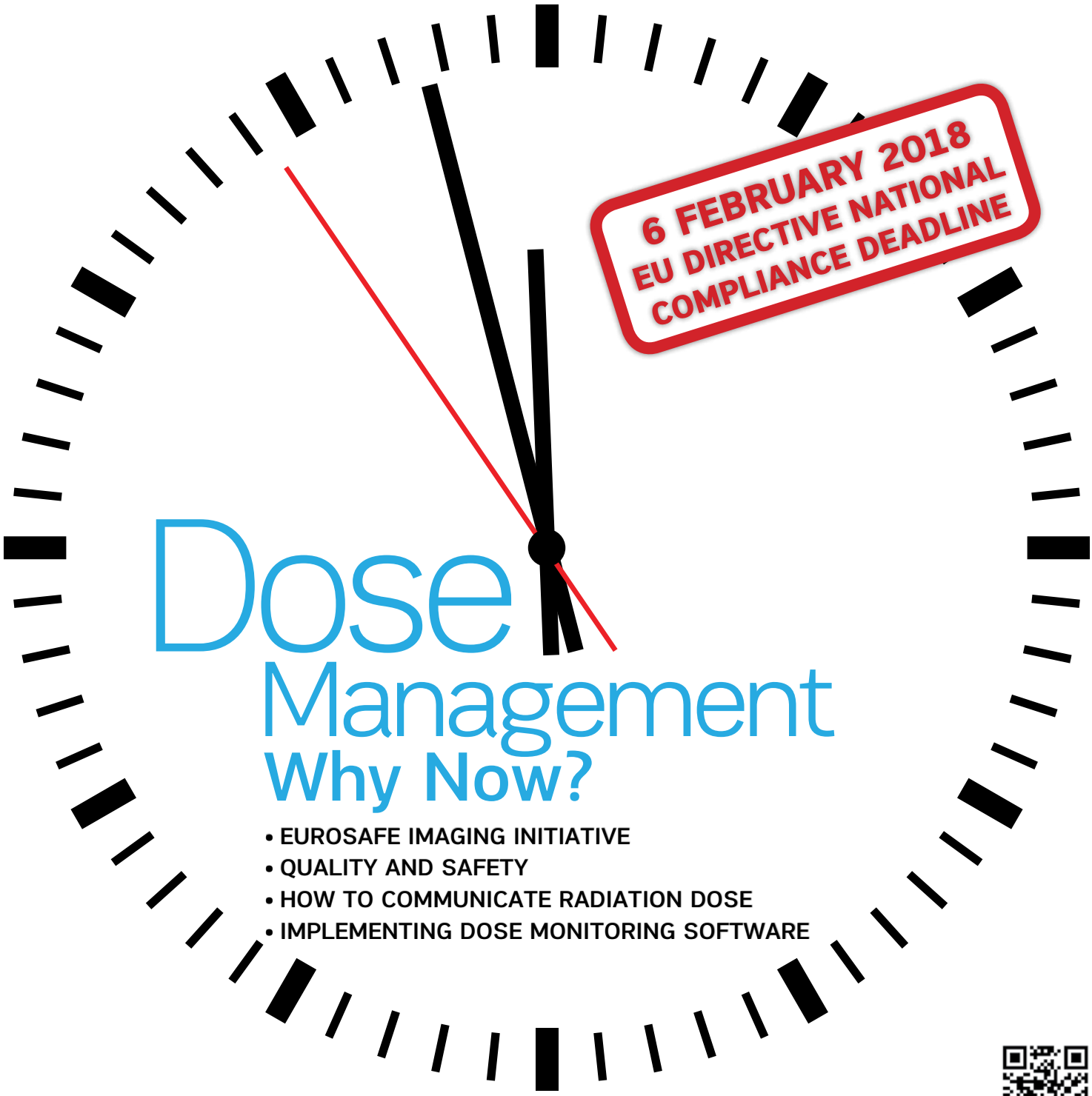
HealthManagement.org
The Journal
LEADERSHIP • CROSS-COLLABORATION • BEST PRACTICE
SPECIAL REPORT / VOLUME 16 • ISSUE 1 • 2016 ISSN = 1377-7629



Dose Management
Why Now?

- EUROSAFE IMAGING INITIATIVE
- QUALITY AND SAFETY
- HOW TO COMMUNICATE RADIATION DOSE
- IMPLEMENTING DOSE MONITORING SOFTWARE

Special Report Supported by an Educational Grant from Agfa HealthCare

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EDITORIAL

WHY DOSE? AND WHY NOW?

RADIATION DOSE – THE RESPONSIBILITY OF ALL

The demand for medical imaging examinations is constantly growing, making safety and quality in radiological practice and the risk of unnecessary radiation more important than ever.

Public awareness and concern have grown across a wide range of media. People are worried, they receive conflicting, sometimes confusing information, and they come to the radiology department with these concerns.

Worldwide, stakeholders and educational initiatives have responded to the challenge of radiation dose awareness, and regulations are starting to mandate radiation tracking.

The European Council Basic Safety Standards Directive (Council Directive 2013/59/EURATOM of 5 December 2013) lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation. EU countries must ensure compliance in national legislation by 6 February 2018.

The International Commission for Radiation Protection (ICRP) calls for imaging examinations to be performed adhering to the three fundamental principles of "justification, optimisation, and limitation".

Nevertheless, reduction of patient dose and risk should never be made at the expense of diagnostic imaging performance. The diagnostic value and the potential risks of an examination should be balanced and it is the responsibility of any radiology department to justify, optimise and limit radiation dose, keeping patients and referring doctors informed.

This special report reviews the initiatives of key European and International organisations, tools and educational supports that are available, the regulations and guidelines in place, how radiology departments can rise to the challenge, as well as a case study of how one department implemented dose monitoring software.

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THE EUROSAFE IMAGING INITIATIVE

ESR'S 12-POINT ACTION PLAN THAT PUTS QUALITY AND PATIENT SAFETY FIRST

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Birth of the EuroSafe Imaging initiative

Since its launch in 2014 by the European Society of Radiology (ESR), the EuroSafe Imaging initiative has placed radiation protection at the forefront of efforts to improve quality and safety in medical imaging in Europe in the most efficient and effective way possible.

The demand for medical imaging examinations is constantly growing with increasing pressure to meet the economic concerns of society and the health sector at large, making safety and quality in radiological practice and the risks of exposure to unnecessary radiation more important than ever.

The ESR has taken a major step in raising awareness of the importance of radiation protection at the clinical decision support level with the launch of EuroSafe Imaging at the European Congress of Radiology (ECR) in March 2014.

Charged with setting the campaign's strategy and overseeing its implementation, the steering committee is chaired by ESR Past-President Prof. Guy Frija, and consists of representatives from the ESR, the European Federation of Organisations for Medical Physics (EFOMP), the European Federation of Radiographer Societies (EFRS), the patient organisation European Federation of Neurological Associations (EFNA) on behalf of the ESR Patient Advisory Group, industry group COCIR and an observer from the European Commission. Other professions have also been invited, including cardiologists, orthopaedists and general practitioners.

The aim is to cover the vast majority of clinical scenarios, indications and recommendations in the areas of breast, cardiac, gastrointestinal, musculoskeletal, neurologic, thoracic, urologic, vascular and women's Imaging.

EuroSafe Imaging's mission to support and strengthen medical radiation protection across Europe following a holistic, inclusive approach, has been translated into the following main objectives:

- promoting appropriateness and justification of radiological procedures;
- maintaining radiation doses within diagnostic reference levels (DRLs);
- promoting the application of the 'as-low-as-reasonably-achievable' (ALARA) principle;
- the use of up-to-date imaging equipment;
- developing a strategic research agenda in radiation protection;
- empowering patients through better information and communication; and,
- joining forces by bringing together a variety of stakeholders.

Soon after its launch, EuroSafe Imaging started implementing measures to deliver its mission by developing a comprehensive strategy in the form of the EuroSafe Imaging Call for Action. This was designed to support the International Atomic Energy Agency and World Health Organisation's 2012 Bonn Call for Action, which identifies responsibilities and proposes priorities for stakeholders regarding radiation protection in medicine (International Atomic Energy Authority and World Health Organisation 2013).

Action Plan

EuroSafe Imaging's 12-point action plan aims to make a significant contribution to each of the ten priority areas in the Bonn Call for Action, and it is also geared towards realising the campaign's own objectives regarding appropriateness, DRLs, the ALARA principle, high quality equipment, as well as cooperation with patients and other stakeholders.

ESR iGuide

Adapted from criteria developed by the American College of Radiology (ACR), an ESR expert group initiated the development process of European imaging referral guidelines, known as the ESR iGuide, a prototype of which was introduced during ECR 2015, with pilots continuing in 2016.

Clinical Audit

The ESR's Clinical Audit Tool was launched in 2016. The Standards and Audit Tool provides guidance on how to perform effective audit against the 18 Patient Safety Standards that the ESR considers represent essential good practice in any imaging service.

The standards cover all aspects of patient safety, but particularly focus on radiation protection of the patient and will ensure that radiology departments comply with the audit requirement of the EURATOM Directive. The tool and templates are free to download from the ESR website (**myesr.org/cms/website.php?id=/en/services/ESRAuditTool.htm**).

Diagnostic Reference Levels (DRLs)

In assuming the lead of a European Commission project on paediatric DRLs entitled 'PiDRL' (eurosafeimaging.org/pidrl),

the ESR also contributed towards implementing measures to maintain radiation doses within DRLs (Action 3).

Education and Training

Education and training to improve radiation protection is of particular importance to the ESR, and the inclusion of 12 modules on radiation protection in its e-learning platform 'Education on Demand' and other orientation sessions were part of the implementation of Action 6 of EuroSafe Imaging's strategy. The ECR in 2015 and again in 2016 included EuroSafe Imaging sessions. More information is available on the EuroSafe Imaging website (**eurosafeimaging.org/training**).

Collaboration, Communication and Data Collection

With the launch of the cooperation with the research platform MELODI (Multidisciplinary European Low Dose Initiative) and the European Association of Nuclear Medicine, European Society for Radiotherapy and Oncology, EFRS, and EFOMP in 2014, the ESR showed its commitment to Action 7.

Implementation of Action 8 was also started, with the 'Is your Imaging EuroSafe?' survey series incorporated in the ESR's monthly member e-newsletter (**esr.frauida.at/gui/newsletter/newsletter.asp?languageId=1&newsletterId=48**). The aim of these surveys is to build a European repository based on DRLs for those clinical indications most helpful for self-benchmarking, thereby also contributing to Action 3.

Conceived as an awareness campaign, communicating EuroSafe Imaging's efforts to improve quality and safety in medical imaging (Action 10) is essential. EuroSafe Imaging has published articles in journals and newsletters, issued press releases, and created a promotional video (**youtube.com/watch?v=jinJ3nwYDCU**).

The ESR also enhanced its cooperation with patients (Action 11), as its Patient Advisory Group for Medical Imaging, founded in 2013, developed a 'driver diagram of patient-centred care'. Other patient-related activities included the publication of an article on EuroSafe Imaging in the European Patients' Forum's newsletter (**eu-patient.eu/News/News/EuroSafe-Imaging-Campaign-Towards-Patient-Safety**) and the addition of patient-centred information to the EuroSafe Imaging website (**eurosafeimaging.org/information-for-patients**).

Joining forces with a variety of stakeholders (Action 12) is an essential part of the structure of EuroSafe Imaging. Not only does the campaign directly incorporate external stakeholders in the EuroSafe Imaging Steering Committee, the ESR also uses the initiative as a framework to actively engage with decision makers at the national, European and international level to effectively represent radiologists' interests. This includes relations with EU institutions, IAEA, WHO and Heads of the Radiological Protection Competent Authorities (HERCA), the association of regulatory authorities for radiation protection in Europe.

EuroSafe Imaging also aims to foster global cooperation on radiation protection by working with initiatives outside Europe, including Image Wisely® and Image Gently®, while EuroSafe Imaging has pledged its support to the AFROSAFE project, an African radiation protection initiative launched at the 2015 Pan African Congress on Radiology (PACORI) in Nairobi. ■

The EuroSafe Imaging Call for Action is summarised as follows:

1. Develop a clinical decision support system for imaging referral guidelines in Europe.
2. Develop and promote a clinical audit tool for imaging to increase the quality of patient care and improve justification.
3. Implement measures to maintain radiation doses within DRLs.
4. Promote the use of up-to-date equipment and provide guidance on how to further reduce doses while maintaining image quality.
5. Establish a dialogue with industry regarding improvement of radiological equipment, the use of up-to-date equipment and the harmonisation of exposure indicators.
6. Organise radiation protection training courses and develop e-learning material to promote a safety culture and raise awareness of radiation protection.
7. Collaborate with research platforms and other medical professions to develop a strategic research agenda for medical radiation protection.
8. Develop the data collection project "Is your imaging EuroSafe?" and educational project on guidelines "Are you imaging appropriately?"
9. Develop criteria for imaging procedures that use ionising radiation in specific exams and anatomical regions.
10. Improve communication with healthcare professionals through media, conferences and training material.
11. Improve information for and communication with patients regarding radiological procedures and related risks in order to ensure empowerment of patients.
12. Engage with other stakeholders and collaboration with related initiatives and regulatory authorities in Europe and beyond to contribute to a global safety culture in medical imaging.

The ESR invites individuals and organisations to support EuroSafe Imaging's mission of improving quality and safety in medical imaging by signing up to become Friends of EuroSafe Imaging at eurosafeimaging.org.

QUALITY AND SAFETY IN RADIOLOGY

A SYMBIOTIC RELATIONSHIP

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Quality of Healthcare

Quality healthcare by definition means safe healthcare, and safety should be managed as an integral part of quality assurance. Safety, as defined by the National Patient Safety Foundation, is *"the degree to which health care processes avoid, prevent, and ameliorate adverse outcomes or injuries that stem from the processes of health care itself"* (National Patient Safety Foundation 2000). The Institute of Medicine defines it as freedom from accidental injury due to medical care, or medical errors (Institute of Medicine 1999).

Safety and quality have been highlighted by the European Commission's Directorate-General on Health that was tasked with considering the core dimensions of quality of healthcare, including patient safety (European Commission Expert Panel on Effective Ways of Investing in Health 2014).

The Expert Panel listed the dimensions of safety and related goals:

- Development of **safety systems** (including authorities, bodies, culture of patient safety, standards/guidelines) and **strategies** (policies, programmes);
- Development of **patient safety information** and learning systems;
- **Education** and training of healthcare workers, management and administrative staff;
- Encouragement of **multidisciplinary** patient safety on-the-job education and training;
- **Empowering** and informing citizens and patients, including patient involvement in safety policies.

The Panel noted that the most frequently used dimensions of quality of care include safety. However, these dimensions are not mutually exclusive and cannot be considered comprehensive.

The European Society of Radiology's *Call for an Action Plan for Medical Imaging to Improve Quality of Care and Patient Safety* was launched in November 2014, and aims to target policy-makers to strengthen efforts of harmonisation in regard to quality and safety, education and training, as well as research and technology, in order to significantly improve European healthcare systems, and ensure better quality and safety for European patients (ESR 2014).

To progress harmonisation of safety in imaging across Europe, the ESR calls on the EU institutions to:

- support the establishment of European quality and safety indicators for imaging;
- support an audit of imaging equipment, doses, image quality and procedures of the medical imaging chain in Europe and to develop plans to modernise equipment;
- support efforts to improve communication with patients;

Clinical Audit

Clinical audit on radiation safety is mandatory under the Basic Safety Standards directive. The European Society of Radiology (ESR)'s Audit and Standards Subcommittee has published Level I (basic) audit templates, which address essential patient safety standards, with a particular emphasis on radiation protection.

Essential Patient Safety Standards

Level I (basic) Audit Templates - ESR Audit and Standards Subcommittee

Authority of requestor policy
Authority of requestor policy implementation
Justification policy
Justification policy implementation
Justification policy for women of child bearing age
Reliable system of recording the pregnancy status in examinations involving ionising radiation
CT radiation dose records
Radiation dose in head CT in children
Dose optimisation in CT policy
Implementation of dose optimisation in CT policy
Policy for patient identification prior to procedure
Implementation of policy for patient identification prior to procedure
Prevention of MRI hazards policy
Implementation of prevention of MRI hazards policy
MRI patient safety check
Process for consent for interventional radiology procedures of non-emergency patients
Reduction of the risk of hypersensitivity reactions to contrast media
Policy on the prevention of contrast induced nephropathy (CIN)
Implementation of policy on the prevention of contrast induced nephropathy (CIN)
Appropriate care of acute contrast media reactions
Resuscitation policy/training
Infection control policy
Implementation of infection control policy by staff
Compliance of facilities with infection control policy
Policy on communication of emergency and unexpected findings
Implementation of policy on communication of emergency and unexpected findings
Audit of use of radiation protection by staff
Audit of doses received
Exposure of workers within MRI
Dose variation in CT chest, abdomen and pelvis in adults
Protocol for inadvertent radiation exposure

Available for download from the ESR website (**https://iii.hm/26e**)

- improve inter-institutional cooperation for more coherent action in the area of health;
- support the EuroSafe Imaging campaign (**eurosafeimaging.org**) to raise awareness of the importance of radiation protection

The International Atomic Energy Authority (IAEA) also issued a draft safety guide *Radiation Protection Safety in Medical Uses of Ionising Radiation* in November 2014 (IAEA 2014).

Patient Safety

The American College of Radiology and the Radiological Society of North America (RSNA)'s public information website **radiologyinfo.org** includes a section on patient safety, with information on radiology benefits and risks, radiation dose in x-ray and CT exams, and a printable medical imaging record card that patients can use to record their medical imaging history. In addition, the ACR has published a Position Statement On Quality Control and Improvement, Safety, Infection Control, and Patient Education (American College of Radiology 1998).

UCSF's radiology department is an example of a well-developed radiation safety programme that includes an experienced faculty member who devotes much of their time to patient safety (**radiology.ucsf.edu/patient-care/patient-safety**). The department's website includes guidelines for use of CT and MRI during pregnancy and lactation, as well as MRI and contrast guidelines. They list ten ways to ensure imaging safety:

1. Choosing the most appropriate imaging study
2. Tailored techniques
3. Careful quality control
4. Latest CT technology
5. Special attention for paediatric patients
6. New low–dose CT protocols
7. Shielding
8. Beam collimation policy
9. Appropriate training
10. Radiation oversight committee

To promote patient understanding of radiation risk, health professionals involved need to establish confidence with the patient, emphasise that potential risks are an estimation and not actual, use the concept of benefit instead of risk and explain the quality of the practice and the equipment.

EuroSafe Imaging with the ESR Patient Advisory Group for Medical Imaging have published patient information on radiation risks on its website (**eurosafeimaging/information-for-patients**).

Classification of major radiological examinations in broad category of radiation dose (Adapted from RPOP website of IAEA).

Procedure	Effective Dose mSv	Equivalent number of PA chest radiograph (each 0.02 mSv)	Increased Risk of Cancer	Equivalent Period of Natural Background
No Dose				
• MRI • Ultrasound	Not defined/ applicable	Not applicable	Not known	Not equivalent
Low Dose				
• Chest X ray • Extremities	0.02 <0.1	1 <5	One in a million	Few days
Intermediate Dose				
• Lumbar spine • Abdomen • CT head and neck • Nuclear medicine: Thyroid scan or liver-spleen or biliary or renal scan	1 – 5	50 – 250	1 in 10,000	Few months to a few years
Higher doses				
• Chest or abdomen CT • Nuclear cardiogram • PET/CT or SPECT/CT • Nuclear: Bone or brain scan or tumour scan • Cardiac angiogram • Barium enema	5 – 20	250 – 1000	1 in 2,000	A couple of years to several years
Natural background	2.4			

Source: eurosafeimaging.org/information-for-patients

Radiology Errors and Prevention

Errors do happen in the radiology department, with failure to correctly identify patients leading to recognised wrong events, with potential for treating the wrong patient, doing the wrong procedure on the wrong side or the wrong site. The main errors are:

- Wrong examination
- Wrong patient
- Wrong side
- Wrong site
- Wrong CA (contrast agent)
- MR safety
- Wrong protocol
- Pregnancy (technician/radiologist not aware that patient is pregnant)

Such errors are caused by incorrect order or requisition entry, failure to confirm patient identity, failure to follow site and procedure verification or procedure qualification processes.

Brook et al. (2010) found that poor communication, whether it was verbal communication or IT-related, caused many errors. Others have highlighted communication as the root of errors, for example:

"Poor communication is at the heart of many medical errors" (Woolf et al. 2004).

"Communication failures that contribute to discontinuity of care stem from a variety of causes, ranging from a lack of interpersonal communication skills to barriers in the work environment to suboptimal use of computer networking tools" (Scott 2007).

Low Awareness of Radiation Risk

Surprisingly, there is still low awareness of radiation risk from imaging procedures among healthcare professionals.

Ramanathan and Ryan (2015) surveyed 92 residents, fellows, technologists and radiologists in a hospital group in Ottawa, and found that knowledge of radiation dose and risk is poor among all radiology workers. Only 23% were aware of dose from both single-view and two-view chest X-ray; 50-70% underestimated dose from common studies; 50-75 % underestimated the risk of fatal cancer.

Source: Ramanathan S, Ryan J (2015) Radiation awareness among radiology residents, technologists, fellows and staff: where do we stand? Insights Imaging, 6(1): 133-9.

A survey of 780 Italian radiographers found that only 12.1 percent of respondents regularly attended radiation protection courses. Despite 90 percent of radiographers stating that they had sufficient awareness of radiation protection issues, most underestimated the radiation dose of almost all radiological procedures. About 5 percent and 4 percent of the participants, respectively, claimed that pelvis magnetic resonance imaging and abdominal ultrasound exposed patients to radiation, while 7 percent of the radiographers stated that mammography does not use ionising radiation.

Source: Paolicchi F, Miniati F, Bastiani L et al. (2015) Assessment of radiation protection awareness and knowledge about radiological examination doses among Italian radiographers. Insights Imaging, Nov 23 [Epub ahead of print].

A survey in Turkey of 300 health professionals (100 interns, 100 radiographers and 100 resident doctors) also found low awareness of radiation dose. 41.4 percent of all participants and 46.3 percent of resident doctors underestimated the radiation doses.

Source: Günalp M, Gülünay B, Polat O et al. (2014) Ionising radiation awareness among resident doctors, interns, and radiographers in a university hospital emergency department. Radiol Med, 119(6): 440-7.

EuroSafe Imaging is providing e-learning materials and radiation protection sessions for health professionals.

Such errors can be prevented with clear procedures on MRI safety, identifying pregnancy and contrast agent procedures for iodinated agents and gadolinium chelates. The ESR's Clinical Audit Templates include a template for implementation of a policy for patient identification prior to procedure.

Safety Reporting

Radiology departments should establish an events registry. One model is the the U.S. Agency for Healthcare Research and Quality-developed Patient Safety Indicators (PSIs) (n.d.) to provide information on potential in-hospital complications and adverse events following surgeries, procedures, and childbirth or the Australian initiative the Radiology Events Register (Mandel 2015).

Variation

It is well-known that radiation dose given during an exam differs between technicians, radiologists, within departments and across countries (Figure 1). The study by Ip et al. (2015) found wide variations in use across the United States and identified potential targets for future imaging quality improvement initiatives, including head CT and lumbar spine MR imaging. "Is my CT justified?" The onus is on the referring physician, in consultation with the radiologist, to prove it.

Is Your Imaging EuroSafe?

Action 8 of EuroSafe Imaging is to develop a data collection project "Is your imaging EuroSafe?" and an educational project on guidelines "Are you imaging appropriately?"

The aim is to build a European repository based on dose exposures for specific clinical indications that can be used for self-benchmarking, for establishing diagnostic reference levels (DRLs) and to provide insights into the influence of the age of the equipment on dose exposure. Data will be collected for adult patients on standard practice and scanner specifications.

Surveys are ongoing on the following procedures:

- CT head: acute stroke
- CT chest: pulmonary embolus (Figure 2)
- CT head: acute head trauma
- CT chest: rule out pulmonary metastases of extrathoracic cancer
- CT chest: HRCT for diffuse parenchymal disease
- CT abdomen: liver metastases
- CT abdomen: urinary calculus
- CT abdomen: appendicitis
- CT Colonography
- Cardiac CT: calcium coronary scoring

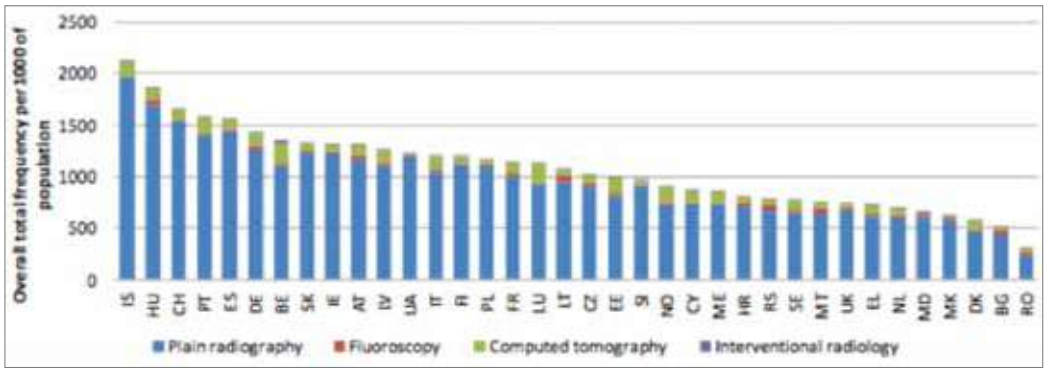

Figure 1. Example of Heterogeneity of Practice
Source: European Commission Directorate General for Energy (2014)

CT chest: pulmonary embolus – Preliminary results

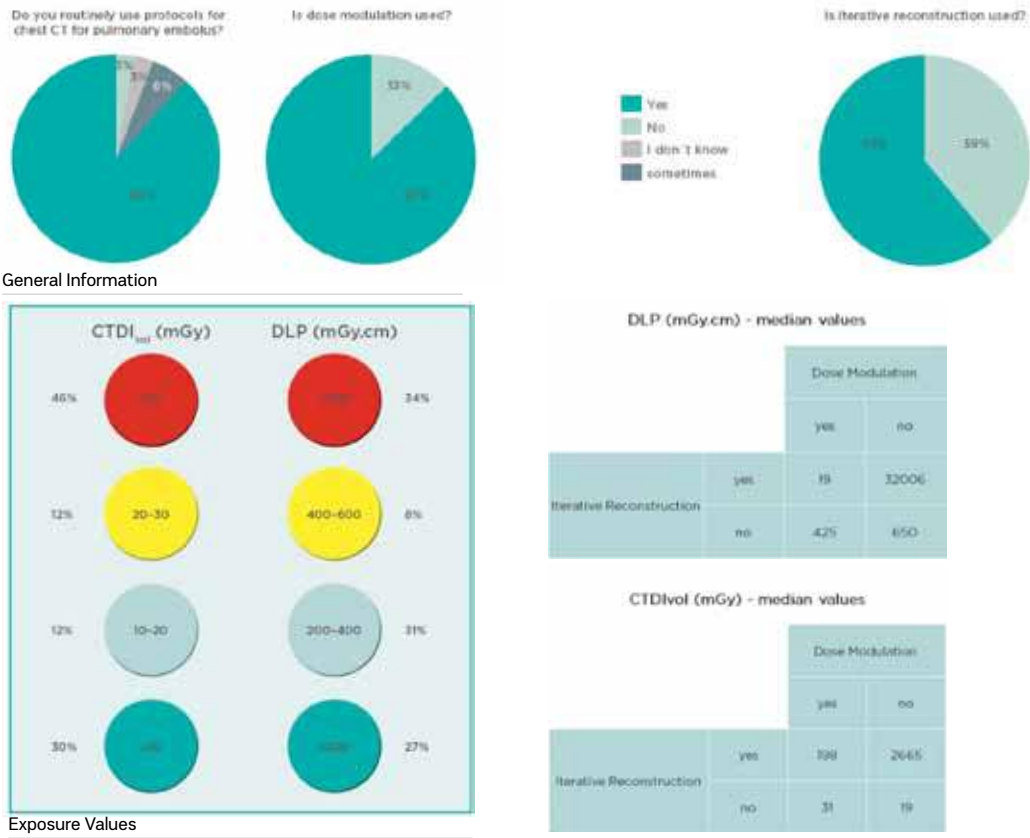

Figure 2. CT chest: pulmonary embolus - Preliminary results
Source: eurosafeimaging.org

Conclusion

Safe use of imaging should remain the main goal. However, quality of practice, organisation and management are absolutely essential for ensuring patient safety, which also implies a need for access to adequate IT tools. Benchmarking, clinical audit and patient information are also essential in this context and should be developed. Involvement of all stakeholders is crucial. ■

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HOW TO COMMUNICATE RADIATION DOSE AND CONTRAST MEDIA INFORMATION

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Public awareness and concern about radiation safety has grown in the last few years, and concerns have been voiced about radiation dose, for example in breast imaging, across a wide range of media. Patients are concerned, as they receive conflicting, sometimes confusing information. Therefore good communication from the radiology department is essential.

How to Communicate

It is a truism, but the choice is never between communicating or not communicating, but between communicating well or badly. When the radiologist does not communicate it encourages the patient to find information on the web, for example on websites that provide a risk calculator where the patient can input data for each study (gender, age, number of exams performed, associated absorbed dose), and the software calculates the effective dose and additional cancer risk. This is very worrisome for patients, because they think, for example, that they are going for a screening examination to ensure early diagnosis of cancer, but at the same time it increases the chances of getting cancer.

> “RADIOLOGY DEPARTMENTS NEED A MARKETING STRATEGY”

When the communication is there, it can be bad, and it may even have the effect of inducing the patient not to accept the examination that is actually useful for his or her health. Radiologists have to control the “scattering” of information, by avoiding use of confusing acronyms and physical dimensions, such as absorbed, equivalent and effective dose that are familiar to professional staff, but may be confusing for the layperson.

Some departments communicate the risk associated with radiation exposure during the medical procedure by using metaphors. Instead of saying that the patient is getting so many millisieverts (mSv), which are associated with a certain increase in health problems, they propose metaphors that take into consideration risky situations that are more familiar to the patient, such as smoking or driving.

Communication Strategy

Patients do not need to be frightened. I have heard patient groups reacting to the new directive, saying, “We don’t want to know the technical details, we’re not interested in millisieverts”. Most have this reaction, because they trust doctors. They say, “I will go and have the x-ray, because you assure me that I need the examination.” They want to be assured that when they go to a hospital to have an examination, they will receive state-of-the-art service. Radiology departments have to develop an appropriate communication strategy that does not frighten or confuse the patient, and is compliant with the regulation.

Following the new directive, departments will have to record in the radiology report the radiation dose given to the patient. However, radiologists can mitigate this information, which might be threatening or incomprehensible to the patient, by adding information about the department where the examination has been performed and the procedures that are in place to ensure that variations which are not clinically justified are reduced to a minimum, thereby ensuring reproducibility, consistency and quality of all examinations.

Marketing Strategy

Radiology departments need a marketing strategy. Yes, x-rays may be dangerous, but patients have an x-ray exam because it is justified. It is useful to have decision support systems that justify the examination, and patients must be given the information that guarantees that the department is committed to quality service also in terms of radiation dose. Radiology departments should be very clear in their mission statement that in their daily practice they aim for the right diagnoses after the right exam performed at the right time with the right protocol for each patient, with respect to different ages, sex and sizes.

Radiology departments need to measure, and they have to systematically use the quantitative approach in order to improve, where there is a margin to improve. Departments have to show that they are performing meticulous dose tracking for the exams most frequently performed in their department, and show that variation, when it is there, is in examinations that are in principle valuable to the clinical conditions of patients that are inherently different.

Information can be more in-depth: for example, histograms are a way of benchmarking the individual examination with respect to the same type of examinations performed in a

department. Histograms that show radiation dose can reassure the patient that he/she is in the group of examinations that are associated with the least amount of radiation dose. It is a subtle way of benchmarking the individual examination. Histograms can also benchmark data with other radiological groups. Patients having repeat examinations may want to have information about accumulated dose, and departments must be prepared to produce this.

Another marketing opportunity in Europe is to promote the radiology department as a Friend of EuroSafe Imaging (**eurosafeimaging.org/friends-of-eurosafe**). Friends of EuroSafe are committed to supporting the EuroSafe objectives:

- Promoting appropriateness;
- Maintaining radiation doses within diagnostic reference levels (DRL);
- Promoting the use of up-to-date equipment;
- Use the As Low As Reasonably Achievable (ALARA) principle;
- Improve communication with patients.

Get Ready

Radiology departments have to prepare for the implementation of the European directive by carrying out rigorous preliminary housekeeping. Marketing efforts are counterproductive, if departments do not work in a very controlled way, and examinations are associated with doses that vary quite randomly. If the line of a patient's examination is on the wrong side of the histogram without a valid clinical reason, this is not good for the department's image. Radiology departments will be increasingly transparent, and when numbers will be on the report they have to be absolutely ready.

> "THE ADOPTION OF RADIATION DOSE AND CONTRAST MEDIUM TRACKING SOFTWARE SOLUTIONS IS NOT AVOIDABLE"

There are many commercially available radiation dose and contrast medium tracking software solutions. There is healthy competition, and the radiological community can choose the tool that is best suited for their local situation, IT infrastructure and PACS system. In my opinion, the adoption of radiation dose and contrast medium tracking software solutions is not avoidable. It is going to be very useful for fine-tuning radiological activities aiming at total quality. Departments need to make sure that variations in contrast media usage and radiation doses are all clinically justified, that there is no random deviation, and that all variations can be explained to patients. Dose tracking is needed to ensure systematic, comprehensive and shared collection of data, and the radiology department must act on it in order to improve.

In our department we started this work some time ago, and it is a lot of additional work. We established a dose team, including our chief technologist, three junior technologists, a medical physicist, an engineer and a medical student. They help me to make sure that this software provides data, and that these data do not contain errors, because sometimes the raw extracted data may need to be analysed further.

It is not easy to obtain additional help in a time of cost-containment, but careful planning should be put in place before embarking on a project of radiation dose and contrast medium tracking, because this will certainly be an additional activity for already busy radiological departments. ■

UNDUE RADIATION EXPOSURE TOP TEN CHECKLIST

TOP TEN EVIDENCE-BASED INTERVENTIONS

PROCESS CHANGE	IN PLACE	NOT DONE	WILL ADOPT	NOTES (RESPONSIBLE AND BY WHOM?)
Develop a process to collect, store, and analyse patient dosimetry data.	☐	☐	☐	
Create and implement a "Don't" list of exams that have little proven value or do not change the course of treatment.	☐	☐	☐	
Participate in the National Dose Index Registry.	☐	☐	☐	
Require informed consents specific to ionising radiation examinations.	☐	☐	☐	
Eliminate routine ionizing radiation orders (eg, a daily chest x-ray).	☐	☐	☐	
Provide patients with tools to track their personal medical imaging history.	☐	☐	☐	
Assess staff/practitioner knowledge about the risks/benefits of ionising radiation.	☐	☐	☐	
Develop a toolkit with educational materials about radiation safety for ordering practitioners.	☐	☐	☐	
Analyse data/information from EMR alerts and redesign and improve standardized processes.	☐	☐	☐	
One size does not fit all: Develop specific criteria for the use of ionising radiation in special cases, e.g. for infants, small children, and pregnant women.	☐	☐	☐	

Source: American Hospital Association, Health Research & Educational Trust (2014) Radiation exposure checklist. Available from hret-hen.org/topics/radiation-exposure/13-14/2014-RadiationChecklist.pdf

DOSE CREEP

THE RIGHT TOOLS TO MONITOR DIAGNOSTIC RADIATION EXPOSURES

Listed at no. 7 among the ECRI Institute's *Top 10 Health Hazards 2015* (ECRI 2014) is 'dose creep', whereby dose exposure levels are increased by clinicians over time in order to achieve better image quality in diagnostic radiography.

"Although it is unlikely to result in immediate harm, it's an insidious problem that can have long-term consequences and that, over time, can affect many patients. Fortunately, tools are now becoming available to help healthcare facilities combat this hazard," according to the ECRI Institute.

'Dose creep' is often seen as an unintended consequence of the progress from film to digital detectors, with the latter considered as 'more forgiving' in diagnostic radiography because they have a much wider dynamic range than film and reduce the likelihood for an imaging exam to be repeated.

However, with digital detectors the quality of the image generally improves as the dose increases with a natural tendency to nudge the dose higher to get better-quality images.

Source: ECRI (2014) Top 10 health technology hazards. Health Devices, November. Available from: ecri.org/Resources/Whitepapers_and_reports/Top_Ten_Technology_Hazards_2015.pdf

ECRI Recommendations

- If your digital diagnostic radiography systems are not already equipped to use the standardised exposure index (EI) — as developed by the International Electrotechnical Commission (IEC 62494-1) and the American Association of Physicists in Medicine (AAPM TG-116) and as implemented by device manufacturers — investigate whether a software upgrade is available to add this capability. For new equipment purchases, incorporate EI capabilities into your request for proposal.
- After it has been incorporated into your imaging systems, use the EI to estimate the patient dose and exposure on the detector.
- Take the steps necessary to display EI values to radiographic technologists as part of their routine workflow. This may require a software upgrade or configuration change.
- Install software tools that automatically import and analyse EI data.
- Define responsibilities for tracking and analysing the EI data for the whole department.
- Work toward defining acceptable EI values and ranges for commonly performed radiography studies.

IMPLEMENTING DOSE MONITORING SOFTWARE IN A RADIOLOGY DEPARTMENT

MEETING THE CHALLENGES

Implementation Considerations

Before planning implementation of dose monitoring software you should be aware of some challenges that need to be met. This is a tool, which offers many options, but the available features may not match your department's expectations and requirements. Awareness of what exactly the department's needs are is essential at the beginning. Furthermore, one should be conscious of the fact that the software indeed is able to register dose data, but it cannot check for plausibility of data.

Step 1: Determine Technical Strategy

If these challenges are accepted the next step is to determine your technical strategy, which includes choosing the right dose monitoring software for your requirements. Consideration of the different modalities that should be linked to the software is important, because not all software allows for connection with all modalities. Moreover, to ensure high quality of data input it should be verified that the software can communicate with the hospital information system (HIS) and radiology information system (RIS) and can also be integrated in the local network.

> "PARTICULARLY AT THE BEGINNING, RESISTANCE TO CHANGE IS OFTEN ENCOUNTERED"

Step 2: Define Organisational Strategy

Then you need to define your organisational strategy, which comprises not only assigning the modalities, but also specifying the scanners/units that ought to be connected with the software to ensure interoperability. This includes considerations about installation of the dose monitoring tool outside the radiology department, where x-rays are used as well (eg, coronary angiography suite).

To successfully implement the software in clinical routine it is advisable to start with one modality only, which preferably should be computed tomography (CT), because CT scans are more standardised than, for example, fluoroscopy-guided procedures, at which various levels of difficulties need to be considered. Moreover, in most countries national defined dose reference levels (DRLs) for indication-based CT examinations are available, which facilitate setting dose thresholds.

Dose Team

To promote implementation of the software, represent dose culture and have contact persons, formation of a dose team is recommended. Ideally this should be composed of one or two radiographers, one board-certified radiologist and the department's IT specialist. Together with the head of the department the dose team should define a few appropriate, measurable, and achievable goals. As particularly at the beginning the dose team faces many tasks, including becoming familiar with the software, they should have protected time for their work.

One of their first challenges is to set reasonable dose reference levels; in our department we either used Swiss DRLs, so far available for 21 indication-based CT examinations (Swiss Federal Authority of Healthcare, 2010), or we derived thresholds by determining the 75th-percentile of the distribution of a defined dosimetric quantity.

Lessons Learnt

After we had installed the dose monitoring software and had started dose data analysis of our CT scanners, we had to solve unanticipated problems.

1. Data Output Relates to Input Quality

Although we knew that a dose monitoring tool is software, we weren't aware that data output depends extensively on the quality of the input. One of our main challenges was to match our own CT protocols with the available national DRLs. For example, our abdominal CT protocols comprise "abdomen and pelvis: unenhanced", "abdomen and pelvis: contrast media-enhanced", "liver protocol", "pancreas protocol" etc., and national DRLs are separated into "abdomen 1: liver, spleen, pancreas, vessels" or "abdomen 2: standard,

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abscess, emergency". Thus our internal processes required intensive adaptation at the beginning, which included cleaning our CT protocol list with removal of no longer employed CT protocols (eg, from former scanners), definition of precise protocol descriptions and uniform usage of protocol names. Thereafter, the different CT protocols were assigned to the national DRLs, if available, or to our own set thresholds.

2. Protocol Changes Not Recognised

When we started with data analysis, we frequently encountered the problem that the software did not recognise changes of protocol made after scanning had already started. For example, a patient with rectal carcinoma was enrolled for a CT of the abdomen and, based on this indication, the CT protocol "abdomen standard (single phase)" was chosen. But due to a so far unknown liver lesion a second phase was ordered by the radiologist on approval of the scan. However, in this case the software compares the scan's dose data with the DRL for "abdomen standard", unless the protocol name is changed manually to "abdomen portal-venous and delayed phase". This modification of protocol name is possible within the software as part of the post-processing, and considerably enhances quality of data analysis by limiting the number of false-positive dose alerts.

> "SUPPORT, BACKING, AND SPONSORSHIP BY THE HEAD OF THE DEPARTMENT ARE CRUCIAL"

3. Change Resistance

Particularly at the beginning, resistance to change is often encountered, based on perceived nuisance and extra work, but also due to neglect when a task was not part of clinical routine before. To overcome this resistance and improve compliance it is important to integrate dose monitoring into the daily workflow and to establish a dose culture. We therefore placed an additional computer next to the CT console, on which the software was permanently running. By immediately displaying the patient dose data, the radiographers' awareness regarding radiation safety increased.

4. Optimisation Processes

After having successfully implemented the software in clinical routine, dose data should be collected for several months before optimisation processes are started. The reason is that optimisation ought to be based on valid data, which are the premise to achieve effective and efficient improvements. It is better to first focus on one modality as well as on the most frequent protocols, as too many changes made at one point may cause confusion, data disorder, and excessive demands of the staff, ultimately leading to failure of the whole dose monitoring project.

5. RIS Integration

Despite being challenging at the beginning there are several advantages that compensate for the efforts to integrate the dose monitoring tool into the RIS. Among these especially the automatic registration of protocol changes during the scanning is valuable, because it considerably alleviates dose data post-processing and analysis (no manual change of protocol name is required) and improves quality of data output. The RIS integration also allows for an automatic display of dose data on each radiological exam report and would enable the use of only one single master IT system, thus significantly enhancing the convenience when dose monitoring software is applied.

Conclusions

Dose monitoring software is a valuable tool for internal and external quality control of dose data. It can be successfully integrated in clinical routine and increases patient and business safety. However, implementation of a dose monitoring tool is a demanding task that requires the support of the head of the department. It is advisable to build a multidisciplinary dose team, which assists in software integration in daily routine and accomplishes a dose culture. It should always be kept in mind that the tool is a software with the quality of data output largely relying on data input. Because of that, dose culture and processes have to be created and implemented by the users, which needs time and resources. ■

REFERENCE

Bundesamt für Gesundhei [Swiss Federal Authority of Healthcare] (2010) Diagnostische Referenzwerte in der Computertomographie Merkblatt [Diagnostic reference levels in computed tomography]. [Accessed: 4 June 2015] Available from bag.admin.ch/themen/strahlung/10463/10958/

ALL ABOUT THE DOSE

The Basic Safety Standards Directive (Council Directive 2013/59/EURATOM of 5 December 2013) lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

EU countries must ensure compliance in national legislation by

6 February 2018

Source: ec.europa.eu/energy/sites/ener/files/documents/CELEX-32013L0059-EN-TXT.pdf

RAISING AWARENESS

International Patient Safety Day
17 September

International Day of Radiology
8 November

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PRINCIPLES

1	Time	minimising the time of exposure directly reduces radiation dose
2	Distance	increasing the distance between you and the radiation source will reduce exposure by the square of the distance
3	Shielding	using absorber materials is an effective way to reduce radiation exposures

BASIC SAFETY STANDARDS DIRECTIVE KEY POINTS

- ☑ System of radiation protection based on **justification, optimisation** and **dose limitation**
- ☑ **Responsibilities:**
  - Justification (referrer, practitioner)
  - Optimisation (practitioner, medical physicist, radiology technicians)
- ☑ **Patients** must be **informed** about risks and benefits of examinations using ionising radiation
- ☑ Screening of patients who have no symptoms, eg, breast screening, should either be part of a health screening programme or have documented justification, following guidelines from relevant medical organisations. Directive also covers radiological health assessment for other purposes, eg, employment, immigration
- ☑ **Diagnostic reference levels** (DRLs) should be used and regularly reviewed. When DRLs are exceeded, corrective action needs to be taken
- ☑ **Medical physicist role:** dosimetry, optimisation, application and use of diagnostic reference levels (DRLs), equipment selection, acceptance testing, QA, analysis of untoward radiation exposures, staff training
- ☑ New **occupational dose limit** for the lens of the eyes - 20 mSv/year
- ☑ **Education and training** on medical radiological practices and radiation protection
- ☑ **Equipment:** new equipment should show dose amount, and be able to transfer dose information to the medical record. Information relating to patient exposure forms part of the report of the medical radiological procedure
- ☑ **Procedures:** use referral guidelines, follow clinical protocols and perform clinical audits. Analyse and learn from accidental exposures
- ☑ **Population dose evaluation** taking into account age distribution and gender

Source: European Society of Radiology (2015) Summary of the European Directive 2013/59/Euratom: essentials for health professionals in radiology. Insights Imaging, 6: 411-7.

ESR EUROSAFE IMAGING VIDEO

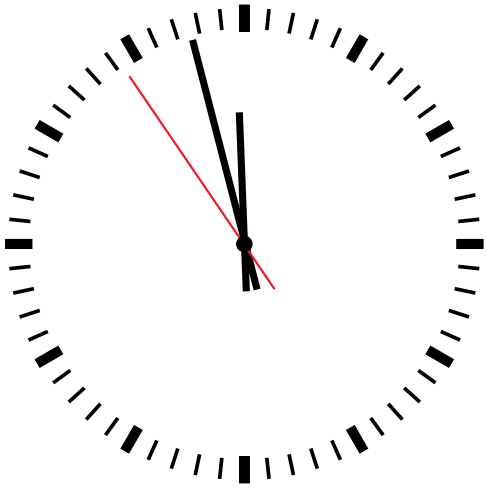
youtube.com/watch?v=jinJ3nwYDCU

FURTHER INFORMATION

EuroSafe Imaging
eurosafeimaging.org
European ALARA Network
eu-alara.net
Canada Safe Imaging
car.ca/en/education/canadasafeimaging
Image Wisely
imagewisely.org
Image Gently
imagegently.org
Radiation Protection of Patients (International Atomic Energy Authority)
rpop.iaea.org/RPoP/RPoP/Content/index.htm
Dose Index Registry
acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry
ESR Basic Patient Safety Standards and Audit Tool
myesr.org/cms/website.php?id=/en/services/ESRAuditTool.htm
ACR/RSNA Patient Information
radiologyinfo.org
EuroSafe Imaging e-learning Platform
eurosafeimaging.org/training

PATIENT INFORMATION

EuroSafe Imaging *eurosafeimaging.org/information-for-patients*
UK National Health Service *nhs.uk/conditions/Radiation/Pages/Introduction.aspx*



About Agfa HealthCare

Agfa HealthCare, a member of the Agfa-Gevaert Group, is a leading global provider of diagnostic imaging and healthcare IT solutions. The company has nearly a century of healthcare experience and has been a pioneer on the healthcare IT market since the early 1990's. Today Agfa HealthCare designs, develops and delivers state-of-the-art systems for capturing, managing and processing diagnostic images and clinical/administrative information for hospitals and healthcare facilities, as well as contrast media solutions to enable effective medical imaging results. The company has sales offices and agents in over 100 markets worldwide. Sales for Agfa HealthCare in 2014 were 1,069 million euro. For more information on Agfa HealthCare, please visit **www.agfahealthcare.com**

AGFA HealthCare

Special Report Supported by an Educational Grant from Agfa HealthCare