Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Monitoring and Regulation of Healthcare Services

Assessment-judgment framework for undertakings providing medical exposure to ionising radiation

Updated November 2023

Safer Better Care

About the Health Information and Quality Authority

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 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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Introduction

The Health Information and Quality Authority (HIQA)[*] has adopted a common 'Authority Monitoring Approach' (AMA) in order to carry out its functions as required by the Health Act 2007 (as amended).

All HIQA staff involved in the regulation and or the monitoring of services against regulations and standards adhere to this approach and to any associated procedures and protocols. AMA does not replace inspectors'[†] professional judgment but rather provides staff with a range of tools and measures to assist them in carrying out their functions. This assessment-judgment framework is one of these tools.

Applying AMA and using the assessment-judgment framework will ensure that each undertaking is treated fairly and the assessment of compliance is timely, consistent and is responsive to risk identified within a medical radiological installation. It also provides transparency for undertakings and the public on how HIQA assesses and makes judgments about compliance and non-compliance.

Applying AMA does not replace or take away from undertakings' responsibilities to ensure that they comply with the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments (referred to in this document as the "regulations") and to provide safe and high-quality care for service users.[‡] Assessment of compliance will be determined against these regulations.

The regulations set the minimum standards for protecting service users who are exposed to ionising radiation, and these regulations must be met by each undertaking carrying out such practices. However, an undertaking striving to deliver a safe and effective service should constantly seek ways to go beyond the minimum requirements set out in these regulations in order to promote best practice and patient safety in radiation protection.

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[*] HIQA refers to the Health Information and Quality Authority as defined in Section 2 of the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018.

[†] Inspector refers to an Authorised Person appointed by HIQA under Regulation 24 of the European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 for the purpose of ensuring compliance with the regulations.

[‡] Service users include patients, asymptomatic individuals, carers and comforters, and volunteers in medical or biomedical research.

The purpose of this assessment-judgment framework is to support HIQA inspectors in gathering evidence when monitoring or assessing an undertaking and making judgments on compliance. The framework sets out the lines of enquiry (questions) to be explored by inspectors in order to assess compliance with the regulations being monitored or assessed.

The assessment-judgment framework also outlines the compliance descriptors of:

- **Compliant:** a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation.
- **Substantially compliant:** a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk.
- **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

The assessment judgment-framework should be applied in conjunction with the following:

- European Union (Basic Safety Standards for Protection against Dangers Arising from Medical Exposure to Ionising Radiation) Regulations 2018 and associated amendments
- Health Act 2007 (as amended)
- Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom
- HIQA's monitoring approach and supporting policies, procedures and guidance.

The assessment-judgment framework is organised into two sections called dimensions, which are:

1. **Governance and management arrangements for medical exposures**
2. **Safe delivery of medical exposures.**

The regulations are organised under each of these dimensions for ease of reporting. The regulations not currently assessed are listed in Appendix 1.

Section 1. Governance and management arrangements for medical exposures

This section focuses on the overall delivery of the service and how the undertaking is assured that effective and safe medical exposures are provided to service users in compliance with the regulations. In the regulations, an undertaking is the term used to describe a person or entity that has overall responsibility for carrying out, or engaging others to carry out, medical radiological procedures. It is important that an undertaking has the appropriate corporate governance, operational and risk management arrangements in place to ensure that those carrying out medical radiological procedures comply with the regulations. In so doing, the undertaking takes responsibility for complying with the regulations. This will require the undertaking to oversee and ensure that any persons employed or engaged by the undertaking is complying with the regulations irrespective of the specific nature of that employment or engagement relationship. For example, this will require the undertaking to have appropriate systems in place to ensure proper and sufficient control and oversight for the medical radiological procedures it carries out or engages others to carry out within the service.

This section includes how the undertaking:

- makes sure there are effective corporate governance structures with clear lines of accountability and oversight so that the undertaking and all members of the workforce and anyone engaged by the undertaking are aware of their responsibilities and to whom they are accountable
- ensures that the necessary resources are in place to support the effective delivery of quality care and support to service users
- designs and implements policies and procedures that will make sure that the facility[§] is run in an effective and safe manner.

The relevant regulations under the dimension of governance and management arrangements for medical exposures are listed in Table 1.

[§] Facility means a medical radiological installation which is a location where medical exposure to ionising radiation is carried out, such as a hospital or a dental practice.

Table 1. Regulations for the dimension of the governance and management arrangements for medical exposures.

Dimension: Governance and management arrangements for medical exposures	
Regulation number	**Regulation title**
4	Referrers
5	Practitioners
6	Undertaking
7	Justification of practices
10	Responsibilities
18	Estimates of population doses
19	Recognition of medical physics experts
20	Responsibilities of medical physics experts
21	Involvement of medical physics experts in medical radiological practices
22	Education, information and training in the field of medical exposure
28	Provision of information to HIQA

Dimension: Governance and management arrangements for medical exposures	
Regulation 4	**Referrers**
Line of enquiry	1. Is the person making a referral for medical radiological procedures to a practitioner one of the following: a. a registered nurse or registered midwife within the meaning of the Nurses and Midwives Act 2011 (No. 41 of 2011) who meets the standards and requirements set down from time to time by the Nursing and Midwifery Board of Ireland in relation to the prescribing of medical ionising radiation by nurses or midwives b. a registered dentist within the meaning of the Dentists Act, 1985 (No. 9 of 1985) c. a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007) d. a person whose name is entered in the register established and maintained by the Radiographers Registration Board in line with section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005), or e. a healthcare professional registered with the General Medical Council of the United Kingdom, and practising medicine in Northern Ireland, who is entitled in line with their employer's procedures to refer individuals for exposure to a practitioner? 2. Does a person only carry out a medical radiological procedure on the basis of a referral from a referrer?
Judgment	**Compliant:** a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant:** a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users —

	will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 5	**Practitioners**
Line of enquiry	1. Is the person who is taking clinical responsibility for an individual medical exposure one of the practitioners listed below: a. a registered dentist within the meaning of the Dentists Act, 1985 (No. 9 of 1985) b. a registered medical practitioner within the meaning of the Medical Practitioners Act 2007 (No. 25 of 2007), or c. a person whose name is entered in the register established and maintained by the Radiographers Registration Board in line with section 36 of the Health and Social Care Professionals Act 2005 (No. 27 of 2005)?
Judgment	**Compliant:** a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant:** a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 6	**Undertaking**
Line of enquiry	1. Has the undertaking notified HIQA, no later than one month before commencing practices, of the proposed commencement, in such form and manner as prescribed by HIQA? 2. Has the undertaking which was carrying out practices on 8 January 2019, notified HIQA no later than 8 April 2019 of such activity, in such form and manner as prescribed by HIQA? 3. Has the undertaking provided a clear allocation of responsibilities for the protection of — patients — asymptomatic individuals — carers and comforters, and — volunteers in medical or biomedical research from medical exposure to ionising radiation? 4. Can the undertaking provide evidence on request of the allocation of responsibilities, as referenced in number three above, in such form and manner as prescribed by HIQA?
Judgment	**Compliant:** a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant:** a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 7	**Justification of practices**
Line of enquiry	1. Does a person only carry out a new type of practice involving medical exposure when that new type of practice has been justified in advance by HIQA? 2. Does a person carry out a class or type of practice which has been reviewed by HIQA under Regulation 7(3) and found not to be justified?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 10	**Responsibilities**
Line of enquiry	1. Has the undertaking ensured that all medical exposures take place under the clinical responsibility of a practitioner? 2. Has the undertaking ensured that the optimisation process for all medical exposures involves: a. the practitioner b. the medical physics expert, and c. those entitled to carry out practical aspects of medical radiological procedures as specified by the undertaking or practitioner under Regulation 10(4)? 3. Has the undertaking ensured that the justification process of individual medical exposures involves: a. the practitioner, and b. the referrer? 4. Are practical aspects of a medical radiological procedure only delegated by: a. the undertaking, or b. the practitioner as appropriate, to one or more individuals: (i) registered by the Dental Council (ii) registered by the Medical Council (iii) registered by the Nursing and Midwifery Board of Ireland (iv) whose name is entered in the register established and maintained by the Radiographers Registration Board in line with section 36 of the Health and Social Care Professionals Act 2005 or (v) recognised by the Minister under Regulation 19 as appropriate, provided that such person(s) have completed training in radiation safety as prescribed or approved under Regulation 22(3) by the appropriate body? 5. Has the undertaking retained a record of each delegation under Regulation 10(4) for a period of five years from the date of the delegation and provided such records to HIQA on request?

	6. Has the undertaking or practitioner only delegated practical aspects of a medical radiological procedure to an individual referred to in Regulation 10(4)? 7. Does only the practitioner, or the person delegated under Regulation 10(4), carry out the practical aspects of a medical radiological procedure?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 18	**Estimates of population doses**
Line of enquiry	1. Has the undertaking provided information, records and data on medical exposures to facilitate the estimation of population doses as specified and requested by HIQA?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant:** a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 19	**Recognition of medical physics experts**
Line of enquiry	1. Has the undertaking put in place the necessary arrangements to ensure the continuity of expertise of persons for whom it is responsible who have been recognised as a medical physics expert under this regulation?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 20	**Responsibilities of medical physics experts**
Line of enquiry	1. Has the undertaking ensured that a medical physics expert, registered in the Register of Medical Physics Experts, acts or gives specialist advice, as appropriate, on matters relating to radiation physics for implementing the requirements of Part 2, Part 4 and Regulation 21 of the regulations; and point (c) of Article 22(4) of Council Directive 2013/59/EURATOM? 2. Has the undertaking ensured, depending on the medical radiological practice, the medical physics expert: a. takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure b. gives advice on medical radiological equipment, and c. contributes, in particular, to the following: i. optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels ii. the definition and performance of quality assurance of the medical radiological equipment iii. acceptance testing of medical radiological equipment iv. the preparation of technical specifications for medical radiological equipment and installation design v. the surveillance of the medical radiological installations vi. the analysis of events involving, or potentially involving, accidental or unintended medical exposures vii. the selection of equipment required to perform radiation protection measurements and viii. the training of practitioners and other staff in relevant aspects of radiation protection? 3. Has the medical physics expert referred to in Regulation 20(1) liaised with the radiation protection adviser, where appropriate?

Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 21	**Involvement of medical physics experts in medical radiological practices**
Line of enquiry	1. Has the undertaking ensured that a medical physics expert is appropriately involved in medical radiological practices, with the level of involvement being in proportion to the radiological risk posed by the practice? 2. In carrying out its obligation under Regulation 21(1) (as referenced above), has the undertaking, in particular, ensured that: a. in radiotherapeutic practices other than standardised therapeutic nuclear medicine practices, a medical physics expert shall be closely involved b. in standardised therapeutical nuclear medicine practices and in radiodiagnostic and interventional radiology practices, involving high doses as referred to in Regulation 15(c), a medical physics expert shall be involved, and c. for other medical radiological practices not covered by subparagraphs (a) and (b), a medical physics expert shall be involved, as appropriate, for consultation and advice on matters relating to radiation protection concerning medical exposure?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and

	welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 22	**Education, information and training in the field of medical exposure**
Line of enquiry	1. Has the undertaking ensured that a. practitioners, and b. individuals to whom the practical aspects of medical radiological procedures are delegated under Regulation 10(4), have adequate education, information and theoretical and practical training for that purpose, as well as relevant competence in radiation protection, in line with the provisions of this regulation, except those participating in practical aspects of a medical radiological procedure as part of a relevant training programme as outlined in Regulation 22(2)? 2. Is a person participating in practical aspects of a medical radiological procedure as part of a relevant training programme, as referenced in Regulation 22(1), supervised by a person who is adequately trained? 3. Subject to Regulation 22(4), have the persons referred to in Regulation 22(1) successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection: a. prescribed by the Dental Council b. prescribed by the Irish College of Physicists in Medicine c. prescribed by the Nursing and Midwifery Board of Ireland d. prescribed by a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such a course or e. approved by the Radiographers Registration Board under Part 5 of the Health and Social Care Professionals Act 2005, as appropriate, taking into account the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175)? 4. Has the undertaking ensured that the persons referred to in Regulation 22(1) have carried out continuing education and training after qualification, including, in the case of clinical use of

	new techniques, training related to these techniques and the relevant radiation protection requirements? 5. Has the undertaking retained records demonstrating compliance with this regulation for a period of five years from the date of the exposure, and provided such records to HIQA on request? 6. Has the undertaking entered into a contract with another party to engage a practitioner or an individual, as referred to in Regulation 22(1)(b), who is employed by the other party? 7. Has the other party, as referenced in subsection 6 above, taken responsibly for keeping the records required by Regulation 22(5) and supplied such records to the undertaking upon request?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Governance and management arrangements for medical exposures	
Regulation 28	**Provision of information to the Health Information and Quality Authority (HIQA)**
Line of enquiry	1. Has the undertaking provided information or statistics, when required by HIQA under Regulation 28(1), within the time period set out in the request?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Section 2. Safe delivery of medical exposures

The focus of this section is on the experiences of the people undergoing a medical exposure to ionising radiation, including how service users in such cases:

- only undergo medical exposures to ionising radiation where the potential benefits outweigh any potential risks
- are only exposed to medical radiological procedures that are kept as low as reasonably achievable in order to meet the objectives of the medical exposure
- undergo medical exposures to ionising radiation in a safe environment
- are empowered to exercise their right to receive information and make choices about the medical radiological procedure they receive.

The relevant regulations under the dimension of safe delivery of medical exposures are listed in Table 2.

Table 2. Regulations for the dimension of safe delivery of medical exposures

Dimension: Safe delivery of medical exposures regulations	
Regulation number	**Regulation title**
8	Justification of medical exposures
9	Optimisation
11	Diagnostic reference levels
12	Dose constraints for medical exposures
13	Procedures
14	Equipment
15	Special practices
16	Special protection during pregnancy and breastfeeding
17	Accidental and unintended exposures and significant events

Dimension: Safe delivery of medical exposures	
Regulation 8	**Justification of medical exposures**
Line of enquiry	1. Has a person only carried out a medical exposure when a. it showed a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to the health of an individual and the benefits to society, against the individual detriment that the exposure might cause, and b. they have taken into account the efficacy, benefits and risks of the alternative techniques available which have the same objective but which involve no or less exposure to ionising radiation? 2. Has the undertaking ensured that for each medical or biomedical research project, involving medical exposure for which it is responsible, there has been an examination of and approval by an ethics committee before such a project starts? 3. Has the undertaking ensured that medical radiological procedures performed as part of a health screening programme are not carried out unless specific justification has been issued by HIQA for the particular medical radiological procedure? 4. Has the undertaking ensured that the following has been adhered to in the case of a medical radiological procedure carried out on an asymptomatic individual and performed for the early detection of disease: a. the procedure is part of a health screening programme, or has specific documented justification for that individual by a practitioner in consultation with the referrer, and is following guidelines published by HIQA and b. special attention is given to the provision of adequate information to the individual, relating to the benefits and risks associated with the radiation dose from the medical exposure? 5. Has the undertaking ensured that all individual medical exposures carried out on its behalf are justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved? 6. Has the undertaking ensured that a specific individual medical exposure, of a type that is not justified in general, is justified,

	where appropriate, in special circumstances, and evaluated by the practitioner on a case-by-case basis and documented? 7. Has a referrer only referred an individual to a practitioner for a medical radiological procedure when the referral: a. is in writing b. has stated the reason for requesting the particular procedure, and c. has been accompanied by sufficient medical data to enable the practitioner to carry out a justification assessment in line with Regulation 8(1)? 8. Has a practitioner carrying out a medical radiological procedure on foot of a referral taken into account any medical data provided by the referrer under Regulation 8(10)(c) and satisfied themself that the procedure as prescribed in the referral is justified? 9. Have the referrer and the practitioner sought, where practicable, to obtain previous diagnostic information or medical records relevant to a planned exposure and considered this data to avoid unnecessary exposure? 10. Has the referrer or the practitioner, wherever practicable and before a medical exposure has taken place, ensured that: a. the patient or their representative b. in the case of a patient who is under 16 years of age, a parent or legal guardian of the patient, or c. in the case of a patient who lacks, or may lack, capacity under the Assisted Decision-Making (Capacity) Act 2015 (No. 64 of 2015), the intervener in respect of the patient has been provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure? 11. Has the undertaking ensured that, in circumstances where there is to be an exposure to a carer or comforter, such exposure showed a sufficient net benefit taking into account: a. the direct health benefits to the patient b. the possible benefits to the carer or comforter, and c. the detriment that the exposure might cause? 12. Has the undertaking retained records demonstrating compliance with Regulation 8 for a period of five years from the

	date of the medical exposure, and provided such records to HIQA on request?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant**: a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 9	**Optimisation**
Line of enquiry	1. Has the undertaking ensured that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are kept as low as reasonably achievable consistent with obtaining the required medical information, taking into account economic and societal factors? 2. Has the undertaking ensured that, for all radiotherapeutic medical exposure of patients, the exposures to target volumes: a. are individually planned and b. have their delivery appropriately verified, taking into account that doses to non-target volumes and tissues are as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure? 3. Has the undertaking ensured that for each medical or biomedical research project involving medical exposure: a. the individuals concerned participate voluntarily in the research project and have been informed in advance about the risks of exposure and b. in the case of patients who voluntarily accept to undergo an experimental medical practice and who were expected to receive a diagnostic or therapeutic benefit from this practice, that individual dose levels were considered by the practitioner or the referrer, or both, before the exposure takes place? 4. Has the undertaking ensured that optimisation under Regulation 9 included: a. the selection of equipment b. the consistent production of adequate diagnostic information or therapeutic outcomes c. the practical aspects of medical radiological procedures d. quality assurance, and e. the assessment and evaluation of patient doses or the verification of administered activities, having taken into account economic and societal factors? 5. Has the undertaking established appropriate guidance for the exposure of carers and comforters?

	6. Has the undertaking ensured that, wherever practicable and before the exposure takes place, the practitioner or the referrer had provided the carers and comforters with: a. adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure and b. the guidance established under Regulation 9(5)? 7. In the case of a patient undergoing treatment or diagnosis with radionuclides, has the practitioner or the undertaking in the facility provided: a. the patient or their representative b. in the case of a patient who is under 16 years of age, a parent or legal guardian of the patient, or c. in the case of a patient who lacks, or may lack, capacity under the Assisted Decision-Making (Capacity) Act 2015 (No. 64 of 2015), the intervener in respect of the patient with the information referred to in Regulation 9(8), before they left the hospital or other place where the exposure was carried out? 8. Did the information provided under Regulation 9(7), include the following: a. information on the risks of ionising radiation and b. appropriate written instructions with a view to restricting doses to persons in contact with the patient as far as reasonably achievable?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-

	compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 11	**Diagnostic reference levels**
Line of enquiry	1. Has the undertaking ensured that diagnostic reference levels have been established for radiodiagnostic examinations (and where appropriate for interventional radiology procedures) and are regularly reviewed and used? 2. Has the undertaking ensured that diagnostic reference levels that have been established for radiodiagnostic examinations (and where appropriate for interventional radiology procedures) take into account the national diagnostic reference levels established under Regulation 11(1) where available? 3. Has the undertaking ensured that appropriate reviews had been carried out to determine whether the optimisation of protection and safety for patients had been adequate? 4. Has the undertaking ensured that appropriate corrective action had been or is taken without undue delay where — for a given examination or procedure — typical doses or activities consistently had exceeded or exceed the relevant diagnostic reference level? 5. Has the undertaking retained a record of reviews and corrective actions carried out under Regulation 11(6) for a period of five years from the date of the review, and provided such records to HIQA on request? 6. Has the undertaking made available to the persons listed in Regulation 10(2) the guidance published by HIQA under Regulation 11(3)(c)?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance.

	Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 12	**Dose constraints for medical exposures**
Line of enquiry	1. Has the undertaking ensured that relevant dose constraints established under Regulation 12(1) have been used in the optimisation of protection and safety in any radiological procedure in which an individual acted as a carer or comforter? 2. Has the undertaking ensured that relevant dose constraints established under Regulation 12(1), 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 being used in the optimisation of protection and safety for persons subject to medical exposure as part of medical or biomedical research?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 13	**Procedures**
Line of enquiry	1. Has the undertaking established written protocols for every type of standard medical radiological procedure for each type of equipment for relevant categories of patients? 2. Has the undertaking ensured that information relating to patient exposure forms part of the report of the medical radiological procedure? 3. Has the undertaking ensured that referral guidelines for medical imaging, taking into account the radiation doses, are available to referrers? 4. Has the undertaking ensured that clinical audits are carried out in line with national procedures established by HIQA?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 14	**Equipment**
Line of enquiry	1. Has the undertaking ensured that all medical radiological equipment it uses is kept under strict surveillance regarding radiation protection? 2. Has the undertaking implemented and maintained: a. appropriate quality assurance programmes and b. appropriate programmes of assessment of dose or verification of administered activity? 3. Has the undertaking carried out the following testing on medical radiological equipment in the facility: a. acceptance testing before the first use of the equipment for clinical purposes, and b. performance testing on a regular basis and after any maintenance procedure liable to affect the equipment's performance? 4. Has medical radiological equipment only been used for clinical purposes by a person when testing has been carried out in line with Regulation 14(3)(a)? 5. Has the undertaking: a. taken any measures directed by HIQA under Regulation 14(5)(a), and b. complied with any criteria adopted by HIQA under Regulation 14(5)(b)? 6. Does a person only use fluoroscopy equipment with a device to automatically control the dose rate or with an image intensifier or equivalent device? 7. Has the undertaking ensured, subject to Regulation 14(9) that: a. equipment installed from 6 February 2018 that is used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV has a device to verify key treatment parameters b. any equipment installed from 6 February 2018 that is used for interventional radiology has a device or a feature

	informing the practitioner, and those carrying out practical aspects of the medical procedures, of the quantity of radiation produced by the equipment during the procedure c. any equipment that is used for interventional radiology and computed tomography has a device or a feature informing the practitioner, at the end of the procedure, of relevant parameters for assessing patient dose d. any equipment installed from 6 February 2018 that is used for planning, guiding and verification purposes has a device or a feature informing the practitioner at the end of the procedure of relevant parameters for assessing the patient dose e. equipment installed from 6 February 2018 that is used for interventional radiology and computed tomography has the capacity to transfer the information required under Regulation 14(8)(c) to the record of the examination, and f. without prejudice to Regulation 14(8)(b) to (e), that medical radiodiagnostic equipment installed from 6 February 2018 producing ionising radiation has a device or an equivalent means of informing the practitioner of relevant parameters for assessing the patient dose and, where appropriate, the capacity to transfer this information to the record of the examination? 8. Has the undertaking provided to HIQA on request an up-to-date inventory of medical radiological equipment for each radiological installation, in the form and manner as prescribed by HIQA? 9. Has the undertaking retained records in relation to equipment, including records demonstrating compliance with Regulation 14, for a period of five years from their creation, and provided such records to HIQA on request?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be

	fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 15	**Special practices**
Line of enquiry	1. Has the undertaking ensured that in the case of medical exposure: a. of children b. as part of a health screening programme, or c. involving high doses to the patient, which may be the case in interventional radiology, nuclear medicine, computed tomography or radiotherapy, that appropriate medical radiological equipment, practical techniques and ancillary equipment are being used, and that special attention is given to quality assurance programmes and the assessment of dose or verification of administered activity for these practices?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 16	**Special protection during pregnancy and breastfeeding**
Line of enquiry	1. Has the undertaking ensured that the referrer or a practitioner, as appropriate, has: a. enquired as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and b. recorded the answer to any enquiry under Regulation 16(1)(a) in writing, retained such record for a period of five years, and provided such records to HIQA on request? 2. If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the medical radiological procedure involved, in particular if abdominal and pelvic regions are involved, is special attention given to the justification, particularly the urgency, taking into account both the expectant individual and the unborn child? 3. If pregnancy cannot be ruled out for an individual subject to medical exposure, and depending on the medical radiological procedure involved, in particular if abdominal and pelvic regions are involved, is special attention given to the optimisation, taking into account both the expectant individual and the unborn child? 4. Was special attention given to the justification, particularly the urgency, in the case of a breastfeeding individual in nuclear medicine depending on the medical radiological procedure and taking into account both the individual and the child? 5. Was special attention given to the optimisation in the case of a breastfeeding individual in nuclear medicine depending on the medical radiological procedure and taking into account both the individual and the child? 6. Without prejudice to Regulation 16(1), 16(2) and 16(3), has the undertaking in the facility taken measures to increase the awareness of individuals to whom Regulation 16 applies, through measures such as public notices in appropriate places?

Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Dimension: Safe delivery of medical exposures	
Regulation 17	**Accidental and unintended exposures and significant events**
Line of enquiry	1. Has the undertaking ensured that: a. all reasonable measures are taken to minimise the probability and magnitude of accidental or unintended exposures of individuals subject to medical exposure b. for radiotherapeutic practices, the quality assurance programme included a study of the risk of accidental or unintended exposures c. for all medical exposures, an appropriate system is implemented for the record-keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, in proportion with the radiological risk posed by the practice d. arrangements had been made to inform the referrer, the practitioner and the patient or their representative, of clinically significant unintended or accidental exposures and the results of the analysis e. HIQA was notified promptly and as soon as possible of the occurrence of any significant event, as defined by HIQA in guidelines issued for that purpose, and f. the results of an investigation into any significant event notified under Regulation 17(1)(e) and the corrective measures to avoid such events had been reported to HIQA within the time period specified for such events by HIQA in guidelines issued by it for that purpose?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses

	a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

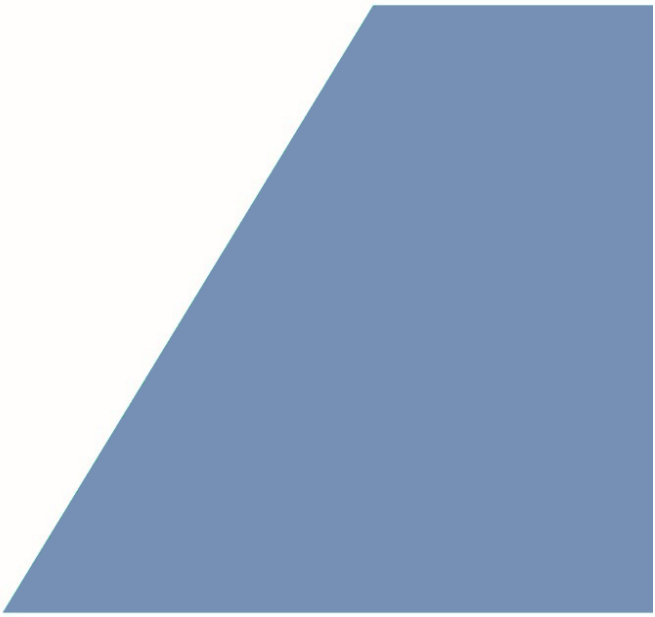
Appendix 1. Regulations not currently included in HIQA's inspection programme

The assessment of an undertaking's compliance with the regulation below has not been included in HIQA's current inspection programme. Further guidance in relation to the requirements of Regulation 8(5) will be published in due course. This assessment judgment framework will be updated when this guidance is published.

Dimension: Safe delivery of medical exposures	
Regulation 8	**Justification of medical exposures**
Line of enquiry	1. Has an undertaking ensured, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease, that: a. the procedure is part of a health screening programme, or has specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines published by HIQA in line with Regulation 8(6), and b. special attention is given to the provision of information to the individual, as required by Regulation 8(13)?
Judgment	**Compliant**: a judgment of compliant means the undertaking or other person is in full compliance with the relevant regulation. **Substantially compliant**: a judgment of substantially compliant means that the undertaking or other person has generally met the requirements of the regulation but some action is required to be fully compliant. This finding will have a risk rating of yellow, which is low risk. **Not compliant:** a judgment of not compliant means the undertaking or other person has not complied with a regulation and that considerable action is required to come into compliance. Continued non-compliance — or where the non-compliance poses a significant risk to the safety, health and welfare of service users — will be risk-rated red (high risk) and the inspector will identify the date by which the undertaking must comply. Where the non-compliance does not pose a significant risk to the safety, health and welfare of service users, it is risk-rated orange (moderate risk) and the undertaking must take action *within a reasonable time frame* to come into compliance.

Revision History

Title/version	Publication date/revision date	Summary of changes
Version 1	07 June 2019	First published
Version 1.1	August 2019	This guidance was revised to reflect amendments to S.I. 256 of 2018.
Version 1.2	September 2019	This guidance was revised to include details of the responsibilities of an undertaking.
Version 1.3	November 2023	This guidance was updated to revise wording and judgment descriptors and to include additional information about Regulations 7, 8, and 13(4) in line with amendments to S.I 256 of 2018. The front and back cover pages were also updated.



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