COCIR, EFOMP and ESTRO launch guidelines for manufacturers of radiation therapy equipment on how to provide information to users

YORK/BRUSSELS – 2 December 2019 - COCIR, EFOMP and ESTRO jointly developed “Guidelines for manufacturers” to meet the requirements of article 78.2 of the Basic Safety Standards (BSS) Directive (96/29/Euratom) which sets out standards for radiation protection in the Member States.

The guidelines, developed also with the cooperation of HERCA, provides guidance to manufacturers how to compile information on radiological risk in a easy to use document, that is addressed to undertakings to help them carry out risk evaluation of radiotherapy departments, as required by article 63 and 78.2 of the BSS Directive.

The guidelines address only External Beam Radiotherapy and Brachytherapy and propose a format that manufacturers are supposed to use as model. The information document will be provided by manufacturers at the time of supply of a new equipment while it would not for old equipment that are not manufactured or sold anymore.

COCIR, EFOMP and ESTRO warn users that the information document they will receive is addressed only to the team in charge of risk evaluation and that it does not substitute or complement the Instruction for Use and accompanying documentation, which must remain the only source for information for the proper and safe use of any medical equipment.

The guidelines can be found here.

COCIR, EFOMP and ESTRO are confident that this ongoing effective collaboration amongst industry and professional societies and the open communication channel with competent authorities for radiation protection, contribute to further improve medical radiation protection for the betterment of healthcare.

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About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

https://www.cocir.org/

About EFOMP

The European Federation of Organisations for Medical Physics (EFOMP) was founded in May 1980 in London to serve as an umbrella organisation for all NMOs (National Member Organisations). The current membership covers 34 national organisations which together represent more than 9000 medical physicists and clinical engineers working in the field of medical physics.

https://www.efomp.org
About ESTRO

The European Society for Radiotherapy & Oncology (ESTRO) is a non-profit and scientific organisation that fosters the role of Radiation Oncology in order to improve patients’ care in the multimodality treatment of cancer since 1980. ESTRO supports all the Radiation Oncology professionals in their daily practice: Radiation Oncologists, Medical Physicists, Radiobiologists and RTTs (Radiation Therapists) and the wider oncology community. ESTRO’s mission is to promote innovation, research, and dissemination of science through its congresses, special meetings, educational courses and publications.

https://www.estro.org/

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