

## **A Guide to Justification for Clinical Radiologists**

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## Foreword

The new Ionising Radiation Regulations place specified responsibilities on organisations and individuals involved in the process of undertaking an investigation involving exposure to ionising radiation. It is vitally important that all those in departments of clinical radiology understand those responsibilities and their implications and have agreed the responsibilities of the respective duty holders.

This document does not represent a statement of College policy, it provides an explanation about the regulations to assist members and Fellows in defining local policies and practices to provide an effective and appropriate service in the context of the legislation. The text outlines the position of the employer, defines referrers, practitioners and operators and discusses the process of justification, giving suitable sample cases to highlight the issues.

I would like to thank Paul Dubbins (Registrar), Peter Armstrong (President) for their work in completing this text, the Clinical Radiology Regional Chairmen's Committee and the Fellows who contributed for their helpful comments.

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## 1 Introduction

1.1 This paper has been prepared to help explain the process of justification, one of the new requirements of the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R)<sup>1</sup> governing medical exposures, which has replaced the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988.<sup>2</sup> The paper concentrates on justification,

because it is the central task of the "practitioner" a newly defined title in IR(ME)R. This will, therefore, be of particular interest to clinical radiologists, other practitioners and those who employ practitioners. Advice contained in this document applies to departments of clinical radiology. The Department of Health published guidance in May 2000<sup>3</sup> in which it was made clear that "the ultimate arbiter in any case of doubt would be the Court. Only it could make a definitive ruling".

1.2 New regulations on the medical use of ionising radiation have been introduced to implement the revised Directive 97/43/Euratom,<sup>4</sup> which was adopted by the EU Council on 30th June 1997. IR(ME)R 2000<sup>1</sup> implements these proposals for medical exposures in the UK and defines the responsibilities of those involved in procedures where an individual receives a radiation dose. They include advice about maintaining exposures to levels as low as reasonably practicable, advice about equipment quality, maintenance and quality assurance. They also stress the need for justification of a medical exposure, which shall "show a sufficient net benefit when the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, 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". Thus the potential value for each exposure will need to be critically assessed in advance of its performance to ensure that, for the individual patient, the benefits to the patient or to society outweigh the risks of the exposure.

1.3 Justification will be applied to individual medical exposures taking into account the specific objectives of the exposure and the characteristics of the individual involved, whether this be part of medical diagnosis or treatment, as part of a programme of occupational health surveillance, consequent upon health screening, as part of medical research or for medico-legal purposes.

Directive 97/43/Euratom<sup>4</sup> recommends extension of the process of justification to:

- new types of practice involving medical exposure in advance of being generally adopted into medical practice;
- existing types of practice involving medical exposure whenever new important evidence about their efficacy or consequences is acquired.

1.4 The following should understand the need for and the process of justification:

- referrers;
- clinical radiologists;
- other medical or dental practitioners suitably trained in radiological procedures;
- radiographers for whom protocols must be adequate to allow authorisation of procedures with confidence;
- radiation protection advisers;
- Trust management boards responsible for the implementation and supervision of clinical governance and with overall responsibility for implementation of IR(ME)R;
- purchasing authorities with a responsibility for commissioning high quality clinical imaging at low cost and with low radiation burden.

1.5 Medical exposures made as part of medical research shall be examined by an Ethics Committee set up in accordance with local or national practice.

1.6 In the justification of individual exposures there are critical roles and responsibilities for several entities. These are discussed in the following sections, and "vignettes" are presented within shaded boxes to provide sample cases in order to illustrate key points.

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## 2 Critical roles and responsibilities in justification of individual exposures

### 2.1 The employer

An employer is usually the National Health Service Trust. However there are a number of situations where diagnostic exposures are made outwith NHS secondary/tertiary care. These may include x-ray installations in general practice premises, in community hospitals and in private practice. The employer in these cases may be the General Practitioner (GP), the Primary Care Trust, a private hospital, or the practitioner him/herself. The employer has a number of responsibilities under the regulations which will have an impact on the process of justification. These are:

- the identification of referrer, practitioner and operator having regard to proper levels of training. This requires the employer to keep a record of training and qualifications available for inspection;
- establishment of recommendations concerning referral criteria for medical exposures which are likely to be based on the Royal College of Radiologists (RCR) guidelines *Making the Best Use of a Department of Clinical Radiology* (MBUR4),<sup>5</sup> but which may be varied according to local circumstances. These locally agreed criteria must be made available to all referrers to that department. There is an obligation to produce these criteria regardless of the size of the department;
- identification of procedures to be followed in the case of exposures performed for medico-legal purposes;
- identification of procedures to identify particular groups at higher risk from the harmful effects of radiation: women who are pregnant or breast feeding for example;
- establishment of procedures to be followed for medical exposures performed as part of research programmes;
- ensuring that written procedures are in place and complied with.

### 2.2 The referrer

2.2.1 The referrer is responsible for the provision of sufficient clinical information to enable the justification of the medical exposure. A referrer is identified as a registered medical or dental practitioner or health professional who is entitled to refer individuals for medical exposure to a practitioner. Non-medically qualified referrers might include

such professionals as radiographers, chiropractors, physiotherapists, osteopaths or nurses.

2.2.2 Robust methods need to be devised to ensure that electronically generated requests for imaging procedures are authorised only by properly trained individuals.

2.2.3 The referrer has a particular responsibility to ensure the completeness and accuracy of data relating to the patient's condition. It is incumbent, therefore, upon the referrer, wherever possible, to be fully informed about patient history, the presenting complaint, the relevant past history and previous radiation exposure relevant to the condition being investigated. The relevance of physical findings as indicators for a medical exposure are also requirements. 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.

## 2.3 The practitioner

2.3.1 A practitioner is defined as a registered medical or dental practitioner or other health professional who is entitled to take responsibility for an individual medical exposure. Practitioners might include radiologists, radiographers, cardiologists, surgeons or others. However, the level of training of the practitioner laid down in the document implies that there should be:

- an understanding of the specific objectives of the exposure and the characteristics of the individual involved;
- an explicit opinion of the total potential diagnostic or therapeutic health benefits including the direct health benefits to the individual and the benefits to society;
- clear knowledge of the individual detriment the exposure may cause;
- information on the efficacy, benefits and risk of available alternative techniques having the same objective but involving no, or less, exposure to ionising radiation.

2.3.2 Decisions on who is entitled to act as a practitioner should be taken at local level by agreement between the employer and the health care professionals involved in medical exposure. The primary responsibility of the practitioner is to justify; he/she will be responsible professionally and legally for the justification of each individual medical exposure. Therefore the practitioner requires extensive knowledge of the properties of radiation, radiation hazards and dosimetry, and any special situations where there are particular risks from ionising radiation. He/she will have been trained in radiological anatomy relevant to the area of practice for which he/she assumes responsibility for justification. He/she will need to be aware of medical conditions in which the ionising radiation has a well-defined benefit to risk ratio, will be able to interpret the value of existing appropriate radiological information, have an appropriate knowledge of alternative techniques which may effect a diagnosis, and be able to evaluate the potential outcome of the individual exposure. He/she will, in collaboration with the operator, ensure the proper and appropriate exposure and the utilisation of appropriate methods of radiation protection.

2.3.3 The breadth of knowledge of a clinical radiologist allows him/her to discharge the role of practitioner for the purposes of justification for all clinical radiological procedures. In some cases, particularly where radiation dose is low and/or the imaging investigation is simple, other health care professionals may assume the role and responsibility of a practitioner. Radiographers will clearly use training and expertise to justify exposure of the appendicular skeleton and of the chest and abdomen for well defined clinical indications using guidelines approved by the radiology department (see Section 4). In certain complex procedures other medical practitioners will have received the breadth of training appropriate to be a practitioner, for example cardiologists experienced in the use of radiography and image intensification, and angiography for cardiac and particularly coronary imaging.

2.3.4 Where it is not practicable for the practitioner to justify an individual exposure the operator may authorise the exposure according to written guidelines approved and issued by the practitioner. It is recommended that the method of authorisation to be used locally is ratified by the employer to ensure a consistent approach.

An orthopaedic surgeon requests fluoroscopy for internal fixation of an unstable fracture of the wrist in a 14-year-old boy. The clinical information conforms to guidelines for fluoroscopy established by the practitioner (clinical radiologist). The internal fixation proceeds. As operator, the radiographer has continuing responsibility to update the surgeon with respect to the radiation exposure, particularly if it exceeds the diagnostic reference level.

## 2.4 The operator

2.4.1 The operator is any person who carries out any practical aspect of the medical exposure. Operators will be trained in those aspects of radiation protection that will ensure proper performance of the examination, optimising the technique to allow maximal diagnostic information while ensuring that the radiation dose is kept within the department's diagnostic reference levels.

2.4.2 The operator will, using department guidelines, authorise certain exposures where it is not practicable for the practitioner to provide immediate justification. Such guidelines will be prepared by the practitioner for common procedures and should be subject to regular audit and review.

2.4.3 The guidelines may be written to allow flexibility, e.g. an agreed range of radiographic projections which may be taken to provide the necessary clinical information. This will allow the operator the appropriate freedom to exercise professional judgement.

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## 3 The process of justification

3.1 The process of justification will require close co-operation between employer, referrer, practitioner and operator. Ultimately, the employer is responsible for ensuring that procedures are in place to allow compliance with the regulations. These procedures will be based, however, on advice from those trained in the processes of ionising radiation protection and risk/benefit.

3.2 Justification of each imaging exposure will require consideration of the following factors by the practitioner.

3.2.1 Determination of the appropriateness of the request.

A GP requests a chest x-ray for a 63-year-old woman who has recently joined his practice.

She is asymptomatic. The practitioner (a clinical radiologist) determines that the clinical details do not justify the exposure and returns the request to the GP with an explanatory letter.

3.2.2 Optimisation of the imaging strategy.

A 24-year-old woman presents with right iliac fossa pain. The pregnancy test is negative, and the referrer (the Accident & Emergency specialist) requests abdominal CT for suspected appendicitis.

The clinical radiologist (the practitioner) recommends ultrasound (including transvaginal and graded compression studies) as an effective alternative technique which does not involve ionising radiation.

3.2.3 The risk versus benefit.

A 35-year-old woman presents with a breast lump. The surgeon requests a mammogram.

The radiographer (operator) does not authorise the mammogram as it falls outwith departmental guidelines. The clinical radiologist (practitioner) determines that the risk to benefit ratio in a patient of this age would not justify an exposure and an ultrasound is performed which confirms features of a benign fibroadenoma.

3.2.4 Understanding the immediate and cumulative radiation effects. This is of particular importance in exposures involving high radiation dose especially when there is a

likelihood that repeated imaging will be required, for example for the long-term monitoring of malignant disease. In these cases the risk to benefit ratio of the imaging procedure should be presented explicitly to the patient through discussion between the referrer (usually an oncology specialist) and the practitioner (the clinical radiologist).

3.2.5 Consideration of age specific issues. For example, the use of imaging examinations that do not involve ionising radiation procedures are important in children, particularly when frequent follow-up imaging is required.

3.2.6 The urgency of the exposure. For example when radiation carries a particular risk, as in pregnancy, and could reasonably be delayed until after delivery.

3.2.7 The efficacy of imaging in different clinical situations.

A patient presents with a fever and abdominal pain after bowel resection. Ultrasound reveals a mass in the right iliac fossa with complex echoes suggestive of gas. Although ultrasound guidance of abscess drainage is frequently possible post-operatively, the practitioner (clinical radiologist) determines that in this situation it is not possible to exclude intervening bowel and performs the drainage under CT guidance.

3.2.8 Appropriate delegation. An example of inappropriate delegation is given in the following vignette.

A nurse practitioner in casualty requests CT of the abdomen for a 44-year-old man with acute abdominal pain. It is 4.00 a.m. and the procedure is carried out without consultation with the clinical radiologist.

There are a number of issues here that require consideration:

- In order for the nurse practitioner to act as referrer in this case it must be demonstrated that he/she possesses the diagnostic skills to evaluate a patient with abdominal pain and to determine with a probability equivalent to that of a medical practitioner within the same department an accurate presumptive diagnosis of renal colic. He/she should be aware of the many possible diagnoses, clinical presentations and of the alternative imaging strategies. For example, acute pancreatitis requires a blood test for serum analysis, and acute pyelonephritis would require no more than renal ultrasound. Currently it is unlikely that the nurse practitioner would be entitled to assume the role of practitioner. Referral for abdominal CT would require entitlement from the employer following agreement with the accident and emergency department, the department of clinical radiology and the nurse practitioner.



- Justification of the procedure in this clinical situation requires knowledge of the symptomatology and its relation to appropriate pathology, as well as knowledge of current practice of clinical radiology. The operator is not in a position to act as practitioner in this case, as he/she cannot determine the appropriateness of the clinical details and the consideration of an alternative imaging strategy. Furthermore urgent CT requires an urgent report.
- The RCR could not support the process of justification outlined in this scenario. In complex situations like this, it is the view of the RCR that the referrer should currently be a medical practitioner, the practitioner should be a clinical radiologist and the operator should be an experienced CT radiographer.

3.2.9 Evaluation of exposures that have no health benefit to the individual but have a perceived benefit to society e.g. immigration chest x-ray.

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## 4 Guidelines

The RCR has published guidelines on referral for most imaging investigations in *Making the Best Use of a Department of Clinical Radiology*.<sup>5</sup> The College has updated and modified this advice regularly. It is likely that the process of justification in individual departments will draw heavily on MBUR.

Approved by the Board of the Faculty of Clinical Radiology: 5 May 2000

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## References

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3 Department of Health (2000) *IRMER Guidance Notes*. Department of Health (Website <http://www.doh.gov.uk/irmer.htm>).

4 Council Directive 97/43/Euratom of 30 June 1997. The Medical Exposures Directive (1997) *Official Journal* **180**:22–27.

5 The Royal College of Radiologists (1998) *Making the Best Use of a Department of Clinical Radiology. Guidelines for Doctors*, 4th Edn. London: The Royal College of Radiologists.