



# Audit methodology and tools and auditor workflow

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# The Audit

- Justification of CT examinations in Europe



- Appropriateness of CT examinations in at least five European countries

## The audit cycle



# The legal background

**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**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

- (1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.
- (2) In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation <sup>(1)</sup>. The Directives have been revised several times, most recently by Council Directive 96/29/Euratom <sup>(2)</sup> which repealed the earlier Directives.
- (3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.
- (4) Council Directive 97/43/Euratom <sup>(3)</sup>, Council Directive 89/618/Euratom <sup>(4)</sup>, Council Directive 90/641/Euratom <sup>(5)</sup> and Council Directive 2003/122/Euratom <sup>(6)</sup> cover different specific aspects complementary to Directive 96/29/Euratom.
- (5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.
- (6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety standards, established according to Articles 30 and 31 of the Euratom Treaty, should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in ICRP Publication 103 <sup>(7)</sup>, and should be revised in the light of new scientific evidence and operational experience.

- The BSSD requires medical exposures to be justified, to ensure that their health benefit outweighs the individual detriment that the exposure might cause.
- The Directive further requires individual radiological procedures to be justified in advance taking into account the specific objectives of the procedure and the patients characteristics.
- The Directive also prescribes a justification process under the clinical responsibility of a radiological practitioner and involving the referring physician.

# Methodology

The methodology of the audit process in Northern Ireland and Luxembourg has been adapted and adopted, taking into account the literature review carried out during the project.

## ORIGINAL ARTICLE

## Open Access

# National audit on the appropriateness of CT and MRI examinations in Luxembourg



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### Abstract

**Objectives:** In Luxembourg, the frequency of CT and MRI examinations per inhabitant is among the highest in Europe. A national audit was conducted to evaluate the appropriateness of CT and MRI examinations according to the national referral guidelines for medical imaging.

**Methods:** Three hundred and eighty-eight CT and 330 MRI requests corresponding to already performed examinations were provided by all radiology departments in Luxembourg. Four external radiologists evaluated the clinical elements for justification present in each request. They consensually assessed the appropriateness of each requested examination with regard to the national referral guidelines and their clinical experience.

**Results:** The appropriateness rate (AR) was higher for MRI requests than for CT requests (79% vs. 61%;  $p < 0.001$ ). AR was higher for requests referred by medical specialists rather than by general practitioners, both for CT requests (70% vs. 37%;  $p < 0.001$ ) and MRI requests (83% vs. 64%;  $p = 0.002$ ). For CT, AR was higher when the requests concerned paediatric rather than adult patients (82% vs. 58%;  $p < 0.001$ ), when the radiology departments were equipped with both CT and MRI units rather than with only CT units (65% vs. 47%,  $p = 0.004$ ) and when the requests concerned head-neck (79%), chest (77%) and chest-abdominal-pelvic (81%) areas rather than spinal (28%), extremity (51%) and abdominal-pelvic (63%) areas ( $p < 0.001$ ).

**Conclusions:** The appropriateness of CT and MRI in Luxembourg is not satisfactory and collective efforts to improve should be continued. The focus should be on general practitioners and on spinal CT examinations.

**Keywords:** Clinical audit, Referral, Guidelines, Computed tomography scanner, Magnetic resonance imaging

### Key points

- A high proportion of CT requests (39%) and MRI (21%) requests are inappropriate.
- Overall, requests from general practitioners are less appropriate than those from medical specialists.
- Requests concerning spinal CT examinations are less appropriate than the others.
- The appropriateness is better for CT requests concerning children than adults.
- The appropriateness is better for CT requests in the radiology departments equipped with both CT and MRI units than in those equipped with only CT units.

### Introduction

There is a growing focus on the implementation of the principle of justification of medical exposures in Europe, promulgated by the European Commission (EC) [1], the national radiological protection competent authorities [2] and professional societies [3, 4]. In 2007, an International Atomic Energy Agency (IAEA) consultation already showed a significant level of inappropriate use of medical exposures [5]. In 2012, the IAEA together with the World Health Organisation (WHO) launched the "Bonn call for action" of which one of the actions is to enhance the implementation of the principle of justification [6]. In 2017, the Heads of the European Radiological protection Competent Authorities (HERCA) identified an urgent need for improvement and coordinated a European Action Week on the inspection of justification, focussing on radiology departments [7].

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# The Standard

- The imaging referral guidelines of the ESR, embedded in the ESR iGuide, were used as a standard for the audits. The guidelines are in the English language.
- The guidelines are based on the American College of Radiology Appropriateness Criteria and additional ACR Select content.
- The ESR guidelines cover all diagnostic imaging modalities including hybrid and nuclear medicine imaging.

*EU JUST CT* 

**ESR**  **iGuide**  
CLINICAL DECISION SUPPORT



# Referral Sampling

- Approximately 1000 referrals of previously performed CT examinations were sampled for a specific date/dates
- For public and private facilities
- The referrals covered all clinical indications
- For adult and pediatric populations
- Radiotherapy treatment planning, SPECT-CT, PET-CT, CBCT and interventional CT were excluded from the audit





- National competent authorities
- Participating hospitals
- Auditors
- Statisticians for data analysis





# National Competent Authorities

Responsible for organizing the audits in their countries by:

- Providing information:
  - on the number of imaging departments to be audited
  - on the number of CT examinations carried out per imaging department
- Presenting the project to the participating centers
- Liaising with the national professional societies and the health authorities
- Requesting and receiving the 1000 referrals
- Carrying out quality checks on the referrals to make sure they were anonymized
- Sending the referrals to the auditors

# Hospitals

- The hospitals were responsible for:
- Providing the referrals for the specific date /dates
- Anonymizing the referrals
- Making sure that the age and sex were retained as they are required by the ESR iGuide



- 4 Auditors per country recruited with the support of the national society of radiology
- Each auditor was provided with:
  - The ESR iGuide tool
  - The audit spreadsheet
  - Training on the use of the iGuide
  - Training on the completion of the spreadsheet
  - A video recording of the training is available on the project website



- Each auditor received 500 referrals
- Each referral was audited by 2 auditors
- Each auditor:
  - evaluated the quality of the referral
  - entered the required data from the referral into the spreadsheet
  - entered the required data into the i-guide tool
  - concluded on whether the requested examination was appropriate or not according to the referral guidelines embedded in the iguide

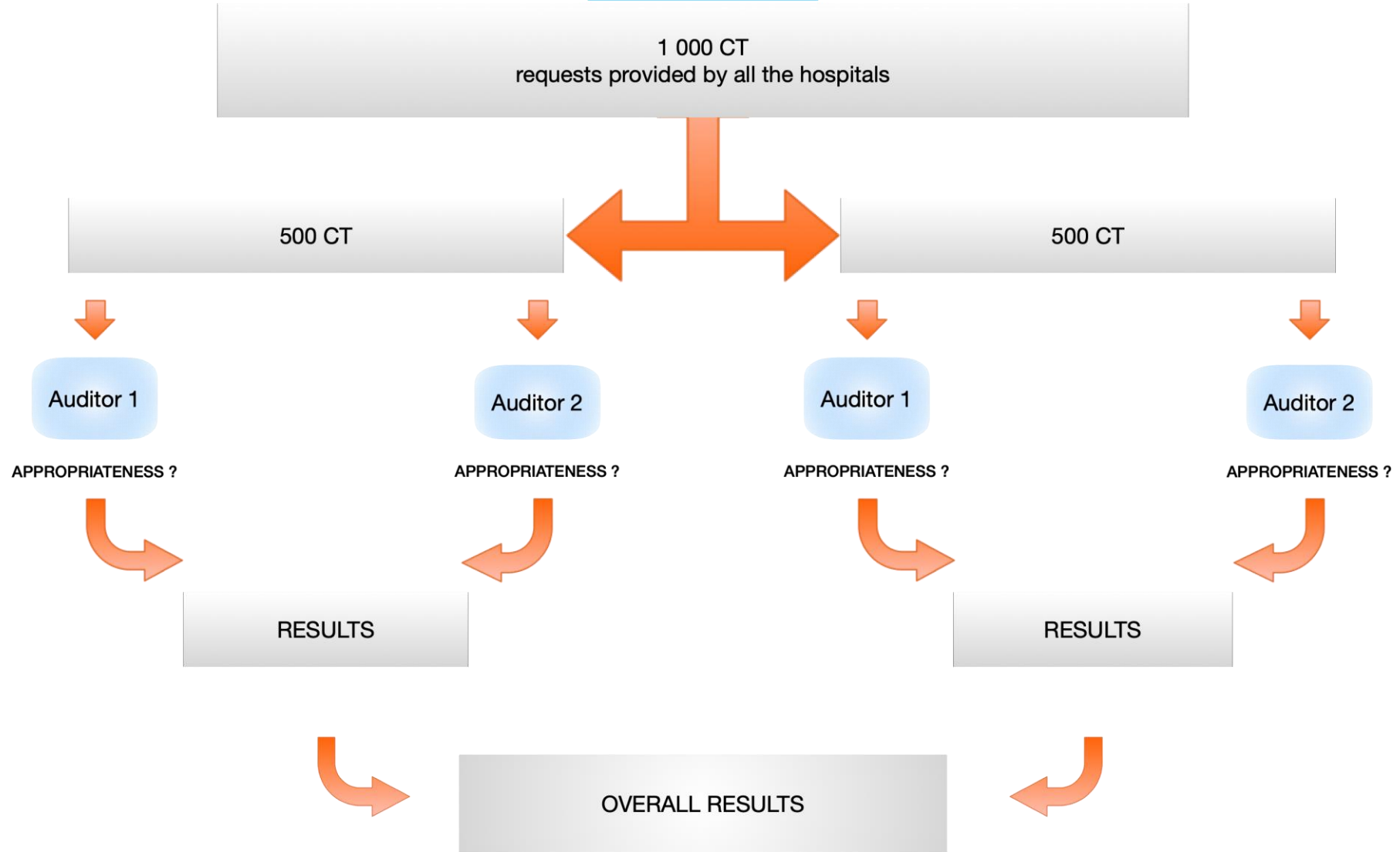


- If the ESR i-Guide did not include a recommendation for a specific indication, auditors could evaluate the appropriateness of the requested examination based on their expert opinion.
- This information was entered in the spreadsheet
- The auditors had three months to carry out the audits
- The finalized audit spreadsheets were sent to the NCAs

AUDITING



# Auditors



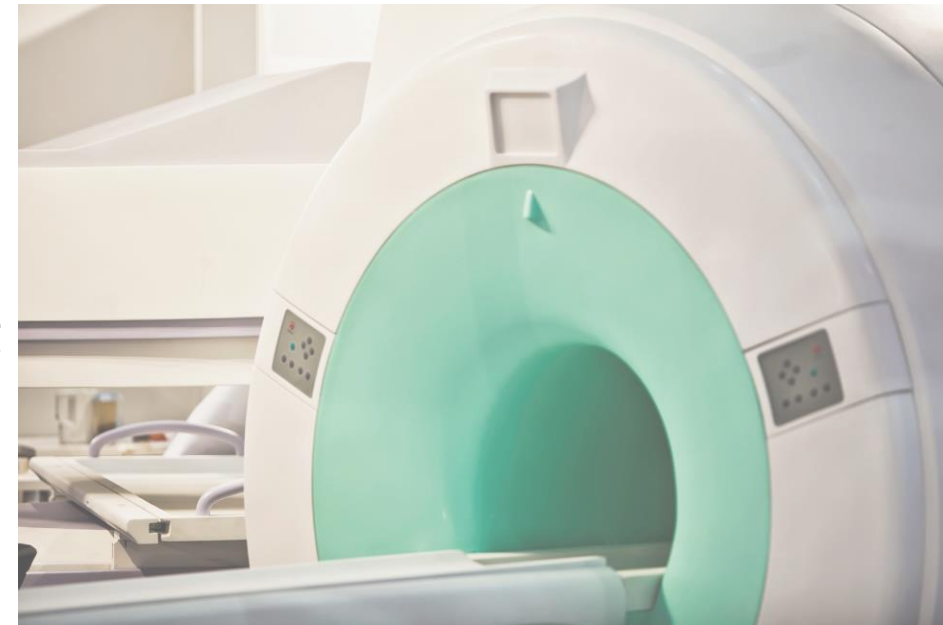
The data was analyzed in order to determine the percentage of appropriateness of the CT examinations according to:

- Country/Region
- Adult/pediatric population
- Public/private hospital
- Anatomical region
- Specialty of referrer



# Data analysis

- Inpatient/outpatient
- In the case of inappropriate CT imaging, what would have been a more appropriate examination
- Hospital/imaging departments
- According to whether the imaging department has MRI or not





# Limitations of the methodology

- Evaluation of appropriateness based on the information provided on the referral only
- No access to previous history nor to previous imaging examinations
- Some examinations evaluated as inappropriate might have been evaluated as appropriate had the auditors had access to the patient history
- This is an accepted limitation of the methodology



- For the evaluation of the implementation of the process of justification in the participating imaging departments a questionnaire was developed
- Sent to all imaging departments with a request to be completed
- The survey covers all key elements of the referral and justification process:
  - Assignment of responsibilities
  - Existence and use of referral guidelines
  - Communication between referrer and radiological practitioner
  - Mechanisms and evidence for resolving conflicting opinions



# Thank you for your attention

For further information see

<http://www.eurosafeimaging.org/eu-just-ct>

