The Evolving Medical Radiation Protection Environment in the European Union

New initiatives and regulatory requirements

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The European Union is undergoing a radical transformation with regard to the radiation protection of healthcare patients and medical providers. Industry efforts to implement radiation dose management programs to promote safety and awareness have been swift and decisive in both North America and Western Europe over the last five years, bringing in new responsibilities for both medical device imaging manufacturers and healthcare providers.

Additionally, to improve awareness of medical imaging risks, providers are now giving patients far more transparent educational information than in the past.

While complex medical imaging exams are necessary, even lifesaving, we still do not completely understand what harmful levels of medical radiation exposure are. Because of this, the importance and need for accurate radiation dose monitoring and tracking cannot be understated. Thus far, the gold standard in imaging clinical practice has been first, justification of the imaging procedure and second, optimization of dose to that specific patient. Now, healthcare providers in Europe are applying dose management as a part of the quality program in their radiology departments.
Several drivers

There are several drivers behind this industry evolution. From a technical standpoint, there has always been a drive to innovate higher power CT scanners to yield higher image resolution. However, the trade-off with increased image quality is increased costs. Linearization is the key to mitigating unnecessary radiation exposure. By optimizing the CT scanner, the goal is to manage patient dose while maintaining adequate image quality, taking into account economic and societal factors. Another key driver behind both geographies is the amount of patient awareness of radiation exposure from medical imaging. There were a few high-profile medical imaging accidents that drove the need for enhanced control and decision-making when managing patients with medical imaging, which led to a call for action in patients about what is factual data and what is theory or assumptions based on scientific evidence. However, the truth about the hazards of medical radiation exposure is that we simply do not know enough to be prescriptive with calculating percentages of cancer incidence. In general, the scientific consensus seems to be that we should not be using the “Linear-No-Threshold” model to prescribe risk from exposure via the 2010 FDA effort to “Reduce Unnecessary Radiation Exposures” (RURE). The amount of patient awareness of radiation exposure from medical imaging has increased as a result of regulatory and societal factors.

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Safety standards

• Article 56 “Optimization” is the bookend to the justification process for the patient. The interpretation is something to clarify when the patient’s dose as low as possible while maintaining adequate image quality, while also taking into account economic and societal factors. For example, this means that a hospital should not buy a top-of-the-line fluoroscopy suite if it can be accomplished with lower cost and less radiation risk. The “non-linear, non-societal” language will give providers the flexibility to optimize imaging protocols and equipment by balancing the cost and use of equipment. Optimization also includes implementing precautions for occupational and patient safety. In the radiology literature, technical factors such as shielding, imaging equipment, and examination protocols are discussed. The patient’s dose as low as possible while maintaining adequate image quality, while also taking into account economic and societal factors. For example, this means that a hospital should not buy a top-of-the-line fluoroscopy suite if it can be accomplished with lower cost and less radiation risk. The “non-linear, non-societal” language will give providers the flexibility to optimize imaging protocols and equipment by balancing the cost and use of equipment. Optimization also includes implementing precautions for occupational and patient safety. In the radiology literature, technical factors such as shielding, imaging equipment, and examination protocols are discussed.

• Article 55 “Justification” is something introduced by ICRP 103. It is also important to mention that DRLs for interventional radiology procedures are difficult to establish due to their unique complexities and patient conditions. The concept of “Reference Levels” was established in ICRP 117. It provides radiation dose recommendations for fluoroscopically guided interventions based on actual patient doses in lieu of phantom studies, and creates the basis for comparing common procedures. While the most important reason to use Reference Levels is to improve patient care, it is also critical for addressing system-wide conformity in the utilization of appropriate imaging and exam protocols, and allows radiology departments to tailor the details to their individual scope and complexity that may benefit from process reform.

Eurosafe Imaging Call for Action

Synchronic to the Council Directive, is the EurosafE Imaging Call for Action launched by the European Society of Radiology (ESR) in 2014. It served to ignite action to address radiation safety in Europe. Since its beginning, the awareness initiative has placed radiation protection at the forefront of efforts to improve safety in medical imaging across Europe in the most effective and efficient way possible to support and strengthen patient care. The EurosafE initiative has 12 main points’ summarized below:

1. Action 1: Develop a Clinical Decision Support System for imaging referral guidelines in Europe

2. Action 2: Develop and promote a clinical audit tool for imaging to increase the quality of patient care and adherence to imaging guidelines.

3. Action 3: Implement measures to maintain radiation doses within diagnostic reference levels (DRLs)

4. Action 4: Promote the use of up-to-date equipment and provide guidance on how to further reduce doses while maintaining image quality

5. Action 5: Establish a dialogue with industry regarding imaging technologies and equipment, the use of up-to-date equipment and the harmonization of exposure indicators

DRLs

DRLs are an important concept in medical imaging and form the basis of all dose reduction initiatives. Measuring X-ray exposure, the goal is to manage patient dose while maintaining adequate image quality, while also taking into account economic and societal factors. For example, this means that a hospital should not buy a top-of-the-line fluoroscopy suite if it can be accomplished with lower cost and less radiation risk. The “non-linear, non-societal” language will give providers the flexibility to optimize imaging protocols and equipment by balancing the cost and use of equipment. Optimization also includes implementing precautions for occupational and patient safety. In the radiology literature, technical factors such as shielding, imaging equipment, and examination protocols are discussed. The interpretation is something to clarify when the patient’s dose as low as possible while maintaining adequate image quality, while also taking into account economic and societal factors. For example, this means that a hospital should not buy a top-of-the-line fluoroscopy suite if it can be accomplished with lower cost and less radiation risk. The “non-linear, non-societal” language will give providers the flexibility to optimize imaging protocols and equipment by balancing the cost and use of equipment. Optimization also includes implementing precautions for occupational and patient safety. In the radiology literature, technical factors such as shielding, imaging equipment, and examination protocols are discussed.
• Action 6: Organize radiation protection training courses and develop e-learning material to promote a safety culture and raise awareness of radiation protection.

• Action 7: Collaborate with research platforms and other medical professions to develop a strategic research agenda for medical radiation protection.

• Action 8: Develop data collection project “Is your imaging EuroSafe?” and educational project on guidelines “Are you imaging appropriately?”

• Action 9: Develop criteria for imaging procedures that use ionizing radiation in specific exams and anatomical regions.

• Action 10: Improve communication with health professionals through EuroSafe Imaging Steering Committee, website, newsletters, conferences, training material and social media.

• Action 11: Improve information for and communication with patients regarding radiological procedures and related risks in order to ensure empowerment of patients.

• Action 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.

Monitor radiation dose
As the points suggest, the time is now for manufacturers, regulators and healthcare providers to work together to develop and implement cost-effective, realistic and meaningful programs to monitor radiation dose. As more hospitals in the EU begin to focus on dose management, they need to design and implement a process for this new data into their existing radiation safety programs to sustain them long-term. As the transition unfolds, establishing partnerships that can offer overarching support – including education on best practices and how to best manage dose data, as well as technical support in performance quality for improved dose optimization – will become critical for the future success of radiation safety programs.

Summary
In summary, the groundwork laid out by the upcoming EU Council Directive and the EuroSafe Imaging Call for Action are great steps in the right direction for improving safety in radiologic imaging. They seek to improve the regulatory environment within the EU and allow lawmakers to gain insights to best practices as prescribed by leaders in the radiology industry. However, these changes require significant efforts in some places and may take time and resources that hospital radiation safety and quality departments do not currently have in place. It would be prudent for all affected providers to begin to review the upcoming EU Directive rules8 specifically outlined in Chapter VII “Medical Exposures” and plan their resource requirements accordingly.

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2 https://www.nytimes.com/2014/01/31/opinion/we-are-giving-ourselves-cancer.html?_r=0
4 http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm
5 http://www.jointcommission.org/assets/1/18/sea_471.pdf
7 http://www.eurosafeimaging.org/about/call-for-action