

Is regulatory compliance enough to ensure excellence in medicine?

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La radiologia medica

Official Journal of the Italian Society of
Medical Radiology

ISSN 0033-8362

Radiol med

DOI 10.1007/s11547-020-01171-5



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Received: 13 December 2019 / Accepted: 10 March 2020
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Dear Editor in Chief,

We read with interest the article of Torresin et al. [1] about the implementation of DE 59/2013 in clinical practice published in the related special issue of your journal. We would like to thank the Editor in Chief and the authors for the effort on educating the radiology community towards a comprehensive and consistent application of the new European Directive. The article perfectly described all the points of emphasis, the most relevant changes compared with the existing regulatory scenario, as well as the new imaging medical physics responsibilities introduced by the new law. The application of the Directive is crucial in the radiology community effort of improving patient care and designing the future of our field.

As the authors remarked in the article, the Directive was approved “on December 2013 after 4 years of work”. Some European countries have implemented the new law in 2018, as the European Council dictated, whereas other countries are still in the process of completing the adoption. As medical practitioners, we should ask a question: are we sure that we are doing the best for the patients by designing the future of our profession following a Directive written almost ten years ago? A decade ago, digital breast tomosynthesis was far to be the elective procedure for breast cancer screening; iterative reconstruction algorithms in CT were not implemented in many of the scanners commercially available, and

techniques such as deep learning, radiomics, and artificial intelligence were in no way related to radiology.

In this scenario, emblematic is the example of the Diagnostic Reference Levels use emphasized in the Directive: the focus is only in the radiation dose constraint disregarding image quality. Such assumption conflicts with the recent ICRP and IAEA recommendations that clearly stated that radiation dose is only “one of the steps in the overall process of optimization” [2] and that “the application of the DRL process is not sufficient, by itself, for optimization of protection. [...] Image quality or, more generally, the diagnostic information provided by the examination (including the effects of post-processing) must also be evaluated. Methods to achieve optimization that encompass both the DRL process and image quality evaluation should be implemented. In some cases, optimization may result in an increase in dose” [3].

To really embody the essence of ICRP and IAEA recommendations, DRL should be expanded to include diagnostic image quality [4] as an attribute that can be correlated with the exam diagnostic information and, therefore, with the overall radiological procedure benefit [5]. Furthermore, the evaluation of the “diagnostic information provided by the examination including the effects of post-processing” can be achieved only by assessing diagnostic performance in clinical population. A phantom study, instead, may only provide information related to the diagnostic device performance in a highly constrained (hopefully representative) setup. This gap is magnified by the implementation of modern radiology techniques, such as automatic exposure system or iterative reconstruction algorithm, that have changed the classic, statistical relationships between radiation dose and image quality.

Of course, regulatory compliance is mandatory, but radiology is a very high technological discipline and it is impossible for the legislator to pursue the incredible innovation speed of the field. Thus, the regulatory conformity can represent only a first step towards operation quality. Only a comprehensive patient-centred and evidence-based approach can enable best practices towards healthcare excellence [6].

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards The manuscript does not contain clinical studies or patient data.

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