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COMMISSION RECOMMENDATION (EU) 2024/1112

of 18 April 2024

on clinical audits of medical radiological practices carried out pursuant to Council Directive 2013/59/Euratom

THE EUROPEAN COMMISSION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 33, second paragraph, and Article 106a thereof referring to Article 292 of the Treaty on the Functioning of the European Union,

Whereas:

(1) Article 2, point (b), of the Treaty establishing the European Atomic Energy Community ('Euratom Treaty') provides for the establishment of uniform safety standards to protect the health of workers and of the general public against the dangers arising from ionising radiation.

(2) In order to achieve that objective, Article 31 of the Euratom Treaty entrusts the Council with the task of establishing basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations on a proposal from the Commission, while Article 32 allows those basic standards to be revised or supplemented.

(3) The Council has adopted several directives laying down those basic safety standards. The most recent one is Council Directive 2013/59/Euratom ([1]).

(4) The standards established by Directive 2013/59/Euratom apply among others to medical radiological practices, where 'medical radiological' are defined as pertaining to radiodiagnostic and radiotherapeutic procedures, and interventional radiology or other medical uses of ionising radiation for planning, guiding and verification purposes. Directive 2013/59/Euratom further defines 'radiodiagnostic' as pertaining to in-vivo diagnostic nuclear medicine, medical diagnostic radiology using ionising radiation, and dental radiology, and 'radiotherapeutic' as pertaining to radiotherapy, including nuclear medicine for therapeutic purposes.

(5) Article 58, point (e), of Directive 2013/59/Euratom requires Member States to carry out clinical audits in accordance with national procedures. A 'clinical audit' is defined as a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.

(6) Medical uses of ionising radiation are an essential component of modern medical diagnosis and treatment which, if conducted appropriately, offer significant benefits to patients and society. At the same time, medical procedures remain by far the largest artificial source of exposure to ionising radiation of Union citizens, with particular safety and quality challenges identified in diagnostic and interventional radiology, radiotherapy, and nuclear medicine procedures.

(7) It is of paramount importance to ensure effective protection of patients against the potential undesirable effects arising from medical exposure to ionising radiation, as well as of workers and members of the public from associated occupational and public exposures respectively.

([1]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1, ELI: http://data.europa.eu/eli/dir/2013/59/oj).

(8) A clinical audit of medical radiological procedures is an essential tool within clinical governance that ensures continuous quality and safety improvement of healthcare services, and thus results in improved healthcare for patients. Ensuring quality and safety of medical applications contributes to the implementation of the Europe's Beating Cancer Plan ([2]), which aims to deliver higher-quality care to cancer patients.

(9) While a clinical audit is an essential part of ensuring quality in healthcare, the use of ionising radiation is only one of the many practices and risks that has to be managed. Moreover, a clinical audit of practices and risks not covered by Directive 2013/59/Euratom, such as contrast agents, magnetic resonance, and ultrasound imaging, would contribute to the overall quality and safety of medical imaging.

(10) The concept of clinical audit is complementary to, and should not be confused with, inspections performed by the competent authorities, and regulatory audits, which may be performed by the undertaking.

(11) Experience acquired after many years of implementation of clinical audits across the Community showcases that Member States differ considerably in the way they implement them and face differing challenges in establishing or developing an effective clinical audit infrastructure.

(12) A recent Commission study ([3]) found that, despite some progress, clinical audit uptake and implementation still remain variable across the Community. The study concluded that a clinical audit, as defined in Directive 2013/59/Euratom, is most effective when incorporated as a core element of existing clinical audit infrastructure within the wider healthcare system. It further identified common barriers and areas of future work for enhancing the clinical audit uptake and implementation in Member States.

(13) Good practices, guidance and various resources relating to clinical audits have been developed by Member States, professional bodies, and international organisations, including examples, practical guidelines and manuals in the medical disciplines of radiology, radiotherapy, and nuclear medicine.

(14) Furthermore, the importance of properly established clinical audits has been emphasized by the Council ([4]), and further guidance was issued in this area by the Commission ([5]) and by the Heads of the European Radiological protection Competent Authorities (HERCA) ([6]).

(15) It is therefore appropriate to make recommendations for harmonising the provisions applicable in the Member States regarding the implementation of the provisions of Directive 2013/59/Euratom on the clinical audit of medical radiological practices, in order to promote a more harmonised approach at Community level.

(16) This Recommendation takes into account the positions put forward by the Steering Group on Quality and Safety of medical applications of ionising radiation ('SGQS') ([7]), whose objective is to support the implementation in Member States of activities in the area of quality and safety of medical applications of ionising radiation,

([2]) https://health.ec.europa.eu/non-communicable-diseases/cancer_en#policy-framework

([3]) Radiation Protection 198 (RP198) 'Current Status and Recommendations for Improving Uptake and Implementation of Clinical Audit of Medical Radiological Procedures', European Commission, 2022.

([4]) Council conclusions of 3 December 2015 on the 'Justification of medical imaging involving exposure to ionising radiation' (document 14617/15).

([5]) 'European Commission Guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy), Radiation Protection publication No 159 (2009)'.

([6]) HERCA Position Paper Clinical Audit in medical Radiological practices (October 2019), Addendum to the HERCA clinical audit position paper (June 2021).

([7]) Register of Commission Expert Groups and Other Similar Entities, reference code E03845.

HAS ADOPTED THIS RECOMMENDATION:

National framework and infrastructure for clinical audits

1. Member States should establish a national framework and infrastructure, including legal and administrative provisions, associating the appropriate bodies and providing human and financial resources, for the effective implementation of clinical audits carried out pursuant to Article 58, point (e), of Directive 2013/59/Euratom ('clinical audits') in all medical practices using ionising radiation, including those carried out outside the radiology, nuclear medicine and radiotherapy departments of hospitals or medical centres, commensurate with the level of radiological risk.

2. Member States should support the involvement of health and radiation protection authorities and national professional and clinical specialty societies in developing the national framework and infrastructure for clinical audits.

3. Member States should identify the relevant standards of good clinical practice to carry out clinical audits of medical radiological procedures.

4. Member States should seek to incorporate clinical audits of medical procedures using ionising radiation into wider systems of audit and quality of healthcare, where those are already in place.

5. Member States should assign to the appropriate body or bodies at national level the following responsibilities:

(a) define clinical audit policy and responsibilities and identify and allocate available financial, human, and technical resources.

(b) provide administrative support to the implementation of clinical audits.

(c) develop audit guidance and manuals and share these and other relevant references and good practices among entities involved in clinical audits.

(d) provide effective mechanisms for the collection and communication of quantitative and qualitative data for clinical audits, supported whenever possible, by functional IT solutions.

(e) compare and benchmark results of clinical audits at national and, as far as possible, at Community level, and provide feedback to the radiation protection and healthcare policy decision-makers.

(f) ensure access to training programmes for auditors carrying out clinical audits and identify trained auditors.

(g) develop appropriate educational resources in clinical audits for the relevant groups of healthcare professionals and support their introduction in education and training programmes.

Regulatory control of clinical audits

6. Member States should include a regular assessment of the implementation of clinical audits in the inspection programmes of authorities responsible for radiation protection in medicine and quality of healthcare.

7. Member States should support the inclusion of aspects, such as training of auditors, composition of the audit team, relevance of the audit topics, identification of agreed standards, a clinical audit report and follow-up (including adjustment of practices if needed), in the regulatory control of implementation of clinical audits.

8. Member States should apply a graded approach to the inspection of implementation of clinical audits by adapting its frequency, timing, and depth, depending on the radiological risk associated with the practice, from an individual patient perspective as well as from a population perspective.

9. Member States should provide regular information on inspection outcomes with regard to the implementation of clinical audits, including any relevant metrics and indices, as part of the public activity reports of the competent authorities.

Hospital and medical practices accreditation and certification

10. Member States should include criteria for clinical audits in accreditation and certification standards and programmes concerning medical practices using ionising radiation.

11. Member States should put in place appropriate procedures to systematically verify the implementation of clinical audits in initial and follow-up accreditation and certification activities concerning medical practices using ionising radiation.

Enablers and support for the successful implementation of clinical audit

12. Member States should support the incorporation of clinical audit teaching in initial and continuous education and training curricula of healthcare professionals, including administrative and manager profiles.

13. Member States should foster a culture of clinical audits involving a no-blame, holistic, and positive attitude to clinical audits for the effective implementation of clinical audits in all medical practices using ionising radiation.

14. Member States should integrate clinical audits into the organisation of relevant departments and make arrangements so that hospital management is engaged in, and provides support and resources for, the implementation of clinical audits.

15. Member States should share information on clinical audits, such as clinical audit guidelines, standards for good medical radiological procedures, audit outcomes and other reference documents, making full use of digital technology, including, where appropriate, the development of a common digital platform for that purpose.

Patient involvement and access to patient data

16. Member States should support the involvement of patient representatives in clinical audit projects and in developing national and local clinical audit policies and guidelines. Where appropriate, clinical audits should take account of patients' feedback and expectations.

17. Member States should support access to patient data to the extent needed for clinical audits, by using anonymised data as necessary, in full compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council ([8]).

Done at Brussels, 18 April 2024.

For the Commission
Kadri SIMON
Member of the Commission

([8]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).