

Introduction:

In France, for Radiology and Medical Imaging (excluding radiotherapy), there is only one Clinical Audit made mandatory since 1st of July 2019, which is the translation into French law of Euratom standard 2013/59 (1).

It was established from the French Nuclear Authority decree (Decision No. 2019-DC-0660 of 15th of January 2019) and concerns the radiation protection of patients:

- Formalisation of principles for justification and optimization.
- Written protocols by type of acts.
- Maintenance and control of equipment.
- Evaluation of optimization, especially dose collection and analysis.
- Patient information and conformity of reports.
- Radiovigilances and their declaration to the relevant authorities.
- Risk identification.
- Accreditation / authorisation of professionals
- Introduction of feedback through the management of adverse events and the realization of systemic analysis.

At present, French Nuclear Authority inspections (mandatory verification and technical checks of equipment using X-ray emission) can verify the commitment of each imaging centre in this process.

Since 1st of July 2019, the 8000 or so clinical radiologists practicing in France, divided about half into liberal and public practice, are required to comply.

Background

Various certification and clinical audit processes exist in France (2):

- ISO 9001 is an organizational compliance and internal management standard applicable to all sectors of the economy, not specific to the practice of medical imaging.
- Certifications of health facilities have been in place since 1999, made compulsory by the HAS (High Health Authority), for all private or public hospital facilities, and must be carried out every 4 years. The fifth version dates from 2020, but the standards for medical imaging are limited (mainly the practice of interventional radiology in the operating room).
- Accreditation of medical teams has been in place since 2006 led by the HAS (High Health Authority) based on the reporting of adverse events related to care, aimed at assessing and preventing the risks of a care activity.
- The quality label "Labelix" created in 2004, deployed in 2006, supported by the National Professional Council (consisting of scientific, professional and trade union bodies: CERF (college of radiology teachers in France), FNMR (National Federation of Radiologists), SFR (French Society of Radiology), SRH (Union of Hospital Radiologists)) has developed a labelling standard built around the patient pathway, incorporating ISO 9001 standards to the practice of medical imaging.

Description of activity and work performed :



The French "Labelix" quality standard (latest version 2019)(3) assesses the entire organization of the imaging centre and the patient journey:

- Patient reception, information, obtaining the patient's consent to perform the imaging act.
- Justification-optimization.
- Risk and safety management.
- Hygiene.
- Materiovigilance, pharmacovigilance, identitovigilance, radiovigilance.
- Radiation protection and magnetoprotection of workers and patients.
- Management of medical incidents and accidents.
- Organization of teleradiology.
- GDPR compliance
- Quality policy, documentation organization

These quality approaches to the imaging site are measured and improved.

All the requirements of the French Nuclear Authority decree 2019-DC-0660 have been incorporated into this labelling.

The implementation of this label "Labelix" requires a first self-assessment (internal audit) based on the required references. After working with the support of an approved consulting firm (only 9 for whole country) most often for several months, an external audit by one of the only 2 independent companies approved by the Labelix association is undertaken. Then a labelling commission bringing together various professional representatives (paying organizations, user associations, French Radiology Society, Nuclear Safety Authority, medical unions) can award this label or not for a period of 4 years with intermediate documentary review after 2 years. The process starts again every four years.

To date, 135 medical imaging centres are labelled or are being labelled, including 5 public and 130 private structures, or about 10% of all organizations.



A shift from the labelling system to a clinical peer audit, including an evaluation of medical practices, based on a new standard, is being considered.

Conclusions and recommendations

In France, therefore, there is a national approach to compliance with Euratom 2013/59 European standards, which has been included in a wider certification process for the entire patient care journey. It is based on internal and external audits by companies accredited by radiological professional bodies, which overlap most of the items defined in the ESR clinical Booklet Audit Esperanto 2019 (4,5).

It must be noted that the implementation of compliance with patient radiation protection made mandatory in July 2019 in our country, has since enabled many of our French colleagues to become aware of these quality approaches and the need to put them into practice.

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References:

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2. Quality in Radiology and Medical Imaging: Development of existing different radiology JC Leclerc, JP Beregi Journal of Diagnostic and Interventional Imaging 2019;114-117
3. <https://labelix.fr/>
4. European Society of Radiology (ESR). The ESR Audit Tool (Esperanto): genesis, content and pilot. *Insights Imaging* **9**, 899-903 (2018)
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