Establishing a justification policy and process for imaging examinations using ionising radiation

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Background/introduction

According to the European Directive 2013/59/EURATOM "Laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation", any medical exposure should show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation [1,2].

All individual medical exposures must be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved. The referrer and the practitioner/radiologist should seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure [1,3].
A policy establishing the justification guidelines for imaging examinations using ionizing radiation has been piloted for implementation from February 2018 in all Affidea centers, in order to comply to the European Directive 2013/59/EURATOM and ensure that the benefit from the medical imaging procedure outweighs the increased lifetime cancer risk (Image 1).

The justification policy defines clear roles and responsibilities for the referrer, the radiologist and the operator.

1. The **referrer** is any person entitled to refer individuals for medical exposure and is responsible to provide sufficient clinical information to enable the justification process. He or she must ensure the completeness and accuracy of data relating to the patient's relevant history, present condition, reasons for the request and previous radiation exposure. Failure to provide such information might result in an inappropriate exposure being performed or an exposure not being performed because of lack of relevant information.

2. The **practitioner**, defined as any healthcare professional who is entitled to take responsibility for an individual medical exposure, is responsible for the justification of each medical exposure and should have extensive knowledge of the properties of radiation, radiation hazards and potential risks.

3. The **operator**, the person who performs the medical exposure, must ensure proper performance of the examination by optimizing the technique to allow maximal diagnostic information while ensuring that the radiation dose is kept within the department's and the national diagnostic reference levels (DRLs). The radiologist in collaboration with the operator must ensure the proper and appropriate exposure and use appropriate methods of radiation protection [3,4].

The procedure to be implemented in all Affidea centers includes evaluation of the appropriateness and urgency of the examination as well as justification of the exposure. A radiological examination is performed to answer a certain clinical question and the answer will influence the further decision-making process and treatment of the patient. A comprehensive referral, including the clinical question, must exist. The referral is reviewed by a radiologist before the examination is carried out to ensure the appropriateness of the examination, the choice of modality and imaging protocol/procedure based on international guidelines [3,4,5]. The radiologist has the responsibility to make further judgements about the appropriate modality. Modalities based on non-ionising radiation (magnetic resonance, ultrasound) should be preferred whenever appropriate, taking into account the benefits and risks of the respective methods [2,3].
The justification process requires consideration of several factors by the radiologist like the determination of the appropriateness of the request, the optimisation of the imaging strategy, the risk versus benefit, previous examinations, the age of the patient, the urgency of the exposure and the efficacy of imaging in different clinical situations [2,3].

All imaging requests are justified by the radiologist to ensure that they are appropriate for the patient and the optimum imaging examination protocol is followed, taking into account the specific objectives of the exposure and the characteristics of the individual involved. For urgent examinations, standing protocols are in place to be performed by the operator without requiring prior justification approval.

The radiologist can and should change the examination to an examination considered more appropriate. This may involve a change in the imaging modality, the area to be examined or the way the examination is performed, as for example the use or omission of contrast agent. The radiologist can and should decline an examination if inappropriate. Clinical Decision Support (CDS) systems are being reviewed to be used as an auditable justification tool.

A justification form (Image 2) is to be completed by the responsible radiologist before the examination is performed for each patient scheduled for imaging examinations with ionising radiation. For urgent examinations, the justification form is not required and standing protocols are performed. The form includes several questions regarding the referral and the appropriateness of the examination and provides a detailed decision tree (Image 3).
Fig. 1: Affidea's Policy on Justification of Imaging Examinations Using Ionising Radiation.

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Fig. 2: Justification form. Prior to any examination performed, the justification form must be completed.

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**Fig. 3:** Justification Decision Tree. Easy guide for the justification of exposures.

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Conclusion and recommendations

The policy establishing the justification guidelines for non-urgent imaging examinations using ionizing radiation that is piloted to be implemented in February 2018 in all Affidea centers, ensures that all imaging exposures performed provide a sufficient benefit to the patient when balanced against possible detriment that the examination might cause and harmonizes the practice with the latest European Directive. The introduction of CDS will digitize and optimise the efficiency and efficacy of the justification process.
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References


