



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Regulation of
Health and Social
Care Services

**Guidance on Dose Constraints
for Carers and Comforters and
Individuals Participating in
Medical and Biomedical
Research Involving Medical
Exposures to Ionising Radiation**

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Safer Better Care

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Office of the Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

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1. Introduction

Regulation of medical exposure to ionising radiation is required due to the association between exposure to ionising radiation and potential adverse biological effects.^{1,2,3} The principles of radiation protection are justification* and optimisation† of are two fundamental methods to help minimise inadvertent or unnecessary radiation dose.¹

The European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and 2019, requires, under Regulation 12, the establishment of dose constraints for the medical exposure of carers and comforters and individuals participating in medical or biomedical research involving medical exposure to ionising radiation where no direct medical benefit is expected from the exposure.⁴

A dose constraint is a upper level for individual doses that is used to outline the range of options considered during the optimisation processes for planned medical exposures.⁵ A dose constraint differs from a dose limit. A dose limit is a specific value for a patient dose over a specific period of time which shall not be exceeded. Dose constraints are not considered as limits. Rather, some circumstances may arise, despite all practicable and reasonable measures of optimisation, where the dose received may be higher than the established constraint.¹

The establishment of dose constraints for carers and comforters and individuals participating in research (with no direct medical benefit) will ensure that the dose received by these groups from medical exposures will adhere to the as low as reasonably achievable (ALARA) principle of optimisation.¹ When the dose from the medical exposure considered during the planning stage will exceed the dose constraint, other options should be considered.

The use of dose constraints in guiding optimisation processes aims to lessen the occurrence of adverse effects potentially arising from an exposure to ionising radiation. Under the regulations, an undertaking has a statutory requirement to ensure that the dose constraints established by HIQA are used in the optimisation, protection and safety of these persons.^{1,4,5}

In order to review existing dose constraints, HIQA established an Expert Advisory Group to facilitate consultation on the adoption of criteria and positions. Reports and guidance published by the Medical Council,⁶ the UK's Health and Safety Executive,⁷ the International Commission on Radiological Protection¹ and the European Commission⁵ were also considered.

* Justification is the process of weighing up the potential benefit of a medical exposure against the detriment for that individual.

† Optimisation is the process by which doses that are as low as reasonably achievable (ALARA).

2. Carers and comforters

The European directive defines carers and comforters as '...individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone medical exposure'.⁵

For carers and comforters undergoing a medical exposure, the regulations state that a sufficient net benefit must exist to the health of the patient or for the benefit of the carer or comforter (when the potential risk of an exposure is considered) to justify the exposure.⁴

The regulations also state that an undertaking shall establish appropriate guidance for the exposure of carers and comforters and ensure that, wherever practicable and prior to the exposure taking place, the practitioner or the referrer provides the carers and comforters with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.⁴ Exceeding national dose constraints is considered a significant event, and HIQA must be notified when it occurs.⁸

2.1 National dose constraints for carers and comforters

The regulations require HIQA, under Regulation 12(2), to establish dose constraints for the medical exposure of carers and comforters in terms of 'individual effective or equivalent dose over a defined appropriate time period'.⁴ Table 1 outlines national annual effective dose constraints for carers and comforters.

Table 1. National annual dose constraints for carers and comforters

Dose Constraint	Category of Carer and Comforter
3 mSv per event or duration of exposure	Adult (not pregnant)
15 mSv per event or duration of exposure	Adult (over 60 years)

General guidance

In addition to the proposed dose constraints for carers and comforters, the following steps should be considered to protect carers and comforters:

- An undertaking shall ensure that, wherever practicable and prior to the exposure taking place, the practitioner or the referrer provides the carers and comforters with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure.⁴

- The control of the exposure of carers and comforters and associated issues should be addressed in an undertaking's policies and procedures.⁷
- Persons who assist the patient as part of their occupation must comply with occupational dose limits as distinct from dose constraints.
- Although doses to carers of patients undergoing medical procedures involving ionising radiation will, in the majority of circumstances, be considered to be of low significance, in some instances the dose to the carer and comforter can be high.
- If a procedure involves a substantial dose to a carer or comforter, as may be the case in therapeutic nuclear medicine procedures, a meeting between the practitioner, patient, and carer or comforter should take place prior to the procedure to ensure that all risks are explained and understood.⁴
- The exposure of carers and comforters of patients undergoing medical procedures involving ionising radiation should be subject to a prior risk assessment and where necessary the issue of control measures. The proactive risk assessment can be generic for types of procedures or may address specific carer and comforter circumstances.⁷
- The risk assessment and precautions can be based on any combination of published guidance from professional bodies or locally validated measurements.⁷
- The Medical Physics Expert (MPE) must be consulted during the preparation of risk assessments and has a clear role in the application of appropriate dose constraints and any associated control measures.⁷
- Due to the increased sensitivity to ionising radiation of children and unborn children,^{1,3} children and pregnant women should generally not act as carers and comforters. In exceptional circumstances where this is unavoidable, an undertaking shall apply a dose constraint of 0.3 mSv per event to the pregnant individual and apply a dose constraint of 1mSv to the unborn child over the term of the pregnancy.^{6,7} In addition, in the unlikely circumstance of a paediatric carer and comforter, it is considered prudent to apply a dose constraint of 1mSv to children. In situations outlined above, the undertaking must ensure procedures are in place to provide appropriate risk communication and to apply risk control measures to such individuals.

3. Individuals participating in medical or biomedical research involving medical exposure to ionising radiation

Medical or biomedical research involving ionising radiation includes all instances where healthy volunteers are exposed to ionising radiation and where additional exposure to ionising radiation is given to patients over and above that which is required for their clinical management.^{9,10,11} An undertaking shall ensure that each medical or biomedical research project involving medical exposure for which it is responsible has been examined and approved by an ethics committee[‡] prior to the commencement of such project.⁴ It is important to note that patients who benefit from the exposure are not subject to a dose constraint.

Participants who voluntarily undergo exposure to ionising radiation as part of medical or biomedical research can be categorised in three groups:

- patients who benefit from the exposure
- patients who agree to take part but who will receive no direct benefit
- healthy volunteers.⁹

The regulations require HIQA to establish dose constraints for medical or biomedical research involving a medical exposure to ionising radiation, where no direct medical benefit is expected from the exposure.⁴

The European Commission has issued guidance on medical exposures in medical and biomedical research. An important component of the European guidance documents is the ethical aspects associated with the irradiation of humans for medical or biomedical research.⁹ This approach is consistent with that of the World Health Organization¹⁰ and the International Commission on Radiological Protection's reports on exposures of ionising radiation for medical and biomedical research.¹¹ Under Regulation 12(5), an undertaking must ensure that the established dose constraints are approved by an ethics committee on a case-by-case basis as part of a proposal for research involving medical exposures of ionising radiation.⁴

Research projects, where no direct medical benefit is expected from the exposure to the individual, must deliver a net benefit to society. In other words, the increase in knowledge must outweigh the potential harm to the individual.¹⁰ European and international guidance on medical and biomedical research dose constraints adopt a risk-based approach based on effective dose categorisation.^{9,11} This allows a comparison between the probability of risk from an exposure (which is proportional to the dose) and the potential benefit to society.

[‡] ethics committee means an ethics committee established or recognised under the European Communities Regulations, S.I. No. 190 of 2004. ¹²

3.1 National dose constraints for individuals participating in medical or biomedical research involving medical exposure

An undertaking shall ensure that dose constraints, as specified or approved by an ethics committee on a case by case basis as part of a proposal for medical or biomedical research, are used in the optimisation of protection and safety for persons. The European Commission Guidance on medical exposures in medical and biomedical research (Radiation Protection 99)⁹ and International Commission on Radiological Protection ICRP 103 guidance documents¹¹ provide useful information for ethics committees when reviewing potential research projects involving the use of ionising radiation.

Ethics committees must consider the radiation dose to the individual and the potential benefit to society. Each dose category acts as a dose constraint as long as the potential societal benefit is commensurate. For example, a project subjecting individuals to an effective radiation dose of 6 mSv should only be granted ethical approval if there is a moderate societal benefit arising from the exposure such as directly aiding the diagnosis cure or prevention of disease. More information is given in Table 2.

Table 2. Effective dose categories/constraints, detriment probability and societal benefit

Effective Dose Categories*	Probability of detriment from exposure	Potential benefit to society
Less than 0.1mSv	One in a million, or less	Minor — This category involves a level of risk which can be considered as trivial. The level of benefit to society from exposures at this level may be minor and include investigations whose primary aim is just to increase knowledge.
0.1–1 mSv	One in a hundred thousand	Intermediate — This category carries a risk of an adverse effect of the order of one in a hundred thousand. The benefits from such an exposure would expect to increase knowledge and lead to a health benefit.
1–10 mSv	One in ten thousand	Moderate — An exposure in this dose category carries a risk of one in ten thousand to the irradiated individual. Therefore, to justify such an exposure the benefit to society would be expected to directly aid the diagnosis, cure or prevention of disease.
Greater than 10 mSv	Greater than one in a thousand	Substantial — For an irradiated individual having received doses in this category, the probability of an adverse effect occurring are in the order of one in a thousand. This level of risk might be considered as verging on unacceptable for continued or repeated exposure. Justification of exposures in this category would usually be directly related to the saving of a life or the prevention or mitigation of serious disease. Doses should not exceed the threshold for tissue reactions.

*For adults over 50 years, the effective dose can be increased by a factor of five to ten. In the case of children, the effective dose should be reduced by a factor of two to three.

General guidance

For medical or biomedical research involving medical exposure:

- the potential benefits should outweigh the hazards
- the potential subject is able to consent, knowingly and willingly, having appreciation and understanding of the relevant facts which should include:
 - aims
 - methods
 - benefits
 - potential hazards
 - any potential discomfort¹⁰
- a reliable assessment of the likely doses to be delivered must be made.⁹
- the use of ionising radiation should only be undertaken by practitioners after approval by an ethics committee in line with the regulations⁴
- approval should only be granted in such cases as potential hazards involved are judged to be predictable^{9,11}
- in circumstances where the dose might exceed the level for tissue reactions, such as interventional radiology and radiotherapy, the risk of tissue reactions must be considered and suitable methods to avoid such adverse reactions taken.¹¹

4. Conclusion

The establishment of dose constraints for carers and comforters and for participants in research is an important aspect of radiation protection. Dose constraints are an important tool in optimising the doses received by these groups in an effort to reduce unnecessarily high dose and ensure adherence to the as low as reasonably achievable principle.

Each undertaking should note the values and guidance in this document to ensure the optimisation of protection and safety for any radiological procedure in which an individual acts as a carer or comfort and persons subject to medical exposure as part of medical or biomedical research as required by Regulation 12.

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Regulation Directorate
Health Information and Quality Authority (HIQA)
Unit 1301, City Gate,
Mahon,
Cork,
T12 Y2XT