

Justification and authorisation of planned Medical Exposures

BONN CALL FOR ACTION  Justification and authorisation of planned Medical exposures.

1/27/2016

<http://www.isrrt.org/NewsBot.asp?MODE=VIEW&ID=24452>

The new Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards (BSS) was published by the International Atomic Energy Agency (IAEA) as General Safety Requirements Part 3 in July 2014.

In terms of Justification of medical exposures the BSS covers four areas of responsibilities for the protection and safety of patients. It states that the person or organisation responsible for facilities and activities that give rise to radiation risk shall have the prime responsibility for protection and safety. Paragraphs 2.40 and 2.41 state that other parties such as the referring medical practitioner, medical physicist, and Medical Radiation Technologists (MRT) (radiographer), shall also have specified responsibilities.

Justification can be explained as the process of weighing the expected benefits of an exposure against the possible detriment of the associated dose. The benefit or versus detriment may relate to the individual and/or to society as a whole.

The following narrative includes extracts from the new BSS and puts into context the roles and responsibilities of various groups and key personnel specifically related to the delivery, authorisation and justification of medical exposure. The BSS should be read in detail for further information.

Requirement 35 – Responsibilities of the regulatory body specific to medical exposures

Paragraph 3.149 states that the regulatory body shall ensure that the **authorisation for medical exposures** performed at a particular medical radiation facility allows personnel such as radiological medical practitioners (radiologists), medical physicists, MRTs (radiographers) and any other health professionals with specified duties in relation to the radiation protection of patients to take on the responsibilities specified in these standards only if they:

- a) Are specialised in the appropriate area
- b) Meet the respective requirements for education, training and competence in radiation protection, in accordance with paragraph 2.32
- c) Are named in a list maintained up to date by the registrant or licensee

Requirement 36: Responsibilities of registrants and licensees specific to medical exposure

This section outlines the responsibilities of registrants and licensees specific to medical exposure.

Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, appropriate responsibility has been assumed for ensuring protection and safety and the person subject to exposure has been informed of the expected benefits and risks

Paragraph 3.150 states that Registrants and licensees shall ensure that no patient, whether symptomatic or asymptomatic undergoes a medical exposure unless:-

- a) The radiological procedure has been requested by a referring medical practitioner and information regarding the clinical context has been provided or it is part of an approved health screening programme;
- b) The medical exposure has been **justified** through consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate or it is part of an approved health screening programmes;
- c) The radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in paragraph 3.153(a)
- d) The patient or the patient's legal authorized representative has been informed as, appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks

Requirement 37: Justification of medical exposures

This section highlights that relevant parties shall ensure that medical exposures **are justified** and addresses issues such as 'benefits and risks', generic justification carried out by health authorities and the consultation relationship between the radiological medical practitioner and the referring medical practitioner. Paragraph 3.156 spells out what should be taken into account in terms of the consultations as well as identifying the important issues relating to pregnant or breast-feeding patients and paediatric patients. Criteria to be considered are:-

- a) The appropriateness of the request
- b) The urgency of the request
- c) The characteristics of the medical exposure
- d) The characteristics of the individual patient
- e) Relevant information from the patient's previous radiological procedures

Paragraph 3.157 highlights the importance of **referral guidelines** in the justification process prior to the exposure of an individual patient in a radiological procedure whilst the remaining paragraphs address issues relating to justification for radiological procedures pertaining to health screening, early detection of disease in asymptomatic individuals and medical exposure of volunteers as part of a programme of biomedical research.

General Principles and working examples

When **authorising and justifying an exposure**, there are a number of considerations for healthcare professionals to take into account. For example will the exposure contribute to or

change the individual's healthcare management, what previous imaging is available and are there alternative techniques that will answer the question but do not involve ionizing radiation?

Justification is an intellectual activity and is the primary role of the radiological medical practitioner. When justifying an exposure, appropriate weight must be given to matters outlined in the table below.

Consider

| | | |
|---|---|---|
| a | The specific objectives of the exposure | What is to be gained by carrying out the exposure? How may the outcome affect the management of the patient? |
| b | The characteristics of the individual involved | Such as previous imaging, medical history, age or pregnancy status of the patient, body habitus. |
| c | The potential diagnostic or therapeutic benefits to the individual from the exposure | What is the expected benefit of the medical exposure? Will the patient's treatment be altered? |
| d | The detriment the exposure may cause | What is the possible detriment from the associated radiation dose? |
| e | The efficacy, benefits and risk of alternative techniques having the same objective but involving no or less exposure to ionising radiation | What other alternative imaging modalities are available that could answer the diagnostic question but involve less or no radiation? |

(ref 'British Institute of Radiology, Society and College of Radiographers and The Royal College of Radiologists. *A guide to understanding the implications of Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology*' London: The Royal College of Radiologists, 2015. Ref No BFCR (15)2)

Authorisation is the documentation that the intellectual activity of justification has taken place.

Authorisation may be carried out by either the radiological medical practitioner (radiologist) or a MRT/Radiographer working in accordance with the guidelines issued by the practitioner. Authorisation may be demonstrated by signing or initialling the referral in a predetermined place or by entering an electronic password. The employer's procedure should describe clearly how authorisation is to be demonstrated.

When operating such guidelines it is important to include the actions necessary when there are issues which conflict with the general principles in determining justification. This will normally involve the Radiological practitioner (radiologist or delegated radiographer/technologist) resolving such issues with the referrer. This process will either result with continuation, modification or cancellation of the examination. If the examination is cancelled details of the reasons should be inserted in the patient's notes.

It is recognised that, in addition to radiologists, in some countries the MRT/radiographer is permitted to act as practitioners for a specific range of diagnostic procedures. In every country, the MRT/Radiographer has a responsibility to contribute to the imaging team to ensure that patients do not receive additional exposure due to duplicate procedures or inappropriate procedures. However, it is not feasible for a radiologist, acting as a practitioner, to review every imaging request and therefore appropriately entitled MRTs/radiographers can authorise an exposure using written guidelines that a practitioner has written. Whilst adopting this approach, the practitioner remains responsible for the justification element for authorisation and following the guidelines.

Authorisation guidelines are normally produced by the lead radiologist who assumes the responsibility as the practitioner and is therefore responsible for any exposure authorised using these guidelines.

Such guidelines, including specific examination referral guidelines, should reflect the most current accepted practice, reflect service provisions, and be reviewed on a regular basis.

It is important to remember that in developing and implementing protocols and improvements in practice for Justification that these should be tested against the 3A's, i.e. Awareness, Appropriateness and Audit (Clinical).

A summary of the action relating to the process of authorisation and justification of medical exposures to ionising radiation is give below.

Flow Chart - Summary of actions in the process of authorisation and justification of medical exposure to ionising radiation.

