Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Regulation of Health and Social Care Services

Guidance on Criteria for the Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy

February 2020

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

Patient safety is paramount when carrying out medical exposures to ionising radiation.[1] Two fundamental methods of ensuring patient safety through radiation protection are justification* and optimisation.† The use of, and adherence, to technical parameters for the acceptability of medical radiological equipment assists patient dose optimisation as it ensures equipment operates at an optimised and safe level.

The aim of criteria for acceptability is to define key parameters essential for the minimum requirements of safe performance of medical radiological equipment.[1] Such criteria have to be achieved at acceptance testing‡, before the first clinical use of the equipment and at regular intervals throughout the lifetime of the equipment consistent with guidance, standards and accepted best practice.[1, 2]

2. Criteria for acceptability of medical radiological equipment (RP162)

The requirement for European Union member states to adopt criteria for acceptability is not a new one. Council Directive 97/43/EURATOM also required the adoption of criteria for acceptability of medical radiological equipment.[4] The Health Service Executive Medical Exposure Radiation Unit (MERU) adopted the European Commission's Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, Radiation Protection No. 91 (referred to as RP91 in this document).[5] RP91 was revised and replaced with RP162 in 2012.[3]

The criteria for acceptability of medical radiological equipment presented in RP162 are divided into two categories: qualitative and quantitative. Qualitative criteria are derived from legislation and accepted norms of best and safe practices, for example, the prohibition of the use of direct fluoroscopy. Quantitative criteria are measurements which are the absolute numerical limits of minimum acceptable and safe performance. The quantitative criteria presented in RP162 are in the form of suspension levels. Suspension levels are measurements which are regarded as a safety parameter. When equipment contravenes a suspension level, this indicates that immediate action is necessary to ensure the safety and welfare of service users undergoing medical exposures on this equipment. The immediate action which must

* 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).

‡ Acceptance testing is carried out on new equipment prior to its use on humans. Suspension levels should be incorporated into this testing and should be clearly defined as the minimum requirements for acceptance into use.

be taken when equipment fails to meet a suspension level is the removal of the equipment from clinical use, pending a risk assessment by a medical physics expert (MPE).[3]

The intended audience of RP162 are undertakings, specifically the MPE, practitioners, and any staff involved in carrying of the practical aspects of a medical radiological procedure.§ Suspension levels included in RP162 form only part of a quality assurance (QA) programme. Issues relating to facility design, IT networks and display monitors are considered outside the scope of RP162. The rapid development of radiological equipment means not all equipment types can be covered in RP 162. Issues relating to mechanical, electrical, standards of operation safety, or the wider issues associated with medical exposures of ionising radiation must also be considered. Frequency of testing and remedial levels** should also form part of a QA programme. Remedial levels or testing frequency are not included in RP162, but are published in numerous, well-established quality assurance publications included in the extensive reference section of RP 162 and abbreviated in Appendix 1 of this document.

2.1 HIQA's role

To fulfil its statutory obligations as competent authority under the regulations, HIQA must adopt acceptability criteria specific to radiological, nuclear medicine and radiotherapy equipment which are used to perform medical exposures of ionising radiation. Regulation 14 states that HIQA shall:

> take steps to ensure that the necessary measures are taken by an undertaking to improve inadequate or defective performance of medical radiological equipment in use, and adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.[2]

It should be noted that criteria for acceptability give only the minimum requirement for acceptability of medical radiological equipment. A comprehensive QA programme should include more elements than those suggested in RP162.

§ Practical aspects of medical radiological procedures mean the physical conduct of a medical exposure and any supporting aspects.
** Remedial levels are levels of performance considered close to satisfactory performance, not reducing clinical effectiveness or equipment safety, but requiring remedial action to restore satisfactory performance.

2.2 The undertaking's role

The undertaking must implement and maintain appropriate quality assurance programmes and programmes of dose and injected activity assessment. Testing of medical radiological equipment must include acceptance testing and performance testing. Performance testing must be carried out on a regular basis and after any maintenance liable to affect the equipment's performance.[2] Generally, quality assurance testing of medical radiological equipment must be conducted annually. Quality assurance testing of dental radiological equipment must be conducted every two years. Quality assurance programmes may be enhanced with more frequent performance testing throughout the year.

Verification of acceptability should be carried out by competent persons. Under the regulations, this competent person is the MPE.[2] The undertaking has a responsibility to ensure that an MPE is involved in the design and implementation of the QA programme. The QA programme should take into account the regulatory requirements of the undertaking and commensurate to the radiological risk posed by the medical exposure. Failure of an undertaking to implement and maintain an appropriate QA programme is an offence under Regulation 14(1)(a).

All records relating to QA programmes, including performance testing and adherence to the criteria for acceptability of equipment as adopted by HIQA, must be retained for a period of five years from creation and must be provided to HIQA on request.[††] Failure to provide records to HIQA on request is an offence under Regulation 14(11).

3. Conclusion

The safe and efficient performance of medical radiological equipment is a key component in ensuring the optimisation of medical radiological exposures.

HIQA has adopted the European Commission's Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, Radiation Protection No 162. RP162 is the only free, widely-available compendium of acceptability criteria. It defines the level of performance which medical radiological equipment, in normal use, must achieve to be considered clinically effective.

Suspension levels as suggested in RP162 form only a part of a comprehensive QA program. Many issues are outside the scope of RP162. The constant evolution and development of radiological equipment means that suspension levels cannot be

[††] Initially, all records must be retained from commencement of the regulations for a period of 5 years. Once this date has been reached, records must be retained for 5 years from creation of the record.

provided for all equipment types, and remedial levels or frequency of testing are not included in RP162.

In order to establish an appropriate QA programme, an undertaking must ensure that an MPE is involved at a level commensurate with the radiological risk posed by the practice.

4. References

1. Gilley DB, Holmberg O. Addressing patient safety through the use of 'criteria of acceptability' for medical radiation equipment. *Radiation Protection Dosimetry*. 2013;153(2):155-7.
2. European Union (Basic Safety Standards for Protection Against Dangers Arising from Medical Exposures to Ionising Radiation) Regulations 256, 2018. Dublin: The Stationery Office; 2018. Available online from: http://www.irishstatutebook.ie/eli/2018/si/256/made/en/print?q=S.I.+No.+256/2018. Accessed on: 03 February 2020
3. European Commission. *Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, Radiation Protection 162.* Luxemburg: European Commission; 2012.
4. Council Directive 97/43/ EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. L 180/22. Luxemburg: Official Journal of the European Union; 1997. Available online from: https://op.europa.eu/en/publication-detail/-/publication/aa7564fa-fd07-4872-943c-66df8f4f1099/language-en. Accessed on: 03 February 2020.
5. European Commission. *Radiation Criteria for Acceptability of Medical Radiological Equipment Used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, Radiation Protection 91.* Luxemburg: European Commission; 1997.

Appendix 1: Quality assurance and quality control programme literature[‡‡]

Organisation	Area(s) of speciality	Publication[§§]	Country of origin
American Association of Physics in Medicine (AAPM)	Diagnostic radiology, nuclear medicine, radiotherapy	Multiple published guidelines and reports available on website[6-18]	United States
European Commission	Diagnostic radiology (dental)	RP-136 European Guidelines on Radiation Protection in Dental Radiology	European
European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services (EUREF)	Diagnostic radiology (breast)	Protocol for the Quality Control of the Physical and Technical Aspects of Digital Breast Tomosynthesis Systems European guidelines for quality assurance in breast cancer screening and diagnosis	European
European Society for Nuclear Medicine (EANM)	Nuclear medicine	Acceptance testing for nuclear medicine instrumentation Routine quality control recommendations for nuclear medicine instrumentation	European

[‡‡] This is a sample of available literature considered as best practice for quality assurance programmes. This list is not an exhaustive list of literature and a more comprehensive list is included in the references section of RP162.[3]

European Society for Radiotherapy and oncology (ESTRO)	Radiotherapy	Recommendations for a Quality Assurance Programme in External Radiotherapy Quality Assurance of Treatment Planning Systems – Practical Examples for non-IMRT Photon Beams A Practical Guide to Quality Control of Brachytherapy Equipment	European
Institute of Physics and Engineering in Medicine	Diagnostic radiology, muclear medicine, radiotherapy	IPEM Report Series	United Kingdom
International Atomic Energy Agency (IAEA)	Diagnostic radiology, nuclear medicine, radiotherapy	Published guidelines and reports including: ▪ Accuracy Requirements and Uncertainties in Radiotherapy ▪ Commissioning of Radiotherapy Treatment Planning Systems: Testing for Typical External Beam Treatment Techniques	International
International Commission on Radiological Protection (ICRP)	Diagnostic radiology, nuclear medicine, radiotherapy	ICRP publications, in particular: ▪ ICRP 103 ▪ ICRP 105	International

International Electrotechnical Commission (IEC)	Diagnostic radiology, nuclear medicine, radiotherapy	Multiple published standards	International
International Society for Clinical Densitometry	Diagnostic radiology (DXA)	ISCD Official Position Statements on FRAX, Pediatric and Adult imaging.	International
National Electrical Manufactures Association	Diagnostic radiology, nuclear medicine, radiotherapy	Published standards and guidelines, for example: ▪ NU3-2004: Performance Measurements and Quality Control Guidelines for Non-Imaging Intra-operative Gamma Probes. ▪ NU 1-2007: Performance Measurements of Gamma Cameras. ▪ NU 2-2007: Performance Measurements of Positron Emission Tomographs.	United States

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