHO on 15-17 December 2008. Attended by 65 participants, including experts from 26 MS and representatives of 14 international organizations, professional associations and scientific societies<sup>5</sup>, this Technical Meeting was a follow up step to the Expert Consultancy held on June 2008 to advance the development of the WHO GI.

### 3. Opening session

The meeting was opened by Dr. Maria Neira, Director of the Department of Public Health and Environment (PHE), who welcomed and thanked participants for contributing to this initiative aimed to improve radiation safety in health care. Welcome addresses were also delivered by Dr. Steffen Groth, Director of the Department of Essential Health Technologies (EHT) and Dr. Carlos Dora, Acting coordinator of the PHE Unit Interventions for Healthy Environments (IHE).

It was noted that this initiative will contribute to the engagement of the health sector in primary prevention by reducing unnecessary radiation health risks. The GI fits very well with the strategic objectives of WHO's medium-term strategic plan 2008-2013.

Moving from evidence to policy and interventions to promote healthier environments in health care settings, it could be possible to achieve co-benefits impacting on energy and climate change. The health care sector should be transformed, to make it more ecologically sustainable so that it is no longer a source of harm to public health and the environment.

It was highlighted that this initiative will contribute to implement the recommendations contained in the World Health Report 2008, focused on primary health care (PHC), which proposes a set of PHC reforms to address the need for: universal coverage, people-centered services, integration of health in all policies, and strengthened leadership of health authorities.

Following the introduction of participants, Dr. Shengli Niu (ILO), Dr. Hans Ringertz (ISR) and Dr. Jürgen Griebel (BfS; NEA) were elected as Chairs for the sessions of the first, second and third day respectively. The program of work was adopted and Dr. Lawrence Lau accepted the role of Rapporteur of the meeting.

#### 3.1 WHO activities on radiation and health

Dr. Pablo Jiménez (AMRO/PAHO) presented an overview on WHO activities related to radiation and health promoted under various work units, programs, and alliances. These are handled from WHO Headquarters (HQ), the 6 Regional Offices and the International Agency for Research on Cancer (IARC),

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<sup>3</sup> Argentina, Australia, Bahrain, Belgium, Czech Republic, China, Finland, France, Germany, Greece, Ireland, Japan, Norway, Qatar, South Korea, Spain, Sweden, Switzerland, United Kingdom, and United States.

<sup>4</sup> FORO is the Iberian- American Forum of Regulatory Bodies of Argentina, Brazil, Chile, Cuba, Mexico, Spain and Uruguay.

<sup>5</sup> See list of participants page 81

some of them in collaboration with other agencies. The Department of Public Health and Environment (PHE) under the Health Security and Environment (HSE) cluster includes the Interventions for Healthy Environments (IHE) unit, which runs the radiation and environmental health program (RAD). The Department of Essential Health Technology (EHT) under the Health Systems and Services (HSS) cluster includes the Diagnostic Imaging and Medical Devices (DIM) unit. The Cancer Control Programme is run under the Non-communicable Diseases & Mental Health (NMH) cluster. The World Alliance for Patient Safety (WAPS) is connected to the Information, Evidence and Research cluster.

There is a range of challenges in radiation safety and human health. Some countries do not have regulatory authorities to appropriately regulate the medical use of radiation, and some countries which are WHO MS are not MS of the IAEA. There is an alarming shortage of workforce, particularly of radiologists and medical physicists. Potentially unsafe practices could result in radiation risks to patients, staff and the public due to a poorly trained workforce. New technologies are being introduced, raising new safety issues and solutions are required. There is a need to properly tackle issues such as infrastructure, equipment, workforce and QA programs.

#### WHO efforts in radiation health

The WHO tackles these challenges by:

- facilitating the adoption and application of regulations;
- evaluating radiation medicine services comprehensively;
- educating and training the workforce;
- providing advice for the incorporation of appropriate technologies; and
- publishing, co-sponsoring and disseminating guidelines and technical documents.

Promoting the application of the BSS is an essential step. However, countries vary greatly in their infrastructures dealing with regulation in the medical field; health workforce; education & training on radiation protection for diagnostic radiology, interventional radiology, nuclear medicine and radiotherapy. Radiation medicine services may be regulated by radiation / nuclear safety agencies and / or health authorities and cooperation at national level between competent authorities dealing with medical exposures is insufficient. Participation in QA programs is one of the regulatory requirements to ensure radiation safety and to improve clinical outcome.

The WHO undertakes feasibility studies including the planning of services, workforce, budget, maintenance and infrastructure needs to prepare advice to Member States for the incorporation of appropriate technologies. Technical specifications are documented and are ready for the Member States when requested to assist them with the purchase of these equipments. An on-going evaluation of radiological services by the WHO is a very important activity to improve quality, safety and access to these services.

The WHO organizes and promotes QA courses for medical physicists, radiation medicine practitioners, radiological technologists and radiographers worldwide. The WHO Headquarters and its Regional Offices produce and distribute publications in radiation safety and QA manuals in diagnostic radiology, interventional radiology, nuclear medicine and radiotherapy. Translated versions into the local languages are also available. The WHO collaborates and co-sponsor publications with other organizations, e.g. IAEA Safety Report Series. The WHO also distributes scientific publications on behalf of other organizations.

#### Multi-dimensional actions to promote radiation safety

In summary, countries should adopt, apply and monitor the implementation of appropriate radiation safety regulations. There must be a closer relationship between health authorities and other national competent

regulatory authorities. There must be a system of continuous assessment of radiation protection in the medical use of radiation. The application of new and rapidly evolving technologies raises new issues which require solutions. The implementation of QA programs is essential to improve clinical outcome and ensure radiation safety. Measures to address the global shortage of qualified personnel for radiation medicine, particularly of medical physicists and radiologists are needed. Health professionals who are engaged in referring, diagnosis or treatment should be properly and regularly trained in radiation protection.

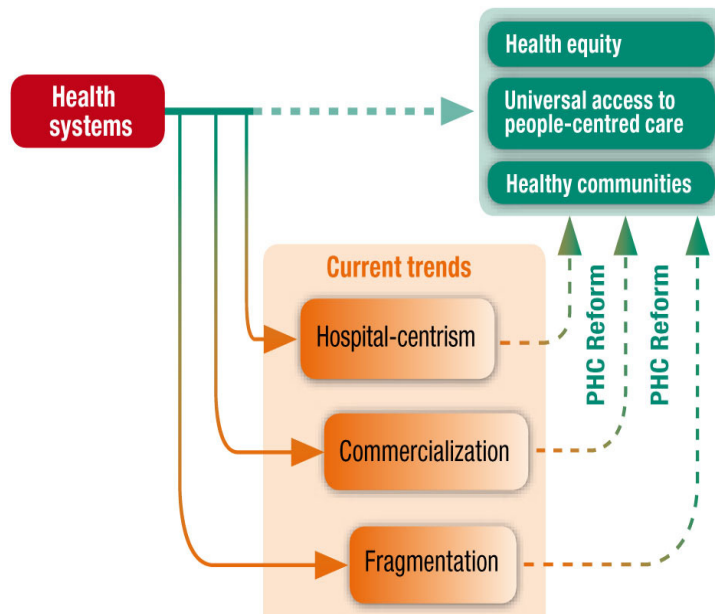
### 3.2 The Global Initiative: concept and proposed strategy

Dr. María del Rosario Pérez (PHE/IHE/RAD) highlighted that in the 2008 World Health Report<sup>2</sup> a set of values and principles were documented to guide the development of healthcare systems. Four sets of reforms are proposed to improve primary healthcare (Figures 3 and 4):

1. universal coverage reforms to improve equity;
2. service delivery reforms to make health systems people-centered;
3. leadership reforms to make authorities more reliable; and
4. public policies reforms to promote and protect the health of communities.



**Figure 3. Primary Healthcare Reform 1.** The primary healthcare reforms necessary to refocus health systems towards better health for all. (WHO World Health Report 2008)



**Figure 4. Primary Healthcare Reform 2.** The current trends in health systems and how the primary healthcare (PHC) reforms can refocus health systems towards better health for all. (WHO World Health Report 2008)

### Radiation and environmental health

Environmental and health issues are closely linked: about one quarter of all diseases in the world and around one third for all childhood diseases could be prevented through available environmental health strategies. There is therefore a need to coordinate international efforts to develop environmental health policies and implement preventive strategies.

In the WHO Medium-Term Strategic Plan 2008 - 2013<sup>3</sup> there are 13 strategic objectives. The strategic objective 8 (SO8) deals with environmental health aiming to promote a healthier environment, to strengthen primary prevention, and to influence public policies in all sectors to address the root causes of environmental threats to health. These environmental threats cover biological, chemical, physical and psychosocial hazards, thus including radiation. One of the current challenges in this area is to ensure a safer and more effective use of radiation in healthcare while reducing unnecessary radiation exposure.

### Radiation safety in healthcare

The use of radiation in healthcare is the main contributor to the exposure of the general population from artificial sources. Access to radiation medicine services and medical radiation exposures are unevenly distributed, with marked contrast between industrialized and developing countries and within these countries.

The numerous recent advances in radiation medicine have delivered enormous benefits to the patients. As new technologies are being introduced, more resources are required by the healthcare systems. The global spending for health is growing rapidly, but the health sector remains under-resourced in many countries. The demand for radiological medical procedures will significantly increase, particularly in industrialized countries and emerging economies.

The safe and effective use of medical radiation is one of the cornerstones for GOOD MEDICAL PRACTICE (GMP). Although an individual's cancer risk associated with diagnostic exposures is relatively low, the medical exposures to the population are becoming a public health concern due to the widespread use of radiation in healthcare. While modern technology brings new benefits and the new medical equipments are much safer, inappropriate or unskilled use can result in potential health hazards for the

patients and workers. There is a need to control and minimize these risks, and maximize the benefits from the use of radiation in healthcare.

### Strategic approach

The Global Initiative aims to improve radiation safety in medical settings by developing and facilitating the implementation of scientific evidence-based policies and recommendations covering diagnostic radiology, interventional radiology, nuclear medicine and radiotherapy; focusing in the public health aspects and considering the risks and benefits of the use of radiation in healthcare.

WHO proposes a multi-sector strategic approach by engaging and collaborating with stakeholders from the healthcare sector and relevant non-health sectors. The initiative's activities will be outcome-driven rather than process-driven. This will be achieved by providing policy recommendations to health authorities and decision makers; and by delivering practical tools to radiation medicine workers to protect patients and workers. The Global Initiative aims to complement the activities under the International Action Plan for the Radiological Protection of Patients and the International Action Plan on Occupational Radiation Protection developed by the IAEA.

A strategic approach adopted by the Global Initiative in tackling risks in radiation medicine is by employing a continuous process of risk assessment, risk management and risk communication (Figure 5).



Figure 5. Strategic approach to tackle radiation risks

### Strategies, issues and activities

Based on this strategic approach, a number of issues are identified under risk assessment, risk management and risk communication (Table 1). Activities will be developed for each of these issues and expected results include: a better understanding of the risks in radiation medicine to underpin policy and decision making; a reduction of unnecessary medical radiation exposures; an enhancement of knowledge, skills and safety attitude of staff; a better prevention of unintended exposures; and an increased awareness of the benefits and risks of the medical use of radiation among the stakeholders.

Strategies	Issues
Risk assessment	Population dose due to the use of radiation in healthcare Research on the health effects of medical radiation exposure, focusing in children
Risk management	Implementation of regulations Reduction of unnecessary medical exposures (justification and optimization). Prevention of unintended exposures, (QA, error reporting) Occupational health Education, training and staffing
Risk communication	Advocacy and communication to provide information and raise awareness

Table 1. Key issues: a range of issues are listed under each strategy

### The Global Initiative process

The Global Initiative will be delivered by a number of steps, to: assess national capacities; identify realistic interventions and targets; agree on priorities; develop activities; agree on the divisions of work, roles and responsibilities between the partners; prepare work plans and timelines; develop strategies to mobilize resources; and agree on indicators to monitor progress and evaluate impact.

As a result of this Technical Meeting and the discussions, the strategy will be consolidated; the activities will be mapped out; gaps, needs, and possible synergies between partners will be identified; and the proposed work plan for 2009 - 2011 will be refined.

### Stakeholder engagement and international collaboration

Advancing radiation protection in medicine is an international effort and requires the involvement of all stakeholders. This collaboration will prevent duplication of efforts and identify overlaps, gaps and needs. Cooperation and concerted efforts will deliver better results.

The Global Initiative will encourage the involvement of stakeholders as partners in activities and / or as end-users of the deliverables e.g. consumers; referrers; providers; payers; regulators; professional, academic, scientific societies; medical defence organizations; international agencies; and equipment manufacturers.

In the Expert Consultation held in June there was an awareness of the key stakeholders involved and the existing efforts in the promotion of safer and more effective use of radiation in a healthcare settings. Those pieces of the "jigsaw" will fall into place as the discussions progress.

### Outlook

Quality improvements in healthcare include efforts in radiation safety. Concerted and coordinated efforts are required to improve radiation safety, quality and sustainability of health systems. Health authorities, relevant competent authorities, policy and decision makers should cooperate and collaborate in this task by identifying and engaging the key stakeholders. From a public health perspective, the impact of the GI will be seen in the long term. Time is needed to promote awareness, to enrol collaboration teams, to develop framework, systems, templates, processes and to trial, implement and refine recommendations. The GI is an opportunity to build a global partnership to shift culture and change practice towards a safer and more appropriate use of radiation in healthcare.

## 4. The role of international institutions

### 4.1 Cooperation with international organizations

#### 4.1.1. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)

Dr. Malcolm Crick (UNSCEAR) apologized for his absence. On his behalf, Dr. Ferid Shannoun (PHE/IHE/RAD) made this presentation based on the power point slides provided by the author.

UNSCEAR is a scientific committee that works in the collection, analysis, publication and dissemination of data on the levels, effects and risks of ionizing radiation affecting the general public, workers and patients. It includes members from 21 UN MS.

#### Population exposure survey

Data concerning radiation exposure is collected from MS by questionnaires and published literature. These include natural and man-made exposures involving public, patients and workers from planned, existing or accidental situations. In healthcare, this information covers the routine and accidental exposures due to diagnostic radiology, nuclear medicine, radiotherapy and biomedical research for patients and workers.

The information is managed and disseminated on a global basis to the UN Assembly, MS policy-makers, the scientific community and the public. UNSCEAR provides scientific data on the effects and risks of radiation exposures to the ICRP to develop recommendations on radiation protection. These recommendations assist the IAEA, WHO, ILO and FAO in the development of norms and standards. UNSCEAR intends to collect new data by 2012 and to analyse global exposures by 2013.

In relation to the collected data, UNSCEAR is considering a range of issues including data ownership, credibility, authorization, quality assurance and sustainability. The organization is developing quality improvement processes in data collection, analysis, publication and dissemination. Some examples include the inclusion, grouping and classification of data; the development of a medical terms glossary and the application of informatics. On data processing, dose calculation directly by UNSCEAR will ensure consistent methodology. A closer liaison with MS will improve data quality, response and completeness. A review of the efforts from and the collaboration with other UN agencies will minimize repetition and duplication.

UNSCEAR encourages the stakeholders to participate, cooperate and provide data; recommends continuing consultations with scientists and experts; and urges the UN Environment Programme (UNEP) to provide support for dissemination of findings.

To summarize, there are many good reasons to collaborate in order to improve data collection, analysis and dissemination. The interested parties will develop common road maps. UNSCEAR fully supports the WHO Global Initiative and looks forward to collaborating on risk assessment by population exposure surveys for the benefits of the constituencies.

#### 4.1.2. International Commission on Radiological Protection (ICRP)

Dr. Eliseo Vaño (ICRP) explained that the ICRP is an international advisory body providing recommendations and guidance on radiation protection. It was established in 1928 by the International

Society of Radiology. The ICRP is involved in the International Action Plan for Radiation Protection of Patients initiated by the IAEA in 2002.

The Commission is supported by five Committees: C1 Radiation effects; C2 Doses from radiation exposure; C3 Protection in medicine; C4 Application of ICRP recommendations and C5 Protection of the environment. Committee 2 is concerned with the development of dose coefficients for the assessment of internal and external radiation exposures. Committee 3 provides recommendations and guidance on radiation protection in the routine use and accidental exposures in diagnostic radiology, nuclear medicine, radiotherapy and biomedical research, addressing both patients and health worker's protection. Committee 3 members include scientific and clinical experts with observers from EC, ICRU, IEC, ILO, UNSCEAR and WHO. Committee 4 provides advice on the applications of the ICRP recommendations for occupational and public exposure. It acts as the major point of contact with other organisations and professional societies. An ICRP Working Party with representatives from C2, C3 and C4 is preparing a report on the use of effective dose, including the approaches in situations for which effective dose is not applicable.

#### Policy recommendations

The ICRP has produced a range of publications and is working on a number of on-going and new documents on radiation exposure, radiation safety, and radiation protection topics for diagnostic radiology, nuclear medicine, radiotherapy and biomedical research.

With respect to the WHO Global Initiative, there are many relevant recommendations produced by the ICRP to improve radiation safety in healthcare, but many stakeholders in the health sector are unaware of their existence. WHO could promote an awareness of these ICRP recommendations and facilitate the dissemination of these documents in the health sector. The ICRP could align more closely with the GI activities when promoting new recommendations.

These include the development of advocacy tools on radiation safety for hospitals; fact sheets on the prevention of unintended exposures; promotion of the use of evidence-based referral guidelines and appropriateness criteria; education and training of health workers; tools for the estimation of the benefits of new technology and its radiation risks and communication strategies.

#### **4.1.3. International Atomic Energy Agency (IAEA)**

Dr. Renate Czarwinski (IAEA Department of Nuclear Safety and Security) explained that the IAEA establishes, in consultation and where appropriate in collaboration with the competent organs of the UN, standards of safety for protection of health and minimization of danger to life and provides for the application of these standards in the field of atomic energy. The Radiation Safety and Monitoring (RSM) section of the IAEA works in the development, publication, dissemination and promotion of radiation safety standards, guides and policy recommendations in radiation medicine.

#### Policy recommendations

The BSS<sup>4</sup> were published in 1996 and are currently being revised and updated. The BSS cover the safety requirements for medical exposures including justification, optimization and the investigation of accidental medical exposures.

The International Action Plan for the Radiological Protection of Patients (IAPRPoP) was endorsed by the MS in 2002. The vision is to coordinate efforts and to provide guidance on the protection of patients. The objective is to achieve progress in RPoP as a whole, when using radiation in medicine. The Steering



Panel members include representatives from other UN agencies (WHO, PAHO, UNSCEAR) and international organizations (EC, ESTRO, ICRP, ICRU, IEC, IOMP, IRPA, ISRRT, ISR, ISO and WFNMB). The IAPRPoP will continue and strengthen efforts in the development of reporting systems and the training of radiation medicine practitioners. It will encourage researches in the evaluation of absorbed dose, optimization of radiation protection, and dose management; and promote the use of referral guidelines and appropriateness criteria. The collaboration with WHO, EC, ICRP and relevant professional bodies is on-going. Networking with and the involvement of technical and scientific support organizations to share experience and lessons learnt from radiation medicine incidents and accidents are encouraged.

#### Occupational health

The RSM section is reviewing the radiation protection guidance for medical workers. A Technical Meeting was attended by 24 participants from 16 countries in 2008. The objective is to identify gaps and needs in radiation protection for medical workers, the guidance and its application; and to recommend to the IAEA on implementation strategies and actions. The recommended actions are to:

- continue the promotion of occupational radiation protection;
- develop guidance on the monitoring of individuals working from more than one facility;
- develop guidance on the monitoring of individuals receiving less than 1 mSv per annum;
- standardize the dose monitoring and the assessment of dose and risk from the dose readings;
- continue the development of training tools and to promote means for training in radiation protection for workers;
- investigate the feasibility for an incident reporting system; and
- interact with clinical end-users and professional organizations.

#### Education and training in justification and optimization

Radiation protection in medicine is underpinned by justification and optimization.

The importance of justification of procedures in reducing radiation exposure in radiation medicine is recognized and there is a need to develop a framework and guidance by: communicating the radiation risks to the public, patients and radiation health professionals to improve awareness; developing and harmonizing referral criteria including alternative options to make these evidence-based; and devising and implementing effective clinical audits to improve compliance. A project on justification started in 2007, the IAEA will develop a report of the findings, guidance is currently under development and the strategy for further steps is being established. The IAEA and EC will organize a workshop on justification during 2009. The role of the WHO would be the dissemination of the results and the communication with stakeholders.

Towards better optimization of radiation medicine procedures, the equipment vendor is one of the key stakeholders to strengthen the radiation safety requirements for equipments. This should be considered in the revised BSS and in future guidance documents. A Technical Meeting involving manufacturers was organized just before IRPA12 Congress in Buenos Aires (October 2008). A project on long-term record of patient dose (Smart Card) has commenced.

The issues and technological challenges relating to the protection of patient undergoing radiotherapy need to be addressed. The intention is to develop actions to keep up with these challenges arising from new technologies and to adopt a prospective approach to minimize risk. The International Conference on "Modern Radiotherapy: Advances and Challenges in Radiation Protection of Patients" to be held in Paris on 2-4 December 2009 is organized by the ASN and jointly cosponsored by EC, IAEA and WHO.

The IAEA produces education material and delivers training activities on optimization of medical exposures: publication entitled "Dose reduction in CT while maintaining diagnostic confidence"; CD and internet based training packages for health professionals; and training courses for cardiologists and medical physicists. The IAEA RPoP website is a global knowledge base and information exchange hub for the stakeholders. The new website to be launched in early 2009 will include an information section for patients.

#### Education in adverse events and errors

Following consultations with the stakeholders and experts, development is underway for an "Educational radiation usage reporting system for fluoroscopic-guided invasive interventional procedures." The system is developed for the reporting of high exposure events in interventional procedures and will feature anonymous reporting; reporting forms; event follow-up and material for the participants. A "Safety reporting system for radiotherapy" will also be developed aiming to avoid the duplication of efforts from other related projects (e.g. ROSIS etc.).

#### WHO participation

The WHO participates in the BSS and IAPRPoP activities. To advance the radiation protection of radiation medicine workers, the WHO with its network of MS health authorities could assist and play a valuable role by disseminating and promoting the implementation of these policy recommendations. Towards the justification and optimization of procedures, the WHO could assist by communicating these messages to the stakeholders and disseminating the results. In promoting the awareness of and learning from adverse events and errors, strong involvement of the WHO and World Alliance for Patient Safety would be welcomed to assist by inviting hospitals to participate in the pilot study and encouraging end-users to use these tools in every day practice.

#### **4.1.4. International Labour Organization (ILO)**

Dr. Shengli Niu (ILO Program on Safety and Health at Work and the Environment) explained that the ILO is a tripartite UN agency which brings governments, employers and workers together to jointly promote decent work throughout the world. Its mandate is to promote social justice and to recognize human and labour rights. The ILO aims to protect workers against sickness, disease and injury as a result of employment. The basic principles in occupational safety and health recognize workers' rights, employers' responsibilities and the role of competent authorities.

There are 4 ILO strategic objectives to promote decent work: to promote and realize standards, fundamental principles and rights at work; to create better opportunities for workers to secure decent employment and income; to enhance the cover and effectiveness of social protection for all; and to deepen tripartism and social dialogue by strengthening the capabilities and knowledge base of the social partners.

#### Policy recommendations

Standard setting is one of the means for the ILO to achieve its objectives and to improve the working conditions of workers. ILO standards are conventions and recommendations adopted by the International Labour Conferences. Many of these standards, guidelines, manuals are related to occupational health and safety. These are developed and published by the ILO or in collaboration with other UN agencies e.g. WHO and IAEA, with employer and worker participation.

Convention 115 (C.115) and Recommendation 114 (R.114) concerned with the protection of workers against ionizing radiation were adopted in 1960. C.115 and R.114 provide the basic principles and framework for the protection of workers. These documents also cover the protective measures required, the monitoring

of radiation dose and the medical supervision of workers. By 2008, C.115 was ratified by 48 countries. MS implement these standards by law, regulation, and code of practice or other appropriate means. The key points in C.115 include:

- Article 1: The protective measures are based on the knowledge available at the time;
- Article 5: The exposure to radiation of medicine workers shall be kept at the lowest practicable level and any unnecessary exposure shall be avoided;
- Article 6: The dose limit for the various categories of workers shall be fixed and shall be kept under regular review;
- Article 7: The dose limit for young workers shall be fixed and workers under 16 are forbidden to undertake work involving ionizing radiation;
- Article 8: An appropriate exposure level shall be fixed for those workers who are not directly engaged in radiation work but who may be exposed to ionizing radiation or radioactive substances;
- Article 9: Appropriate warning devices shall be available in radiation medicine practices to indicate the presence of hazards from ionizing radiation and adequate training and education shall be provided to workers before and during employment;
- Article 10: Establishes a requirement to inform radiation medicine workers of work-related exposures to ionizing radiation in the course of their work; and
- Article 11: Addresses the monitoring of the work environment and the assessment of radiation medicine workers' exposure.

Other ILO Conventions and Recommendations relevant to the radiation protection of workers include: Occupational Cancer Convention C.139 and Recommendations R.147, Working Environment C.148 and R.156, Employment Injury Benefit C.121, and List of Occupational Diseases R.194.

The ILO collaborates with the IAEA in the International Action Plan for Occupational Radiation Protection. The action 14 of this plan was the development of guidance on attributability of detrimental health effects to occupational ionizing radiation exposure and its application in compensation programmes for cancer. This document was jointly produced by ILO, IAEA and WHO and will be published by ILO during 2009. The ILO is collaborating in the revision of the WHO Manual for RP in hospitals. The organization also participates in the Interagency Committee for Response to Nuclear Accidents (IACRNA) and the Interagency Committee on Radiation Safety (IACRS).

#### **4.1.5. Nuclear Energy Agency (NEA)**

Dr. Jürgen Griebel (BfS, Germany) explained that the NEA is an agency within the Organisation for Economic Co-operation and Development (OECD). Its mission is to assist its member countries to maintain and develop, through international co-operation, the scientific, technological and legal bases required for the safe, environmentally friendly and economical use of nuclear energy for peaceful purposes. The NEA is a forum for sharing experience and technical expertise to facilitate the analysis and development of consensus based policies. The NEA's current membership consists of 28 countries from Europe, North America and the Asia-Pacific region.

#### Policy recommendations

The mission of NEA's Committee on Radiation Protection and Public Health (CRPPH) is to identify and analyse emerging issues on radiation protection and to recommend actions to enhance protection regulations and their implementation. The consensus developed by the CRPPH supports the policy and regulation development in member countries to promote good practice. The NEA collaborated with the ICRP in updating the 1990 Recommendations (Publication 60) and provided technical input during the

drafting of the ICRP Publication 103. As one of the cosponsors, NEA is participating in the revision of the BSS.

#### Advocacy and communication

There is a need for a better dialogue between scientists and regulators. There is an increasing trend to adopt a broader view when considering public health risks. The radiation protection objectives and priorities might be addressed differently when social and public health factors are included in addition to scientific considerations. The NEA Expert Group on the Public Health Perspective in Radiological Protection (EGPH) was created to explore this broader "public health perspective" incorporating scientific, social and public health elements.

The EGP has identified a range of areas that could be further explored. These include the management of radon exposures; the justification of medical exposures; the incorporation of emerging science in public health judgements and the management of individual differences. Factors such as age, gender and genetic susceptibility will be taken into account in identifying, assessing and managing public health risks. The rapid advances in technology, differing needs for different countries, varying management and approaches will impact on the justification of medical exposures. Risk management in medical imaging will be based on a detailed assessment of the risks and benefits. The handling of emerging issues such as possible link between vascular disease and chronic lifetime radiation exposures, and the management of scientific uncertainty versus precautionary principle are some of the challenges.

To address emerging challenges in RP the NEA organized a CRPPH workshop on "Science and Values in Radiological Protection", held in cooperation with STUK in Helsinki, Finland, on 15-17 January 2008. The second CRPPH workshop on "Science and Values in Radiological Protection" will be held in cooperation with the IRSN in Vaulx de Cernay, France from 30 November to 2 December 2009.

#### **4.1.6. European Commission (EC)**

Dr. Georgi Simeonov (EC) explained that within the EC, radiation protection matters are handled by unit H4, Directorate H Nuclear Energy, under the Directorate-General for Energy and Transport (DG TREN). The European Atomic Energy Community (Euratom) focuses in the research and development of standards towards a safer and peaceful uses of nuclear energy to protect the workers and the public.

#### Policy recommendations

##### *Euratom Directives*

The Euratom Council has published basic safety standards since 1959. Council Directive 96/29/Euratom provides radiation protection standards for workers and the public. Directive 97/43/Euratom deals with radiation protection in medical exposure. This includes the protection of patients in diagnosis and treatment, occupational health surveillance, health screening, research, medico-legal purposes, and protection of carers and comforters. The key provisions include: justification, optimization, stakeholders' responsibilities, referral criteria, training, equipment, QA, protection of pregnancy, potential exposures and estimation of population doses. As required in Article 31 of the Euratom Treaty, a group of scientific experts attached to the EC have advisory status for elaboration of EU BSS. The article 31 working party on medical exposure is currently chaired by Dr. Eliseo Vañó.

##### *European guidelines on Radiation Protection (RP) in medicine*

These EC guidelines are developed with DG TREN funding, usually following recommendation from the Working Party on Medical Exposure. These guidelines are available on-line<sup>6</sup>. Examples include: RP91 Criteria for acceptability of radiological, radiotherapy and nuclear medicine installations; RP97 Radiation protection following I-131 therapy; RP99 Guidance on medical exposure in research; RP100 Guidance for protection of unborn children and infants irradiated due to parental medical exposure; RP109 Guidance on diagnostic reference levels for medical exposure; RP116 Guidance on education and training on radiation protection for medical exposures; RP118 Referral guidelines for imaging published in 2000, based on guidelines produced by the UK Royal College of radiologists (new update to be launched in 2009); RP136 Radiation protection in dental radiology; and RP154 European guidance on estimating population doses from medical X-Ray procedures. RP "European guidance on clinical audit for medical radiological practices" will be published in 2009.

#### Other DG TREN funded activities

These include two workshops on medico-legal procedure and guidance to be developed; annual scientific seminars of the Research Implications on Health and Safety Standards Working Party (RIHSS WP); and the European Medical ALARA Network (EMAN). EMAN provides a forum for information exchange and development of measures to implement ALARA, especially in the use of CT, interventional procedures and x-ray outside radiology departments.

The Directorate-General of Research manages the budget for research projects funded by the EC. Past Euratom projects included justification, optimisation and development of quality criteria for imaging. In recent years there is an increasing focus in CT. There is little or no research in nuclear medicine and radiation therapy. The EC 7<sup>th</sup> Framework Programme (FP7) provides funding from 2007 to 2013. The Euratom FP7 objectives are to enhance safety and efficacy of medical uses of radiation in diagnosis and therapy (including nuclear medicine) through new technological developments and to achieve a balance between the benefits and risks of radiation. Some Euratom FP7 projects include breast CT; Project SEDENTEXCT (use of cone beam CT in dentistry), Project MADEIRA (Minimizing Activities and Doses by Enhancing Image Quality in Radiopharmaceutical Administration) and Project ORAMED (Optimization of Radiation protection for Medical staff<sup>7</sup>).

#### **4.1.7. Foro Iberoamericano de Organismos Reguladores Radiologicos y Nucleares (FORO)**

Dr. Ana Maria Larcher (FORO) explained that the FORO is an association of Ibero-American Radiological and Nuclear Regulatory Agencies, created in 1997 with the aim to promote the radiological and nuclear safety and security at the highest level in the region. Its members are from Argentina, Brazil, Chile, Cuba, Mexico, Spain and Uruguay.

FORO has commissioned two radiation protection projects. Project 1 is on the "Safety and regulatory control of radiotherapy through the application of risk identification and analysis techniques" and Project 2 is on the "Continuous improvement of the regulatory framework for the control of medical exposure in Ibero-America".

#### Error minimization

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<sup>6</sup> [http://ec.europa.eu/energy/nuclear/radiation\\_protection/publications\\_en.htm](http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm)

<sup>7</sup> <http://www.oramed-fp7.eu>

Project 1 aims to examine the advantages of risk identification and analysis and their impact in improving safety in radiotherapy. Learning from past errors may be not enough to prevent accidents. A proactive approach is adopted to reduce risks arising from radiotherapy regimes employing new techniques and new technologies with increased complexity. This requires a closer attention to details and the application of double-checking measures. In this project, a systematic approach is adopted using two risk analysis methods: Probabilistic Safety Assessments (PSA) and Risk Matrix Assessments (RMA).

#### Regulation implementation

The objectives of Project 2 are to develop practical solutions to improve the efficiency and effectiveness of national radiation protection programs and to enable a continuous improvement of the regulatory processes. The first part involves a comprehensive analysis of the national Regulatory Programs offered by FORO countries, the identification of barriers for radiation protection and the development of solutions. The second part involves the development of self-assessment questionnaires covering the important aspects of the regulatory system which will enable a competent authority to identify its strengths, weaknesses and opportunities for improvement.

The major weaknesses identified so far are: the overlap of responsibilities when there is more than one regulatory agency; the inadequate legal support for some health authorities; the non risk-based approach to authorization and inspection; the reactive approach to policy development and the poor communication strategies by not using the right message, employing the right media or targeting the right audience.

The risk analysis tools for Project 1 and the self-assessment tool for Project 2 will be field tested in the near future in FORO countries and other countries in the region through agreements between the FORO and IAEA.

#### FORO and the Global Initiative

FORO is committed to the promotion of radiological safety and the success of the WHO Global Initiative. FORO could assist by translating radiation protection material and functioning as a link for dissemination of information in the region. Its good working relationship with IAEA and PAHO will enhance this cooperation. The outcomes from the FORO radiation protection projects could also be relevant to some of the Global Initiative's projects.

## **4.2 Perspectives of professional bodies**

### **4.2.1. International Society of Radiology (ISR)**

Dr. Hans Ringertz (ISR) explained that ISR is a confederation of over 80 national radiological societies representing around 280,000 radiologists worldwide. The Executive Committee consists of the office bearers and representatives from continental and national societies. Its mission is defined broadly as education in radiology, the advancement of radiology practice, radiation science and protection. The ISR relates to the WHO, IAEA etc. and hosts the annual World Leadership Council meeting which is attended by key radiological organizations including the ACR, ESR, AOSR, and RSNA etc.

As the leading international professional organization for radiology, the ISR initiated the formation of three other international organizations: the International Commission on Radiological Protection (ICRP); the International Commission on Radiological Units and Measurements (ICRU) and the International Commission on Radiological Education (ICRE).

The ICRP was established in 1928 during the Second Congress of Radiology, as a Commission linked to the ISR. Over time, the ICRP's scope has broadened from radiation protection in medical exposure to all aspects of protection against ionizing radiation. The ISR is an Independent Registered Charity, i.e. a not-for-profit organization.

The ICRU was originally known as the International X-Ray Unit Committee and later as the International Committee on Radiological Units. It was conceived at the 1<sup>st</sup> International Congress of Radiology in 1925 and officially came into being in 1928. The primary objective was to propose a unit for measurement of medical exposure. From 1950 the ICRU expanded its role significantly to embrace a wider field.

#### Education and training

The society has organized International Congresses in Radiology since 1925. In the past decade, the ISR has broadened its efforts beyond congress sponsorship. The International Commission on Radiological Education revived under ICRE chairman, Holger Pettersson. The society emphasizes its liaison efforts with the IAEA, ILO, PAHO, WHO and other international scientific bodies to advance education and training in radiology.

The ISR serves as co-chair together with the WHO in the WHO Global Steering Group for Education and Training in Diagnostic Imaging. This Steering Group was established in 1999 and the overall objective is to coordinate training activities organized by international and regional societies, and to join forces to improve the quality, quantity, and equity of diagnostic imaging services worldwide, but with strong emphasis on countries in most need.

The ISR organizes International Congresses in Radiology which are held every second year in areas of the world where education and training are more necessary. A recent ISR initiative is the ISR Virtual Congress which is freely available through the internet to all participants. This is particularly helpful to those radiologists who could not attend major international meetings. Organized also every second year, more than 5,000 participants have attended, many of whom are from the developing countries.

#### From science to regulations

Scientific evidence and knowledge underpin the development of radiation protection regulations. For example, the data collected, evaluated and disseminated by UNSCEAR, BEIR etc. will enable organizations like the ICRP to develop policy recommendations on radiation protection. These recommendations in turn will assist FAO, IAEA, IEC, ILO, ISO, NEA, PAHO and WHO etc. in the preparation of guidelines and standards, e.g. BSS, industry standards, which will be implemented as regulations by competent health authorities.

The radiologists are the recipients of these recommendations / requirements and the regulators encourage radiologists and referrers to adopt these recommendations / requirements. Such recommendations come from many sources and could result in significant impacts to practice. Despite these implications, there is generally little interest from most radiologists to actively engage in and contribute to the development of radiation protection policies. However, this trend is slowly changing due to new initiatives. Regulators need to cooperate and work jointly to unify the message. This is a team effort requiring contribution and collaborations from all stakeholders. International organizations and agencies should also cooperate.

#### **4.2.2. International Radiology Quality Network (IRQN)**

Dr. Lawrence Lau (IRQN) presented the IRQN, a network for quality in radiology with members from international, continental and national radiological organizations representing radiologists and radiographers. Its objective is to promote quality and safety in radiology through collaboration, experience sharing and mutual assistance.

### International collaboration

The network encourages international collaboration by undertaking activities in quality and safety. These include the Principles for International Clinical Teleradiology, a Performance Metrics Benchmarking Project, a Quality Improvement in Practices Competition, and an Awareness Program. The vision and aims of the WHO Global Initiative align with IRQN's objectives. The network looks forward to collaborating with the WHO and contributing to the initiative.

### WHO Global Initiative

A range of options relating to the development of the initiative was presented. It is possible to achieve a safer use, to reduce unnecessary exposures, to maximize the benefits and to minimize the risks of radiation in medicine by employing good practice, adopting a safety culture and using evidence-based referral guidelines and technique optimization. These aims will be supported by information packages and training tools for the public, referrers and providers and policy recommendations, guidelines and standards for Member State health authorities.

### *Approach*

The initiative will be inclusive and targeted to protect patient, workers and the public and be able to meet the needs of differing economies. The initiative's activities will be comprehensive, integrated, staged and prioritized and the recommendations and tools will be credible, realistic and implementable. The supporting tools will cover communication, implementation and evaluation. Communication will keep the participants and stakeholders up-to-date and will monitor developing trends. The initiative and activities will be evaluated to determine value and effectiveness.

### *Activities*

The initiative will include generic and specific activities, catering for the different disciplines. An analysis of the "patient safety and quality activities map" will identify the radiation risks in the workplace for which radiation protection measures could be developed. The issues, stakeholders and activities can be analyzed in a table to identify possible overlap and synergy opportunities.

### *Deliverables*

The stakeholders will develop the deliverables, i.e. training tools and policy recommendations. The relevant stakeholders and the end-users will be consulted and their feedback incorporated before publication and trial. These drafts will be further refined following the trial prior to their dissemination to Member State health authorities and end-user groups for implementation. The uptake of these tools and policy recommendations will be monitored and on-going improvement measures will be applied.

### *Collaboration*

**Collaboration is strength** and will prevent duplication and re-invention. There are many stakeholders for radiation safety and radiation protection in medicine. These groups have already developed or are in possession of a range of radiation protection resources; e.g. exposure data, education and training material for justification and optimization, radiation protection recommendations, standards and policies. It will be useful to review and identify possible gaps in this existing knowledge base.



To further advance radiation safety and protection worldwide, it is paramount to share and value-add to these experience, resources, and knowledge base and to collaborate in a coordinated way. Collaboration by sharing information and resources will avoid duplication. An inventory of these resources could be developed to provide a useful reference data base.

#### *Funding and supporting infrastructure*

Financial support for the initiative will include WHO funds for the planning and co-ordination and additional funding opportunities from other sources. The initiative's activities could be funded or sponsored by WHO, UN, Member States or NGOs. For example, a participant could select and sponsor an activity relevant to its needs. The initiative's outcomes, experience and know-how will be shared between all participants.

Ideally, the fund-raising activities could be coordinated by a team consisting of WHO working with the local clinical, scientific and technological organizations to approach potential sponsors. There is value for a coordinator to plan, raise, allocate and manage these funds, to ensure accountability.

The initiative's infrastructure could include a management board, a scientific advisory council, expert reference groups, a coordinating team and a coordinator or project manager.

#### *Outlook*

The initiative has a very ambitious scope. It is useful to set a realistic timetable to manage expectations as it is unlikely to achieve tangible changes in the short term. Lead time is required to promote awareness, enroll teams, develop framework, systems, templates and processes, trial projects and implement policies.

The challenges ahead are numerous and include the tight budgetary environment under the current global financial crisis, the turnover of leadership and key personnel, the varying organization readiness and available resources and individuals' workload. However, with determination, commitment and collaboration, the stakeholders are quietly confident that the initiative's objective will be achieved in the coming years.

#### **4.2.3. International Society of Radiographers and Radiological Technologists (ISRRT)**

Dr. Alexandre Yule (ISRRT) explained that the ISRRT was founded in 1962 and its membership is available to national radiographer or radiological technologist societies. Its members come from over 80 countries and it represents over 400,000 individual members. The society is a UK based charity and is an UN recognized NGO. The mission is "to improve the standards of delivery and practice of medical imaging and radiation therapy throughout the world by acting as the international liaison organization for medical radiation technologists and by promoting quality patient care, education and research in the radiation medicine sciences". The ISRRT officially relates to the WHO, IAEA, ICRP, IRPA and IRQN and works closely with PAHO, WHO Regional Offices and other bodies such as ISR. The IRPA and ISRRT leaders met in 2008 and both parties look forward to collaborations towards protecting the community from unnecessary exposure to radiation.

#### Education and training

Together with the IAEA, the ISRRT prepared training material on radiation protection in diagnostic radiology, interventional radiology and radiotherapy. The ISRRT is a member of the WHO Global Steering Group for Education and Training in Diagnostic Imaging and is involved with the setting up of WHO Collaboration Centres to train radiological technologists in Suzuka, Kenya, Uganda, and Fiji. With the WHO, the ISRRT has prepared a series of training manuals. Manuals such as "X-ray equipment

maintenance and repairs workbook" are very useful and form an integral part of the "training the trainers" project. The ISRRT provides text books, printed materials and translations to developing countries and conducts technical seminars and workshops e.g. Botswana, Burkina Faso, Uganda, Cameroon, Fiji, Samoa, Eritrea, Benin, India, Ecuador, Guyana and Guatemala.

#### Advocacy

ISRRT representatives have addressed WHO regional assemblies and individual ISRRT members act as advisors in specific WHO programs. The ISRRT supports developing countries by providing advice to national societies and governmental bodies; and by sending experts to study systems and recommending action plans, e.g. Ghana, Romania and India. In 2007, digital equipment was donated to three Tanzanian hospitals in a pilot project. The hospitals required high quality and high resolution equipment to detect the subtle changes of cancer. However, these installations were not supported by workstations, printers or archiving devices. The images stayed with the digital equipment and could not be distributed. No formal training was given. The lessons learnt from this pilot project are: hands on training, including QA and QC must be provided as soon as possible after installation and equipment specifications must meet local needs. Furthermore, reliable and user friendly equipment should be chosen, if technical support was not readily available, especially in an oncology environment.

As one of the world's leading radiological organization, the ISRRT looks forward to cooperating with WHO in this initiative by informing and educating its members to improve awareness on the safer use of radiation and optimization; supporting the WHO, IAEA, and other organizations in radiation medicine quality and safety activities; extending its advisory role to a larger number of countries; and providing workshops and appropriate training material in conjunction with the WHO and incorporating the experience and knowledge gained from its past activities.

#### **4.2.4. International Organization for Medical Physics (IOMP)**

Dr. Caridad Borrás (IOMP) presented the activities of the IOMP, which began in 1963. It represents over 17,000 medical physicists worldwide, 80 adhering national member organizations and 2 corporate members. The IOMP is a founding member of the International Union for Physical and Engineering Sciences in Medicine (IUPESM). Through IUPESM it is one of the 26 members of the International Council of Scientific Unions (ICSU). IOMP is supported by a Council, an Executive Committee and a range of Committees including Education, Professional Relations, Science and Publications etc.

#### International collaboration

The objectives of the IOMP are to organize international cooperation in medical physics and allied subjects; to contribute to the advancement of medical physics in all its aspects, especially in developing countries; and to encourage and advise on the formation of national organizations of medical physics.

The IOMP cooperates and collaborates with the four regional medical physics organizations and other international agencies, including the WHO, IAEA, ICRP, IRPA, BIPM etc. It provides scientific feedback and expert input on medical physics matters in drafts, reports and consultancies, e.g. ICRP Reports, BSS revision process etc.

IOMP is committed to work with the WHO and IAEA in advancing radiation safety internationally: with the WHO under the World Alliance for Patient Safety Program and the Global Initiative, and with the IAEA under Action Plan for the Radiological Protection of Patients. In order to support the health sector towards the implementation of the BSS it would be really useful to provide guidance on the list of requirements which are applicable in the medical field, not only to those specifically addressed in the

section on medical exposures but also in other sections / chapters of BSS. For the Global Initiative, the IOMP could prepare and distribute guides identifying and listing those BSS requirements which are relevant and applicable to radiology, nuclear medicine or radiation therapy practices.

#### Education and training

The IOMP publishes *Medical Physics World*, *Physics in Medicine and Biology*, *Physiological Measurement*, *Medical Physics* and *Journal of Applied Clinical Medical Physics* and co-sponsors radiation safety and QA publications for diagnostic radiology, interventional procedures and radiotherapy. IOMP organizes, co-sponsors, collaborates, endorses or participates in many international scientific conferences, scientific symposia, educational events and training programs.

The programs for the developing countries include the IOMP/AAPM Library Program with 68 active libraries in 41 countries, the IOMP Equipment Donation Program and the IUPESM Health Technology and Training Task Group.

#### Advocacy

The IOMP maintains an interactive Website. IOMP interacts with the ILO in the reclassification of medical physicist as a health professional<sup>8</sup>. IOMP produced two policy statements on (i) qualification and (ii) education and training of medical physicists. IOMP contributed to the definition of medical physicist in the BSS under revision. The organization is preparing a list of medical physicists who are interested to serve as consultants for specific assignments and conducts professional development symposia for medical physicists.

The World Congress on Medical Physics and Biomedical Engineering will be held in September 2009. A training course on prevention of accidents in radiotherapy will be organized by the IAEA. IOMP invited the WHO to organize an educational event during the meeting.

#### **4.2.5. International Radiation Protection Association (IRPA)**

Dr. Bernard Le Guen (IRPA) noted that IRPA was founded in 1964 as an international health physics organization. IRPA primary purpose is to facilitate communication between the radiation protection stakeholders and to advance the safe use of radiation and radiation protection in science, medicine and industry for the benefit of mankind and environment. It covers the disciplines of science, medicine, engineering, technology and law. The IRPA interacts with international bodies in radiation protection, including governmental, non-governmental and professional organizations.

#### Advocacy and communication

There has been considerable progress in the application of radiation protection in the last 40 years supported by an enthusiastic generation of professionals. It is important to stay vigilant and to maintain these levels of protection so that the tradition will continue in future generations, to avoid losing the RP heritage. We need to root the RP culture as part of the general safety culture in the medical field.

There are many challenging issues for radiation protection, including: the developments and new applications in medicine and nuclear industry; the use of radiation by new players; and the turnovers and retirements of experienced radiation protection stakeholders. A decline in protection will result without proactive strategies. The challenge is to maintain competency, to develop, to continuously improve and to

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<sup>8</sup> S. Niu (ILO) noted this comment which warrants further discussions, and will bring this to the attention of his Director.

implement radiation protection measures under this changing environment. A possible approach is for the users to adopt radiation protection measures as an integral part of the general safety culture.

This strategic approach supports and promotes radiation protection by sharing knowledge and optimizing initiatives to achieve continuous improvements of radiation protection in practices. The culture is based on competency, knowledge, attitude, transparency, and clearly defines stakeholder responsibilities, from workers to regulators.

This radiation protection culture and its values will be developed, shared and handed down to future generations. The underpinning measures to advance this culture will include: 1) the development, standardization and dissemination of teaching tools and materials to support knowledge on quality and safety, technique optimization, risk reduction and best practices; 2) the advocacy for, support, promotion and implementation of a radiation protection culture in the workplace by qualified experts; and 3) the development of implementation strategies by leading organizations such as the IRPA.

These efforts require the commitment from the radiation protection community and will ensure professional credibility. The successful incorporation of this culture will reduce avoidable risks due to uncontrolled or unnecessary exposures. After discussions with other stakeholders, a working group (WG) was established in 2008. The guiding principles on stakeholder engagement were developed and work has commenced to define and develop this radiation protection culture. Professional associations as IRPA should lead and promote such safety culture. Working group meetings are scheduled for the coming three years and the outcomes will be discussed by the IRPA. WHO's contribution to this IRPA WG is strategic to promote radiation safety culture in hospitals. If accepted, these proposals will be further developed into IRPA guidelines.

#### **4.2.6. European Society for Therapeutic Radiology and Oncology (ESTRO)**

Dr. Dag Rune Olsen (ESTRO) explained that ESTRO was established in 1980 to advance all aspects of radiation oncology for its members and the community. Therapeutic Radiology and Oncology used to have an international federation but now these responsibilities are shared by different organizations at regional level e.g. ESTRO, ASTRO and ALATRO.

ESTRO promotes excellence through education, professional development and research. ESTRO focuses in the improvement of patient care and supports the role of radiation oncology in the multidisciplinary treatment of cancer. Its work is supported by a Board and ESTRO Committees covering, Clinical, Physics, Radiobiology, Education and Training etc.

To maximize the benefits and minimize the risks of radiation in radiation oncology, it is important to maintain a balance between local tumor control and radiation-induced adverse side effects. Regarding risk assessment, in addition to the risk of early / late adverse effects of radiotherapy, the risk of radiation induced second cancers should be also considered (i.e. both deterministic and stochastic effects). As cancer treatment outcome has significantly improved, cancer patients tend to live longer. Evidence-based medicine requires randomized trials including risk assessment for second cancers in the long-term follow-up.

IMRT and other complex technologies require good quality management systems. A safe and optimal utilization of radiation in oncology can be achieved by a range of measures. New technology such as CT/PET will identify the cancer target more accurately and new irradiation delivery techniques will deliver a more confined treatment beam, thus reducing the adverse effects. Regarding health technology

assessment, randomized trials are required in a number of countries before using new technology. Evidence-based medicine criteria should be considered for dealing with emerging technology. The undertaking of risk assessment is not as trivial as it used to be for RT patients and should include long term follow up studies. Regarding risk management, a quality management group identifies pitfalls and tools. Clinical audits are proposed not only for reviewing dosimetry but also to delineate target volume and to review the entire chain of the medical practice.

Other measures included in the implementation of risk management interventions are the application of individualized and adapted therapy. Personalized ("tailored") treatment considering patient's sensitivity (e.g. genetic profiles) will contribute in the future to an optimum use of radiation in oncology.

#### Education and training

Other key measures to promote safe and optimal utilization in radiation oncology include the provision of on-going education by continuing professional development, teaching and training courses, scientific conferences; and the development of an accreditation system. ESTRO is an internationally recognized provider of high quality education to meet the need for basic training and continuing professional development in radiotherapy and oncology. The ESTRO School of Radiotherapy and Oncology (ESRO) promotes multidisciplinary education in oncology, with the objective of standardizing knowledge and clinical practice, whilst recognizing the diversity of radiation oncology practice in different parts of the world. ESTRO contributed to the development of a core curriculum for radiation oncologists, medical physicists (in cooperation with EFOMP) and technologists; including the ability to work together as a team and to use a common platform for communication. ESTRO also cooperates with EANM on the education and training on PET for radiation oncologists.

#### Advocacy and communication

The ESTRO Radiotherapy Information Centre is an open access resource with sections for communication with patients, health professionals, journalists and researchers as well as data on cancer and its treatment across Europe. It is important to show the benefits of radiotherapy for cancer patients when addressing radiation safety in this field, and this should be taken into account when considering how to communicate such risks. ESTRO would be happy to contribute to the GI in the area of communication.

It is estimated by 2020, there will be a significant increase in cancer cases in the developing and newly industrialized countries with a corresponding percentage increase in cancer-related deaths. Despite this developing trend, the access to radiation treatment is poor in countries with limited resources. The stakeholders should take note of these two contrasting scenarios: unjustified / unintended medical exposures on the one hand and the poor access to justified radiation exposures on the other. A concerted effort from the stakeholders is required to tackle this challenge of great concern.

#### **4.2.7. Latin American Association of Therapeutic Radiology and Oncology / Asociacion Latinoamericana de Terapia Radiante Oncológica (ALATRO)**

Dr. Miquel Macià (ALATRO) mentioned that ALATRO is an international organization created for the advancement of radiation oncology in Latin America and represents radiation therapy and oncology specialists from the Spanish and Portuguese speaking countries of Central and South America. It was founded in 2005 as the result of merging the CRILA<sup>9</sup> with the Brachytherapy Group.

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<sup>9</sup> CRILA: Circulo de Radioterapeutas Ibero-Latinoamericanos

The organization has concluded reciprocal agreements with ESTRO which provide its members with: 1) on-line access to ESTRO publications, journal and education materials and 2) attendance to ESTRO conferences, courses and other activities at the same cost as ESTRO members. ALATRO has reached an agreement with ASTRO for ASTRO to provide specialized training courses for ALATRO members in various Latin American countries.

ALATRO is developing a certification program for medical specialists, medical physicists, and radiobiological technologists working in radiation oncology facilities in Latin America. The program aims to provide certification to specialists who have achieved specialized training and developed competency levels in radiation oncology at an internationally recognized standard. The second ALATRO congress will be held in Cancun in June 2009.

#### **4.2.8. National Institute of Radiological Sciences, Japan (NIRS)**

Following an invitation to Member States to present their activities, views and perspective, Dr. Keiichi Akahane (Radiological Protection Section NIRS) noted that there are a number of radiation risk assessment works from Japan which will be of interest to the WHO Global Initiative.

##### Population exposure

###### *Paediatric CT exposure*

There are three hospital-based studies on the frequency and/or exposure for pediatric CT in varying stages of development: Nagasaki University, in 2006; Kagoshima University, in preparation and National Center for Child Health and Development, yet to commence. By a review of the medical records, data is collected for: equipment, exposure factors, indication, type of study and irradiated site(s). Based on this data, the organ dose is estimated.

###### *National CT exposure surveys*

There are three national questionnaire surveys on the frequency and/or exposure for CT: National Institute of Radiological Science, in 2004; National Center for Child Health and Development on MDCT, in 2005 and Oita University of Nursing and Health Sciences, in preparation. The preliminary results show a marked increase in the number of whole body studies in recent years with highest number of exposures to patients between 65 to 75 years of age.

##### Research on the health effects of medical radiation

###### *Research on low dose exposure*

Between 2006 and 2011, the NIRS Experimental Radiobiology for Children's Health Research Group will undertake studies on the risks of low dose radiation during fetal and infant periods. These studies will include the assessment of medical exposure to children; the undertaking of animal studies; the analysis of the biological effects and the susceptible windows for leukemia, breast, lung and liver tumors; the assessment of relative biological effectiveness of neutron and heavy ions for fetuses and children; the development of a molecular mechanism of carcinogenesis in fetuses and children; and the undertaking of epidemiological studies. The studies results will be shared with stakeholders in risk communication workshops.

###### *Other epidemiological studies*

A number of other epidemiological studies on the health effects of medical radiation are under consideration: 1) a study of radiological technologists' children by a questionnaire survey; 2) the continuation of a hospital-based case-control study of childhood leukemia in Kagoshima; and 3) a possible collaboration with the national study of 100,000 children and adolescent subjects on the effects of

chemicals and mobile phones by collecting additional data on CT exposure (taken as a potential confounder).

#### Potential Global Initiative activities

In Japan, there are many existing guidelines on medical radiation published by regulatory authorities, academic and professional bodies for diagnostic radiology, nuclear medicine and radiation therapy. To advance radiation safety and radiation protection more efforts are required; for example by: 1) collecting and analyzing CT exposure data, especially for children and applying this information to reduce exposure and advance radiation protection; 2) promoting fundamental (biological) and applied (epidemiological) researches on the health effects of radiation in medicine and 3) developing practice-based protection guidelines employing evidence-based justification, optimization and diagnostic reference levels (DRL).

#### **4.2.9. Q & A: discussion**

The fact that WHO has gathered all these stakeholders around a table showed that WHO is keen to work on this initiative. The stakeholders attended to collaborate and complement each other's efforts and not to compete. It is important to engage the MS because different countries have different strengths. The GI should expand the scope of the target audience to include patients, doctors, and other health workers. In the previous experience in the UK, the NRPB was focused in informing physicists but now HPA has changed the focus to health care providers. The IAEA could address radiation technology and provide the main technical information while others (i.e. WHO, professional bodies) could disseminate that information among the users.

RP officers have a good understanding of the important of RP issues, but the Ministries of Health (MoH) are not engaged enough. In Bahrain, only one officer at the MoH is responsible for RP issues. The GI should approach the MoH and draw their attention to the issues concerned. Furthermore, the provision of radiation services in health care are often by other health workers who are less informed than RP officers.

The Global Initiative could serve as a platform and the stakeholders should start working at different levels, to identify the problems and the priorities. WHO should establish and strengthen the link between the regulatory authorities and the health authorities to (i) disseminate the messages at country level and (ii) translate technical messages into a language which is easily understood by health care providers.

It would be useful to look at the activities listed under "risk management" to identify if some of these are ongoing activities under the IAEA IAP for the RPoP and then, to see how the GI can take these to the health authorities. Based on these activities, the stakeholders could determine which WG are required under the GI. The stakeholders have to define the message and the intended recipient. One option might be to establish individual teams to bring results / products / tools to the end-users in the health care sector.

WHO and ILO collaborations at the global level are necessary. For instance, in some Arabic countries there are regional sections / offices which do not handle radiation safety issues in health care settings. The Global Initiative could improve this situation.

In hospitals, it is important for the staff to be motivated and feel engaged with a RP policy, i.e. strengthening of the RP culture. WHO can approach and mobilize the health sector. When RP efforts are introduced through the hospital's own / natural channels, it will make a huge difference and have a much better impact. Based on the Canadian experience in patient care and patient protection, it is essential to

involve the national professional bodies and health authorities. If the information on radiation doses comes from the health sector the impact will be stronger.

There was a discussion about referral guidelines. It was suggested that if practitioners were unaware of the source of these recommendations, i.e. whether they are from another country; it is not easy to persuade them to adopt and use these guidelines. WHO could assist countries to disseminate, adopt and apply these guidelines. It was noted that most medical practitioner follows the recommendations from its national professional bodies and that it would be helpful for the GI to collaborate with the international professional bodies.

Regarding the UNSCEAR survey the engagement of national health authorities is crucial and they should be the ones to conduct such surveys.

It was highlighted that this GI is unique in terms of gathering so many stakeholders and this is a good start. If there is a wish to change practice, inputs from the stakeholders as well as the regulatory bodies are needed. This was the lesson learned in the UK for referral guidelines. The RCR referral guidelines are evidence-based but all of the stakeholders were involved in the development of the 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> editions and also now in the ongoing 7<sup>th</sup> edition. It was noted that involvement of the manufacturers is necessary but it might be difficult from the point of view of national regulatory bodies.

The view that education rather than regulation will improve safety culture in the health sector was supported by several participants, noting that creating good practice by improving safety culture is more effective than by legal requirements. It was pointed out that radiation safety culture among radiologists comes with experience, and the stakeholders should maintain and strengthen this culture by addressing the next generation to ensure the sustainability of this experience and expertise.

The ESTRO representative informed the delegates of a joint meeting with JASTRO, ALATRO, ESTRO and ASTRO which will be held in May 2009 and that it could be an opportunity to raise awareness about these issues and see how they can contribute on this GI.

The Chairman concluded the discussion highlighting some issues including:

- Qualified professional experts (staffing needs);
- Prevent overlap / duplication;
- Avoid gaps;
- Prioritize tasks;
- Promote collaboration between the international organizations;
- Strengthen WHO's role to address its counterparts at country level (MoH);
- Scale-up the contribution of the professional bodies (to educate practitioners and to advocate the professional agenda); and
- Engage the stakeholders.

## 5. Risk assessment

### 5.1 Introduction

To achieve a safer and appropriate use of radiation in healthcare settings, a range of risk assessment and management measures will be applied. Monitoring population exposure by conducting regular surveys



supports one of the six WHO core functions, namely "monitoring the health situation and assessing health trends".

#### Population exposure from medical use of radiation: trends and tools for estimation

A number of institutions and agencies collect, analyse, and publish data on population exposure, e.g. UNSCEAR, EC etc. These population surveys provide valuable information in the frequency of procedures, annual average effective dose / person, temporal trends etc. for different healthcare levels. Under the Global Initiative, the proposed activities focusing in population dose estimation (Table 2) will include:

Population dose estimation	<ul style="list-style-type: none"> <li>○ Develop tools for population medical exposure estimation;</li> <li>○ Develop and revise questionnaires; and</li> <li>○ Assist Member States to conduct national surveys</li> </ul>
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Table 2. Initial activities proposed for population dose estimation

#### Research agenda: from science to policy and action

Another of the six WHO core functions is "shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge". Under the Global Initiative, the proposed activities dealing with research on the health effects of medical radiation (Table 3) will include:

Setting a research agenda	<p>Promote research on the effects of medical radiation exposure by:</p> <ul style="list-style-type: none"> <li>○ epidemiological research, e.g. paediatric procedures;</li> <li>○ clinical research, e.g. cataract, skin damage; and</li> <li>○ experimental research, e.g. molecular and cellular effects</li> </ul>
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Table 3. Initial activities proposed for research in radiation safety

## **5.2 Population exposure from medical use of ionizing radiation: trends and tools for estimation**

### **5.2.1. Estimating population radiation dose from medical imaging**

Dr. Abbas Aroua (IRA, Switzerland) reminded that UNSCEAR has collected, assessed, published and disseminated data on population exposure from the medical use of ionizing radiation for over 50 years. Data on the EU survey started in the fifties, similarly to UNSCEAR, with a periodicity of around every 10 years. He presented the history of the Dose Datamed Project. In 2002, they compared doses due to medical exposures in Switzerland and Germany (1mSv and 2mSv respectively) and decided to establish an expert group to see why this difference existed. This first EU working group started in 6 countries and then was expanded to 10 countries. The European Working Group on "Population Exposure from Medical X-ray Imaging" reviewed and analyzed data from national population exposure surveys for diagnostic and interventional radiology. The aim was to develop a common approach to the assessment of population exposure. Subsequently, a project was proposed to the EC. The EC Dose Datamed Project (2005-2007) was funded by the DG-TREN to develop a harmonized method on dose data processing for exposures from medical imaging. The Project partners were: Switzerland, Germany, France, Norway, Netherlands, UK, Sweden, Belgium, Denmark and Luxemburg. A review of recent European population exposure surveys from medical use of ionizing radiation was undertaken. Ten countries participated in the diagnostic imaging project and eight in the nuclear medicine project.

The data analyzed included: the range of modalities; the type of examinations; the number of examinations/yr/1000 population and typical dose; the population age and gender profiles; the population

dose and individual dose (microSv/yr); the exposure trends within and between countries; the regional exposure variations; and the medical exposures compare to non-medical exposures. The variation in population exposures probably is due to a combination of differences in: health care systems; equipment availability, especially with CT units; definition of "an examination"; use of referral criteria; non-radiologist doctor as referrer (justification) and provider; reimbursement systems and the extrapolation of exposures from a small sample for the whole country.

As a result of this project, the EC publication "Radiation Protection 154: European guidance on estimating population doses from medical X-ray procedures" was published in 2008. It provided a definition of "an x-ray examination"<sup>10</sup> to assist future surveys. Dose data under low, average and high categories were published under the Datamed Project for plain films, radiography, fluoroscopy, CT and interventional radiology. The survey examined 225 specific examination types and 70 broader examination categories. The "Top 20" examinations which represent 50-70% in terms of frequency and 70-90% in terms of collective dose were identified. The Dose Datamed group will continue as an advisory team.

#### Potential Global Initiative activities

This "Top 20" approach could be adopted by the GI. Under the WHO GI, population exposure surveys will be encouraged at national and regional levels, to be coordinated by national and regional authorities and supported by national and regional professional bodies. Such data provides the scientific basis in assessing risks due to the medical use of ionizing radiation. International agencies such as UNSCEAR, ICRP, IAEA, ILO, NEA etc. and professional organizations will support and address the issues raised by UNSCEAR. Measures will be developed to reduce inconsistencies in future surveys by harmonizing data collection processes and updating the questionnaires.

#### Q & A, discussion

Screening mammography could come under the definition of radiological medical examination since it could be considered that the clinical question is breast cancer. Some X-Ray exams involve high doses, like cardiac CT. This "Top 20" approach will need to be updated as this is an area under continuous development. Cooperation with the IAEA Technical Cooperation projects could be foreseen.

Dr. Jamila Salem Al Suwaidi (Dubai Hospital, UAE) summarized the results of an IAEA Regional Cooperation Project conducted in United Arab Emirates on the monitoring of patient doses for CT and fluoroscopy. The regulators are currently involved in radiation safety in the hospitals. However, to facilitate the implementation of safety standards, WHO should propose regional projects which would include clinical audit and referral criteria.

## **5.3 Research agenda: from science to policy and action**

### **5.3.1. Health effects following medical exposures early in life**

Dr. Ausrele Kesminiene (IARC) stressed that well designed research on the effects of ionizing radiation can provide a scientific basis for developing policies and actions to promote a safer use of radiation in medicine. To maximize the benefits and minimize the risks of radiation, the aim in radiotherapy is to limit

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<sup>10</sup> 'An x-ray examination or interventional procedure is defined as one or a series of X-ray exposures of one anatomical region / organ / organ system, using a single imaging modality (i.e. radiography, fluoroscopy or CT), needed to answer a specific diagnostic problem or clinical question, during one visit to the radiology department, hospital or clinic'.

the exposure to the neighboring tissues while in diagnostic imaging - to use the minimal dose to get a high quality of image.

Several studies have reported an increase in risk for developing a second cancer later in life following ionizing radiation for malignant diseases in childhood and adolescence (e.g. leukemia, breast cancer after Hodgkin disease treatment). Second cancers after radiotherapy mainly occur outside the target volume where the delivered dose is too low to ensure cell killing. In epidemiological studies the use of individual organ doses is absolutely necessary (not "effective doses").

IARC recently has expanded the scope of radiation studies to medical exposures (therapeutic and diagnostic). The *Gene-Rad-Risk* Project studies the impact of the genetic susceptibility on the risk of radiation induced breast cancer following radiotherapy for first cancer or diagnostic imaging early in life. The radiotherapy component of the *Gene-Rad-Risk* Project is a nested case-control study of 600 breast cancers from France, Italy, the Netherlands and UK among women who had radiotherapy for childhood cancers and Hodgkin lymphoma. . Another component of the *Gene-Rad-Risk* Project is a study of 1,300 breast cancer cases from France, the Netherlands and UK in the carriers of BRCA1 or BRCA2 mutation in relation to the exposures from imaging radiation procedures before the age of 35y. These two complementary studies focus on two populations - one with high prevalence of therapeutic radiation exposure, another - known to be highly susceptible to breast cancer. Data collection is nearly complete and the findings could change the management of those patients with potentially higher risks for radiation induced breast cancer, i.e. the carriers of mutations that increase susceptibility to radiation. In such cases, alternative imaging and / or anti-cancer therapy strategies may be required.

There is a concern about the effects of ionizing radiation from diagnostic imaging due to the large number of patients involved. Several studies have demonstrated increased risk for breast cancer in patients who had X-rays for scoliosis or from fluoroscopy. In recent years, the particular concern was raised about increasing use of computed tomography, especially for paediatric patients. Doses from CT are substantially greater than from conventional X-rays. In addition, children are more sensitive to the effects of ionizing radiation, may receive higher doses than adults and have a longer life span to express these side effects. Based on the current usage, it was suggested that 1.5 to 2.0% of all cancers in the USA may be attributable to the ionizing radiation from the use of CT. No large-scale epidemiological studies of cancer risks associated with CT scans have been reported yet.

CHILD-MED-RAD is a Euratom FP7 Project to evaluate the feasibility of establishing a trans-national European cohort of children who had substantial medical diagnostic exposures and who are suitable for a prospective long term follow up study. Substantial exposures from CT, interventional radiology and x-rays in premature babies are included. Three options of possible study design are considered: 1) retrospective study based on electronic records; 2) retrospective study based on electronic images; 3) completely prospective study with full dosimetric information that allows to calculate organ doses for all patients within the cohort. The two first options would require conducting Phase 2 - a nested case-control study, to collect information for more precise estimates of organ and bone marrow dose for individual procedures.

#### Potential Global Initiative activities

To apply knowledge from scientific research on the health effects of ionizing radiation early in life to policy development and implementation, coordinated efforts are needed. These include: promoting research on the effects of ionizing radiation in children undergoing not only CT but also interventional cardiology and in premature babies; undertaking survey and evaluation of patient exposures in various countries and hospitals; inviting collaboration from manufacturers by incorporating exposure parameter

records as an integral part of the equipment design; and enlisting the support from and encouraging the involvement of radiologists.

### **5.3.2. Uncertainty of low dose radiation health effects: need for multi-disciplinary basic research**

Dr. Shunichi Yamashita (Nagasaki University, Japan) addressed the uncertainties on low dose radiation effects and how to challenge those uncertainties. To achieve a safer use of ionizing radiation in healthcare settings, it is useful to build rational risk control measures, policies and regulations from scientific knowledge based on epidemiological studies, clinical research, molecular and cellular radiobiology experiments. In recent years these studies have provided valuable information on: dose-effect relationship; deterministic effect; age dependent effect; direct and/or indirect causes; genetic susceptibility; and combined effects (confounding factors).

CT exams deliver a radiation dose of around 10mSv. The prevention of unjustified use and the reduction of the risks associated with CT are needed. While exposures >1,000mSv will lead to radiation syndrome in the acute stage and exposures 100 to 1000mSv will result in increase cancer risk in the longer term; the health effects from radiation exposures between 10 - 100mSv are uncertain. There is no direct evidence linking low dose exposure to cancer and more multi-disciplinary basic research on this subject is needed.

The ICRP Task Group 1 is currently reviewing the existing evidence on the role of stem cells in cancer induction. It is known that there is an influence of individual radiation sensitivity in the induction of cancer as well as deterministic effects. Molecular and cellular radiobiology studies provide an understanding on the processes of DNA damage by ionizing radiation and the repair responses which are dose dependent. DNA damage can occur even at low doses ~1mSv. The DNA damage repair capacity is high; however some individuals have a higher DNA instability. Radiation damage could cause cell death (apoptosis) or lead to an accumulation of genetic alterations resulting in genomic instability to follow. Non-targeted effects also include bystander effects and adaptive response. Together with other multi-factorial confounders, these radiation induced effects may result in carcinogenesis. However, the effect for low dose radiation is uncertain.

Scientific studies into the health effects from low dose exposure will provide a better understanding of the molecular and cellular mechanisms of cancer induction. This could change risk assessment by identifying those vulnerable groups and radiation susceptible or resistant individuals. This knowledge will improve risk management in clinical practice by preventive action or intervention regarding the use of ionizing radiation in diagnostic imaging and radiotherapy.

#### Potential Global Initiative activities

The Global Initiative could serve as a bridge between radiation science and policy recommendations by developing and recommending scientific evidence-based radiation protection policies; by providing technical support to end-users and by facilitating capacity building on radiation protection in healthcare settings. It will focus in the public health aspect and strike a balance between the risks and benefits from the use of radiation in medicine. The initiative will recognize the important role of radiation science research and encourage multi-disciplinary studies on the radiation health effects arising from low dose exposures, high dose procedures and in vulnerable groups. The challenge is to ensure a safer and more effective use of radiation, to prevent unintended exposures and to reduce unnecessary exposures.

#### Q & A; discussion

Hypersensitivity is an important issue to be considered for risk assessment in medical exposures. Further research is needed in the area of individual radiosensitivity. Based on the experience in France during the

Epinal accident, it is also important to have a better understanding of the prevalence of adverse effects in radiotherapy.

Scientific evidence is essential when dealing with new emerging technology, and assessing the risk of secondary cancers after radiotherapy and with the use of CT.

It would be helpful to establish a working group on research. Funding for research on radiation health effects was limited. Funding for RP is available for fusion / fission projects in EC but not for other areas of research. It is difficult to shape a research agenda. Sometimes it is perceived as a "free enterprise" where regulations and even recommendations are difficult to be followed. However, despite these challenges, it is important to establish a working group on the research on radiation health effects under the GI.

## 6. Risk management

### 6.1 Introduction

Under the Global Initiative, a number of activities concerning risk management are proposed.

#### Preventing unnecessary medical radiation exposure

Unnecessary medical radiation exposure will be reduced by justification and optimization. Evidence-based decision making guidelines are useful tools for justification. The initiative will advocate a wider use of decision making guidelines in healthcare and to raise awareness of their benefits in reducing dose. Concrete efforts are required to bridge the gap between guideline publication and the integration of this into day-to-day practice.

The WHO has published guidelines on rational use of diagnostic imaging many years ago: "A rational approach to radio-diagnostic investigations: report of a WHO scientific group on the indications for and limitations of major x-Ray diagnostic investigations" (1983), "Rational use of diagnostic imaging in paediatrics: report of a WHO study group" (1987), and "Effective choices for diagnostic imaging in clinical practice: report of a WHO scientific group" (1990).

By applying optimization, the minimal appropriate dose is determined by the medical need, the equipment capability and the individual's body size. Diagnostic reference levels (DRLs) are useful tools for optimization in diagnostic applications. However, their usefulness in practice depends on an understanding of their roles, applications and significance. There is a need to strike a balance between patient dose, image quality and diagnostic confidence. The proposed activities to reduce unnecessary medical exposure (Table 4) will include:

Reduction of unnecessary medical exposures	<ul style="list-style-type: none"> <li>○ Promote the use of referral guidelines and appropriateness criteria as justification tools;</li> <li>○ Develop guidance tools on optimization including the use of DRLs;</li> <li>○ Produce a good practice manual on paediatrics CT; and</li> <li>○ Support Member States in the implementation of policies to reduce unnecessary exposures</li> </ul>
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Table 4. Initial activities proposed to reduce unnecessary medical exposures

### Clinical audit in medical radiological practice

Clinical audit is a quality improvement process that aims to improve care and outcomes through a multi-disciplinary structured and systematic review of procedures against good practice criteria and the implementation of corrective actions where indicated. The proposed activities concerning clinical audit and quality improvement (Table 5) will include:

Clinical audit and quality improvement	<ul style="list-style-type: none"><li>○ Develop and disseminate guidance on clinical audit and conducting "train the trainers" activities; and</li><li>○ Support Member States in the implementation of national programs on clinical audit and quality improvement for radiation medicine services</li></ul>
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Table 5. Initial activities proposed to promote clinical audits and quality improvement

### Radiation protection of healthcare workers

The number of workers affected by occupational radiation exposure is increasing, particularly in radiation medicine. About 7 million health workers receive radiation doses attributable to their occupation each year around the world. Occupational exposure for health workers is high in some instances and could result in serious consequences if appropriate radiation protection measures are not implemented. Under the Global Initiative, the proposed activities relating to radiation protection of healthcare workers (Table 6) will include:

Occupational health	<ul style="list-style-type: none"><li>○ Review the occupational health and risk profiles for different work environments, e.g. interventional radiology;</li><li>○ Develop a toolkit on radiation risk management in the workplace; and</li><li>○ Develop and disseminate guidance for occupational health services to protect radiation medicine workers</li></ul>
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Table 6. Initial activities for occupation health of radiation medicine workers

### Scaling-up the role of medical physicists, radiographers and technologists; strengthening education and training

One of WHO's core functions is "providing technical support, catalysing change and building sustainable institutional capacity". Providing appropriate education and training will empower radiation medicine workers with the required skills and attributes to provide safer and more effective healthcare. The initiative will identify new opportunities and apply new approaches to education and training by e-learning, open learning, on-the-job learning, mentoring, and coaching.

It will also lobby academic institutions, international societies and health authorities to include radiation safety, protection, and justification topics in medical and public health curricula. The proposed activities (Table 7) will include:

Resources for radiation medicine workers	<ul style="list-style-type: none"><li>○ Develop a strategy to address the needs of radiation medicine workers, i.e. medical physicists, radiographers and technologists;</li><li>○ Promote sustainability of expertise and develop multi-disciplinary training packages, knowledge transfer, delivery of training, and training models;</li><li>○ Disseminate guidance on RP including the translation of the existing documents or recommendations e.g. ICRP;</li><li>○ Advocate the inclusion of RP topics in medical and public health</li></ul>
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	<ul style="list-style-type: none"> <li>o curricula; and</li> <li>o Foster co-operation between health and nuclear / radiological authorities towards medical education</li> </ul>
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Table 7. Initial activities for to provide resources for radiation medicine workers

### Error reporting systems and classification of events in radiotherapy

There is a need to harmonize the error reporting criteria and classification of adverse events. Error reporting systems can improve patient safety by assisting stakeholders to learn from errors and corrective measures; and to develop a safety culture with a positive approach, without blaming individuals. These systems should be constructive and based on analysis of risk profiles and dissemination of lessons to prevent future errors. WHO launched World Alliance for Patient Safety (WAPS) in 2004 in response to a World Health Assembly Resolution which urged WHO and Member States to pay the closest possible attention to patient safety. WAPS has developed a Technical Manual on radiotherapy risk profile which will be available from the WAPS website in January 2009. Under the GI, the proposed activities relating to the prevention of unintended medical exposure (Table 8) will include:

Prevention of unintended exposures	<ul style="list-style-type: none"> <li>o Harmonize the criteria for error reporting including severity grading scale and taxonomy; analyze the risk profiles and disseminate the lessons learnt;</li> <li>o Support Member States in the prevention of unintended medical exposures by capacity building through education and training</li> </ul>
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Table 8. Initial activities for the prevention of unintended exposures

## 6.2 Preventing unnecessary medical radiation exposure

### 6.2.1. Justification: the value of the Royal College of Radiologists (RCR) Referral Guidelines

Dr. Denis Remedios (RCR, UK) pointed out that the RCR has published referral guidelines: "Making the best use of clinical radiology services" since 1989. These guidelines are updated regularly and provide recommendations to patients, referrers and radiology practitioners on the appropriate use of diagnostic imaging. The 6<sup>th</sup> edition<sup>11</sup> with 315 guidelines was released in 2007 in printed and interactive on-line formats (available within UK). The 7<sup>th</sup> Edition is under development. They improved the level of recommendations with the idea of "Keep it Short and Simple" (KISS). The priorities for recommending an imaging modality were firstly evidence-based diagnostic impact, secondly radiation safety and finally economic impact. Local availability and expertise does not influence the order of recommendations but does influence choice.

The guidelines were developed by 16 expert panels. Following centralized literature searches, an e-mail based Delphi process with a maximum of 3 rounds was used to evaluate the evidence and to achieve agreement. Draft guidelines were strengthened through consultation with over 100 organizations in the UK and Europe.

There is emerging evidence linking an improvement in quality and safety, and a reduction in dose and cost by using referral guidelines. Studies in the UK and USA suggested their use will result in a reduction in inappropriate referrals in the short term. However, other strategies are needed to achieve longer term changes. For instance in the UK the number of requests for lumbar spine radiographs reduced by 13%

<sup>11</sup> Making the best use of clinical radiology services. London: The Royal College of Radiologists, 2007.

using the referral guidelines. But reduction in the request rate found in the early years was not sustained. Without General Practitioners' co-operation it is not possible to succeed. Guidelines that are acceptable to all stakeholders will improve compliance and reduce unnecessary exposures, e.g. the reduction of unnecessary skull X-rays in children following head trauma.

The RCR is actively promoting awareness and the applications of referral guidelines in clinical audits. The RCR runs audit projects, audit poster competition and an audit forum. Of the posters submitted to the Annual Scientific Meeting audit poster competition, 20 audits were based on RCR guidelines. The RCR AuditLive is a web-based resource of guidelines and audit templates to assist individuals and practices to conduct clinical audits.

Effective field-tested implementation strategies are required to maximize the benefits of referral guidelines. Individual guideline-based feedback messages embedded in an x-ray report can reduce inappropriate use by up to 20%. Other approaches aiming to modify clinical behavior by audit and feedback, reminders, and educational outreach; and to make guidelines more specific will improve the outcome. The more precisely behaviors are specified, the more likely they will be carried out.

#### Potential Global Initiative activities

There are challenges to the application of global referral guidelines and solutions are needed. Examples of issues include local applicability, acceptance, distribution, potential abuse by commercial organizations to limit practice and self presentation for screening<sup>12</sup> etc. CT is one of the current challenges, especially with the increasing use of MDCT. It was suggested that the application of guidelines could lead to a potential, but unlikely achievable, dose reduction of up to 44%.

There is a need for the on-going development and regular update of referral guidelines to maximize the benefit and minimize the risks of ionizing radiation in medicine. Field-tested presentation format, distribution, and implementation strategies will enhance uptake and ensure a more sustainable change in clinical behavior in the longer term.

#### **6.2.2. The ACR Appropriateness Criteria**

Dr. Donald Miller (ACR, USA) said that the ACR Appropriateness Criteria started in the 1970s and is a set of evidence-based guidelines to guide referrers, radiologists and radiation oncologists towards an appropriate use of diagnostic imaging and therapeutic techniques. The goals are to improve quality care by doing the right examination the right way for the right reason. These criteria are reviewed annually and the 2008 edition<sup>5</sup> covers over 160 clinical conditions with over 900 variants. Web-based and PDA versions are also available.

There are variations in choosing the most appropriate imaging or treatment technique after considering the patient need, equipment access, expertise, and local protocol. Most referrers wish to do the right thing for their patients. However, insufficient or outdated knowledge for the referrers and the increasing choices in, increasing complexity for and rapidly changing trends in modern imaging could result in inappropriate choices.

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<sup>12</sup> 12th COMARE report. Health Protection Agency for the Committee on Medical Aspects of Radiation in the Environment ISBN 978-0-85951-611-2



The Appropriateness Criteria are supported by 17 Expert Panels: 9 for diagnostic subspecialties and 8 for therapeutic subspecialties covering interventional radiology and radiation oncology. An expert Panel is chaired by an acknowledged expert with 12 members. There is broad representation on the panel, including academic, community practice and non-radiologist representatives. In addition, other specialty societies are invited to send representatives to these panels when indicated.

Clinical topics are chosen by disease prevalence, economic impact and potential for morbidity, mortality and improved care. Criteria are developed employing the principles used by the Institute of Medicine and the Agency for Healthcare Research and Quality. A modified Delphi methodology of 3 voting rounds is used to consider the evidence gathered from a literature review. The decisions are based on scientific evidence and experience. For a clinical condition, different procedures are evaluated and rated for suitability. The procedures are ranked from 9 (most appropriate) to 1 (least appropriate). Relative Radiation Levels (RRL) comparing radiation risk between the techniques was added in the 2008 Appropriateness Criteria. A similar approach is used in UK and Canada.

#### Potential Global Initiative activities

There is evidence supporting the usefulness of referral guidelines in reducing inappropriate requests and in avoiding duplicative examinations. In most practices, radiologists cannot monitor every request before an examination. By integrating appropriateness criteria / referral guidelines into the Radiology Information System (RIS) and Hospital Information System (HIS), the system will identify inappropriate requests and suggest alternatives and more appropriate examinations. After clinical decision support was added to the Massachusetts General Hospital's RIS, the total number of CT decreased and quarterly growth rate also decreased from 3.1% to 0.2%. In an Israeli healthcare program with 1.7 million members, radiologists preauthorize CT and MRI requests using the ACR Appropriateness Criteria and RCR referral guidelines. This has resulted in a 33% decrease in CT and an overall decrease in referral rate, suggesting an educational effect.

#### **6.2.3. Lowering radiation dose delivered with CT**

Dr. Denis Tack (Hôpital RHMS, Belgium) noted that the CT diagnostic reference levels (DRLs) in EU were historically high. Surveys are conducted to define the baseline DRL, and the follow-up survey should show a lower DRL. There is wide variation in international dose surveys due to many factors including the number of examinations, number of acquisitions / examination and dose / acquisition. In 2008, some EU countries still do not have their own DRLs.

The goals for low dose CT were presented. Low dose CT is associated with a dose not higher than that received for plain films for the same condition. The image is noisier, lower in image quality, might have marginal effect on interpretation confidence, but the diagnostic accuracy is preserved. Unless for paranasal sinuses, low dose CT is not used very often. Optimized dose by using the ALARA principle provides adequate image quality without excessive radiation. Standard dose by adopting manufacturer's recommended parameters is often used in practice which could be substantially reduced without compromising image quality.

A DRL is the dose for an examination in a group of standard size patients and for broadly defined types of equipment. Using DRL as a reference and working within these levels will reduce variability; promote good practice and radiation protection in practices. In establishing the optimized dose target, the CT dose index (CTDI) and dose-length product (DLP) are compared with DRL. DRLs are established taking into account the 75<sup>th</sup> percentile. The aim of low dose CT is to reduce CTDI<sub>vol</sub> and DLP values for optimized

dose close to 25<sup>th</sup> percentile while obtaining the necessary information to answer the clinical question. Sometimes the radiographer cannot make this decision.

To promote optimization, support from radiologists, radiographers, physicists and equipment vendors is required. Exposures in MDCT will be lowered by using Automatic Exposure Control (AEC), low kVp, mAs and selection of appropriate image quality index.<sup>6</sup> AEC is important but the user can take additional actions. Using AEC and low dose technique the CTDIvol for abdomen is 3mGy and for chest is 1.5mGy. However, some operators find AEC complex, difficult to understand and to use. It is frequently not used properly or switched off.

The Luxemburg Ministry of Health dose survey in 2007 showed high number of CT examinations, high number of acquisitions / examination and high dose / examination. Expert radiologists attended 8 MDCT departments to discuss and implement optimized protocols and observe compliance. Preliminary results showed a dose reduction by 30 to 64%. It is anticipated the DRL in the 2009 survey will fall by 40% from the 2007 levels. For this project, further dose reduction could be achieved by reducing number of acquisitions and Z coverage (DLP); by tailoring protocol to the problem; and by promoting compliance to guidelines.

#### Potential Global Initiative activities

Optimized dose technique for MDCT can lead to 1/4 to 1/3 of the historic DRL. To achieve this goal, stakeholders should adopt dose target P25, perform annual surveys, and educate providers in optimization techniques by selecting AEC, appropriate kVp, mAs and image quality index settings. For those patients at risk, low dose CT should be promoted which offers adequate image quality; excellent accuracy and delivers dose comparable to a radiographic examination.

#### **6.2.4. Q & A; discussion**

The application of referral guidelines and appropriateness criteria in the private sector was discussed, noting that this sector is driven by commercial needs and financial interests. In the UK there are public and private hospitals with NHS doctors working in both. The experience showed that they can successfully use these guidelines. The use of referral criteria is also helpful for the institutions and serves as a guide to good medical practice.

The importance of feed-back to clinicians was discussed. It was important to involve the referrers from the beginning. It was also suggested that it might be seen as an external control. In the Massachusetts experience, the feed-back was private and not intended as a criticism. This effort was successful in the highest level of practice, but less in the community hospitals.

Surgeons might be reluctant to use guidelines, who very often prefer not to be bounded by protocols. They might feel that they are being questioned as competent physicians and being told what to do. It was noted that the web-based interactive system is good but there is a need to educate GPs rather than forcing them to choose "the correct procedure".

WHO has an important role to play in promoting justification of procedures. As these guidelines are already available, it should now be the GI's task to develop the dissemination and implementation strategies. The challenge today is how to make the referral criteria widely available and used by the clinicians.

Regarding optimization, the stakeholders should consider whether the DRLs should be re-evaluated. Low dose CT is a good example of how the dose can be reduced without losing diagnostic information. There are excellent examples of the application of the low dose approach, but surveys have found that the users did not apply this approach. The challenge today is how to engage the users and convince them to adopt this approach. It was agreed that it is not an individual but a team responsibility to promote optimization in the medical settings.

The work developed by the Image Gently campaign for an appropriate use of radiation in pediatric health care was highlighted. Unnecessary radiation dose can be reduced through actions addressing the:

- Frequency of the exams: to reduce the number of inappropriate exams, education tailoring for the referring clinicians is required. This group of stakeholders was not represented in this meeting and the GI will approach and work with them towards reducing unjustified exposures.
- Radiation dose per exam: to implement effective optimization, concerted efforts from radiologists and radiographers are needed.

The stakeholders need to develop efficient strategies to promote the use of referral guidelines. France distributed referral guidelines to 200,000 GPs. The challenge is not in distribution but their use in practice. Web-based guidelines are very useful but WHO should identify the best way to inform the referrers and encourage them to use these guidelines. In fact, before a GP prescribes a particular drug, the alternative options are considered. A similar system for selecting the most appropriate radiological procedures should be adopted.

The difference between "request" and "order" was noted: GPs and other referrers "request" procedures, accept opinion and / or advice rather than "order" them. The important concept of Good Medical practice (GMP); the responsibility of the health authorities (MoHs) to provide guidance on GMP; and the role of WHO in supporting MS were highlighted.

It was mentioned that the translation of the guidelines into other languages would be helpful. The ACR criteria are freely available in the website only in English but translation into other languages is envisaged, e.g. into Spanish and Portuguese. A relatively simple agreement should be signed for translation.

In Europe, there is a requirement to have referral guidelines, but the EC guidelines are not mandatory for physicians. Their use becomes evident through clinical audits. In the UK, practices are assessed for the use of clinical audits and the application of guidelines. However in other countries (e.g. Bahrain) this would not work unless it is mandatory. This could be a problem for the developing countries and the UK experience is not necessarily universal.

As a relevant international organization, WHO can use its network to disseminate the messages and to provide the application tools.

## **6.3 Clinical audit in medical radiological practice**

### **6.3.1. EC Clinical Audit project**

Dr. Hannu Jarvinen (STUK, Finland) presented this project. Clinical audit is a quality improvement process that aims to improve care and outcomes through a multi-disciplinary structured and systematic review of procedures against good practice criteria / standards and the implementation of corrective actions where indicated.

Article 6.4 of EC directive 97/43/Euratom requires medical radiological practices to conduct clinical audits, with respect to national legislation and administrative provisions. EC members vary in their understanding on, approach to, preparedness for and implementation of clinical audits. The aim of the EC Clinical Audit project is to provide guidance and to assist diagnostic radiology, nuclear medicine and radiotherapy practices to comply with Article 6.4. STUK led the project, which was supported by a consortium of 20 scientific experts from 10 countries with contributions from ESR, EANM, ESTRO, ECRRT, EFOMP and EFRS.

Based on a questionnaire survey of the Member States on various clinical audit elements, "EC Guideline on clinical audit" was drafted. This was discussed in a workshop and revised before submission in December 2008. There is general support on the flexible framework, which is realistic and applicable to EU countries. The EC guideline gives recommendations and it is not a legal requirement.

Clinical audit is a continuous, multi-disciplinary, multi-professional and systematic process aiming to improve patients care, resource use, service provision and professional development. Potential clinical audit topics are grouped under 3 categories: structure (e.g. facilities, equipment, workforce), process (what the staff do) and outcome (end result). Clinical audits are not only for auditing radiation safety aspects but the quality of health care as a whole, where radiation safety is one component. For radiological procedures these audits should consider justification and optimization as well as quality control / quality assurance programs. Evaluation of the treatment outcome i.e. methods for patient follow-up, could also be considered. An audit may be comprehensive or partial; generic or specific for a certain procedure; internal or external. Internal audits (self-assessment) would be a logical first step to start auditing. There is an "audit loop" where both, internal and external audits are of equal importance and supplement each other to achieve optimal outcomes.

Good practice standards / criteria are drawn from legal requirements, research, consensus statements, and recommendations by learned societies or local agreements. Clinical audit is not research, regulatory inspection or quality system assessment (certification or accreditation) but is complementary to these quality processes. Quality auditors (quality experts) are different from clinical auditors (clinical experts). In addition to these guidelines from EC, guidance on comprehensive audit has been developed by the IAEA (e.g. 'QUATRO' for radiotherapy) and an audit program is conducted in UK by the RCR (Audit Live).

After drafting the EC Guideline, follow up actions are needed: to promote awareness and encourage uptake by publication, dissemination and hosting conferences; to educate stakeholders on audit principles and to train auditors by organizing training workshops; and to improve the audit process by reviewing the good practice standards.

#### Potential Global Initiative activities

Under the Global Initiative, WHO could promote clinical audit by: endorsing the EC Guideline and the IAEA Guides for global use; produce a policy statement (considering also how to approach developing countries), collect and distribute examples of the benefits of clinical audit and communicate this to clinicians and decision makers; undertake motivation actions such as sponsoring and organizing meetings and training events; and directly involve and/or in-directly support professional and scientific societies to review good practice standards.

### **6.3.2. IAEA activities in comprehensive audit for radiation medicine**

Dr. Eeva Salminen (IAEA, NAHU) presented the activities of the Division of Human Health of the IAEA, engaged in a range of programs to promote the safer use of radiation in medicine including comprehensive audit programs for diagnostic radiology, nuclear medicine and radiotherapy.

### PACT

The Program of Action for Cancer Therapy (PACT) aims to build partnership to stop the global cancer epidemic. PACT was created to: bring IAEA's radiotherapy efforts into a public health model; integrate radiotherapy planning into a broader cancer control capacity building effort; support cancer control planning in collaboration with international and national agencies and partners; propel program development and fundraising through the implementation of pilot projects. PACT assesses Member States' capacity and works with the partners, e.g. WHO, PAHO, IARC, International Network for Cancer Treatment and Research (INCTR), American Cancer Society (ACS), National Cancer Institute (NCI) to plan National Cancer Control programs, promote awareness, and mobilize resources.

### DIRAC

The Directory of Radiotherapy Centers (DIRAC) program started in 1959 and is published in print, CD and online formats. It provides data in equipment, infrastructure, staffing, simulation and dosimetry from over 6,000 radiotherapy centers worldwide. The European data was updated in 2007 (EUNICE project<sup>13</sup>) and Latin-America, China, Japan, India data in 2008. It seen that cobalt-therapy is the basic RT technique in less developed countries and that data are very heterogeneous in terms of distribution of equipment, staff and training in the world.

### IAEA Comprehensive Audit Programs for radiation medicine

The IAEA has engaged in audits in radiation medicine for a long time. It has developed and implemented comprehensive audit programs for radiotherapy, nuclear medicine and diagnostic radiology. A common approach was adopted for the preparation and organization of audits, their implementation and reporting. The audit methodology is tailored to meet the differing needs of the different disciplines.

### *Quality Assurance Team for Radiation Oncology (QUATRO)*

The IAEA collaborates with the WHO in on-going postal dose audits of radiotherapy beam calibration by TLD. In the past 39 years, the postal dose audit program has tested around 7,000 beams from 1,600 hospitals in 119 countries.

QUATRO is a newly implemented comprehensive audit program for radiotherapy. There are 2 types of QUATRO audits: proactive and reactive. Proactive audits are voluntary. The request for a proactive audit usually comes from a radiotherapy department, hospital or Ministry of Health (endorsed by the department). The proactive audit is not designed for the investigation of incidents or reportable medical events which are handled by the reactive audits. It is also not intended for the assessment for entry into cooperative clinical research studies or for regulatory purposes. Therefore, the proactive audit is not an enforcing tool but an impartial source of advice on quality improvement.

The proactive comprehensive audit is a peer review of all the processes involved in radiation therapy: infrastructure, staff qualification, equipment, QA procedures, training programs, patient protection and safety, cancer registry, and overall performance. The QUATRO audit team consists of radiation oncologists, medical physicists and radiation therapy technologists. During an audit areas for improvement

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<sup>13</sup> EUNICE: European Network for Indicators on Cancer, EC project coordinated by WHO/IARC  
[http://ec.europa.eu/health/ph\\_projects/2004/action1/docs/2004\\_1\\_33\\_inter\\_en.pdf](http://ec.europa.eu/health/ph_projects/2004/action1/docs/2004_1_33_inter_en.pdf)

will be identified and the aim is to bring the radiotherapy services to an internationally acceptable level. The goal is quality improvement.

A QUATRO proactive audit typically takes 5 days which will cover: entrance briefing; days 1-3 for tour of department, interviews, review of documentation, procedures, observation of practical work; days 4-5 for preparation of a preliminary report and recommendations, physics measurements covering dosimetry for tele- and brachytherapy, TPS check, benchmark cases, verification of data consistency etc; and exit briefing.

There are three possible audit outcome categories: 1) the institution is suitable to perform the radiotherapy services at an internationally acceptable level; 2) the audit team has identified areas for improvement which are resolvable by the institution; or 3) there are underlying major problems which cannot be resolved by the institution or without significant resources. Follow up audits are recommended for categories 2 and 3. The proactive audit results are collated and findings published. The full audit report is a confidential document and is available to the requestor, typically the director of radiotherapy or department head or to individuals nominated by the institution. The Summary report is available to the national authorities, i.e. National Liaison Officer for Technical Cooperation with IAEA and the Ministry of Health. Since commencement, QUATRO has been active in Africa, Asia, Europe, and Latin America by providing workshops, auditor training and missions.

#### *Quality Assurance for Nuclear Medicine (QUANUM)*

The IAEA audits in nuclear medicine employ comprehensive guidelines applicable for self-appraisal and external assessment. The elements covered by the comprehensive nuclear medicine audit include: the quality of services taking into account of the diversity of nuclear medicine practices; the processes including patient investigations, reports, patient management and outcomes; the infrastructure including human resources, training, equipment, QC and maintenance; the radiation protection and safety measures; and the Quality Management System. The QUANUM methodology is being tested in Africa, Asia, Europe and Latin America.

The QUANUM audit process consists of: self-appraisal; request for an external audit; data input into database; pre-visit questionnaire; on-site review by an audit team categorizing the findings into observations, references and non-conformances; audit conclusion; recommendations; remedial action; and follow-up.

#### *Diagnostic Imaging*

The IAEA audit program for diagnostic imaging is evolving. Audit documentation is being prepared and 2 pilot missions took place in 2008. The diagnostic imaging audit format consists of 3 auditors: radiologist, radiographer and medical physicist. The audit document is designed to promote rapid completion of the audit process after the visit. Audits for diagnostic imaging differ from radiotherapy due to the range of modalities involved, making it difficult to cover any area in depth. Further development work is required in this area.

In conclusion, the IAEA is committed to the on-going development and implementation of comprehensive audits in radiation medicine. IAEA audits provide useful tools for practice improvement. QUATRO is well established, it is available in English and Russian and it is downloadable from the Website. The audit processes for nuclear medicine and diagnostic radiology have been developed and are under implementation. IAEA is the first international organization which has developed the methodology, trained expert auditors and implemented comprehensive audits in radiation medicine worldwide. The IAEA acknowledges and very much appreciates the contributions from the numerous international experts

who have contributed to the development of the IAEA guidelines for comprehensive audits in radiation medicine and conducted audit missions.

### 6.3.3. Q & A, discussion

In principle, the results of an audit are confidential between the auditors and the institution. Confidentiality is a key issue and an absolute necessity. The real effect of the audit would be seen if the results were published. To maintain confidentiality the information could be published but de-identified. In this way practices can be encouraged to participate and avoid mixing pragmatism with idealism. Those departments or countries which under-perform could arrange a visit from a central body for an external audit.

The lack of motivation from some countries or users to conduct audit programs was discussed. In general, the acceptance of clinical audits is higher in radiotherapy than in diagnostic radiology departments. The first part of the EC project was a survey and found that many countries neither had audit programs nor wanted to be audited. Many were confused between clinical audits with regulatory inspections.

The difference between clinical audit and other regulatory tools were highlighted; noting that in health care settings radiation safety is only one of the components of clinical audits. The financial considerations might also be an issue for clinical audits.

The experience of the UK was discussed. In the UK all doctors working in the NHS adopted medical audit into their routine clinical practice since 1989. "Medical audit" was conceived as the systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, the resulting outcome and the quality of life for the patient. In 1993, this concept was widened and the new requirement was "clinical audit" as the audit activities of all health care professionals, including doctors, nurses and other staff. The RCR identified clinical audit as an essential tool for improving the service and defined the relationship between clinical audit and clinical governance. The DoH report "Good Doctors, Safer Patients" (2006)<sup>14</sup> called for the reinvigoration of clinical audit to enable it to reach its potential as a useful tool to support service improvement. In 2007, a National Clinical Audit Advisory Group was established, to drive the reinvigoration programme and provide a national focus for discussion and advice on matters relating to clinical audit in the UK.

The implications of providing guidance on justification, optimization and clinical audit were discussed. The issue of global harmonization was raised. It was suggested that WHO should focus in the dissemination of the existing information instead of harmonization. It was agreed that global harmonization is difficult and the stakeholders should use the terms "adaptation" rather than "harmonization". These tools are already available and discussion should be focused in dissemination options: e.g. leaflets, website, national professional bodies. It was stressed that the professional societies are the key stakeholders and the only way to move forward is by engaging them. Professionals such as clinicians prefer to be informed by the professional bodies.

As an example, it was suggested that the RCR guidelines could be used in Bahrain since the RP views are similar.

It was noted that >25 international organizations and professional bodies have gathered for this meeting and the WHO should convert this initiative into a permanent and on-going programme with a budgeted

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<sup>14</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4137232](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232)

annual work plan, including the involvement of the regional offices, and the monitoring of impact at region and country levels. The IAEA conducts TC projects regarding radiation safety in medicine in the developing countries, but many countries which are not IAEA MS do not have access to these TC projects.

WHO is very active in many public health issues, e.g. vaccination, with huge impacts and successful outcomes. However, WHO's RP activities were negligible in many parts of the world. The MS MoHs and regulatory authorities are the key players to ensure successful national implementation of RP policies. Resolutions from the World Health Assembly provide guidance to the MS competent authorities and will facilitate the national implementation of these policies. The GI should collaborate with the stakeholders and prepare draft recommendations on RP in health care settings, which could be then brought to the attention of the WHO's Executive Board by the MS MoHs.

## 6.4 Radiation protection of healthcare workers

### 6.4.1. Radiation protection of healthcare workers: interventional radiology

Dr. Eliseo Vaño (ICRP) noted that many interventional radiology and interventional cardiology workers do not use dose monitors properly while others may not have training in radiation protection. The occupational doses for some interventional practices are unknown. There is a need for an integral approach to manage radiation protection for patients and workers in these practices. The new ICRP recommendations take into account staff doses when considering generic justification of radiological procedures.

Radiation induced cataracts are predominantly of the posterior sub-capsular (PSC) type. Screenings of asymptomatic interventional radiologists and interventional cardiologists revealed nearly half of those screened had lens changes and signs of PSC were found in 8%(RSNA news, 2004)<sup>15</sup>. The IAEA also conducted a similar study in cardiologists attending a SOLACI meeting (2008)<sup>16</sup>. In a prospective study, PSC was found in 25% of 8,607 Chernobyl clean-up workers assessed for cataract at 12 and 14 years after exposure. This study suggested the dose threshold for radiation induced cataract is probably <700mGy and subcapsular cataracts were described even at 350mGy. A prospective cohort of 35,705 cataract-free US radiologic technologists aged between 24 to 44 years was followed up for nearly 20 years. The findings suggested that the dose threshold for radiation induced cataract is probably substantially less than what was previously thought.

The ICRP will consider these data and their impact on the dose limit for the operators when they become available. In the meantime, interventional practices should adopt a holistic and integrated approach to radiation protection for patients and workers by applying optimization techniques to limit exposures. The importance of good equipment and good techniques in reducing exposures should be stressed. There is a need to improve the training of practitioners. Educational and training resources are available from EC, ICRP, and WHO. The IAEA Website IAPRPoP has very good information. The EC's CD Rom RP119 "Multimedia audiovisual radiation protection training in intervention radiology" (MARTIR)<sup>17</sup> is free and is

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<sup>15</sup> <http://www.rsna.org/Publications/rsnanews/upload/jun2004.pdf#page=7>

<sup>16</sup> IAEA survey on early lens changes among interventional cardiologists attending a meeting of SOLACI (Latin American Society of Interventional Cardiologists), Bogota, Colombia, 24-26 September 2008  
<http://rpop.iaea.org/RPOP/RPoP/Content/ArchivedNews/IAEAStudyRadiationinducedcataract.htm>

<sup>17</sup> MARTIR Project: Multimedia and Audiovisual Radiation Protection Training in Interventional Radiology. CD-ROM. Radiation Protection 119, European Commission. Directorate General Environment, Nuclear Safety and Civil Protection. Luxembourg, 2002 (free availability from the Publication Department of the European Commission, Office for Official Publications of the European Communities, Luxembourg, e-mail: env-radprot@cec.eu.int).



available available in English, French, German and Italian at the DG TREN site. The material covers safety of patients and staff. WHO guidance on interventional radiology was published 1995.

The IAEA convened a Technical Meeting to review radiation protection guidance for medical workers (2008). The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) and Society of Interventional Radiology (SIR) are preparing guidelines on occupational radiation protection. Examples of the topics covered are: personal dosimetry and records, protection tools, international recommendations, advice to reduce occupational radiation risks etc.

#### Potential Global Initiative activities

The exposure to the eyes of interventional radiology and interventional cardiology workers could be very high and deterministic effects could be observed if no appropriate protection measures were applied. This challenge could be addressed under the WHO Global Initiative employing an integrated approach. The initial priority will focus in interventional radiology, interventional cardiology and nuclear medicine by: informing the workers of their occupational radiation risks and the preventive protection measures; evaluating the risk profiles for different workplaces; developing and disseminating guidelines on radiation protection for these workers; and facilitating the implementation of occupational health policies in interventional radiology, interventional cardiology and nuclear medicine practices.

#### **6.4.2. Radiation protection issues in nuclear medicine**

Dr. Habib Zaidi (Geneva University Hospital, Switzerland) highlighted the advances in nuclear medicine from 2-D to multi-modality 5-D imaging by employing new technologies and new techniques. Molecular imaging is a structural and functional display, characterization and quantification of the biological processes at cellular and sub-cellular levels in living organisms for biological, biochemical, diagnostic or therapeutic applications.

PET is a fast growing imaging modality. Bi-modality 5-D imaging with PET/CT and PET/MR adds diagnostic value by fusing these images. Tri-modality imaging combines PET, SPECT with CT. Multi-modality imaging provides structural and functional data, enhances lesion characterization and assists interpretation. Radiation from these techniques will influence the exposures for patients, workers and research volunteers. The dose computation models have evolved from simple to complex; homogeneous to heterogeneous; rigid to deformable and stationary to moving. Deformable and moving 4-D models will soon be available to provide more precise and "person-specific" modeling.

QA programs in practices will improve quality and ensure radiation safety. Regular patient activity audits and image reviews will identify if performance and diagnostic reference levels (DRLs) were acceptable compared to good practice criteria. Analyses and corrective actions are needed if DRLs were repeatedly and substantially exceeded. Participations in such audits will increase if audits become part of accreditation requirements.

The radiopharmaceutical doses delivered to patients were found to vary significantly in a survey of 13 paediatric hospitals. There is a need to overcome controversies, reach consensus, and standardize the minimum doses required to reduce patient exposure and to achieve superior diagnostic images. New technology, instrumentation and software will be applied wherever possible.

Nuclear medicine workers are exposed to radiation from hot lab work, dose dispensing and patient contacts during and after an examination. In a study of mobile PET/CT units, the worker dose is found to be 20% higher than those working from fixed units. An audit has identified the possible causes and

corrective actions were implemented by simplifying the pharmaceutical / patients handling routine and relocating the toilet away from the workstation area.

#### Potential Global Initiative activities

In the last 20 years, radiation protection measures have reduced worker dose by some 5 man Sv. The stakeholders will determine the direction from this point forward, i.e. whether to increase spending to reduce dose further or to reduce spending to keep the dose at the present level. When applying new technologies, the dose impact to patients and workers must be considered. Measures to improve radiation protection in a nuclear medicine practice may include worker education and training and error minimization, i.e. applying steps to prevent wrong patient, wrong tracer, wrong route or wrong dose. Regular audit should be performed to assess if ALARA is achieved. Radiation protection issues and the restriction of human volunteers in research require careful consideration.

#### **6.4.3. Q & A, discussion**

The EC project on 'Optimisation of Radiation Protection of Medical Staff' (ORAMED)<sup>18</sup> was shortly summarized and hardcopies of a briefing on ORAMED were distributed among participants.

Regarding cataract induction in workers, it was mentioned that lead glasses could reduce the dose to the eyes by 20%. Their use should be promoted. It was noted that sometimes workers do not use lead aprons because of potential back problems. However, this is not an issue with lead glasses; i.e. non compliance is probably a safety culture issue. The use of shielding between the patient and the workers should be adopted.

The importance of monitoring the dose to workers was highlighted. There are regions where health workers do not use or have personal dosimeters. This is a serious issue in Latin America, the Caribbean region, and Africa where workers do not practice personal monitoring nor use monitoring badges. An understanding of the different working conditions is required. The Information System on Occupational Exposure (ISOE<sup>19</sup>) data base will be expanded to include occupational exposure in medical facilities to investigate and compare exposure for similar procedures. The first part will focus in interventional radiology. This is a joint IAEA/NEA programme with possible cooperation with ILO and WHO.

In some countries "thyroid dose" readings come from the dosimeters worn outside the lead apron (e.g. US). For interventional procedures, instructions should be given as to where the dosimeters should be worn, to avoid inconsistencies and to make the results more comparable.

The concept of a joint approach to optimize RP for workers and patients was discussed. To address this in interventional radiology dose monitoring for the patient and the workers is needed. In addition to this "joint approach" for optimization of RP for workers, the ICRP's concept of dose reduction to workers by justification of medical procedures was discussed. Some participants considered combining RP for patient and worker controversial.

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<sup>18</sup> <http://www.oramed-fp7.eu>

<sup>19</sup> ISOE was created in 1992 to provide a forum for radiation protection experts from both utilities and national regulatory authorities to discuss, promote and coordinate international co-operative undertakings in the area of worker protection at nuclear power plants. The ISOE System is jointly sponsored and coordinated by the OECD/NEA and the IAEA.

## **6.5 Scaling-up the role of medical physicists, radiographers and technologists**

### **6.5.1. Scaling up the role of the medical physicist in a clinical and research environment**

Dr. Habib Zaidi (Geneva University Hospital, Switzerland) said that the major challenge for medical physicists is their recognition as health professionals. ILO didn't include medical physicists in its profession classification. To achieve this status, national legislations are needed requiring the appointment of medical physicists in all radiation medicine practices.

In developed nations, medical physicists engage in medical physics, clinical science, research, administration, grant application, committee and professional work. There is a global shortage of medical physicists. This requires urgent actions by the decision makers to limit brain drain and to promote the growth of this specialty.

Medical physics in developing countries is a stark contrast and differs markedly to the developed nations. The key issues are the access to and provision of basic services. Radiotherapy, nuclear medicine and diagnostic radiology practices are limited and less computerized. Radiation protection procedures are less regulated. Private practices are limited and prohibitively expensive. Social, political, economical, practical and organizational barriers further reduce what is already an extremely limited access to basic care.

In these developing countries, the shortage of qualified and experienced medical physicists is catastrophic. Some radiation therapy practices and almost all diagnostic imaging units do not have access to expert physics support. Medical physicists in developing countries require talent, diplomacy and good communication skills, to handle complex issues efficiently and to convince decision makers about the importance of their work and its implications on healthcare.

Medical physics organizations provide education and training to assist medical physicists to achieve and maintain high standards required by modern radiation medicine practice. Education and training should be tailored to meet local needs. Peer-review between medical physicists is an efficient way to share ideas and knowledge, to provide constructive suggestions to daily clinical physics issues and to develop preventive actions to improve radiation safety and patient care.

IOMP and other international organizations such as the WHO, IAEA, IRPA etc. work towards an improvement of medical physics support in developing countries. These efforts could be enhanced by improving the training methodology and adopting a more flexible approach to training delivery by cooperating and engaging with other appropriate stakeholders in addition to Member State health authorities.

#### Potential Global Initiative activities

Medical physicists are members in a multidisciplinary team. The stakeholders will determine the cost / benefit of medical physicists under this environment. Strategies are required to improve the education and training of medical physicists in developed and developing countries within the available budget. To assist with future planning, reliable data of the available medical physics resource in developing countries is urgently needed. Towards a more effective delivery of training and education in developing countries, a review of the roles and collaboration policies of international organizations may be considered.

### **6.5.2. Scaling up the role of radiographers and radiation technologists**

Dr. Paivi Wood (ISRRT) noted that, while radiation medicine procedures are under the supervision of clinicians, radiographers operate the equipment, deliver the dose to the patients and decide if repeats are necessary. Over 80% of the medical radiation exposure delivered to the patients is given by radiographers. In developing countries, up to 50% of x-ray procedures are of substandard quality. Many patients are exposed to unnecessary radiation due to repeats.

Radiographers in medical imaging are well trained and the profession is regulated. The ISRRT was requested to set accreditation standards. In addition to other subjects, quality assurance, radiation safety and equipment maintenance are included in the training curriculum. There is an awareness of radiation safety issues amongst radiographers worldwide. One of the major concerns for the profession is the increasing population dose from the increasing use of radiation in medicine due to an increase in the number of examinations, an increase in dose for an individual examination (e.g. CT), and new technologies.

There is a global shortage of radiologists and medical physicists. The roles of radiographers are expanding to fill the gaps left by insufficient medical staff. There is a need for more effective and efficient solutions to meet demand for services and to ensure a safe working environment. A new working model should be developed, not simply based on traditional demarcation lines. The provision of services should depend on ability and not the job title. In developed nations across the globe, the roles for radiographers is changing and evolving. On the other hand, in many developing countries very basic or no training is available to radiographers.

The ISRRT is the link to over 400,000 radiographers worldwide through national professional societies. The organization facilitates the development of training curricula, on-going education, quality assurance programs and standards for radiographers. In the practice of radiation medicine, ISRRT is active in the promotion of radiation awareness and a safety culture. Professional societies play an important role in promoting awareness and delivering radiation safety messages to all stakeholders employing ionizing radiation, including medical staffs.

#### Potential Global Initiative activities

Radiographers play important and key roles in radiation medicine. Radiographers make individual decisions based on the patient referrals; patient interviews; knowledge and knowhow; optimization techniques; QA and QC procedures. This knowledge and working experience underpin the foundation for further role evolution of radiographers in the coming years. Radiographers should be encouraged to join the ISRRT: e.g. the US has more than 300,000 radiographers but just 120,000 are ASR members, with the direct link to ISRRT. The ISRRT has good experience in training and has worked together with PAHO and WHO in joint education and training activities. These activities should be further promoted.

#### **6.5.3. Q & A, discussion**

Regarding staff education and training the stakeholders should make the most use of the existing materials. The ISR has published some very simple and understandable materials; some of these were produced with WHO. The IAEA produced syllabus for radiation therapists (RTT) and radiation oncologists endorsed by ASTRO, ESTRO (post-graduate education). These materials should be disseminated and used.

It was mentioned that IRPA has worked on the recognition of the RP profession in the ILO categorization, and it was finally achieved. However, it was noted that the concept of RP specialist has a different meaning, and the recognition of medical physicists (MPs) as a profession is still an issue. ILO does not recognize the MPs as health workers but as scientists, and medical physics is not recognized as a

profession. This determination has several implications for the inclusion of these professionals in the health sector.

## 6.6 Towards the inclusion of radiation protection in medical education

### 6.6.1. Building partnership to improve education of health professionals

Dr. Hugo Mercer (WHO) said that there is an estimated shortage of 4.3 million health workers worldwide. In 2006 the World Health Assembly adopted Resolution WHA59.23, urging Member States to affirm their commitment to the education and training of more health workers. However, many Member States do not have adequate training capacities, facilities, educators or financial resources to implement this task. Resolution WHA59.23 gives the WHO a mandate to assist Member States in achieving this goal by: providing technical support to revitalize education institutions, seeking support from global health partners, promoting partnerships to improve the capacity and quality of health-professional education in developing countries, supporting the development of health workforce planning teams, and applying innovative information and communications technologies to teaching.

Those countries with a critical shortage of workforce include most of Africa, parts of South East Asia, Eastern Mediterranean, Central and South America. There is a shortage of training capacities for medical, nursing, dental, pharmacy and public health workers. There are disparities in the number of graduates between medical schools, the prevalence of diseases such as malaria and the availability of physicians between the developing and developed nations. There is a need to improve the infrastructure for undergraduate, post graduate education and continuing professional development. This could be achieved by coordinated collaboration between professional organizations, international agencies, academic institutions, donors and development agencies.

The WHO collaborates with others to advance education and training of health workers. Examples include: World Federation for Medical Education (WFME), World Federation of Public Health Associations (WFPHA), International Pharmaceutical Federation (FIP), World Dental Federation (FDI) etc.; United Nations Educational Scientific and Cultural Organization (UNESCO), United Nations Department of Economic and Social Affairs (UN/DESA), European Commission (EC), Global Health Workforce Alliance (GHWA), WHO Regional Offices and other programs within the WHO; the Universities of Copenhagen, Western Cape and Pretoria, Iowa, Consortium of Health Workforce Governance Research etc. and donors and development agencies such as Bill and Melinda Gates Foundation, Rockefeller Foundation, World Bank, African Development Bank etc.

The Global Action Plan for Pharmacy Education is collaboration between FIP, WHO and UNESCO to scale up pharmacy education and practice relevant to needs, with a focus on countries in health workforce crisis. The WHO collaborates with WFPHA to scale up public health workforce development through partnerships, networking and creating databases for knowledge management. WHO, UNESCO and EC developed the Avicenna Virtual Campus to accelerate the adoption of Open Distance Learning in 15 Mediterranean universities. Other WHO sponsored knowledge sharing programs are: online communities of practice and regional networks, knowledge management for public health, AfriHealth database, virtual campus of public health, Public Health Initiative, healthtraining.org and Journal of Public Health Policy etc.

#### Potential Global Initiative activities

The inclusion of RP topics in the education of health professionals will require changes in the curriculum of the medical schools. The stakeholders should also collaborate with medical education associations. The

education of other health workers (e.g. nursing, dentistry, pharmacy, etc) should be included. Regarding post-graduate education, the professional bodies are the key partners.

### 6.6.2. Q & A, discussion

A good approach would be to include radiology in the curricula of medical schools and within radiology to include RP contents. It was pointed out that there are two different but related issues: (i) to include RP in the curriculum of medical education and (ii) to build national capacity by training the staff. For staff training, active participation by the radiographers is required.

It was noted that the IAEA would be a partner for these education activities under the *Global Initiative*. The IAEA produced syllabus for radiographers and radiation oncologists endorsed by ASTRO, ESTRO (post-graduate education). Teaching RP in medical schools requires an integrated approach for medical education.

One-day training courses on radiology are conducted in Bahrain with a one-month rotation to a radiology department. However, other specialities are not included (e.g. nuclear medicine, radiation oncology). RP topics will be included in tutorials. Medical students are not very interested in radiology or biophysics topics.

The efforts EU Project Higher Education Network (HEN) and the European Federation of Radiographer Societies (EFRS) in this project was mentioned as an example of how further education of radiographers can be achieved. This project considers the inclusion of RP in the curricula.

The experience in the UK was discussed. The focus is to educate at the beginning of employment. All new doctors have to apply for induction before starting a job. This may be more effective and enable the young doctors to work together under the different departments. High school students have little to no idea about radiation and RP. After workers are trained, they should be provided with the necessary tools and this is possible when they are already working at the hospitals. This is particularly important when dealing with very modern and complex equipment. Whatever the basic curriculum has provided, training in RP should be given to young doctors prior to the commencement of practice.

## 6.7 Error reporting systems and classification of events in radiotherapy

### 6.7.1. Radiation oncology safety information system (ROSIS)

Dr. Joanne Cunningham (Trinity Centre for Health Science, Ireland) said that incidents can lead to serious consequences in radiation medicine. Learning from these incidences and applying preventive measures will minimize risks in the future. Service providers do not generally disclose their errors and there is a need to raise awareness, share information, learn from past incidents and promote a safety culture in radiation oncology. The Radiation Oncology Safety Information System (ROSIS) is a voluntary web-based incidence reporting and risk control information database.

ROSIS aims to develop and use a global reporting system to reduce incidents in radiation oncology practices by sharing experience learnt from incidence reports; analysing these risks; developing control measures; and disseminating the findings to promote a safety culture and incidence awareness in radiation oncology.

Data collection started in 2001 when Mary Coffey started working with ESTRO based on the Euratom Directive 97/43. A reporting system data base developed in 2003. A website and online data base was established in 2004. In 2005 the website was revised and a course logo was adopted. Since 2006, a classification system was developed and the reporting system and database revised. Now many departments have registered. Collaboration with the UK and Canada is ongoing. Other activities include newsletters, training courses, collaborations and establishment of local ROSIS systems.

ROSIIS itself is the subject of continuous improvement with on-going refinement of the data handling processes, classification, communication, and promotion strategies. A classification system tailored for radiation oncology was developed following a literature review. This system underpins report classification, incidence analysis, education and safety improvement. ROSIS covers all incidents, near-incidents, preventive, and corrective actions relevant to radiation oncology practices. The aim is to maximize learning through a comprehensive database.

Under the ROSIS classification, there are 4 major headings: event / occurrence; severity; detection; and causes / contributing factors. Below these major headings are subgroups. For examples, under "event / occurrence" are the following subgroups: individual affected, radiotherapy technique, process classification and description.

"Process classification" is further stratified into 4 levels according to the patient activity steps. Level 1 include: imaging, simulation, planning, prescription, dose calculation, treatment preparation, and treatment delivery; i.e. during which step did the incidence occur. For an incidence occurred during the "treatment delivery" step, the level 2 options are: patient ID, patient positioning, radiotherapy set-up, beam energy, beam modification and dose; i.e. which element was affected. For an incidence arising from "radiotherapy set-up", the level 3 choices include: collimator angle, couch angle, couch height, field name, field size, gantry angle, object in beam path, treatment distance, and treatment iso-centre; i.e. which component was involved. This detailed stratification assists with the grouping, filing and analysis of incidences and the corresponding corrective actions. Over 100 radiation oncology practices have joined ROSIS by 2008. Practices are encouraged to register with ROSIS to promote radiation safety in radiation oncology.

#### Potential Global Initiative activities

ROSIIS does not collect certain type of data e.g. personal data on patients. There is a need to improve data collection at local level and WHO could assist. For data collection and analysis, ROSIS followed the WHO's guidance for error reporting but have adapted these guidelines to the particular needs for RT practice. There is still room for improvement and the Global Initiative could contribute. The classification of events should be evaluated and information revisited to determine if they should be re-classified. The international WHO classification for patient safety is a good reference. In summary, WHO Global Initiative could contribute to the development of (i) an unique and global classification system and (ii) local systems for error reporting.

#### **6.7.2. Notification system and public information on event affecting patients undergoing a radiotherapy procedure**

Dr Carole Marchal (ASN, France) informed that French radiation medicine licensees are legally required to notify the authority of significant adverse events. Notification criterion 2.1 from draft guidance ASN/DEU/03 deals with "Patient exposure as part of a therapeutic procedure". These significant and notifiable events include accidents arising from the treatment of patients using radioactive material or a

medical device, which have resulted in or will potentially result in unexpected deterministic effects; and/or cases where exposure is significantly higher than the prescribed dose.

"Unexpected" deterministic effects exclude the known side effects ("predictable" effects) such as erythema, temporary alopecia or cataract but include tissue necrosis and radiation induced myelitis. According to the criteria adopted by the ASN overexposure is defined as a target dose greater than 5% of the prescribed dose. This includes events involving wrong patient or wrong target (around 14% of events affecting patients undergoing a radiotherapy procedure are related to patient mis-positioning or mis-identification).

There is a requirement for effective public communication of significant adverse events arising from treatment using radioactive material or a medical device under the 2006 Transparency and Security in the Nuclear Field (TSN) Act. This is particularly important after the Epinal accident. The ASN is responsible for this key role. An ASN-SFRO reporting scale was jointly developed with the French Society of Radiation Oncology (SFRO) and evaluated with the SFRO and the French Society for Medical Physics (SFPM) after a 12 months trial. This is a very useful tool to improve communication to the public on a very sensitive issue in a consistent way. The definitive scale was published in 2008<sup>20</sup>.

Based on severity, the adverse events are rated from Level 0 to Level 7. These are grouped into 5 Grades employing the Common Terminology Criteria for Adverse Events - Cancer Therapy Evaluation Program: Grade 1 mild effects, Grade 2 moderate effects, Grade 3 severe effects, Grade 4 serious or life-threatening effects and Grade 5 death. This classification is compatible with the IAEA International Nuclear Event Scale (INES). Unlike it, the "defence-in-depth" criterion is not incorporated to avoid confusion between the seriousness of a medical condition, the failure of the installation or the breach in the organization of a department. Other communication terms including accident, incident and event are defined to ensure consistency in ASN annual reports, ASN quarterly reports, website incident notices, front page news and press releases.

During the trial period between July 2007 to June 2008, 181 events were notified including 175 Level 0 or Level 1 events and 6 Level 2 events. Ten events concerned with medical devices. Most of these adverse events were due to organizational and human factors: poorly understood or implemented QA systems, due to poorly defined role and responsibility, poor procedure documentation etc.; poor incidents analysis and risk control development; communication errors; inadequate staff training and education; instruction manuals not translated into French; and insufficient staff level including medical physicists and QA personnel etc.

### **6.7.3. World Alliance for Patient Safety (WAPS)**

In 2004, WHO launched WAPS in response to a 2002 World Health Assembly Resolution which urged WHO and Member States to pay the closest possible attention to patient safety. The Alliance raises awareness and political commitment to improve the safety of care and facilitates the development of patient safety policies in the Member States. Each year, WAPS delivers a number of programmes covering systemic and technical aspects to improve patient safety around the world.

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<sup>20</sup> A briefing note on this scale for dealing with radiation protection events affecting patients undergoing radiotherapy procedures was distributed among participants.



One of WAPS's areas of work is risk reduction in radiotherapy. The WHO sponsored a consultancy on safety in radiotherapy in 2007 in response to a number of reported accidents. The radiation oncology experts developed a set of recommendations for the WHO and mapped out the radiotherapy risk-prone areas to enable the development of concrete actions to reduce the risks of accidental over-exposure. A WHO Technical Manual on Radiotherapy Risk Profile was prepared and will be available from the WAPS website in 2009.

The WAPS Radiotherapy Safety Expert Consensus Group recently reached consensus on the classification of the sequential stages of the radiotherapy process. These stages are: patient assessment, treatment decision, treatment protocol prescription, immobilization and positioning, simulation, imaging and volume determination, planning (including equipment and software commissioning), treatment information transfer, patient setup, treatment delivery, and treatment review.

An analysis of the reported incidences of adverse events (n = 3,125) and near misses (n = 4,616) over the last 30 years identified those stages where most risks and errors occurred. The highest number of adverse events occurred in the planning stage (n = 1,702) and the highest number near misses occurred in the treatment information transfer stage (n = 1,732).

By tabulating the risk types according to these stages, risk control opportunities are identified and solutions developed. Several interventions are likely to be effective to reduce risks at multiple stages during the treatment process:

- planning protocol checklists will reduce 20 risk types due to: immobilization and positioning, simulation, imaging and volume determination, and planning;
- independent checking will control 12 risk types due to: treatment information transfer, patient setup, and treatment delivery; and
- specific competency certification will minimize 11 risk types due to: treatment protocol prescription, simulation, imaging and volume determination, planning, patient setup, treatment delivery, treatment verification and monitoring.

#### **6.7.4. Q & A, discussion**

There was a discussion about the proposed threshold for an overexposure to be notified. To set a dose value of >5% to the target was considered too low and difficult to achieve. It was noted that chemotherapy may mask and overlap the effects of radiation and consideration of this contribution is needed.

It was also discussed the need to include under-dosage as events for notification (i.e. errors) since this is not included in the current ASN/SFRO scale. There was a general consensus that under-dosage (under-delivery of dose) should also be reported.

The clinical significance of a certain event and the need to define a tolerance (e.g. exposure to the leg is different from to the brain in terms of tolerance) was discussed. Similar systems for diagnostic procedures should be considered.

It could be useful to identify the generic information about the type of technology employed. Equipment are becoming safer while some of them are old but still usable. This is the situation in many countries.

The delegates were informed that the IAEA is now developing an international system for error reporting. A new staff member who was previously involved in ROSIS has just joined the IAEA and the team is now interacting with Dr. M. Coffey (Ireland) and Dr. R. Dieter (Germany) to develop this new system.

An interesting question was the definition of "patient" and "screening". The term "screening" applied for populations (e.g. mammography screening) is different from the health assessment for asymptomatic individuals. It was proposed that WHO could collaborate with EC to clarify those terms which are not well defined but are important for RP in health care e.g. patient, asymptomatic individuals, screening etc.

## 7. Risk communication

### 7.1 Introduction

Risk communication should have clear messages and achievable objectives. These should be tailored according to the different target audiences (e.g. patients, healthcare professionals, general public) to address potential risks and benefits from the use of radiation in medicine. Radiation risk communication should be a cooperative effort involving both technical experts (e.g. radiation scientists, epidemiologists) and communication experts (e.g. social scientists, psychologists, journalists)<sup>21</sup>. The proposed activities relating to advocacy and communication within the Global Initiative (Table 9) will include:

Advocacy and communication	<ul style="list-style-type: none"> <li>○ Develop a strategy for awareness raising and media communication;</li> <li>○ Disseminate knowledge and promote exchange of information;</li> <li>○ Develop guidance on radiation risk communication in health care, including communication with patients and informed consent; and</li> <li>○ Produce advocacy tools for health authorities, decision-makers, health care providers, patients and public.</li> </ul>
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Table 9. Initial activities for advocacy and communication

### 7.2 Communication strategy

#### 7.2.1. Tailoring the message: the role of risk communication

Dr. Gaya Gamhewage (WHO) pointed out that the concept of risk communication in healthcare has evolved. WHO has a key role to communicate with the different stakeholders. At any moment WHO has 50 MS under emergency situations which require some kind of risk communication actions. Risk communication offers an opportunity to manage the risk. Working on technical information is easier than working on values to transform the scientific evidence in clear messages and this is the challenge of public health communication.

Risk is the probability that damage would occur as a result of exposure to a hazard. A dilemma for health risk communication is that the risks that kill people and the risks that alarm people are completely different. The key factors affecting risk communication are trust, perception and fear. It is now

<sup>21</sup> World Health Organization (2002). Report Establishing a Dialogue on Risks from Electromagnetic Fields. WHO, Geneva.

recognized that proactive, deliberate, and interactive participation by the community is more effective in managing risks.

Risk communication is an interactive process of information and opinion exchange between individuals, groups, and institutions on risk issues. The trust the people have and their risk perception are more important than the messenger's knowledge. Risk communication is a dialogue in which multiple issues are discussed, including the nature of the risks, community concerns, opinions and reactions, and the legal and institutional risk management measures.

The 5 basic building blocks for successful risk communication are: trust, values, technical information, credibility, and expression of care. Between these elements, trust for individuals and organizations is by far the most important factor which will determine the outcome. The elements of trust include commitment, competence, care, openness, and honesty. Trustworthiness, trust and credibility, and the dimension of trust require careful consideration. Trust could be considered as the currency used in public health and to reverse the public's perception could be difficult. The aim of risk communication is to influence policy and behaviour. In public health the stakeholders should work towards evidence-based advocacy, although sometimes it might be "consensus-based".

Risk is less acceptable to people if it was: imposed, especially by a disliked person or organization; manufactured or man-made; unfamiliar; dreadful or disastrous; unfair or targeting a particular group; dangerous to children or future generations; poorly understood; irreversible; invisible; unperceivable; and irresponsive to public concern.

The current challenge for radiation and environmental health is to ensure a safer and more effective use of radiation in healthcare while reducing unnecessary radiation exposure. One strategic approach is an ongoing development and implementation of scientific evidence-based policies and programmes by adopting a continuous process of risk assessment, risk management and risk communication. Risk assessment is the evaluation of the risks and their potential impacts; risk management is the implementation of policies and health interventions; and risk communication is the engagement with and influencing the stakeholders. Under this framework, some initial activities are proposed and tabulated under 3.1.2. "The Global Initiative: concept and proposed strategy".

For any communication strategy, it is essential to adopt a systematic approach to:

1. assess gaps and needs, context, capacity;
2. formulate specific objectives;
3. identify target audiences;
4. select approach;
5. identify activities;
6. estimate resources required;
7. develop, tailor and test messages;
8. manage the delivery;
9. monitor results; and
10. review strategy and plans.

Messages should be targeted to the stakeholders. Risk communication which is not targeted is wasted. Communicating risk to different stakeholders will have different objectives, different deliveries and different ways to monitor the results. The GI should draft these messages carefully, since some of them may be culturally inappropriate depending on the targeted audience. Attention should be given to the

delivery of the messages, i.e. how and by whom. Communication training for GPs and radiological medical practitioners is required. However, "training" is different from "briefing" or "awareness raising".

Engaging the stakeholders and tailoring the messages will improve risk communication. It is important to evaluate the specific needs for each selected stakeholder group: the most appropriate communication approach; the overarching messages; the specific targeted messages; translation issues, if applicable; and the findings of trials. A good formula for one group might not work for another. For a particular stakeholder group, consideration must be given and appropriate approach is adapted to meet the group's specific need according to the basic building blocks, i.e. incorporating trust, values, technical information, credibility, and expression of care. Technical information includes why, what, how and the language used. Consideration should be given to: the values which will affect the group's perception; their trust in the message and messenger; the credibility of the message and messenger; and the expression of care in words, gestures, and settings.

The risk communication outcomes in healthcare settings will be improved by applying the right message and connecting the goal to the audience; by employing the right media to reach the target audience (multimedia is better, but at a cost); by selecting the right setting between workplace, hospital, community or home; by providing the right support in training to the messenger; and by monitoring the results.

#### **7.2.2. Q & A, discussion**

When communicating risks to patients, sometimes it is useful to provide examples, e.g. comparing the risk of a chest X-ray to a common activity such as flying or driving. It was agreed that this approach could be applied but should be used with care.

It may be also useful to explain the risks of doing something versus the risks of not doing anything. The stakeholders have to consider how to tailor messages for referrers and policy makers.

In radiation medicine, there are two related words which have a high-risk connotation for the public: "radiation" and "cancer". If the benefits of medical exposures were not explained adequately, the risk perception would be too negatively biased.

It is important to understand the stakeholders' needs when communicating risks. Engaging the targeted audience will improve the dialogue. The possibility of inadequate or differing background knowledge should be considered. Therefore, the terminology and language used must be chosen with care e.g. "hazard" is now communicated as "risk".

The Epinal accident showed that the country was not prepared and there was a need for better risk communication tools. The WHO Global Initiative could collaborate with the stakeholders: to develop and disseminate tools, and to conduct and promote training programmes on risk communication and media skills.

Risk communication training for health professionals should take into account of how the public is now accessing information. It was agreed that technical knowledge is needed to underpin the key messages and support communication. Guidance and tools focusing in specific area of work are required, i.e. how to communicate radiation risks related to medical exposures. Up to this stage, risk communication has received little attention. The GI should tackle communication as a program rather than as an activity.

### 7.2.3. Wrap up: topical sessions' contributions & discussions

The chair, Dr. Hans Ringertz, concluded that along the different topical sessions held during the second meeting day some possible working groups might be outlined. Based on this proposed list, the participants could discuss the possible future steps during the third day.

The topics which could be considered for working groups are summarized as follows:

1. Population dose estimation;
2. Research agenda;
3. Reducing unnecessary medical radiation exposures (i.e. justification, optimization);
4. Clinical audit;
5. Radiation protection of healthcare workers;
6. Scaling-up the role of MP and radiographers;
7. Education & training (inclusion of RP topics in graduate/post-graduate medical education);
8. Error reporting systems and classification of events; and
9. Risk communication.

## 8. Towards the implementation of the Global Initiative

### 8.1 Review of the global strategy

Dr. Jürgen Griebel (BfS, Germany) chaired the sessions during the third meeting day and raised some key questions. A well-designed work plan detailing the activities, deliverables, time schedule, participating partners and end-users will lay the foundation towards a successful implementation of this challenging initiative.

These activities will be globally oriented and end-user targeted. They will be undertaken by working groups consisting of expert advisors working in close collaboration with the end-users, to ensure the relevance and practicality of the deliverables. Amongst the topics covered in the discussions, those cross-cutting issues which justify the formation of Working Groups will be identified and prioritized. The summary at the end of the second meeting day considered nine issues which were addressed during the topical sessions. However, a Working Group may not be the most appropriate structure to advance some of these topics. It is important to review the existing efforts to avoid duplication and to apply the lessons learnt.

Once the working groups are established, the objectives and deliverables should be defined (e.g. technical documents, policy statements, workshops, etc.) and the targetted collaborating groups should be identified, i.e.:

- health authorities;
- regulators;
- end users: medical doctors (referring doctors, radiological medical practitioners); medical physicists; radiographers & technologists and others;
- consumers (patients); and
- vendors, etc.

The potential contributors to each working group will be identified according to their roles, needs and interests, e.g.:

- international organizations;

- professional bodies;
- academic institutions;
- scientific societies; and
- other stakeholders.

Based on the feedback from the participants, the next steps will be developed and defined by the WHO (i.e. time schedule, work plan, etc).

## 8.2 Overall approach

The global initiative will apply scientific evidence into policies and programs to build and improve a country's capacity to: assess risks and potential impacts; develop and implement policies that take into account potential health impacts and cost-benefit considerations; monitor and evaluate the effectiveness of policies and interventions; and engage and communicate with stakeholders.

Dr. Emilie van Deventer (WHO) reviewed the proposed strategy to implement the Global Initiative covering: stakeholders' engagement (who); work plan and procedures (what); timeline (when); resources mobilization (how); and other relating issues.

### 8.2.1. Stakeholders' engagement

The WHO partners with other organizations to advance radiation issues. These partners are: international organizations, WHO Collaborating Centres (WHO CC) and national authorities. International organizations, both inside and outside the UN system, are key partners. Some of them are NGOs in official relation with WHO (e.g. ICRP).

A WHO CC is an institution designated and recognized by the WHO Director-General as part of an international network which participates in activities supporting WHO programs at all levels. It is a highly valued mechanism of cooperation to advance WHO mandates. Collaborating Centres assist by: supporting the delivery of the strategic objectives at regional and global levels; enhancing the scientific validity of WHO global health plans; and developing and strengthening institutional capacities in countries and regions.

National authorities, through MoH, regulatory bodies and / or any other relevant competent authorities, are also key partners.

In addition to the above, the Global Initiative framework enables the WHO to work with a broader group of stakeholders. The organization will collaborate with all stakeholders and encourage them either as partners in activities or if appropriate as end-users of the outcomes.

The stakeholders for the initiative include:

- Consumers: patients, relatives and general public;
- Referrers: general practitioners (GPs) , specialists and other eligible healthcare providers;
- Providers:
  - Disciplines: radiological practitioners in diagnostic and interventional radiology, radiotherapy, nuclear medicine, medical physics, dentists, cardiologists and others;
  - Teams: clinical, technical and medical physics;
- Payers; public / private insurers, social services, and others;

- Regulators: governments, health authorities, other competent authorities, policy and decision makers;
- International organizations and UN agencies;
- Professional, academic and scientific organizations;
- Medical Defence Organizations; and
- Equipment manufacturers.

A broad range of activities in safety and quality improvement of radiation medicine are being conducted at national, regional and global level, addressing diverse topics and involving many stakeholders. This initiative seeks to provide a common platform for co-operation towards the engagement of the health sector and all stakeholders towards the safe use of radiation in healthcare (Figure 6). It aspires to foster positive relationships and encourage stakeholder involvement as partners as well as target users of the deliverables.



**Figure 6. The Building Blocks for the Global Initiative.** The Global Initiative will engage, consult and collaborate with the stakeholders to develop end-user tools and policy recommendations to meet the needs of the stakeholders.

### 8.2.2. Proposed activities

The proposed approach of the Global Initiative is to apply scientific evidence into the development and implementation of policies and programs on risk assessment, risk management and risk communication issues (Table 10).

Strategies	Issues
Risk assessment	Population dose due to the use of radiation in healthcare Research agenda on the health effects of medical radiation exposure, focusing in children
Risk management	Implementation of regulations Reduction of unnecessary medical exposures by justification and optimization etc. Clinical audit and quality improvement Occupational health Resources for radiation medicine workers, i.e. education, training and staffing Prevention of unintended exposures, including error reporting
Risk communication	Advocacy and communication to provide information and raise awareness

**Table 10.** Key issues: a range of issues are listed under each strategy

An example of a risk management schema modified from the Australian and New Zealand Standards provided by the IRQN is presented in Figure 7. The risks are identified, analysed, evaluated and risk reduction measures developed. Consultation with the stakeholders will enable the sharing of solution ownership. Effective communication will ensure the message is understood. Continuous monitoring and review will determine if the measures do work and emphasize that risk reduction is an on-going process.

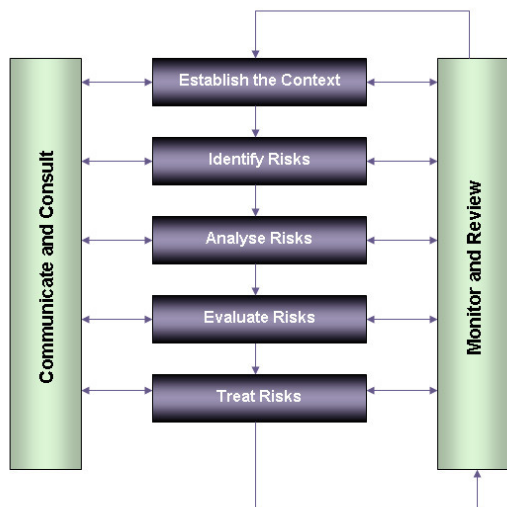


Figure 7. A risk management scheme: an example modified from the Australian and New Zealand Standards AS/NZS 4360

**8.2.3. Master Plan: matching issues to stakeholders' needs**

The issues and the key stakeholder groups are matched and tabulated (Table 11). Based on this table, activities will be developed and prioritized. The issues are either discipline specific or generic / cross-cutting i.e. applicable to all stakeholders. Specific issues for a particular group of stakeholders are listed under the same column. The common issues which involve all the stakeholders groups are shown in the tops rows.



Area	Key Stakeholders Groups			
	Consumers	Referrers	Providers	Regulators & Payers
Risk communication	Promote actions for stakeholders engagement			
	Raise awareness on radiation risks and safe use radiation in healthcare			
	Develop communication strategy including advocacy tools (electronic, printed, audiovisual)			
	Develop guidance on informed consent and communication of risk to patients			
	Develop risk communication tools for patients, family and general public			
Risk assessment				Develop tools for population medical exposure estimation and assist national surveys
				Shape and promote a research agenda on the effects of medical radiation exposure
Risk management	Develop information tools on the benefits and risks of new technologies and the use of justification criteria	Promote the use of evidence-based referral guidelines and appropriateness criteria for justification of radiological medical procedures		Support Member States in the implementation of policies to reduce unnecessary medical exposures
			Develop guidance tools on optimization including the use of DRLs.	Support Member States in the implementation of international safety standards and national regulations, foster cooperation between health authorities and other competent regulatory authorities
			Develop guidance on good practice standards on paediatric CT (justification, optimization)	
			Promote clinical audits by developing and disseminating guidance and conducting training activities	Support Member States in the implementation of clinical audit and quality improvement programs
			Harmonize the criteria for error reporting including taxonomy, analyze the risk profiles and disseminate the lessons learnt.	Support Member States in the prevention of unintended medical exposures by capacity building through education and training
			Review occupational health risk profiles; develop a toolkit on radiation risk management at the workplace; and disseminate guidance for the implementation of policies to protect workers	
			Develop a strategy to address the needs of radiation medicine workers, including workforce, workload, role extension etc.	
			Promote safety culture in health care settings and develop multi-disciplinary training, knowledge transfer, and training models; disseminate guidance on radiation protection including translation of existing materials.	
			Advocate the inclusion of radiation protection topics in medical and public health curricula and foster co-operation between health and nuclear / radiological authorities towards medical education	

Table 11. Global Initiative Master Plan: issues are matched to the needs of the key stakeholder groups

#### 8.2.4. Working Groups: matching activities to stakeholder partners

Based on these prioritized issues, activities are designed, possible partners identified and Working Groups established. Some of these possible initial activities focus in risk assessment; risk management and risk

communication. The potential partners and Working Groups are tabulated (Table 12). These possible initial activities would require further discussion, refinement, selection and prioritization.

Working Group	Activities / tasks	Possible Partners
Risk assessment	<ul style="list-style-type: none"> <li>o a) National surveys on medical exposures:               <ul style="list-style-type: none"> <li>- to develop tools for population dose estimation;</li> <li>- to develop / revise questionnaires;</li> <li>to assist MS to conduct the surveys.</li> </ul> </li> <li>o b) Setting and promoting a research agenda:               <ul style="list-style-type: none"> <li>- epidemiological research (e.g. pediatric procedures);</li> <li>- clinical research (e.g. cataract, skin damage);</li> <li>- experimental research (molecular and cellular effects).</li> </ul> </li> </ul>	UNSCEAR, EC, NEA, IARC, FORO, research centres
Regulatory aspects	<ul style="list-style-type: none"> <li>o Support health authorities to monitor adoption and implementation of regulations;</li> <li>o Foster co-operation between health authorities and nuclear/radiological in the field of medical uses of radiation;</li> </ul>	IAEA, EC, FORO, IAMRA
Reducing unnecessary medical exposures	<ul style="list-style-type: none"> <li>o Review, adapt, disseminate and promote the use of referral guidelines and appropriateness criteria (justification);</li> <li>o Guidance on concept and use of DRLs (optimization);</li> <li>o Good practice guidance on pediatric CT;</li> <li>o Support MS to implement policies to reduce unnecessary doses.</li> </ul>	ISR, ISRRT, IRQN, WFNMB, IOMP, ICRP, WONCA, Image Gently campaign, regional and national professional bodies (e.g. EANM, ESR, RCR, ACR, etc.)
Clinical audit and quality improvement	<ul style="list-style-type: none"> <li>o Develop/disseminate guidance on clinical audit;</li> <li>o Conduct train the trainers activities;</li> <li>o Support MS to implement national programmes on clinical audit;</li> </ul>	IAEA, EC, IRQN
Occupational health	<ul style="list-style-type: none"> <li>o Review occupational health risk profiles for different work environments, e.g. interventional radiology;</li> <li>o Develop a toolkit on radiation risk management at the workplace;</li> <li>o Develop guidance for occupational health services.</li> </ul>	ILO, IAEA, ICRP, EC, NEA
Education, training and staffing	<ul style="list-style-type: none"> <li>o Develop a strategy to address the needs of radiation medicine workers, i.e. medical physicists, radiographers and technologists;</li> <li>o Promote sustainability of expertise and develop multi-disciplinary training packages, knowledge transfer, delivery of training, and training models;</li> <li>o Disseminate guidance on radiation protection including the translation of the existing documents e.g. ICRP recommendations;</li> <li>o Advocate the inclusion of radiation safety topics in medical and public health curricula;</li> <li>o Foster co-operation between health and nuclear / radiological authorities towards medical education.</li> </ul>	ICRP, IRPA, IOMP, ISRRT, IRQN, ILO, NEA, WFME, WMA, IFMSA, Image Gently campaign, regional professional bodies (e.g. EFRS)
Prevention of unintended exposures	<ul style="list-style-type: none"> <li>o Harmonize the criteria for error reporting in radiotherapy including severity grading scale (taxonomy), analyze risk profiles and disseminate the lessons learnt;</li> <li>o Promote similar systems in other disciplines e.g. interventional radiology, CT, nuclear medicine;</li> <li>o Support Member States by capacity building through education and training.</li> </ul>	IAEA, ASTRO, ESTRO, ALATRO, ROSIS, ISRRT, ISR, IRQN, FORO, regional and national professional bodies
Advocacy and communication	<ul style="list-style-type: none"> <li>o Promote actions for stakeholders engagement;</li> <li>o Produce advocacy tools and awareness strategies to communicate messages to health authorities, decision-makers, healthcare workers, patients, parents (pediatrics) and the general public;</li> <li>o Develop guidance on radiation risk communication including informed consent and communication with patients;</li> <li>o Disseminate knowledge, promote information exchange.</li> </ul>	All
Fund raising	<ul style="list-style-type: none"> <li>o Develop and implement a strategy for resource mobilization.</li> </ul>	All

**Table 12. Global Initiative Initial Activities:** the potential partners are identified for the initial activities, which are handled by specific Working Groups

### 8.2.5. Timetable and milestones

The Global Initiative will address diagnostic imaging, intervention radiology, radiotherapy and nuclear medicine considering the different needs and conditions of low, middle and high income countries. A 4 stage timetable is proposed. (Table 13)

Stage 1 Strategy outline	Stage 2 Work Plan development	Stage 3 Initiative implementation	Stage 4 Monitoring & evaluation
December 2008	June 2009	June 2011	December 2011
<ul style="list-style-type: none"> <li>○ Develop proposal</li> <li>○ Internal &amp; external consultation</li> <li>○ Identify &amp; consult stakeholders</li> <li>○ Build partnership</li> </ul>	<ul style="list-style-type: none"> <li>○ Initiate framework</li> <li>○ Develop terms of reference</li> <li>○ Prepare and prioritize list of activities</li> <li>○ Develop a detailed work plan and timeline</li> <li>○ Establish Working Groups and Task Coordination Team</li> <li>○ Prepare budget and mobilize resources</li> </ul>	<ul style="list-style-type: none"> <li>○ Develop priorities</li> <li>○ Pilot and trial</li> <li>○ Activities execution</li> <li>○ Working Groups operating</li> </ul>	<ul style="list-style-type: none"> <li>○ Monitor implementation</li> <li>○ Evaluate impact</li> <li>○ Feedback and communicate results</li> </ul>

Table 13. Global Initiative Timetable and Milestones

### 8.2.6. Resource mobilization

The funding options for the Global Initiative are being explored. The assessed contributions from the Member States in the biennium 2006-2007, i.e. dues, accounts for 28% of the total funding with the remainder 72% from voluntary contributions. The sources for voluntary contributions are: Member States 67%; UN and inter-governmental organizations 17%; Foundations 6%; NGO 4%; supply services funds 2%; local governments, cities, institutions 1%; and private sector 1%.

Based on this situation, there is an urgent need to explore strategies for resource mobilization for the Global Initiative. A dedicated team coordinated by the WHO secretariat working together with national and international partners should develop an effective and convincing template for presentation to potential donors. There is a range of funding options and resources will be mobilized and coordinated through collaboration with stakeholders.

A flyer for resource mobilization is under development, highlighting the background issues on medical exposures and radiation safety in health care settings, WHO's response, the concept and purpose of the Global Initiative, proposed activities, and expected outcomes. This flyer will assist decision making for potential donors to provide funds to advance this initiative. It was agreed that the flyer would be circulated to participants for comments. It was noted that it should be kept in mind that this flyer is targeted to potential donors.

Participants will raise the issue of resource mobilization at country level, focusing in their national health authorities. MS may be interested in the whole proposal or direct the request towards a particular deliverable or activity. The MoH is the institution which can and should give support to this initiative.

The EC could find some ways to support the GI. It is necessary to demonstrate that the activities to be supported do have an added value. WHO adds value by acting as a clearing house. In addition to receiving funding support, the GI also welcomes the cooperation and contribution from countries when undertaking specific tasks.

The role of the private sector was discussed. The private sector could assist in some activities, but any interaction should be transparent. Although it might be difficult to get funds directly from the private

sector, they could fund activities conducted at country level e.g. translation, edition and publication of documents.

#### **8.2.7. WHO's role: leverage and experience**

There are some comparative advantages of WHO to conduct this Global Initiative, such as:

- Its neutral status and impartiality;
- Its strong convening power and nearly universal membership;
- Its unparalleled role in tackling diseases globally;
- Its large repertoire of global normative work;
- Its role and experience in providing standards and assurances in medicines and diagnostic equipment to many countries;
- Its efforts in promoting evidence-based debate;
- Its numerous formal and informal networks around the world; and
- Its regionalized structure providing numerous opportunities to engage with countries.

#### **8.2.8. Q & A, discussion**

It was agreed by the participants that the link between WHO and the health authorities would facilitate the mobilization of the health sector. Indeed, the strength of the WHO is based on its counterparts, the MoHs. This was supported by S. Niu (ILO), who stressed that all participants should lobby the MoHs to provide extra funds for RP at country level.

Some participants suggested making a proposal to the WHA to strength WHO's RP programme. ILO would be fully supportive of this because in the case of protection for radiation health workers the MoHs do pay attention to WHO's recommendations. If some effort could be made in this direction it would be highly appreciated. It was explained by WHO staff members that the way to raise this topic at the WHA (which is held annually in May) at least some countries should raise this in advance to the EB meeting (which is held annually in January). Some participants indicated that they would contact their MoHs and raise this matter.

Regarding the possible inclusion and discussion of this topic in the WHA, the delegates were reminded that WHO is already engaged in radiation safety and is cosponsoring the BSS. PAHO approved a resolution in 1994 to endorse the current BSS. WHO HQ used a different mechanism and endorsed the current BSS by the EB later. WHO and PAHO are currently actively involved in the BSS revision process as members of the BSS Revision Secretariat. The MoHs will have to endorse the revised version of BSS. Therefore, there are many possibilities to raise this issue at a higher level but the WHO Secretariat has to receive positive input from the MS.

To raise this topic at a higher level within WHO, the participants should inform their MoHs and explain why this issue is of public health concern: medical exposures are increasing rapidly, some of them are unjustified and or unnecessary, the implementation of BSS in HCS is insufficient and this is happening worldwide. The most effective way to increase the profile of radiation safety in the WHO agenda is to engage the MoHs. Therefore, participants were encouraged to contact their MoHs.

It was noted that if radiation safety policies were not supported by MoHs it will be very difficult to implement these in health care settings. Radiation safety should be integrated in health programmes to ensure patient protection. The integration of radiation safety in any occupational health programme is essential.

Advocacy for the inclusion of RP in the curricula of the medical school is an important issue; but consideration should also be directed to the provision of some basic information at school level. The Ministries of Education should be approached to see how school students could be taught on some key RP messages.

It was proposed that the GI should be undertaken in stages. "Phase 1" will start by engaging key stakeholders and as many countries as possible. So far, 30 countries have already expressed their willingness to be involved. It will take some time for other countries to join this initiative. As a start, the stakeholders could develop a feasible plan for the next two years. It was noted that engaging national authorities and a national lead are essential because this issue should be raised by a higher level. The WHO EMF project is a good example of the important role of the WHO CCs. This is a useful model and the GI could learn from it.

The IAEA is one of the key partners for this initiative and complementary actions and synergies are expected. There are 143 MS in the IAEA and 193 MS in the WHO. IAEA partners are mainly the regulatory authorities while WHO counterparts are the MoHs. The IAEA works with its MS through Technical Cooperation projects. By interacting with the MoHs, the Global Initiative provides the link between the regulatory bodies and the health authorities to jointly address radiation safety issues in health care settings. As an example, an IAEA expert who attended a medical conference was informed of cases of severe adverse effects in patients undergoing interventional radiology procedures. RP in that country is under the regulation of the MoH. Although the IAEA was willing to provide assistance and support to that country, it would only be possible unless requested by the MoH.

The relatively low number of health authorities represented in this Technical Meeting is an indication of the level of involvement of the health sector in this topic. Dr. R. Czarwinski proposed an outline of the Global Initiative work plan through a "double entry" approach, focusing in three main areas of work including communication (link to the health authorities), education and training, and dissemination of existing guidance/tools, as follows:

<b>Area of work</b>	<b>Output (i.e. product, deliverables)</b>	<b>Outcome (i.e. effect)</b>	<b>Performance indicators</b>
Communication with health authorities			
Education and training			
Dissemination of existing guidance/tools			

It is important to emphasize that there are many cross cutting issues under this GI, e.g. cancer prevention, accident prevention / patient safety, primary health care, universal access to health technology, and cost-effectiveness of health care

When raising awareness of the safe use of radiation in health care, the stakeholders should start with a positive message; i.e. by informing the public of the benefits and not the risks. The GI should advocate for the prevention and reduction of risks by emphasizing there are tools available to improve radiation

safety. Another approach is by including the promotion of good medicine practice through this initiative. The starting message should be: "promoting a safer use"; rather than "safe" use; and should not be too negative.

Impact assessment and project evaluation form part of the GI. Corrective actions may be indicated based on the impact assessment findings after the completion of the activities / interventions. Impact assessment will also improve the design of future programs. The evaluation for this initiative was discussed. There was suggestion that while impact assessment would only be possible at the end of the initiative, the stakeholders should identify indicators / parameters early on to monitor the progress of the working groups. The GI should consider and identify indicators from the beginning, or at least as soon as possible. It was agreed that good indicators are required, and should be developed by the working groups.

## 8.3 Conclusion

### 8.3.1. Final discussion

The Global Initiative was welcomed by the participants, noting that many stakeholders are working towards cost-effectiveness in health, now more than ever. It was stressed that duplication of efforts should be avoided and collaborations should be encouraged. WHO can act as a clearing house to facilitate global co-operation. There are good existing documents and training materials which need to be distributed to the medical community. The WHO GI will facilitate this link, and will also evaluate those materials which should be harmonized and / or adapted.

There are many tasks concerning radiation safety in health care at a global level which requires attention and action. A joint effort is highly desirable. This is an important initiative and the findings should reach the end-users in the most effective way. One of the major tasks is communicating with the MS health authorities, which WHO can play a unique role. WHO can contribute by liaising with the health sector. It has developed a large and established network including MoHs, radiological practitioners, and general practitioners. WHO can contact and invite the participation of other referring groups via the international associations for family and other physicians (e.g. WONCA, International Pediatric Association).

There is an increasing concern from professional organizations and regulatory bodies about the unnecessary use of radiation in health care. Good medical practice includes the use of referral criteria / appropriateness criteria. WHO can improve the safety culture among radiological and general practitioners by informing them about the use of referral guidelines. The MoH should also be aware of these criteria and their use should be promoted. WHO plays a pivotal role in health and will lead this initiative at a global level.

There was a general consensus that the prevention of unintended exposures is a priority and this should be reflected in the GI. The GI should clearly mention the prevention of accidents, unintended exposures, and medical errors in the materials relating to radiation safety.

Creative strategies for fund raising should be developed and explored, targeting the interested parties to support this initiative. Secondment could be considered as an additional means of indirect funding. Some participants indicated that they would lobby their countries for support not only by participating in the Global Initiative but also by providing financial contribution.

The Global Initiative can have a significant impact on the implementation of the BSS in the health sector. The proposed matrix (i.e. areas of work, activities, tasks, and partners etc.) may be refined over time, taking into account of the proposals received during this meeting. It is important and most encouraging to have the strong supports from the participants who have provided valuable feedback. One of the key recommendations is to ensure the RP message is delivered to the health community. An important step is to translate the existing material not only into the national languages but also into the "health sector language", to make this easily understood. It was agreed by the stakeholders that they will work together and will complement each other in the most cost-effective way.

### 8.3.2. Concluding remarks

When radiation is used for diagnostic or therapeutic purposes, concerted efforts are required to improve radiation safety, quality and sustainability of the healthcare systems. Health authorities, other relevant competent authorities, policy and decision-makers should co-operate, identify and engage the key stakeholders to achieve these goals. It is important to conduct regular reviews and evaluations because needs do vary between Member States and safety and quality improvement is a continuum.

Quality and safety measures could be expensive in the short and medium term, especially if uncoordinated. It is, however, inevitable and indispensable in the long term supporting professionalism and risk minimization. WHO is proposing a **Global Initiative on Radiation Safety in Healthcare Settings** because quality improvement in healthcare encompasses radiation safety. To stay on track of this journey, professional leadership is required to inspire the un-informed, convert the skeptics and guide the committed to advance quality and safety in an integrated way.

Operating from its Geneva Headquarters and supported by an infrastructure of 6 regional and 147 country offices, the WHO interacts with its 193 Member States around the world. This structure providing a strong communication network and its experience in successfully delivering major undertakings on global health matters put WHO in a unique position to lead this challenging task.

The objectives and activities of the **Global Initiative on Radiation Safety in Healthcare Settings** are in keeping with the WHO's core functions:

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. Setting norms and standards, and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalysing change, and building sustainable institutional capacity; and
6. Monitoring the health situation and assessing health trends.

The WHO will work with the stakeholders to develop and implement the **Global Initiative on Radiation Safety in Healthcare Settings** to: promote development; foster health security; strengthen health systems; harness research, information and evidence; enhance partnerships; and improve performance. This collaborative and coordinated approach is in keeping with WHO's health agenda.

## 9. Appendix 1: Meeting Program



### TECHNICAL MEETING

#### Global Initiative on Radiation Safety in Healthcare Settings

WHO Headquarters, Geneva, Switzerland  
Main Building, Salle B

Monday 15 December to Wednesday 17 December 2008

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#### AGENDA

**Monday 15 December**

**Chair: S. Niu**

09:30 Coffee - Registration

#### Opening

10:00 Welcome address

*M. Neira, Director, PHE  
S. Groth, Director, EHT  
C. Dora, Coordinator, IHE*

Adoption of Agenda  
Introduction of participants

WHO activities on radiation and health  
The Global Initiative: concept and proposed strategy

*P. Jiménez  
M. Pérez*

#### The Role of International Institutions

11:00 Cooperation with international organizations

*United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)  
International Commission on Radiological Protection (ICRP)  
International Atomic Energy Agency (IAEA)  
International Labour Organization (ILO)  
Nuclear Energy Agency (NEA/OECD)  
European Commission (EC)  
Iberoamerican Forum of Nuclear Regulators (FORO)*

*M. Crick  
E. Vaňo  
R. Czarwinski  
S. Niu  
J. Griebel  
G. Simeonov  
A. Larcher*

12:30 Lunch

13:30 Perspectives of professional bodies

*International Society of Radiology (ISR)  
International Radiology Quality Network (IRQN)*

*H. Ringertz  
L. Lau*



*International Society of Radiographers and Radiological Technologists (ISRRT)*  
*International Organization of Medical Physics (IOMP)*  
*International Radiation Protection Association (IRPA)*  
*European Society of Therapeutic Radiology and Oncology (ESTRO)*  
*Latin American Society of Therapeutic Radiology and Oncology (ALATRO)*  
*National Institute of Radiological Sciences (NIRS)*

*A. Yule*  
*C. Borrás*  
*B. Le Guen*  
*D. Olsen*  
*M. Macià*  
*K. Akahane*

15:30 Coffee Break

16:00 Mapping out activities  
 review ongoing/planned activities (international, regional, country level)  
 identify gaps and needs  
 discuss possible synergies and areas for co-operation

18:00 Close

18:15 Reception

## Tuesday 16 December

Chair: H. Ringertz

09:00 Setting the scene

Topical sessions conducted as follows

- *Scope*
- *Overview presentation(s)*
- *Discussion*

### Risk assessment

*M. Pérez / F. Shannoun*

09:05 Population exposure from medical use of IR: trends and tools for estimation  
*Estimating population radiation dose from medical imaging*

*A. Aroua*

09:35 Research agenda: from science to policy and action  
*Health effects following medical exposures early in life*  
*Uncertainty of low dose radiation health effects: from science to policy and action*

*A. Kesminiene*  
*S. Yamashita*

10:15 Coffee Break

### Risk management

10:45 Preventing unnecessary medical radiation exposures  
*Justification: the value of referral guidelines*  
*The ACR appropriateness criteria*  
*Lowering radiation dose delivered with CT*

*D. Remedios*  
*D. Miller*  
*D. Tack*

12:15 Clinical audit in medical radiological practice  
*Guidance on clinical audit: the EC project*  
*IAEA activities in comprehensive audit for radiation medicine*

*H. Jarvinen*  
*E. Salminen*

13:00 Lunch

14:00 Radiation protection of healthcare workers  
*Radiation protection in interventional radiology*

*E. Vañó*

- Radiation protection in nuclear medicine* *H. Zaidi*
- 14:45 Scaling up the role of medical physicists, radiographers and technologists  
*The view of medical physicists* *H. Zaidi*  
*The view of radiographers and radiation technologists* *P. Wood*
- 15:30 Towards the inclusion of radiation protection in medical education  
*Building partnership to improve education of health professionals* *H. Mercer*
- 16:00 Coffee Break
- 16:30 Error reporting systems and classification of events in Radiotherapy  
*Radiation Oncology Safety Information System (ROSIS)* *J. Cunningham*  
*Reporting criteria and grade scale* *C. Marchal*  
*World Alliance for Patient Safety (WAPS)* *C. Lemer*
- Risk communication** *E. Van Deventer*
- 17:30 Communication strategy  
*Advocacy and communication: tailoring the messages* *G. Gamhewage*
- 18:00 Wrap-up
- 18:15 Close

## **Wednesday 17 December**

**Chair: J. Griebel**

- 09:00 Debriefing
- Towards the implementation of the Global Initiative** *E. Van Deventer*
- 09:15 Review of the global strategy  
 Work plan and timeline  
 Working procedures
- 10:30 Coffee Break
- 11:00 Stakeholders engagement  
 Resource mobilization strategy
- Final discussion and closing remarks
- 12:30 End of the meeting

## 10. Appendix 2: List of participants

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Technical Meeting  
December 15-17 2008 - WHO HQ, Geneva, Switzerland

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## 11. Appendix 3: Glossary

**Academic institutions:** institutions dedicated to research and education, which grant academic degrees.

**Civil society:** organized bodies and representative groups of the non-governmental sector of society, i.e. unions, churches, charities, non-governmental organizations (NGOs), minority groups, foundations, etc.

**General public:** people, members of the public who are not in the focus of any given issue; lay people.

**Government:** any representative or part of the governing administration at any level of the Executive - i.e. Office of the President, Chancellor, Prime Minister, Ministry (central level or lower level jurisdiction - state, region, province, department, municipality), federal or national technical agencies.

**Healthcare provider:** medical and non-medical personnel and services such as physicians, nurses, physician assistants, pharmacists, technicians, dentists, medical physicists, healthcare facilities (hospitals, clinics, polyclinics, health centres), as well as their professional associations or interest groups. Providers can be classified as private, public, corporate, or mixed and can operate as for-profit or not-for-profit; governmental or non-governmental institutions.

**International organizations:** organizations with international membership, in the context of this document they are mainly inter-governmental organizations established by the Member States.

**Media:** public communication channels through which news, entertainment, educative or promotional messages are disseminated, including newspapers, magazines, journals, television, internet, radio, telephone, fax, etc.

**Patient / consumer:** a person in, before or after a specific treatment situation, with the concept of "consumer" in the broader sense of the word. Patient groups, self-help-groups, relatives, parents of pediatric patients, and consumer interest groups fall under this category as well.

**Payers:** purchasers of healthcare services, i.e. public or private insurers offering comprehensive or partial, statutory or voluntary coverage. Depending on the healthcare system, payers can also be the state, local authorities, social services institutions covering determined population groups, compensation schemes, charity or welfare organizations, employers' contribution schemes, households and / or individuals.

**Practitioner / Radiological practitioner:** a registered medical, dental or other healthcare practitioner who is licensed to use radiation in healthcare settings. Radiological practitioners include radiologists, radiation oncologists, nuclear medicine physicians, radiographers, radiation technologists, medical physicists, dentists, cardiologists, surgeons or others.

**Private sector:** pharmaceutical industry, medical equipment and medical devices vendors, private hospital operators, professional health management organizations, private finance institutions or investors.

**Professional organizations:** organizations for a group of professional practitioners which protect the practitioners' and the public's interest by maintaining and enforcing standards of training and ethics in the profession.

Referring health professionals (referrers): a registered medical, dental or other healthcare practitioner who is permitted to refer an individual to a radiological practitioner for a radiation medicine procedure. Referrers cover general practitioners, specialists and certain paramedical practitioners, e.g. chiropractors, physiotherapists, osteopaths or nurses.

Scientific community: all public and / or private research institutions, e.g. universities, specialized research institutes, scientific societies.

## 12. Appendix 4: Useful links

American Society for Radiation Oncology (ASTRO)	<a href="http://www.astro.org">www.astro.org</a>
Asociacion Latinoamericana de Terapia Radiante Oncológica (ALATRO)	<a href="http://www.alatro.org">www.alatro.org</a>
Atomic Bomb Disease Institute, Nagasaki University, Japan	<a href="http://www-sdc.med.nagasaki-u.ac.jp/">www-sdc.med.nagasaki-u.ac.jp/</a>
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	<a href="http://www.arpansa.gov.au">www.arpansa.gov.au</a>
Autorité de Sureté Nucléaire, France (ASN)	<a href="http://www.asn.fr">www.asn.fr</a>
Bundesamt für Strahlenschutz, Germany (BfS)	<a href="http://www.bfs.de">www.bfs.de</a>
Bureau of Health Devices and Technology, Philippines	<a href="http://www.doh.gov.ph/taxonomy/term/429">www.doh.gov.ph/taxonomy/term/429</a>
Department of Radiation Protection, Luxembourg	<a href="http://www.ms.etat.lu">www.ms.etat.lu</a>
Egyptian Atomic Energy Authority (EAEA)	<a href="http://www.eaea.org.eg">www.eaea.org.eg</a>
European Commission (EC)	<a href="http://ec.europa.eu">ec.europa.eu</a>
European Federation of Radiographer Societies (EFRS)	<a href="http://www.efrs.eu">www.efrs.eu</a>
European Society for Therapeutic Radiology and Oncology (ESTRO)	<a href="http://www.estro.be">www.estro.be</a>
Federal Agency for Nuclear Control, Belgium (FANC)	<a href="http://www.fanc.fgov.be">www.fanc.fgov.be</a>
Federal Office of Public Health, Switzerland	<a href="http://www.bag.admin.ch">www.bag.admin.ch</a>
Greek Atomic Energy Commission (GAEC)	<a href="http://www.gaec.gr">www.gaec.gr</a>
Health Canada	<a href="http://www.hc-sc.gc.ca">www.hc-sc.gc.ca</a>
Health Protection Agency, UK (HPA)	<a href="http://www.hpa.org.uk">www.hpa.org.uk</a>
Iberoamerican Forum of Radiological & Nuclear Regulatory Agencies (FORO)	<a href="http://www.foroiberam.org">www.foroiberam.org</a>
Image Gently Campaign - Alliance for Radiation Safety in Pediatric Imaging	<a href="http://www.pedrad.org/associations/5364/ig">www.pedrad.org/associations/5364/ig</a>
Institut de Radioprotection et de Sureté Nucléaire, France (IRSN)	<a href="http://www.irsn.fr">www.irsn.fr</a>
International Agency for Research on Cancer (IARC)	<a href="http://www.iarc.fr">www.iarc.fr</a>
International Atomic Energy Agency (IAEA)	<a href="http://www.iaea.org">www.iaea.org</a>
International Commission on Radiological Protection (ICRP)	<a href="http://www.icrp.org">www.icrp.org</a>
International Labour Organization (ILO)	<a href="http://www.ilo.org">www.ilo.org</a>
International Organization for Medical Physics (IOMP)	<a href="http://www.iomp.org">www.iomp.org</a>
International Radiation Protection Association (IRPA)	<a href="http://www.irpa.net">www.irpa.net</a>
International Radiology Quality Network (IRQN)	<a href="http://www.irqn.org">www.irqn.org</a>
International Society of Radiology (ISR)	<a href="http://www.isradiology.org">www.isradiology.org</a>
International Society of Radiographers & Radiological Technologists (ISRRT)	<a href="http://www.isrirt.org">www.isrirt.org</a>
Ministry of Health, Kingdom of Bahrain	<a href="http://www.health.gov.bh">www.health.gov.bh</a>
Ministry of Health and Consumer Affairs of Spain	<a href="http://www.msc.es">www.msc.es</a>
National Institute for Radiological Protection, China	<a href="http://www.nirp.cn">www.nirp.cn</a>
National Institute of Radiological Sciences, Japan (NIRS)	<a href="http://www.nirs.go.jp/">www.nirs.go.jp/</a>
National Nuclear Energy Commission, Brazil	<a href="http://www.cnen.gov.br">www.cnen.gov.br</a>
Norwegian Radiation Protection Authority (NRPA)	<a href="http://www.nrpa.no">www.nrpa.no</a>
Nuclear Regulatory Authority, Argentina	<a href="http://www.arn.gov.ar">www.arn.gov.ar</a>
Pan American Health Organization (PAHO)	<a href="http://new.paho.org">new.paho.org</a>
Radiation and Nuclear Safety Authority, Finland (STUK)	<a href="http://www.stuk.fi">www.stuk.fi</a>
Radiation Oncology Safety Information System (ROSIS)	<a href="http://www.clin.radfys.lu.se">www.clin.radfys.lu.se</a>
Radiation Protection, Ministry of Health, United Arab Emirates	<a href="http://www.moh.gov.ae/en/Page_1239.aspx">www.moh.gov.ae/en/Page_1239.aspx</a>
State Office for Nuclear Safety, Czech Republic	<a href="http://www.sujb.cz">www.sujb.cz</a>
Swedish Radiation Protection Authority (SSI)	<a href="http://www.stralsakerhetsmyndigheten.se">www.stralsakerhetsmyndigheten.se</a>
UN Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)	<a href="http://www.unscear.org">www.unscear.org</a>
World Health Organization (WHO)	<a href="http://www.who.org">www.who.org</a>

## 13. Appendix 5: References

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### Disclaimer

This report contains the collective views of an international group of experts, and does not necessarily represent the decisions or the stated policy of the World Health Organization.