

By Dominic Siewko

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. From a manufacturing standpoint, the trend has always been to innovate higher power CT scanners to yield higher image resolution—however, the trade-off with increased image quality is increased radiation dose. Dose optimization is the key to mitigating unnecessary radiation exposure. By optimizing the patient's radiation exposure, the goal is to manage patient dose while maintaining adequate image quality, taking into account economic and societal factors.

Europe is embarking on the same radiation dose reduction journey as we have seen in the United States [1] via the 2010 FDA effort to “Reduce Unnecessary Radiation Exposure from Medical Imaging” and from a compliance

perspective with The Joint Commission Sentinel [2] Event Alert. The EURATOM Council Directive 2013/59, recently issued by the European Commission (EC), is due to take effect February 6, 2018. It proposes changes in legislation and EU hospital compliance to establish safety standards for protection against the dangers arising from exposure to ionizing radiation and improve the regulatory environment within the EU. While the EC Council Directive attempts to codify these requirements, there are some challenges ahead for EU radiology providers to meet these goals and adopt them into law locally. Not only will this take an investment of resources as well as time including policy and procedure creation to alter the “normal” way of working, it will also require actions that are time-consuming and complex, including the development of a clinical decision support system, comprised of clinical audit tools/checklists, and implementing Diagnostic Reference Levels (DRLs).

Radiation Dose Tracking software tools for automated collection of data in real time are widely available but have been slow to be adopted for various reasons, most likely due to budget constraints and the intricacies of adding such a tool to the informatics workflow within the hospital. However, it can result in significant workflow and quality benefits for radiology departments, including the ability to discover trends in data across their suite of imaging equipment (allowing for protocol adjustments and the normalizing of exam exposures), while also allowing bringing patient exposures into one place allowing hospitals to segment, analyze and track dose to individual patients. From a procedural standpoint, the data from these tools allow providers to review and analyze a referring physician's order against the appropriateness of the diagnostic imaging exam being chosen. The purpose is to strike a balance between the risk and benefit of the procedure to manage the patient's exposure to radiation. An example of this in practice could be a clinician's decision to order a diagnostic X-ray versus a CT scan due to the belief he or she could get the same clinical outcome desired, resulting in lower patient dose and saving on the cost of the exam itself.

The suggestion of implementing clinical audit tools will be a new process for many, and there are few best

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practices available for reference. Since radiation dose optimization is still a relatively new concept within radiology, many healthcare providers are still trying to determine how to best manage these recommendations. This led the European Society of Radiology to create and offer its “Clinical Audit Templates” [3] that should satisfy the radiologic protection requirement as suggested by the European Society of Radiology. These free templates provide a great roadmap for building a successful clinical audit program allowing the facilities to tailor the details to their individual scope and complexity including resources.

Diagnostic Reference Levels (DRLs) are an important concept in medical imaging and form the basis of establishing a benchmark, or measuring stick, for healthcare providers to compare their patient dose metrics to. While DRLs do not define what an acceptable or unacceptable exam result is, they are quality metrics that enable providers to understand how their exam types compare to each other, and how dose varies across machines and by similar patients within the DRL range. ICRP Publication 105 (Radiological Protection in Medicine) provides good guidance and background on DRLs and expands upon previous guidance in ICRP Publications 60 and 73. 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 NCRP 172. 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 techniques and exam protocols, and allows radiology departments to identify areas that may benefit from process reform.

Symbiotic to the Council Directive, is the EuroSafe Imaging Call for Action,

- Action 1: Develop a Clinical Decision Support system for imaging referral guidelines in Europe
- Action 2: Develop and promote a clinical audit tool for imaging to increase the quality of patient care and improve justification
- Action 3: Implement measures to maintain radiation doses within diagnostic reference levels (DRLs)
- Action 4: Promote the use of up-to-date equipment and provide guidance on how to further reduce doses while maintaining image quality
- Action 5: Establish a dialogue with industry regarding improvement of radiological equipment, the use of up-to-date equipment and the harmonization of exposure indicators
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- 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

The EuroSafe initiative has 12 main points summarized above [4].

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.

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.

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 rules [5] specifically outlined in Chapter VII “Medical Exposures” and plan their resource requirements accordingly.

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