Radiation Safety, Health Technology and Health Information Systems

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- Global benchmark for radiation safety, cosponsored by 8 international organizations.

- The safety requirements in new International BSS and in the new EURATOM BSS are consistent.

- In both the new international and EURATOM BSS, the safety requirements on medical exposures have been substantially expanded.

- A key challenge today: to implement the new BSS in medical uses of radiation.
Bonn Call for Action

10 actions to improve radiation protection in medicine

1. Enhancing implementation of **justification** of procedures
2. Enhancing implementation of **optimization** of protection and safety
3. Strengthening **managers’** contribution to radiation safety
4. Strengthening RP **education and training** of health professionals
5. Shaping & promoting a **strategic research agenda** for RP in medicine
6. Improving **data collection** on radiation exposures of patients and workers
7. Improving primary **prevention of incidents and adverse events**
8. Strengthening radiation **safety culture** in health care
9. Fostering an improved radiation **benefit-risk-dialogue**
10. Strengthening the implementation of safety requirements (BSS) globally

http://www.who.int/ionizing_radiation/about/med_exposure/en
Radiation safety, health information systems and health technology

- Are the **BSS** and the **Bonn Call for Action** relevant for those who work in the field of health technology and medical devices?

- Which are the links between universal health coverage (UHC), access to health technology and medical devices and **radiation safety**?

- Is it possible to integrate **radiation safety** into policies, strategies, regulations on health technology and medical devices?
All the BSS requirements for medical exposures are relevant for the use of medical devices

- R. 34: **Authorizations** to relevant parties to assume roles/ responsibilities
- R. 35: **Education, training and competence** of health professionals.
- R. 36: Appropriate **referral, protection & safety, information** to patients.
- R. 37: All medical exposures shall be **JUSTIFIED**
- R. 38: Protection & safety shall be **OPTIMIZED** for each medical exposure
- R. 39: Protection of **pregnant** and **breast-feeding** patients
- R. 40: **Release of patients** after radionuclide therapy
- R. 41: Prevention of **unintended and accidental medical exposures**
- R. 41: Radiological **reviews** performed and **records** maintained
BSS and the optimization of protection & safety for the use of medical devices

- **Design** considerations (medical radiological equipment and software)
- **Operational** considerations (cooperation between rad. medical practitioner, medical physicist and rad. technologist to ensure that appropriate equipment/software, and appropriate techniques/parameters are used)
- **Particular considerations** (children, research, health screening, pregnancy, breastfeeding, high-dose procedures).
- **Patient dosimetry** performed and documented and diagnostic reference levels (DRLs) established and periodically reviewed
- **Quality assurance** by, or under the supervision of a medical physicist (acceptance of the equipment, commissioning prior use, maintenance, installation of new software, verifications, calibrations, records, …)
Implementing the Bonn Call for Action to enhance safety and quality in the use of health technology and medical devices.

We will see now some examples of actions and related sub-actions which have links with health technology, medical devices and health information systems …

1. Enhancing implementation of justification of procedures
2. Enhancing implementation of optimization of protection and safety
3. Strengthening manufacturers’ contribution to radiation safety
4. Strengthening RP education and training of health professionals
5. Shaping & promoting a strategic research agenda for RP in medicine
6. Improving data collection on radiation exposures of patients and workers
7. Improving primary prevention of incidents and adverse events
8. Strengthening radiation safety culture in health care
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http://www.who.int/medical_devices/med_dev_exposure/en
Enhance the implementation of the principle of justification

- Introduce and apply the 3A’s (awareness, appropriateness and audit), which are seen as tools that are likely to facilitate and enhance justification in practice;
- Develop harmonized evidence-based criteria to strengthen the appropriateness of clinical imaging, including diagnostic nuclear medicine and non-ionizing radiation procedures, and involve all stakeholders in this development;
- Implement clinical imaging referral guidelines globally, keeping local and regional variations in mind, and ensure regular updating, sustainability and availability of these guidelines;
- Strengthen the application of clinical audit in relation to justification, ensuring that justification becomes an effective, transparent and accountable part of normal radiological practice;
- Introduce information technology solutions, such as decision support tools in clinical imaging, and ensure that these are available and freely accessible at the point-of-care;
- Further develop criteria for justification of health screening programmes for asymptomatic populations (e.g. mammography screening) and for medical imaging of asymptomatic individuals who are not participating in approved health screening programmes (e.g. use of CT for individual health surveillance).

Enhance the implementation of the principle of optimization of protection and safety

- Ensure establishment, use of, and regular update of diagnostic reference levels for radiological procedures, including interventional procedures, in particular for children;
- Strengthen the establishment of quality assurance programmes for medical exposures, as part of the application of comprehensive quality management systems;
- Implement harmonized criteria for release of patients after radionuclide therapy, and develop further detailed guidance as necessary;
- Develop and apply technological solutions for patient exposure records, harmonize the dose data formats provided by imaging equipment, and increase utilization of electronic health records.
Strengthen manufacturers’ role in contributing to the overall safety regime

- Ensure improved safety of medical devices by enhancing the radiation protection features in the design of both physical equipment and software and to make these available as default features rather than optional extra features;
- Support development of technical solutions for reduction of radiation exposure of patients, while maintaining clinical outcome, as well as of health workers;
- Enhance the provision of tools and support in order to give training for users that is specific to the particular medical devices, taking into account radiation protection and safety aspects;
- Reinforce the conformance to applicable standards of equipment with regard to performance, safety and dose parameters;
- Address the special needs of health care settings with limited infrastructure, such as sustainability and performance of equipment, whether new or refurbished;
- Strengthen cooperation and communication between manufacturers and other stakeholders, such as health professionals and professional societies;
- Support usage of platforms for interaction between manufacturers and health and radiation regulatory authorities and their representative organizations.

Strengthen radiation protection education and training of health professionals

- Prioritize radiation protection education and training for health professionals globally, targeting professionals using radiation in all medical and dental areas;
- Further develop the use of newer platforms such as specific training applications on the Internet for reaching larger groups for training purposes;
- Integrate radiation protection into the curricula of medical and dental schools, ensuring the establishment of a core competency in these areas;
- Strengthen collaboration in relation to education and training among education providers in health care settings with limited infrastructure as well as among these providers and international organizations and professional societies;
- Pay particular attention to the training of health professionals in situations of implementing new technology.
Shape and promote a strategic research agenda for radiation protection in medicine

- Explore the re-balancing of radiation research budgets in recognition of the fact that an overwhelming percentage of human exposure to man-made sources is medical;

- Strengthen investigations in low-dose health effects and radiological risks from external and internal exposures, especially in children and pregnant women, with an aim to reduce uncertainties in risk estimates at low doses;

- Study the occurrence of and mechanisms for individual differences in radiosensitivity and hyper-sensitivity to ionizing radiation, and their potential impact on the radiation protection system and practices;

- Explore the possibilities of identifying biological markers specific to ionizing radiation;

- Advance research in specialized areas of radiation effects, such as characterization of deterministic health effects, cardiovascular effects, and post-accident treatment of overexposed individuals;

- Promote research to improve methods for organ dose assessment, including patient dosimetry when using unsealed radioactive sources, as well as external beam small-field dosimetry.

Increase availability of improved global information on medical exposures and occupational exposures in medicine

- Improve collection of dose data and trends on medical exposures globally, and especially in low- and middle-income countries, by fostering international co-operation;

- Improve data collection on occupational exposures in medicine globally, also focussing on corresponding radiation protection measures taken in practice;

- Make the data available as a tool for quality management and for trend analysis, decision making and resource allocation.
Improve prevention of medical radiation incidents and accidents

☐ Implement and support voluntary educational safety reporting systems for the purpose of learning from the return of experience of safety related events in medical uses of radiation;

☐ Harmonize taxonomy in relation to medical radiation incidents and accidents, as well as related communication tools such as severity scales, and consider harmonization with safety taxonomy in other medical areas;

☐ Work towards inclusion of all modalities of medical usage of ionizing radiation in voluntary safety reporting, with an emphasis on brachytherapy, interventional radiology, and therapeutic nuclear medicine in addition to external beam radiotherapy;

☐ Implement prospective risk analysis methods to enhance safety in clinical practice;

☐ Ensure prioritization of independent verification of safety at critical steps, as an essential component of safety measures in medical uses of radiation.

Strengthen radiation safety culture in health care

☐ Establish patient safety as a strategic priority in medical uses of ionizing radiation, and recognize leadership as a critical element of strengthening radiation safety culture;

☐ Foster closer co-operation between radiation regulatory authorities, health authorities and professional societies;

☐ Foster closer co-operation on radiation protection between different disciplines of medical radiation applications as well as between different areas of radiation protection overall, including professional societies and patient associations;

☐ Learn about best practices for instilling a safety culture from other areas, such as the nuclear power industry and the aviation industry;

☐ Support integration of radiation protection aspects in health technology assessment;

☐ Work towards recognition of medical physics as an independent profession in health care, with radiation protection responsibilities;

☐ Enhance information exchange among peers on radiation protection and safety-related issues, utilizing advances in information technology.
Foster an improved radiation benefit-risk-dialogue

- Increase awareness about radiation benefits and risks among health professionals, patients and the public;
- Support improvement of risk communication skills of health care providers and radiation protection professionals – involve both technical and communication experts, in collaboration with patient associations, in a concerted action to develop clear messages tailored to specific target groups;
- Work towards an active informed decision making process for patients.

Strengthen the implementation of safety requirements globally

- Develop practical guidance to provide for the implementation of the International Basic Safety Standards in health care globally;
- Further the establishment of sufficient legislative and administrative framework for the protection of patients, workers and the public at national level, including enforcing requirements for radiation protection education and training of health professionals, and performing on-site inspections to identify deficits in the application of the requirements of this framework.
Good medical practice encompasses radiation safety

- Good health services are those which deliver safe and effective health interventions to those that need them, when and where needed, with minimum waste of resources.

- **Radiation safety** is embedded in the safety and quality of health services and is therefore linked to **Universal Health Coverage**.
Thank you very much!

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