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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 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. Another key driver for the changes in both geographies is the amount of patient awareness of radiation exposure from medical sources. In the United States there were a few high-profile medical imaging accidents[1] that drove the need for enhanced control and decision making when imaging patients which led to media exposure[2], which resulted in confusion to 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 induction. In general, the scientific consensus[3] seems to indicate that we should not be using the "Linear-No-Threshold" model to prescribe risk from exposure nor should we be quantifying cancer risk from medical exposure due to DNA damage.

Safety standards

This year, Europe is embarking on the same radiation dose reduction journey as we have seen in the United States[4] via the 2010 FDA effort to "Reduce Unnecessary Radiation Exposure from Medical Imaging" and from a compliance perspective with The Joint Commission[5] Sentinel Event Alert. The EURATOM Council Directive 21013/59, 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). A quick review and brief interpretation of some key points of the Directive are below that may help providers stimulate thoughts on their upcoming compliance plans:

- Article 55 "Justification" is something introduced by ICRP 103 that really begins the replacement of the traditional "ALARA" concept. In truth, the ALARA guidance was meant to be for occupationally exposed nuclear workers, however it lends itself well for medical imaging in general. With justification, the goal is for providers to ensure that the benefit of that prescribed imaging study using X-ray radiation outweighs the risk. This has been extended to also include healthcare providers by limiting exposure to occupationally exposed workers near patients. Overall, justification should be conducted on a case-by-case basis and not generalized by exam type, and the patient's previous exam history should also be evaluated as part of the justification process.
- Article 56 "Optimization" is the bookend to the justification requirement above. By optimizing the patient's radiation exposure, the goal of this requirement is to keep 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 procedures can be accomplished with hybrid diagnostic equipment. The "economic and societal factor" language will give providers the flexibility to maintain costs and reduce the proliferation of X-ray equipment by balancing the cost and use of equipment. Optimization also includes implementing precautions for healthcare providers, similar to the ALARA concept, including adequate shielding and dosimetry for providers that receive high amounts of occupational exposure, such as Nuclear Medicine Technologists and Interventional Radiology staff.
- Article 57 "Responsibilities" of the Standard requires that the referring physician and the radiologist be involved in the imaging exam justification process for the patient. This means that common knowledge must be shared throughout the imaging chain to ensure that the referring physician has the correct amount of knowledge and patient history to ensure they are prescribing the correct imaging exam. The radiologist should at this point review this order and "protocol" it to ensure that the correct piece of imaging equipment is used based on the patient's clinical indication.
- Article 58 "Procedures" is another new requirement that may take significant time and resources to address. Hospitals will now be required to keep written procedures for each imaging exam they perform. It is likely that hospitals already have imaging procedures for each exam; however, they may be outdated. There is the possibility that existing imaging procedures do not address, or take advantage of, newer equipment dose reduction features. This is where imaging manufacturers should work closely with healthcare providers to ensure that the proper amount of training is given when new equipment is installed and imaging Technologists are utilizing it.
- Article 58 also requires that a Medical Physicist be involved commensurate with the risk of the procedure. The interpretation is something to clarify when the Directive is implemented into law but it certainly ties into the above requirement to inform patients on the differing risks of certain imaging procedures. While Medical Physicists are undoubtedly already involved in such activities, healthcare providers should make sure they are fulfilling the spirit of the new rule for compliance purposes.
- The last important piece of Article 58 is the need to track, review and undertake corrective actions when DRLs are consistently exceeded. It goes without saying that member countries must define what "consistently exceeds" means, which is critical to the compliance of this requirement. The outputs of these DRL exceedances is key to the basis of the radiology quality program as they will most likely identify variances in local imaging procedures, gaps in training or identifying outdated imaging technology. This is also where dose monitoring software can become very useful for the tracking of imaging exam results over time compared to key variables, such as BMI.
- Article 60 "Equipment" has several key initiatives that providers should be aware of. The EU is keen on ensuring that the proliferation of X-ray equipment does not grow too rapidly to control medical exposure to the public. Radiology equipment must be kept under surveillance and an up-to-date inventory must be maintained at all times. One of the other key requirements in this Article is the necessity of equipment acceptance testing prior to clinical use, on a regular basis and after major equipment services. While healthcare providers certainly service equipment now, these new requirements may change the current laws in a member country, or they may become more restrictive.
- Article 62 "Special protection during pregnancy and breastfeeding" is a requirement that is most likely already addressed in a developed radiation safety program in radiology, but it provides a good opportunity for healthcare providers to revisit their procedure around ensuring that processes are in place to identify potentially pregnant women and then the justification procedure of the benefit versus the risk of the imaging to the abdomen/pelvis region. It should be noted that Nuclear Medicine is included in this rule and that this poses special issues with breastfeeding mothers that have been administered a radiopharmaceutical.
- Article 63 "Accidental and unintended exposures" will likely be one of the more difficult requirements to implement. The requirement says that unintended exposures must be minimized for all radiologic procedures, taking all steps necessary for both diagnostic and therapeutic procedures. This requires that reporting mechanisms be implemented in the member countries and that, assumingly, this information will be shared/aggregated to review for incidents of accidental or unintended exposures. This of course presents many challenges to the regulatory bodies that must create limits to what is considered to be "accidental" exposure and then the mechanism for reporting to the local competent authority.

Smooth transition

As providers adjust to these requirements, it will be important to consider investing in services and resources to ensure a smooth transition. 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 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.

Clinical audit tools

The suggestion of implementing clinical audit tools will be a new process for many, and there are few best 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[6]" 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.

DRLs

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.

EuroSafe Imaging Call for Action

Symbiotic 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[7] summarized below:

- **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

- **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 rules[8] specifically outlined in Chapter VII "Medical Exposures" and plan their resource requirements accordingly.

[1] http://www.nytimes.com/2009/10/16/us/16radiation.html
[2] https://www.nytimes.com/2014/01/31/opinion/we-are-giving-ourselves-cancer.html?_r=0
[3] https://hps.org/documents/radiationrisk.pdf
[4] http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm2007191.htm
[5] http://www.jointcommission.org/assets/1/18/sea_471.pdf
[6] https://www.myesr.org/quality-safety/esr-basic-patient-safety-standards-and-audit-tool
[7] http://www.eurosafeimaging.org/about/call-for-action
[8] https://ec.europa.eu/energy/sites/ener/files/documents/CELEX-32013L0059-EN-TXT.pdf

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