## Quality Standard for Imaging

Version 1.2



The Royal College of Radiologists

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## Introduction and context

The quality standard for imaging (QSI) is designed to be used within a service as a measure of quality against which quality improvement, patient experience and involvement can be achieved. It articulates the expectations of good imaging services. Services that demonstrate their achievement of the QSI are eligible to apply for the award of the QSI Quality Mark.

#### Disclaimer

While the College of Radiographers (CoR) and The Royal College of Radiologists (RCR) have taken reasonable steps to ensure that the standard is fit for the purpose for the providers of imaging services in the UK, this is not warranted and (to the maximum extent permitted by law) neither the CoR nor the RCR will have any liability to the service provider or any other person in the event that the standards are not fit for such purpose.

The provision of imaging services by the service provider in accordance with such standards does not guarantee that the service provider will comply with its legal obligations to any third party (including the proper discharge of any duty of care) in providing such imaging services. QSI 2021 has undergone a rigorous development and review process and represents the judgements of panels of lay representatives, radiographers, radiologists, medical physicists, clinical technologists and sonographers who have overseen its creation and revision. It reflects wide consultation and valuable comments and suggestions received from professional colleagues and relevant UK government agencies, professional and regulatory bodies. The QSI has been assessed for country-specific applicability.

The QSI aims to improve the quality of care for people attending an imaging service. It sets out best practice in order to improve patient care and outcomes. Clinical practice is a continually evolving field, and the QSI will be independently reviewed every four years.

#### Aim of the Quality Standard for Imaging

The QSI is written to support services in improving the quality of care; it sets a minimum level of expectation rather than a ceiling of quality.

The QSI is written to stand alone, and services can use it as part of their own internal improvement assessment. However, the QSI has a stronger impact when used as part of a peer review or formal quality assessment process. Services are expected to be working to meet the standards at all times, not just in the weeks preceding a quality assessment. Reviewers will expect to see that processes are embedded and in routine use rather than only being in place at the time of the visit. To achieve this requires a culture of quality and a vision of 'this is how we do things round here'. Whilst led from the top of the service, a culture of quality is everyone's responsibility.

#### Scope

Imaging is a multifaceted service, with each part having its unique aspect of technique, technology and professional practice. In the judgement of the imaging professionals in the groups that derived this standard, generic quality standards can describe the quality of care provided by the service for many of these imaging specialties. In regards to some imaging modalities it was agreed that there are unique elements that require a small number of individual quality statements.

### Introduction and context

QSI covers the range of investigations and examinations provided by diagnostic imaging services, including Community Diagnostic Centres (CDCs). Some screening services are supported by their own quality assurance processes, but nonetheless can be covered by the QSI.

#### Definitions

The term used continuously throughout the QSI in respect of a person attending for an imaging investigation, examination or study is 'patient'. Someone who attends with a patient to provide support is referred to as the patient's 'carer', and this term will also include a patient's representative. In some other specialties and guidance, the term 'service user' is often used to refer to a patient, but in imaging services, the term 'service user' can also be used in respect of a clinician making a referral. The terms 'patient' and 'carer' are therefore used to avoid doubt.

In these standards the term 'clinician' is used in the widest context to mean an appropriately clinically qualified person. It may therefore include radiographic and nursing staff and is not restricted to medical staff.

#### **Quality Standard (QS)**

Each standard describes the service quality required in the quality statement.

#### **Quality statement**

A required or agreed definition of quality to be achieved. A quality statement must be unambiguous, objective and measurable.

#### Audit

Improves the quality of patient care by looking at current practice and modifying it where necessary. Frequency of audit is not stated but audits should be sufficiently frequent to provide assurance for the service.

#### Children and young people

The age definition of children and young people used in the service should be consistent with that used by your trust/organisation.

#### Guideline

This sets out recommendations for best practice in a particular process or application. Written by professional bodies or similar organisations of high regard, guidelines should have been peer reviewed. Guidelines are not mandatory, but they reflect the professionally agreed best practice. Clinical guidelines do not replace professional judgement and discretion.

#### Protocol

A document laying down in precise detail the tests or steps that must be performed. Agreed by the service or organisation, it provides direction for the healthcare professional. Note that within the lonising Radiation (Medical Exposure) Regulations 2024 (IR(ME)R) the term 'protocol' has a very distinct meaning. In this QS, the term protocol is used in its non-IR(ME)R context.

#### **Policy**

This sets out the service expectation and organisational mandatory requirements for areas of practice or approaches. A policy is formally agreed by the service or provider governance processes.

#### Pathway

This describes the multidisciplinary approach for patients, usually in a disease-specific care journey. Often accompanied by a visual graphic that is easy to follow, it should encompass a journey of care for a patient group. Multiple guidelines, policies and protocols may sit within one pathway of care.

#### Standard operating procedure (SOP)

A document that sets out in a step-by-step approach the way the organisation expects a procedure, protocol or process to be followed.

Imaging procedure. For the purposes of this standard the term imaging procedure is used throughout the document. This could refer to the whole process in its entirety from referral to production of report. Services should interpret the term in context with the particular standard statement and service that they deliver.

### ۔ Introduction and context

#### Structure of the Quality Standard for Imaging

The generic quality standards (QS) are defined by the prefix 'XR-' and apply to the whole imaging service. There are specific additional quality standards for five modalities that must also meet the generic quality statements where applicable.

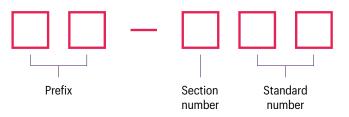
Quality statements apply to the following modality areas:

- Computerised tomography
- Interventional Radiology
- Magnetic resonance imaging
- Nuclear medicine and molecular imaging
- Ultrasound

The QSI references the legislative and regulatory requirements of all four nations of the United Kingdom. It is not the role or intention of the QSI to confirm regulatory compliance to meet the relevant quality statement. The colleges would expect services to be meeting regulatory compliance.

#### **Quality Standards Reference Structure**

Quality standard reference numbers have the following structure:



Each standard is structured as follows:

Reference number (Ref)	This column contains a unique reference number for each quality statement and is used for all cross-referencing.
Quality standard (QS)	Standard name         This describes how the quality statement will be known.         Quality statement         The quality statement describes the service quality required.         Outcome measure         The outcome measure describes the expected high-quality achievement.         Indicative inputs         The indicative inputs provide a range of examples which may help you achieve the outcome measure.         They are not a prescriptive list of requirements. Notes:
	The notes give more detail about either the interpretation or the applicability of the quality standard. The notes are prompts designed for the review team, the service and stakeholders.

### ہ Introduction and context

All the XR quality standards are applicable for the whole imaging service, including all aspects of a general imaging service, plain X-ray, fluoroscopy, theatre and mobile, dental, DEXA and symptomatic mammography. These will also apply to providers of individual services such as teleradiology, stand-alone specific modality services and Community Diagnostic Centres (CDCs).

The modality-specific quality standards apply in additional areas where the quality statements are specific to a particular modality. Each section covers the following topics:

Imaging Service Standards	
XR-1	Information and Support for Patients and Carers
XR-2	Imaging Workforce
XR-3	Scientific, Technical and Support for Equipment
XR-4	Facilities and Equipment
XR-5	Guidelines, Protocols and Clinical Safety
XR-6	Service Organisation and Liaison with Other Services
XR-7	Governance
CT/IR/MR/NM/US-8	Modality-Specific Standards

#### **Service Letters**

The quality statements are in the following sections:

XR-	Service level
CT-	Computerised tomography
IR-	Interventional radiology
MR-	Magnetic resonance imaging
NM-	Nuclear medicine and molecular imaging
US-	Ultrasound

### Information and Support for Patients and Carers

Ref	Standard
XR-101	Imaging Service Information
	Quality statement
	Patients and their carers are offered information about the service they are to attend.
	Outcome measure
	Patients and their carers confirm they have received sufficient information to support their understanding of, and access to, the service, in a format and language they can understand.
	Indicative inputs
	• Information should be made available, when required, to all patient groups in a format and language they can understand.
	<ul> <li>Written information should be in clear, plain language and should be available in formats appropriate to the needs of the patients, including developmentally appropriate information for young people and people with learning disabilities.</li> </ul>
	• Information should be provided for children and young people in an age-relevant format.
	• Evidence should be provided of the information made available to patients and the process for its distribution or access.
	Contact arrangements should be made for additional questions or information.
	Information should be available covering at least:
	a. The imaging services provided and organisation of the service, such as opening hours and modality-specific availability times (if different from standard opening times)
	b. Staff whom patients are likely to meet, and facilities available
	c. How to contact the service for help and advice, including out of hours and aftercare (XR-103)
	d. A request for patients to inform staff if they are/may be pregnant or are breastfeeding
	<ul> <li>e. Radiation risks, including information for patients attending the service who are, or may be, pregnant or breastfeeding.</li> </ul>
	f. How patients' data will be used, including information on how to opt out if they so choose
	• Translation facilities should be available and offered routinely for patients whose first language may not be English.

### Information and Support for Patients and Carers

Ref	Standard
XR-101	Notes: <ol> <li>Ideally information should be written, although in some cases (for example. same day referral) there may be insufficient time to provide a full range of written information. The service should consider how it addresses the needs of patients who are unable to read through sight loss or who are illiterate.</li> </ol>
	2. Information should be provided regardless of age, gender, ethnicity or other protected characteristics.
	<ol> <li>Information for young people should meet the 'Quality Criteria for Young People Friendly Health Services' (DH, 2011) <u>https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services</u></li> </ol>
	4. Information for patients in Wales will need to comply with the Welsh Language Act 1993. This only applies to services working within Wales. Information should be available setting out how translation services for patients whose first language may not be English should be accessed.
	5. Information may be in paper or electronic format, or made available on a website or through other digital technologies. Guidance on how to access information is sufficient for compliance so long as this points to easily available information of appropriate quality. If the information is provided only in individual patient letters, then examples will need to be seen by reviewers.
	6. Information may be general provider information. If so, services which are specific to one pathway should be clearly identified. If the information is provided only in individual patient letters, then examples of these will need to be available to reviewers.
	7. Information may be combined with imaging-specific information (XR-102) and should be clear about the information carers can receive with and without the patient's permission.
	8. Pregnancy information and risk should follow the latest professional body guidance.
	<ol><li>Meeting this QS requires the service to engage actively with patients; this QS cannot be met solely by relying on unsolicited complaints and general comments.</li></ol>
	10. The patient partnership described in XR-109 should influence the development of the information described in this QS.

### Information and Support for Patients and Carers

Ref	Standard
XR-102	Procedure-specific Information
	Quality statement For each imaging procedure and investigation, patients are offered information and have the opportunity to discuss this.
	Outcome measure Patients and their carers confirm they have received sufficient information to support their understanding of their clinical investigation or procedure in a format they can understand, along with the opportunity to discuss concerns or questions.
	<ul> <li>Indicative inputs</li> <li>Information should be made available to all patient groups in a language they can understand.</li> </ul>
	<ul> <li>Written information should be in clear, plain language and should be available in formats, when required, appropriate to the needs of the patients, including developmentally appropriate information for young people and people with learning disabilities.</li> </ul>
	• Evidence should be provided of the information made available to patients and the process for its distribution or access.
	The information should cover at least:
	<ul> <li>a. Preparation for the procedure</li> <li>b. Staff who will be present at or who will perform the procedure</li> <li>c. Any side effects</li> </ul>
	<ul> <li>d. Risks relating to the procedure (see note 6)</li> <li>e. How, when and by whom results will be communicated</li> <li>f. Staff roles and uniforms</li> </ul>
	g. Aftercare information if appropriate for the procedure.
	• Information should be provided for children and young people separately in an age-relevant format.
	<ul> <li>Procedure information should be easily available to referring clinicians as well as being sent to patients attending on an outpatient basis.</li> </ul>
	• Translation facilities should be available and offered routinely for patients whose first language may not be English.
	<ul> <li>There should be evidence of a clear process for obtaining feedback about the information provided from patients and their carers.</li> </ul>
	Notes: 1. As XR-101 notes 1, 2, 3 and 4.
	<ol> <li>As XR-101 notes 1, 2, 3 and 4.</li> <li>For patient information please note that 'all patients groups' includes inpatients.</li> </ol>
	3. Information may be combined with service information (XR-101).
	<ol> <li>4. Information should cover both the stages before the procedure and, where relevant, the stages of the procedure.</li> </ol>
	<ol> <li>Reviewers should enquire whether information on alternative procedures has been made available.</li> </ol>
	<ol> <li>6. This QS links with XR-502 about consent procedures: the information should be appropriate to support patients in giving informed consent.</li> </ol>
	<ol> <li>Meeting this QS requires the service to engage actively with patients; this QS cannot be met solely by relying on unsolicited complaints and general comments.</li> </ol>
	8. The patient partnership described in XR-109 should influence the development of the information described in this QS.

### Information and Support for Patients and Carers

Ref	Standard
XR-103	Contact for Queries, Advice and Aftercare
	Quality statement
	A contact point within the service for queries and advice is available for each patient and, where appropriate, their carer.
	Outcome measure
	Patients and their carers understand they have an opportunity to contact the service for advice and aftercare where they believe this is necessary.
	Indicative inputs
	• Evidence should be provided of the information made available to patients and the process for its distribution or access.
	• If advice and support is not immediately available, then the timescales for a response should be clear.
	<ul> <li>All contacts for advice, and a sample of actual response time, should be documented. Response times should be no longer than the end of the next working day.</li> </ul>
	The service should be able to demonstrate that it meets the agreed response times.
	• There should be evidence of a clear process for obtaining feedback from patients and their carers.
	Notes:
	1. The requirement for a response by the end of the next working day means that there should be a response by, or following discussion with, a health or social care professional who is a member of the team. It does not mean that the particular health or social care professional involved in the individual's care will respond by the end of the next working day.
	2. Information may be combined with service information (XR-101).
	<ol><li>Meeting this QS requires the service to engage actively with patients; this QS cannot be met solely by relying on unsolicited complaints and general comments.</li></ol>

### Information and Support for Patients and Carers

Ref	Standard
XR-104	Respect
	Quality statement
	Patients and their carers are treated with respect.
	Outcome measure
	Patients and their carers confirm they have been treated with respect.
	Indicative inputs
	<ul> <li>A statement of intent by the service should guide the approach of staff within the service.</li> <li>A focus of person-centred care should be clear.</li> </ul>
	<ul> <li>All staff who interact with the patient or their carers should introduce themselves and identify the patient's preferred form of address.</li> </ul>
	Patients should be introduced to all staff with whom they may come into contact.
	Name badges should be worn and be visible, in line with organisational policy.
	Staff should make time to explain procedures to patients and to listen to their concerns.
	Notes:
	1. Meeting this QS is not about the presence or absence of a policy but rather about the culture of the service.
	2. Reviewers should ask how equality, diversity and inclusion are addressed in meeting this QS.
	<ol><li>Evidence of compliance goes beyond the approach of individual staff, and reviewers should consider whether patients confirm they have been treated with respect.</li></ol>
	<ol> <li>This QS requires the service to engage actively with patients; this QS cannot be met solely by relying on unsolicited complaints and general comments.</li> </ol>
	5. A routine approach, such as 'Hello, my name is' should be used to maintain consistency.
	6. This QS should be clearly linked to XR-601.
	<ol><li>Where relevent, the service should have a process of clarifying and recording the patient's preferred form of address for subsequent contacts.</li></ol>
	8. Reviewers should be able to identify ' <u>Duty of Candour</u> ' in England; <u>Putting Things Right Leaflet (nhs.wales)</u> (see XR-601); ' <u>Duty of Candour</u> ' in Scotland and Northern Ireland guidance when published. Principles of openness and honesty should be embedded in the response to this QS.

### Information and Support for Patients and Carers

Ref	Standard
XR-105	Privacy, Dignity and Security
	Quality statement Patients' privacy, dignity and security are maintained at all times.
	Outcome measure Patients and their carers confirm their privacy and dignity have been maintained.
	Indicative inputs
	<ul> <li>The service should have a policy in place to describe how they manage the privacy and dignity of patients, both generally within the department and while undergoing examination. This should align with the organisational policy on privacy and dignity.</li> </ul>
	• The service should have a policy in place regarding the use of chaperones (see also US-801).
	A separate policy may be in place to describe security arrangements.
	• Patients should be offered gowns that seek to maintain their dignity while in any waiting area (see note 2).
	• Separate waiting areas should be available for patients who are dressed and for those who are either in night clothes or changed for examination (see notes 8 and 9).
	<ul> <li>The service should be able to demonstrate that patients and their carers confirm their belongings have been secure during their visit.</li> </ul>
	<ul> <li>There should be evidence of a clear process for obtaining feedback from patients and their carers about privacy, dignity and security when attending the service.</li> </ul>
	Notes:
	<ol> <li>Reviewers should visit/enquire about restricted access to areas where patients may not be fully clothed or have left personal possessions.</li> </ol>
	<ol><li>For certain groups of patients or procedures (for example children) who may be imaged in their own clothes, the use of gowns may not apply. The principles of dignity remain.</li></ol>
	3. Reviewers should enquire about whether suitable toilet facilities to meet patients' needs are available.
	<ol><li>Reviewers should consider the arrangements for the safe and secure storage of valuables, clothing and personal belongings during examinations and procedures. Note that possessions that are valuable to patients may not have a monetary value.</li></ol>
	5. Reviewers may want to take into account arrangements for mobile units regarding security of personal belongings.
	<ol><li>Meeting this QS requires the service to engage actively with patients; this QS cannot be met solely by relying on complaints and general comments.</li></ol>
	7. Reviewers will want to understand how the service has assured itself that the measures taken are sufficient to maintain the privacy and dignity of individual patients, including transgender patients and those patients who may require alternative arrangements.
	8. The patient partnership described in XR-109 should influence the development of the policy described in this QS.
	<ol><li>Accommodation and building constraints may make separate waiting areas not possible. The service should use screens, separate inpatient and outpatient lists or consider other measures to overcome this.</li></ol>
	10. A clear distinction is made between those patients attending in outdoor clothes and those who are either an inpatient in their nightwear or in some form of undress in preparation for their procedure or examination.

### Information and Support for Patients and Carers

Ref	Standard
XR-106	Communication Aids
	Quality statement
	Communication aids are available to enable patients to participate as fully as possible in decisions about their care.
	Outcome measure
	Patients and their carers who require the use of communication aids confirm they have been able to participate in decisions about their care.
	Indicative inputs
	The service should have a range of aids available for staff to use, which may include:
	a. Hearing loop
	b. Picture or symbol cards
	c. Large print information
	<ul> <li>d. Visual impairment aids such as screen readers, Braille or other tactile communication systems</li> <li>e. Access to sign language interpreters.</li> </ul>
	The service should be able to evidence that staff have been trained in the use of communication aids.
	<ul> <li>Translation services should be available, which may be via telephone access.</li> </ul>
	The service should have information on communication aids clearly available to patients.
	Notes:
	<ol> <li>Reviewers should enquire as to how patients are made aware of the use of these aids and the possibility of accessing them in advance of them being required.</li> </ol>
	2. Reviewers should enquire as to how time and personal space is made available for patients to use communication aids effectively.
	<ol><li>Reviewers should ask about staff training in the use of communication aids and processes for patients who are able to highlight communication challenges.</li></ol>
	<ol><li>This QS relates to physical aids to communication. Reviewers will want to enquire about understanding and use of these aids with patients who are neurodiverse.</li></ol>
	<ol><li>Reviewers should ask how these processes have been developed, and especially whether this has been with the engagement of patients with communication difficulties.</li></ol>

### Information and Support for Patients and Carers

Ref	Standard
XR-107	Environment
	Quality statement
	The environment is suitable and safe for all patients, carers and visitors.
	Outcome measure
	Patients and their carers recognise that the environment meets their needs.
	Indicative inputs
	The environment, includes:
	a. Appropriate signage
	b. Suitable lighting
	c. Appropriate colour scheming (for example dementia friendly)
	d. Accessibility including wheelchair use
	e. Safe transport of patients
	f. Consideration of the needs of LGBTQ+ patients (see note 6)
	g. Suitable arrangements for people using mobility aids or with visual impairment
	h. Suitable environment for children and young people.
	<ul> <li>The environment in all locations at which the service is delivered should be suitable for all groups of patients and carers, for example those living with dementia sight loss or neurodiversity.</li> </ul>
	• There should be evidence of a clear process for obtaining views and input from patients and their carers.
	Notes:
	<ol> <li>Suitability of facilities is not strictly defined but should include clear signage, appropriate flooring, rooms for confidential conversations, and facilities for people with disabilities.</li> </ol>
	2. New facilities should be compliant with the latest Health Building Note. DH health building notes - GOV.UK (www.gov.uk)
	3. This QS applies to all facilities attended by patients and carers (see note 5 below).
	4. Some services can be provided in facilities that may include aged estate and space constraints. Reviewers will want to understand how the service has adapted its environment to meet this QS. The organisation's risk register should show how the service is mitigating problems with the facilities.
	5. In services for which a response to an urgent situation has required temporary facilities or arrangements, reviewers will need to consider whether the service has taken reasonable measures to meet this QS. Reviewers will want to consider that the longer a 'temporary arrangement' continues, the greater opportunity the service will have had to meet this QS.
	6. Patients who are gender non-conforming should feel safe on entering the environment. This may include posters welcoming patients and assuring them of the organisation's commitment to be free from discrimination.
	7. This QS links to XR-401.
	8. The patient partnership described in XR-109 should influence the development of the information described in this QS.

### Information and Support for Patients and Carers

Ref	Standard
XR-108	General Support for Patients and Carers
	Quality statement
	Patients and carers have easy access or signposting to other services to support the personal and holistic needs associated with their care.
	Outcome measure
	Patients and their carers are able to access information on an appropriate range of services.
	Indicative inputs
	The service should make information readily available.
	Information about other relevant services should be easily available.
	These other services may include (but should not be limited to):
	<ul> <li>a. Interpreter services, including British Sign Language</li> <li>b. Complaints procedures</li> <li>c. Patient Advice and Liaison Service (PALS) or equivalent</li> <li>d. HealthWatch UK <u>Home   Healthwatch</u></li> <li>e. <u>NHS Webpages The NHS website - NHS (www.nhs.uk)</u></li> <li>f. Health promotion</li> <li>g. Social prescribing</li> <li>h. Relevant voluntary organisations providing support and advice</li> <li>i. Social workers</li> <li>j. Benefits advice</li> <li>k. Spiritual support.</li> </ul>
	Notes:
	1. As XR-101 note 2.
	<ol><li>This QS is about signposting to relevant services. Reviewers may consider leaflets and telephone numbers for these services to be sufficient if they are clearly available.</li></ol>
	3. The actual services available may be different in different areas.
	4. Availability of support services should be appropriate for the patient population and needs of patients and their carers.
	<ol> <li>Information should explain patients' rights under the <u>NHS Constitution England</u>; <u>Patients' rights Wales</u>; <u>Patient Services Scotland</u>; <u>Department of Health NI</u></li> </ol>
	6. This QS relates to information that may be relevant to this care episode.

### Information and Support for Patients and Carers

Ref	Standard
XR-109	Patient, Carer and Service Partnerships
	Quality statement Patient partnerships with the service are used to design and improve future care and service provision.
	Outcome measure The service can demonstrate changes that have been made as a result of patient partnerships and the feedback received.
	<ul> <li>Indicative inputs</li> <li>A policy on patient and service partnerships should be in place.</li> </ul>
	A statement of intent should sit either as part of the policy or separately.
	The service should focus more on co-production than on seeking patient approval.
	The policy should have:
	<ul> <li>a. Mechanisms for receiving regular feedback from patients and carers about the treatment and care they receive</li> <li>b. Mechanisms for involving patients and carers in decisions about the organisation of the service</li> <li>c. A process for involving patients in service design</li> </ul>
	d. A process for providing information to patients on changes as a result of feedback received.
	• There should be examples of changes made as a result of the feedback and involvement of patients and carers.
	There should be evidence of a clear process for obtaining feedback from patients and their carers.
	The service should regularly audit responses to patient feedback.
	Notes:
	1. The service may rely on the organisation's policy on patient and service partnerships as long as this is relevant to the service. <u>Patient Public and Practitioner Partnerships within Imaging and Radiotherapry: Guiding Principles SoR</u>
	2. Meeting this QS requires more than undertaking a regular patient survey, and should focus on engagement with patients and their carers, leading to improvement. Reviewers will want to look at the process, along with the results/outcomes.
	3. The arrangements for receiving feedback from patients and carers may involve surveys, including the national patient survey, focus groups and/or other arrangements. They may also involve provider-wide arrangements, as long as issues relating to the specific service can be identified.
	4. Reviewers will want to consider whether the changes are sustainable.
	5. Reviewers will want to consider the frequency of patient engagement processes.
	6. Reviewers should enquire about leadership of patient and public involvement within the service.

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## **Imaging Workforce**

Ref	Standard
XR-201	Service Leadership
	Quality statement The leadership of the service is clearly identified.
	Outcome measure
	There is an organisational structure naming the individuals who hold leadership roles.
	Indicative inputs
	• An appropriate management structure for the service delivery model in the organisation should be in place.
	<ul> <li>There should be job descriptions for the roles and the responsibilities of the posts.</li> </ul>
	<ul> <li>Imaging services should have a medical lead, a healthcare professional lead and a service manager (or equivalent) with responsibility for staffing, training, guidelines and protocols, service organisation, governance and liaison with other services.</li> </ul>
	Notes:
	1. Leadership roles should be appropriate to the nature of the service being provided
	2. The Clinical Lead must be registered with the appropriate body. The 'professional lead' could be known by a variety of job titles and is often a Health and Care Professions Council (HCPC) registered radiographer with responsibility for the whole service. Where the lead healthcare professional is not HCPC registered, they should have an understanding of regulatory body reporting mechanisms for reporting of professional matters. They should be registered with either another regulatory body (for example Nursing and Midwifery Council NMC) or with a voluntary register where statutory registration is unavailable, for example Sonographers Register of Clinical Technologists accredited by the Professional Standards Authority ( <u>http://therct.org.uk</u> ).
	3. Non-statutory regulated imaging professionals, for example sonographers or nuclear medicine technologists, may undertake the role of service lead. In this case, professional reporting for HCPC registered staff should be clear.
	4. Where the professional lead and the service manager are the same person, reviewers should be clear that the duties of the healthcare professional lead role can be discharged by that person.
	5. Organisational charts should show reporting and accountability.
	6. Job descriptions should be agreed at appointment and reviewed if the role changes significantly.

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## **Imaging Workforce**

Ref	Standard
XR-202	Local Modality-specific Service Leadership
	Quality statement
	Leads for key areas of the service are clearly identified.
	Outcome measure
	There are named individuals who are responsible for key areas of service provision.
	<ul> <li>Indicative inputs</li> <li>Leads (for at least the following areas where provided) should be identified:</li> </ul>
	• Leads (for at least the following areas where provided) should be identified:
	a. Audit
	b. Breast imaging
	c. Cardiac catheterisation imaging
	<ul> <li>d. Computerised tomography (CT)</li> <li>e. DEXA (bone density) scanning</li> </ul>
	<ul> <li>f. Governance including the quality management system (QMS)</li> </ul>
	g. Infection prevention and control
	h. Interventional radiology
	i. Intraoperative imaging
	j. IR(ME)R and radiation safety
	k. Magnetic resonance imaging (MR)
	I. Medicines management
	m. Nuclear medicine
	n. Nursing
	o. PACS, RIS, IT and emerging digital technologies
	p. Paediatrics
	q. Patient partnerships (see XR-109)
	r. Practice educator/Educational lead for both medical and radiographic staff
	s. Plain X-rays t. QSI lead
	u. Radiation protection
	v. Research
	w. Service administration and clerical work
	x. Ultrasound.
	• An organisational structure should be available naming the individuals who hold these roles.
	• A summary of the responsibilities should be agreed with the individual lead.
	Staff should know who the leads are for each of the areas above.

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## **Imaging Workforce**

Ref	Standard
XR-202	Notes:
	<ol> <li>The list of leads above is an indicative list. Reviewers will want to ensure that any modality or specialty has a designated lead.</li> </ol>
	<ol><li>The professional discipline and role of the lead is not stipulated; however, reviewers will want to ensure that the lead has sufficient training, education and experience for the role.</li></ol>
	3. Some leads may not be under the radiology management structure (for example the lead for medicines management). They should still be identified on the organisational chart.
	<ol><li>Leads may have responsibility for more than one area. If so, reviewers should enquire whether the postholder has sufficient capacity to provide leadership in multiple areas.</li></ol>
	5. Reviewers will want to understand how leads are supported in the professional development of their role.
	6. Reviewers should enquire whether staff working in a subspecialty are aware of the name of the lead person.

Ref	Standard
XR-203	Staffing Levels and Skill Mix
	Quality statement
	Sufficient staff, with appropriate competences, are available for the expected number of diagnostic and interventional procedures for the usual case mix of patients within expected timescales.
	Outcome measure
	A review of required competences and capacity matches the demand requirements of the service.
	Indicative inputs
	• Demand and capacity reviews should be regularly refreshed within the current requirements of the service.
	A clear methodology should be used to determine appropriate staffing levels and skill mix.
	<ul> <li>An appropriate skill mix of staff should be available, including medical, radiographic and nursing staff, support workers and other staff required to deliver the range of diagnostic and interventional procedures offered by the service.</li> </ul>
	<ul> <li>Cover for absences should be available so that the patient pathway is not unreasonably delayed and patient outcomes and experience are not adversely affected when individual members of staff are away.</li> </ul>
	Staffing and skills mix should take into account:
	a. The number of patients, and the usual case mix, usually cared for by the service
	b. The service's role in the patient pathway and expected timescales
	c. Transfer of care to other services.
	• The service should be able to demonstrate how the current establishment enables these levels to be achieved in all areas.
	<ul> <li>A business continuity plan should detail how the service will respond to issues of staffing availability when this QS is not met. This should include contingency and escalation plans.</li> </ul>

## **Imaging Workforce**

Ref	Standard
XR-203	Notes:           1. Staff should have time allocated for their role in the service. Roles may be part-time, and staff may be shared with other services.
	2. Reviewers should consider whether latest guidance of the relevant professional college on determining staffing levels has been implemented. <u>Principles of Safe Staffing for Radiography Leaders   SoR</u>
	3. Healthcare support workers should normally have, or be working towards, relevant qualifications. Skills for Health competence frameworks may be helpful in defining appropriate competences: <a href="https://www.skillsforhealth.org.uk">www.skillsforhealth.org.uk</a>
	<ol> <li>In acute settings, expected timescales for the patient pathway should be similar throughout the week, including weekends.</li> </ol>
	<ol><li>Cover for leave should include annual leave, mandatory training, study leave/professional development and a recognition of sickness absence.</li></ol>
	6. This QS relates to the safe delivery of services. Where organisations are unable to meet their full staffing establishments, assessment and mitigation of risk should be clearly recorded.
	7. Reviewers will want to be aware of whether the provider organisation is mandating a number of vacancies be held as part of any cost improvement or headcount management process, and to understand the mitigation strategies employed to manage this.
	8. When the service is non-compliant reviewers should see this in the risk register XR-603.
	9. Reviewers should consider how this QS relates to XR-605 and the department's future strategy.
	10. Organisational structures should detail all those roles that assure the effective delivery of the service, including support staff such as radiology department assistants. <u>SoR guidance for Diagnostic Imaging Support Worker Roles</u> and <u>SoR The Radiography Support and Assistant Workforce: regulatory compliance, governance arrangement, supervision and delegation. (2023)</u>
	11. The reviewers will want to see arrangements in place should staff from another organisation work for the service, for example covering interventional procedures out of hours whereby the staff and not the patients move across sites. Arrangement should include contracts, training and competence (see also XR-514).
	12. Guidance for diagnostic imaging support workers.
	13. NHS guidance for <u>Developing Workforce Safeguards</u> ; <u>NHS Long Term Workforce Plan</u> ; <u>The Kings Fund, Workforce</u> <u>Planning in the NHS</u> and <u>Workforce burnout and resilience in the NHS and social care</u> should be consulted.

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## **Imaging Workforce**

Ref	Standard
XR-204	Service Competences and Training Plan
	Quality statement A competence framework is in place defining roles and tasks within the service.
	Outcome measure
	There is a record that shows that staff have the range of competences required for the roles and tasks that they are expected to undertake.
	Indicative inputs
	• A competence framework should be in place for all staff (both clinical and support staff).
	<ul> <li>The service should be able to demonstrate how, collectively, the competence of all staff is linked to the needs of the service.</li> </ul>
	<ul> <li>The service should record pre-employment checks, which include confirmation of registration to practice where this is required for the role.</li> </ul>
	• A training and development programme should ensure that all staff have, and are maintaining, these competences.
	• The framework should show how the induction of new staff (whether they be new to the service or new to the role but already employed by the service) demonstrates the assurance of competence. The service should record this assurance of competence.
	• A preceptorship programme should be in place to support both newly qualified staff and those new to a role.
	<ul> <li>Services should maintain appropriate competence and training records for all staff (including those in substantive and locum roles, and those in training), demonstrating the attainment and maintenance of competence in the following aspects of safety as appropriate to their role:</li> </ul>
	<ul> <li>a. Ionising radiation awareness, including IR(ME)R, IR(ME)R (NI) 2024 and the Ionising Radiation Regulations 2017 (IRR), (IRR(NI)17)</li> </ul>
	b. MR Safety
	c. Hazardous substances
	<ul> <li>d. Cannulation</li> <li>e. Use of specific ablative and therapeutic devices</li> </ul>
	f. Medical devices
	g. The provider's general statutory and mandatory training requirements
	h. Safeguarding, including female genital mutilation (FGM)
	i. Consent, mental capacity and deprivation of liberty safeguards
	j. Good clinical practice for staff involved in research
	k. Any imaging service-specific aspects of:
	Health and safety
	• Equality/human rights
	Moving and handling (XR-403)
	Infection control
	Use of drugs and medicines
	Information governance, including ensuring confidentiality of patient information and images.
	<ul> <li>A review of practising privileges processes for medical staff in independent healthcare organisations should be clearly recorded.</li> </ul>

## **Imaging Workforce**

Ref	Standard
XR-204	<ul> <li>Notes:</li> <li>1. This QS is about the needs of the service, and cannot be met solely by individual staff appraisals and personal development reviews (PDRs). Reviewers may, however, request information about specific aspects of relevance to the service, particularly where a therapeutic intervention or activity is undertaken rarely and/or where competence may not be maintained by the individual's usual clinical practice.</li> </ul>
	2. For compliance with this QS the service should provide a matrix of the roles within the service, the competences expected and the approach to maintaining competences.
	<ol><li>Training may be delivered through a variety of mechanisms, including e-learning, provider-wide training and departmental training.</li></ol>
	4. Compliance with statutory and mandatory training may be found in provider-wide systems.
	5. Competence in MR safety awareness should be maintained regardless of whether the person's role routinely takes them into the MR unit. All staff in a service in which MR is provided should have a basic MR safety knowledge. Reviewers should enquire about how this is managed.
	6. Health and safety, moving and handling, infection control, information governance, Xsecuurcitation and safeguarding vulnerable adults and children should be covered by the provider's mandatory training but are included here because of their importance for imaging services. If imaging-specific aspects are fully covered in mandatory training then services need to provide only a summary of departmental compliance with mandatory training; if not, details of the completion of additional training should be available.
	7. Where the service provides forensic imaging, individual competences will be agreed.
	8. The competence framework should cover the service's approach to ensuring radiologists are maintaining competences, including for revalidation. Ideally, this approach should be based on an analysis of procedures undertaken and actions needed to ensure competence is maintained, for example through medical job planning.
	<ol><li>The competence framework should ensure registered healthcare professionals are maintaining their professional registration to practice and fulfilling their CPD requirements.</li></ol>
	10. There should be dedicated time and access to supporting professional development for all members of the radiology service
	<ol> <li>Information in use by the service as evidence for this QS may be in an electronic system, but should be accessible and easy to understand.</li> </ol>
	12. MR Safety Hazard training should form part of the induction training for all staff.
	13. Allied Health Professional Educator Career Framework.

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## **Imaging Workforce**

Ref	Standard
XR-205	Agency, Bank and Locum Staff
	Quality statement
	Before an individual starts work in the service, local induction and a review of competence for the expected role in diagnostic and interventional procedures are completed for all agency, bank and locum staff.
	Outcome measure
	The service regularly audits the induction training of temporary staff of all levels.
	Indicative inputs
	• A policy and process should be in place for the recruitment and induction of all temporary staff.
	<ul> <li>For radiographic or medical staff requiring registration to practice, there should be a process for confirming that this is in place before the temporary staff member starts a shift.</li> </ul>
	<ul> <li>Services should document the competences required for roles being filled by temporary staff. Temporary staff should provide evidence that they have the required competences, and the natures of the evidence considered should be included on the staff competence and training record.</li> </ul>
	• Learning from the recruitment of temporary staff should be evident as an output of the audit.
	• Records of induction, including the confirmation by the member of staff of that induction, should be kept by the service.
	• The substantive staff member who is responsible for the supervision of the temporary staff member should be clearly agreed and identified.
	<i>Notes:</i> 1. Reviewers will want to ask substantive staff who have supervised temporary staff about the effectiveness of the process.

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## **Imaging Workforce**

Ref	Standard
XR-206	On-call and Out-of-hours' (Non-core) Working
	Quality statement Staff with appropriate competences are available outside planned sessions to respond to urgent and emergency requests.
	Outcome measure The service can demonstrate it meets the staffing and competency requirements for on-call and out-of-hours' service provision.
	Indicative inputs
	<ul> <li>The service should define what are meant by core hours and non-core hours.</li> <li>The service should be able to demonstrate a robust staffing rota, mapped to the required competences, for on-call and out-of-hours' working.</li> </ul>
	<ul> <li>Staffing requirements for support services should be taken into consideration.</li> </ul>
	Challenges with meeting an out-of-hours' rota should be recognised on the service risk register.
	<ul> <li>Urgent requests include advice, review of previously obtained images, and carrying out and reporting urgent examinations.</li> </ul>
	<ul> <li>A business continuity plan should detail how the service will respond to issues of staffing availability. This should include contingency and escalation plans.</li> </ul>
	<ul> <li>Competences for emergency work should be maintained through appropriate continuing professional development and/or daytime job-planned work.</li> </ul>
	<ul> <li>Processes should be in place when using outsourced teleradiology services out of hours.</li> </ul>
	The service should regularly audit ongoing compliance with this QS.
	On-site staff have access to rest facilities when working on-call/overnight.
	Notes: 1. This QS links to XR-203, XR-204 and XR-205.
	<ol><li>Staffing should be consistent with the guidelines on access to a network (if applicable), or more specialist services pathways and with condition-specific guidelines, and input to multidisciplinary team meetings.</li></ol>
	3. Reviewers will want to consider percentage fill rates for shifts, and will focus on average fill rates rather than individual shifts.
	4. Reviewers will want to be assured that an audit against the policy demonstrates that effective mitigation is in place.
	5. Reviewers will want to ensure that staff are able to rest before driving home after working on-call or overnight
	6. For the purposes of this QS the aim is to eliminate problems with out-of-hours' and on-call working.
	7. Guidance regarding compensatory rest: <u>bma-compensatory-rest-guidance-25-march-2022.pdf</u>

## **Imaging Workforce**

Ref	Standard
XR-207	Administrative and Clerical Support
	Quality statement
	Administrative, clerical and data collection support are available.
	Outcome measure
	The service can demonstrate an appropriate level of trained administrative and clerical workforce in order to support clinical functions.
	Indicative inputs
	• The service should be able to demonstrate a staffing structure for the service's administrative needs.
	<ul> <li>The service should be able to demonstrate how its current administrative and clerical establishment provides sufficient support for the service's clinical function in all areas.</li> </ul>
	• Records of induction and training (statutory, mandatory and role-specific) should be kept by the service.
	• Adequate PACS and RIS support staffing should be available, in addition to service administrative roles.
	Notes:
	1. This links to XR-203.
	<ol><li>Reviewers should note if the service is affected, such as delayed appointments, by a lack of admin staff or lack of suitable skills within the admin team.</li></ol>
	3. Reviewers should enquire about the extent to which clinical staff receive the necessary administrative support required for providing effective care.
	<ol><li>Reviewers will want to ensure that the admin staff are trained in all aspects of the radiology service relevant to their job description.</li></ol>
	5. The amount of administrative, clerical and data collection support is not defined. Clinical staff should not, however, be spending unreasonable amounts of time on administrative tasks.

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## **Imaging Workforce**

Ref	Standard
XR-208	Supporting Staff and Staff Wellbeing
	Quality statement People employed by the service are supported in their work by the organisation and their colleagues.
	Outcome measure Staff employed within the service feel that they are supported at work.
	<ul> <li>Indicative inputs</li> <li>The service should have a range of measures in place, including (but not limited to):</li> </ul>
	<ul> <li>a. Pastoral care initiatives</li> <li>b. Ensuring staff are able to take regular rest/refreshment breaks with suitable facilities such as staff rooms</li> </ul>
	<ul> <li>c. A range of staff support programmes</li> <li>d. Access to work-based mental and physical health services</li> <li>e. Support systems in place following incidents and accidents</li> </ul>
	<ul> <li>f. A mentor system for new staff</li> <li>g. Support for homeworking and remote working</li> </ul>
	h. Ensure inclusivity and reasonable adjustments considerations are in place.
	• There should be a programme of support for staff who report bullying or significant peer pressure.
	There should be a staff development programme.
	There should be regular one-to-one meetings, personal development plans and appraisals.
	<ul> <li>There should be regular feedback, including:</li> <li>a. Regular departmental surveys</li> </ul>
	<ul> <li>b. Organisational surveys</li> <li>c. A clear mechanism for staff to raise concerns (such as a freedom to speak up guardian).</li> </ul>
	<ul> <li>There should be support for learning and professional development.</li> </ul>
	<ul> <li>There should be regular team communications, including team meetings, interdisciplinary and other forms of communication eg staff newsletter, posters etc.</li> </ul>
	• The service should monitor sickness levels and provide support for staff returning to work.
	• A review of the staff response to the outcome measure should be considered by the service management team.
	• There should be a policy on homeworking detailing where and when this is possible (see also XR-401).
	Notes:
	1. This QS cannot be met by an organisational survey alone unless the questions within the survey are service-specific.
	2. Facilities should be appropriate to the service setting and accessible for all staff.
	3. Reviewers will want to enquire how the process of staff raising concerns ensures confidentiality and encourages people to use this channel of communication.
	4. Staff joining the service from outside the UK may require additional support in understanding the health system, culture and ways of working. Reviewers should enquire how the service makes additional support available to these individuals.
	5. The questions in the staff survey should be designed to elicit staff views regarding the support that they receive.
	6. There should be evidence that actions were taken as a result of staff survey feedback.
	7. Reviewers should be assured that the findings of the survey(s) are consistent with discussions with staff in the service.

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## **Imaging Workforce**

Ref	Standard
XR-209	Supporting Staff in Training
	Quality statement
	Staff in training within the service are supported by the service during their training programme.
	Outcome measure
	People in a training post feel that the service and their colleagues support them during their training.
	Indicative inputs
	There should be a mentor system.
	Educational leads should be identified.
	• There should be a programme of support for those in training who report bullying or significant peer pressure.
	Facilities should be available such as:
	a. Room/space for learning
	<ul> <li>b. Protected access to IT</li> <li>c. Quiet areas for reading</li> </ul>
	d. Training aids.
	There should be protected access to equipment and time for training/learning.
	There should be service orientation for the beginning of each placement.
	Support for learning and professional development should be given.
	There should be clear links with training establishments.
	Regular feedback should be obtained from people in training.
	Notes:
	<ol> <li>This QS is designed to describe the support given by the service to people in training; it is not intended to address the quality of training or education received.</li> </ol>
	2. This QS applies in addition to the requirement for staff support in XR-208.
	3. Compliance with this QS is in respect of all staff in any training role, not only student radiographers and trainee radiologists.
	4. Feedback regarding training must be in a timely manner and any action taken must be followed up.
	<ol> <li>Training aids, as appropriate, such as virtual support simulation; physical aids such as skeletons; stocks of images; online journals; virtual supports tools; e-learning etc.</li> </ol>
	<ol> <li><u>Radiographer Advancing Practice</u> – FutureNHS Collaboration Platform which provides a safe workspace for Radiographers at all stages to share knowledge and experience, with links to useful professional resources and orums to support all existing and emerging areas of enhances, advanced and consultant practice.</li> </ol>

### Scientific, Technical and Support for Equipment

Ref	Standard
XR-301	Clinical Scientific and Technical Support
	Quality statement
	Scientific advice and technical support are an integral part of the imaging service.
	Outcome measure
	Scientific expertise, advice and support is available and defined through a Service Level Agreement (SLA) or other agreement.
	Indicative inputs
	Timely access to clinical scientific and clinical engineering support should be clearly defined and agreed.
	<ul> <li>Valid contracts, SLAs or other agreements for the level of services provided should be in place, including evidence that the required key personnel are in post.</li> </ul>
	<ul> <li>At least the following services should be available (where applicable):</li> <li>a. Radiation Protection Advisor (RPA)</li> </ul>
	<ul> <li>b. A medical physics expert (MPE) for ionising radiation or a clinical scientist/clinical engineer</li> <li>c. An MR safety expert (MRSE)</li> </ul>
	d. A radioactive waste adviser (RWA).
	• The RPA should advise (as appropriate) on the requirements of IRR 17 and IRR(NI)17 regulation 14 and schedule 4.
	• The MPE should advise (as appropriate) on the requirements of IR(ME)R Regulation 14.
	<ul> <li>There should be assurance that all scientific and technical staff have regular assessments, and competence appropriate to their roles.</li> </ul>
	• A multidisciplinary approach should be taken to obtain new or replacement equipment and should involve the clinical scientist/clinical engineer, the MPE (for ionising radiation), or the MRSE (for MR).
	Notes:
	<ol> <li>This QS covers medical physics, clinical engineering, and other scientific staff, appropriate to the equipment available, employed by the provider or related organisations. The focus of the QS is on clinical scientific support, however derived or provided.</li> </ol>
	<ol><li>This QS may be met through staff managed by the imaging service, other staff employed by the provider, staff from other imaging services within the network, or staff from non-NHS providers, or a mixture of these arrangements.</li></ol>
	<ol><li>Where this is all externally sourced through contracts, reviewers should enquire as to any on-site scientific support or maintenance for ancillary equipment.</li></ol>
	4. Please see MR-801 for guidance regarding MRSE.
	5. SLAs are not needed if the support service is internal to the Trust/Board.

### Scientific, Technical and Support for Equipment

Ref	Standard
XR-302	Equipment Management
	Quality statement
	Arrangements for equipment management are in place.
	Outcome measure
	The service can demonstrate that the 'uptime' of its equipment is in the range set by the service.
	Indicative inputs
	Clear contracts or agreements with machine manufacturers, or third-party arrangements, should be in place.
	<ul> <li>Equipment management records should be kept covering:</li> <li>a. Procurement and management of equipment and consumables</li> </ul>
	b. Installation acceptance and testing
	c. Calibration, operation and performance of equipment
	d. Infection prevention and control processes.
	<ul> <li>There should be arrangements for equipment maintenance (service contracts and maintenance schedules) covering planned maintenance and breakdown or unscheduled maintenance. Response times should be agreed including for out-of-hours' maintenance.</li> </ul>
	Contingency plans should be in place in the event of equipment breakdown or power failure.
	<ul> <li>There should be monitoring and management of equipment failures and faults.</li> </ul>
	• Equipment safety warnings, alerts and recalls should be circulated and acted upon within specified timescales.
	<ul> <li>A programme of equipment replacement should be in place and there should be risk management of equipment used beyond its replacement date.</li> </ul>
	<ul> <li>Procurement processes should be in place to ensure equipment is evaluated and selected by staff who are competent to do so.</li> </ul>
	Notes:
	<ol> <li>This QS relates to external manufacturers or support agreed with a third-party provider. The focus of the QS is on repair, maintenance and service continuity.</li> </ol>
	<ol><li>Support for emergency breakdown out of hours applies only to equipment used outside normal working hours, or equipment for which the service determines uptime is critical.</li></ol>
	3. XR-301 relates to scientific and technical support. Reviewers will want to ensure that XR-302 together with XR-301 covers the range of equipment and support services provided by the service.
	4. One policy may cover all these areas, or there may be several policies. Where one element is covered within more than one policy, each policy should cross-reference the other.
	5. These arrangements should link with provider-wide arrangements for the governance of medical equipment.
	6. Clinical Imaging Board (CIB): Imaging equipment from procurement to installation and commissioning.
	7. Reviewers should discuss with the service the sustainability and environmental impact of equipment and facilities' purchasing decisions.

### Scientific, Technical and Support for Equipment

Ref	Standard
XR-303	Equipment Quality Control and Quality Assurance
	Quality statement
	The service follows national guidance on quality control (QC) and quality assurance (QA) for equipment.
	Outcome measure
	The service is able to show compliance with the latest professional guidance and regulatory publication on QC and QA, and adherence to schedules (frequency of tests), including taking action if equipment is outside tolerance levels.
	Indicative inputs
	• Advice of a clinical scientist/clinical engineer, MPE (for ionising radiation), or MRSE (for MR) should be sought to ensure the guidance is correctly interpreted.
	• The service should have a policy in place detailing the QC and QA tests that are carried out on its equipment, the frequency with which those tests are completed, by whom, how the results of those tests are communicated to those using the equipment, and what steps should be taken if equipment is found to outside tolerance levels.
	• There should be procedures and records to show that radiographers, clinical technologists, sonographers and assistant practitioners perform appropriate and regular quality control checks on imaging equipment in line with the service's policy, both before use and when equipment conditions indicate this is necessary.
	Quality checks should be evidenced by either manual or electronic recording.
	• Details should be kept of corrective action taken where testing shows parameters outside tolerance or expected levels.
	Staff performing regular QC and QA should be trained to do so.
	There should be records of requirements for QA testing of lead PPE.
	Adherence to the QC and QA policy should be regularly audited.
	<i>Notes:</i> <ol> <li>QA for US guidance recommended by BMUS and SoR <u>Guidelines for professional ultrasound practice</u>.</li> </ol>

### Scientific, Technical and Support for Equipment

Ref	Standard
XR-304	Support Services
	Quality statement
	Timely access is available to services that support the delivery of an effective imaging service.
	Outcome measure
	The service can demonstrate that delays or cancellations of patient appointments are as low as reasonably possible during the preceding 12 months related to support services.
	Indicative inputs
	• Timely access to at least the following services (but see note 2) should be available:
	a. Cleaning
	<ul> <li>b. Clinical sterile services</li> <li>c. IT support</li> </ul>
	d. Linen supplies
	e. Medical records
	f. Patient transport
	g. Porters
	h. Security.
	<ul> <li>The service should have a Service Level Agreement, contract or other measure of agreed response times with each external service provider.</li> </ul>
	The service should demonstrate monitoring systems to identify problems and trends.
	<ul> <li>The service should have processes for regular analysis, including collecting and reporting of delays relating to waiting times.</li> </ul>
	• There should be a reference to this QS in the service business continuity plan (see XR-601).
	<ul> <li>The service should audit delays to the patient pathways caused by the non-availability or delayed response of support services (XR-702).</li> </ul>
	Notes:
	1. 'Timely' is not strictly defined, but availability of these services should not unreasonably delay the patient pathway.
	<ol><li>Where a support service is not used (for example if the service does not use clinical sterile services) then this should be excluded from the assessment.</li></ol>
	3. Reviewers will want to enquire about the process for reporting delays by clinical and ancillary staff.
	4. Reviewers will understand that some aspects of this QS fall outside the direct control of the service. Reviewers should enquire about the steps taken and the escalation processes where local agreement cannot be reached. Reviewers will want to assure themselves that there are ongoing efforts.

## Facilities and Equipment

Ref	Standard
XR-401	Facilities and Equipment
	Quality statement
	Appropriate facilities and equipment are available to deliver the expected number of diagnostic and interventional procedures for the usual case mix of patients within expected timescales.
	Outcome measure
	The service can demonstrate they are able to meet their KPIs associated with imaging and evidence that delays and cancellations are as low as reasonably achievable.
	Indicative inputs
	Facilities and equipment should comply with all relevant standards and should ensure:
	a. Appropriate privacy, dignity and security for patients (XR-105)
	b. Appropriate facilities for both inpatients and outpatients, with space for each
	c. Sufficient space for undertaking each examination. This may be especially relevant in modalities (for example ultrasound) where both the imaging device and the patient support system are mobile
	<ul> <li>Ventilation of the room, especially recognising that imaging suites are unlikely to have natural ventilation and that some equipment is heat generating</li> </ul>
	e. Room lighting sufficient for the procedure, dimmable where required
	f. Protection of other patients, staff and members of the public from radiation, radioactive sources and magnetic fields
	g. Appropriate areas for children, young people and adults
	h. Facilities and equipment for scanning anaesthetised and ventilated patients (where this service is provided)
	i. Immediate availability of resuscitation equipment for both children and adults
	j. Ability to deliver the technical requirements for the range of examinations performed
	<b>k.</b> Arrangements for patients to summon staff in areas that are not permanently supervised.
	<ul> <li>The service should include all delays in its assessments, even where the services are provided off-site (for example teleradiology or homeworking).</li> </ul>
	<ul> <li>The service must maintain an asset register for all its equipment that also meets the requirements of the IR(ME)R regulations (Reg 15(2)).</li> </ul>
	• The service should have a risk-assessed equipment replacement programme agreed with the provider.
	<ul> <li>The service should have processes for regular analysis of key performance indicators and incident reports relating to equipment provision.</li> </ul>
	• Imaging timescales are defined in XR-602.
	<ul> <li>Staff should have designated access to IT equipment to be able to receive and respond to electronic communication required in line with their role.</li> </ul>
	The service should audit ongoing compliance with this QS regularly.

## Facilities and Equipment

Ref	Standard
XR-401	Notes:
	<ol> <li>The focus of this QS is to reduce the impact to patients of delays and cancellations rather than purely to reduce delays in machine uptime.</li> </ol>
	<ol><li>For the purposes of this QS the aim is to reduce delays; where the level of delays is extremely low, reviewers should enquire about whether this is sustainable, rather than focusing on reduction as an end-point.</li></ol>
	3. Reviewers will want to consider physical space in relation to privacy and dignity.
	4. Asset registers should include more than just the high-value capital assets; they should include IT.
	5. XR-107 relates to the environment meeting the needs of patients with specific requirements.
	<ol><li>Governance arrangements for homeworking may be in the wider organisations homeworking policy, but should also include details to address the viewing of clinical images away from the work base (see XR-208).</li></ol>
	7. <u>RCR Guidance for homeworking for radiologists</u> .
	8. Where facilities and equipment are on the risk register there should be a plan to rectify the situation as soon as possible.

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## Facilities and Equipment

Ref	Standard
XR-402	Picture Archiving and Communication System (PACS) and Radiology IT Systems
	Quality statement
	An IT system for the storage, retrieval and transmission of patient information is in use.
	Outcome measure
	An integrated system manages all images and radiology-level patient information required for the service.
	Indicative inputs
	The service should comply with national PACS standards.
	A radiology information system (RIS) should be in routine use.
	<ul> <li>There should be a system to support transfer of information and images to users based at different physical locations covered by the service, to external providers (eg teleradiology) and to other organisations with which the service has a working relationship (eg those within an imaging network).</li> </ul>
	• The system should be able to collect the data required to support national reporting (eg dose data).
	<ul> <li>Systems should have regular quality checks (for example removing old lists, data cleansing and checking functionality of lists) to ensure they perform as expected.</li> </ul>
	All equipment in use in the service should be integrated into the same IT infrastructure.
	Specific arrangements should be in place for mobile equipment.
	<ul> <li>There should be contingency planning in case of failure of PACS. This may include networking arrangements with neighbouring providers.</li> </ul>
	• IT and technical support must be defined and provided (for at least the working hours of the service if this is not 24/7).
	• The service should have undertaken a risk assessment of any imaging modality that does not upload its output to PACS.
	• The service should define the role of PACS for teaching, audit and research. If data are being used in this context, patients should be consented.
	Notes:
	<ol> <li>Meeting this QS is not dependent on having a single named manufacturer or single location for the system. Reviewers should concentrate on the integrated nature of the solution the service has implemented.</li> </ol>
	2. Reviewers should consider if the service has good relationships with IT at their wider organisations level as well as local department level.
	3. A designated individual with time and appropriate competences to manage the system is covered at XR-202.

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## Facilities and Equipment

Ref	Standard
XR-403	Moving and Handling Aids
	Quality statement Moving and handling aids are available and appropriately maintained.
	Outcome measure Staff are trained in the use of moving and handling aids.
	<ul><li>Indicative inputs</li><li>A full range of equipment should be available.</li></ul>
	<ul> <li>Training should be in place to support staff in the correct use of this equipment.</li> </ul>
	• The service should be able to demonstrate regular maintenance checks or servicing on all equipment in use.
	Risk assessments for the use of moving and handling aids should have been undertaken.
	• Provision to support the management of patients with severe obesity should also be available (see XR-404).
	Notes:
	1. Reviewers will want to obtain evidence of training and the availability of equipment.
	<ol><li>Availability of moving and handling equipment is not specified in detail, but this availability should not unreasonably delay the patient pathway or the achievement of the expected timescales (XR-602).</li></ol>
	3. Reviewers should visually check storage locations for ease and accessibility.
	4. Reviewers will want to ensure that the use of moving and handling equipment is recognised in XR-204.
	5. Services may want to consider having a separate moving and handling equipment asset list to meet this standard and they may need to liaise with their 'Medical Devices Safety Officer' to ensure compliance.
	6. Where services share equipment there should be clear, documented records of who services and maintains that equipment.

## Facilities and Equipment

Ref	Standard
XR-404	Equipment for Patients with Obesity
	Quality statement
	There is access to appropriate equipment, moving and handling aids and gowns to meet the needs of patients with obesity.
	Outcome measure
	The service can demonstrate an appropriate range of equipment through regular audit.
	Indicative inputs
	• A full range of moving and handling equipment should be available (see note 4).
	• The service should have a policy and training in place to support staff in the correct use of this equipment.
	<ul> <li>The training and, if in place, a policy should describe/differentiate between the approach for obesity and the approach for severe obesity.</li> </ul>
	<ul> <li>Safe operating weight limits of all couches, imaging tables and other equipment in use should be clearly identified.</li> <li>Actions to take when these limits are exceeded should be clearly set out in the training/policy.</li> </ul>
	Gowns should be sufficient to maintain patient dignity at all times (see XR-105).
	Notes:
	<ol> <li>This QS may be achieved through network arrangements unless the provider is commissioned to provide a bariatric surgery service. Obesity is defined as having a body mass index (BMI) of 35–39 kg/m2 (obesity II) with co-morbidities, and severe obesity as having a BMI of 40 kg/m2 or more (obesity III).</li> </ol>
	2. Note NHS Wales defines a BMI of more than 40 kg/m2 as morbidly obese.
	<ol><li>Reviewers should note that services may not have a separate policy but it may be incorporated into other policies such as 'privacy and dignity'.</li></ol>
	4. Equipment may be stored elsewhere or offsite or need to be ordered but must be available for the patient's appointment
	<ol><li>Training should emphasise maintaining patient dignity and avoiding stereotyping such as assuming that obese patients don't have a full range of movements.</li></ol>
	6. Reviewers will want to ask about training and about the availability of equipment.
	7. Training records should be kept as set out in XR-204.
	8. Reviewers should enquire whether the service receives advance notification of patients with severe obesity.
	9. Reviewers should enquire about storage of, and access to, sufficient stocks of gowns.

### **Guidelines, Protocols** and Clinical Safety

Ref	Standard
	All guidelines and protocols should be based on legal and regulatory requirements, guidance from the RCR and SoR, other national standards and guidance, and evidence-based peer-reviewed sources. Each country in the United Kingdom has its own agreed legal framework and guidance.
	Guidelines and protocols may have different names; one protocol may cover several quality standards, and several protocols may cover one quality standard. The naming and organisation of guidelines and protocols is for local determination so long as, taken together, they cover the areas identified in the quality statements.
	Use of national guidance without consideration of local implementation is not sufficient for compliance with these QS.

Ref	Standard
XR-501	Referral Management Guidelines
	Quality statement A referral management protocol is in place.
	Outcome measure The referral management protocol is available to all staff and entitled referring clinicians. Audit shows that this protocol is being followed and reviewed.
	<ul> <li>Indicative inputs</li> <li>A process is in place for ensuring the appropriateness of referrals and this information is available all relevant staff.</li> <li>There is a list of approved staff/job roles/titles, including clerical staff, who can approve or reject referrals.</li> </ul>
	<ul> <li>Guidelines on the information to be sent with each referral are agreed, circulated and accessible to all referring GPs, referring clinicians and non-medical referrers.</li> </ul>
	<ul> <li>This should include:</li> <li>a. The referral process</li> <li>b. Information to be given to patients</li> <li>c. Consent</li> <li>d. Pre-existing conditions and co-morbidities</li> <li>e. Minimum dataset and clinical information required.</li> </ul>
	<ul> <li>Information sent to referring clinicians should be clearly available.</li> <li>There should be a process for updating guidelines (see XR-701).</li> </ul>
	<ul> <li>A process for distribution should be agreed.</li> <li>The authorisation process and scope of practice of non-medical referrers should be clearly documented.</li> </ul>
	Notes: 1. Reviewers will want to ensure that the guidance also covers non-medical referrers.
	<ol> <li>For ionising radiation, the availability of this guidance is a requirement under IR(ME)R (6(5)(a)).</li> <li>Referrers need to be aware of clinical support tools such as the RCR radiological investigation guidelines tool, <u>iRefer</u>.</li> </ol>

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-502	Consent
	Quality statement All patients are supported in their decisions regarding consent for their imaging procedures.
	Outcome measure The imaging service has appropriate arrangements in place for ensuring patients consent to the imaging procedure.
	<ul> <li>Indicative inputs</li> <li>The consent procedure used by the service should: <ul> <li>a. Be consistent with the wider organisation's consent procedure (if applicable)</li> <li>b. Have appropriate additional detail to ensure compliance with professional body guidance (see note 3)</li> <li>c. Cover both written and verbal consent</li> <li>d. Recognise that patients may choose to withhold consent.</li> </ul> </li> </ul>
	The service should ensure that the consent process is sufficient for procedures that are invasive.
	The service should regularly audit ongoing compliance with this QS.
	<ul> <li>The consent procedure should cover issues such as:</li> <li>e. Communication of risk and benefit, including limitations and alternatives</li> <li>f. Advocacy</li> </ul>
	<ul> <li>g. Shared decision-making</li> <li>h. Capacity, including patients with a deprivation of liberty order in place</li> <li>i. Practicalities of the consent process</li> </ul>
	<ul> <li>j. Specific arrangements for children and young people, including Gillick Competence</li> <li>k. Use of chaperones</li> <li>I. Withdrawing consent.</li> </ul>
	Notes: 1. This QS links with XR-102 about patient information.
	2. Reviewers may want to enquire about the understanding within the service of 'capacity' relating to consent and decision-making, as defined within the Mental Capacity Act.
	3. The SoR guidance on <u>Obtaining Consent: A Clinical Guideline for the Diagnostic Imaging and Radiotherapy Workforce'</u> (2018) and the General Medical Council (GMC) <u>Guidance on professional standards and ethics for doctors: Decision</u> making and consent (2020).
	4. Reviewers should see that those obtaining consent have an appropriate understanding of principles through mandatory training (see XR-204).
	5. Reviewers should enquire about the translation facilities available and how easily they can be accessed. (Reviewers should enquire about the use of relatives in the translation process).
	6. The Mental Capacity Act is relevant only in England, Wales and Northern Ireland. In Scotland, 'Adults with Incapacity (Scotland) Act 2000' provides the legal framework.
	7. https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-8-gillick-competency-fraser-guidelines.
	8. SoR Guidance on intimate examinations and the use of Chaperones (May 2023).

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-503	Image Optimisation
	Quality statement
	Image optimisation is considered in all clinical protocols.
	Outcome measure
	The service can demonstrate improvements to image quality through image quality audits.
	Indicative inputs
	<ul> <li>Clinical protocols should reflect the balance between patient exposure and the requirement to achieve optimum image quality.</li> </ul>
	• The service should have a multidisciplinary image optimisation team approach for setting up processes across modalities. For ionising radiation this should include dose management, evaluating their impact and communicating outcomes widely.
	• A clear process for the development, implementation and audit of imaging protocols should be in place.
	• There should be a system in place to ensure that, when clinical protocols are updated, the corresponding protocols on RIS are updated so that these align.
	<ul> <li>There should be a multidisciplinary protocol development process, including expert advice, with consideration of the 'costs' to improving image quality (examples are radiation dose, time, money, nephrotoxicity, staff wellbeing).</li> </ul>
	<ul> <li>Audits of diagnostic reference level (DRL) quantities, with a clear process for the establishment and use of local DRLs with the advice of an MPE, should be regularly undertaken.</li> </ul>
	Notes:
	1. Reviewers will want to enquire about staff access to protocols.
	<ol><li>Reviewers will want to understand the process for awareness and distribution of updates, including removal of out-of-date or superseded protocols.</li></ol>
	3. Reviewers should enquire about the process used to update protocols.
	4. A risk-based equipment replacement programme should be in place (XR-401).

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-504	Imaging in Pregnancy
	Quality statement
	A protocol is in use covering the imaging of patients attending the service who are or who may be pregnant.
	Outcome measure
	No incidents of avoidable accidental or unintended exposure of a foetus to ionising or non-ionising radiation occur.
	Indicative inputs
	A protocol should be agreed by the service.
	<ul> <li>A procedure should be in place for making enquiries of individuals of childbearing potential, to establish whether the individual is or may be pregnant.</li> </ul>
	<ul> <li>Information should be clearly available within the service advising patients who think they may be pregnant to discuss this with the imaging team (XR-101). This should include clear visual displays (for example posters).</li> </ul>
	<ul> <li>If a person who is known to be pregnant requires an imaging examination that has potential risks for the foetus, a clear documentation of the risk/benefit should have been made by the referrer.</li> </ul>
	The service should audit compliance with this QS regularly.
	Notes:
	<ol> <li>This QS may be met by separate guidelines or by the inclusion of imaging of patients attending the service who are or who may be pregnant in image acquisition protocols (XR-503).</li> </ol>
	2. Service guidelines must reference the latest professional and regulatory guidance.
	<ol><li>Reviewers should enquire about the process for patients who, after the imaging examination has taken place, notify the service that they are pregnant; and particularly how the pre-imaging checks are audited in these cases.</li></ol>
	4. <u>SOR Inclusive pregnancy status guidance</u> .

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-505	Imaging of Children and Young People
	Quality statement
	A specific protocol is in use covering the imaging of children and young people.
	Outcome measure
	The service can demonstrate compliance with national and local guidelines for the imaging of children and young people (through audit of the protocol).
	Indicative inputs
	The protocol should include as a minimum:
	a. Paediatric authorisation (entitled to justify exposures for paediatric patients)
	b. Action to take if suspected physical abuse is identified (see also XR-512)
	c. Reporting by a radiologist or appropriately trained radiographer/sonographer
	d. Consent (see XR-502)
	e. Rationale for and application of immobilisation equipment or methods
	f. Booking processes to ensure on-site paediatric specialty input is available if required
	g. Arrangements that are in place when children move from one service to another.
	The protocol should:
	h. Clarify the arrangements for ensuring availability of appropriately trained staff
	i. Have a process in place to follow up if paediatric patients do not attend their appointment.
	<ul> <li>The protocol should reference (as a minimum) the paediatric specific requirements of XR-101, XR-102, XR-502, XR-506, CT-805, MR-809 and IR-807. The service should regularly audit ongoing compliance with this QS.</li> </ul>
	Notes:
	<ol> <li>If a radiologist or reporting radiographer (or, where appropriate, sonographer) with expertise in reporting images of children is not available 24/7 then the protocol under XR-510 should include referral to a paediatric radiologist at times when local expertise is not available.</li> </ol>
	2. This protocol is required under IR(ME)R 12(8)(a) for exposures of ionising radiation.
	3. Reviewers may want to ask about specific services for children and young people such as play specialists.
	4. A service level agreement (SLA) should be in place for referral to a paediatric radiologist when local expertise is not available.
	5. The radiological investigation for suspected physical abuse in children. RCR (2017).

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-506	Imaging of Patients with Additional Requirements
	Quality statement
	Guidelines are in use covering the imaging of patients who require additional support during their examination.
	Outcome measure
	The service can demonstrate compliance with national and local guidelines for the imaging of patients with additional requirements through audit of the standard operating procedure (SOP).
	Indicative inputs
	• The SOP should recognise that patients with additional requirements include (but are not limited to):
	a. Patients with neurodiverse conditions
	b. Patients with dementia
	c. Vulnerable adults
	d. Vulnerable children
	e. Patients with chronic conditions, for example cancer, heart disease and so on.
	f. Patients with mobility challenges, especially challenges unrelated to their imaging examination
	g. Patients with communication difficulties (see also XR-106)
	h. Patients suffering with claustrophobia
	i. Patients with anxiety or similar conditions that may change their focus on the current environment
	j. Patients with hidden conditions.
	The SOP should include as a minimum:
	k. Arrangements, where known in advance, for ensuring that appointment times are appropriately established when time and capacity is available
	I. A recognition that patients with additional requirements may not always be identified in advance
	<ul> <li>Mathematical and the second state of the second state</li></ul>
	n. Arrangements for appointment times to reflect the needs of patients who require a quieter environment
	o. Arrangements for any additional time requirements during procedures
	p. Processes for staff training to recognise the need for support for these patients.
	The SOP should indicate minimum expected levels of achievement.
	The service should audit compliance with this QS regularly.
	Notes:
	<ol> <li>Audit is not sufficient alone to demonstrate compliance with this QS. Reviewers will want to identify improvements made to the service for patients who have additional needs.</li> </ol>
	2. This QS reflects the additional measures required in the processes and procedures of the service to support patients. It is not intended to replace the imaging protocols for the examination. XR-106 relates to communication aids and XR-107 relates to environmental considerations.
	3. The SOP should make reference to the SoR <u>Patient Public and Practitioner Partnerships within Imaging and</u> <u>Radiotherapy: Guiding Principles (2018)</u> .
	4. Compliance with this QS may be met with more than one SOP.
	5. Reviewers will want to understand how feedback from the patient partnership described in XR-109 informs development and improvement in compliance with this QS.

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-507	Infection Prevention and Control
	Quality statement
	A policy on infection prevention and control (IPC) is in use.
	Outcome measure
	The service can evidence improvements to practice as a result of regularly reviewing IPC data within the service.
	Indicative inputs
	The IPC policy should cover:
	a. Cleaning equipment and the environment
	b. Frequency of cleaning
	c. Record-keeping and/or use of visual indicators
	<ul> <li>Imaging of patients with suspected or confirmed contagious and communicable diseases and/or suppressed immune systems, including patient care before, during and after imaging</li> </ul>
	e. Decontamination of equipment and environment following use by patients with suspected or confirmed contagious or communicable diseases
	f. Routine cleaning and deep cleaning
	<ul> <li>g. Occupational safety/managing prevention of exposure, including sharps and use of appropriate personal protective equipment (PPE)</li> </ul>
	h. Safe management of blood and bodily fluids.
	• The policy should be consistent with, and may be part of, the wider organisation's (if applicable) infection control policy.
	• The policy should have been approved by the director of infection prevention and control (or equivalent).
	The service should have a dashboard of key IPC metrics that inform the regular review.
	<ul> <li>Mandatory IPC training compliance should form part of the key metrics.</li> </ul>
	Arrangements for undertaking observational audits for IPC assurance should be in place.
	The service should regularly audit compliance with this QS.
	Notes:
	<ol> <li>Reviewers will want to identify that the guidelines cover both individual patient measures and measures to be taken in the event of an outbreak within the service/wider organisation.</li> </ol>
	2. The lead for infection control may be from outside the service.
	3. This links to XR 204 and compliance with mandatory training in IPC.
	4. Reviewers will want to ensure that the person(s) named in XR-202 is clearly involved in the demonstration of compliance.
	<ol><li>Reviewers will want to enquire about the communication processes between the service lead for IPC and the wider organisation's IPC lead (if applicable).</li></ol>
	6. Services should follow NHS England and NHS Improvement <u>Standard infection control precautions: national hand</u> hygiene and personal protective equipment policy.

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-508	Imaging Reporting Policy
	Quality statement
	An imaging reporting policy is in use.
	Outcome measure
	An audit of compliance with the imaging reporting policy has been conducted by the service, with audit outcomes documented and an appropriate action plan is in place to meet national and local guidelines.
	Indicative inputs
	The policy should cover as a minimum:
	a. Roles, responsibilities and scope
	b. Agreed reporting KPIs
	c. Agreed reporting formats
	d. A system to assure quality, accuracy and verification of reports
	e. Preliminary clinical evaluation (see note 2 below)
	f. A system to ensure amendments are issued within specified timescales (when required)
	g. Further imaging, linking to radiology events and learning meetings
	h. Peer review of reporting
	i. Access to a second opinion
	j. Agreed communication of reports.
	Reporting of images by other clinicians (for example emergency department).
	<ul> <li>Incidents and non-compliance with the guidelines should be shared and discussed within the service. Processes included where double reporting is clinically indicated. The service should be able to demonstrate compliance with the guidance from the RCR <u>Standards for interpretation and reporting of imaging investigations</u> and SoR <u>Preliminary</u> <u>Clinical Evaluation and Clinical Reporting by Radiographers: Policy and Practice Guidance</u>.</li> </ul>
	The service should regularly audit compliance with this QS.
	Notes:
	<ol> <li>Radiographers with appropriate knowledge, skills and competence will report independently. Reviewers should ensure that any recording of preliminary clinical evaluation is seen separately.</li> </ol>
	<ol><li>Reviewers will want to ensure that the audit of compliance is sufficiently comprehensive to provide assurance of compliance.</li></ol>
	3. NHS Guidance regarding <u>Changes to cancer waiting times standards from 1 October 2023</u> should be taken into consideration.
	4. Guidance published by the Academy of Medical Royal Colleges <u>Recommendations on alerts and notification</u> <u>of imaging report, 2022</u> .
	5. Guidance for image turnaround times can be found here: <u>NHS England - diagnostic imaging reporting turnaround times</u>
	6. This QS links to XR-704 and XR-510.

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-509	Quantification
	Quality statement
	Systems used in the measurement of clinical images allow consistent interpretation.
	Outcome measure
	Quantification software for the measurement of clinical findings or between points of reference has reproducible results between clinical systems in use by the service.
	Indicative inputs
	Systems in use in the imaging service should have measurement parameters calibrated and checked.
	The imaging service should use a consistent approach to software to ensure reproducibility.
	Calibration requirements and measurement of uncertainty should be documented.
	When the service works across a clinical network, consistency checks should be applied.
	<ul> <li>The service should record which systems are in use to ensure that patients returning for checks on progression of their clinical findings can have consistent measurements.</li> </ul>
	Notes:
	<ol> <li>This QS has greater significance for patients returning for repeat or future measurement of a clinical finding or disease progression. Reviewers should enquire how the service manages this cohort of returning patients.</li> </ol>
	2. Guidance for ultrasound can be found in the Multi-Medix QA Manual.

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-510	Unexpected Diagnoses and Potential Medical Emergencies
XR-510	Quality statement         A protocol covering the management of unexpected diagnoses and indications of potential medical emergencies is in use.         Outcome measure         An audit of compliance with the management of unexpected diagnoses and indications of potential medical emergencies has been carried outby the service and an appropriate action plan is in place.         Indicative inputs         • The protocol should clarify the process and timescales for:         a. Alerting referrers to unexpected findings         b. Ensuring acknowledgements of the alert are received by the service         c. Management of anon-acknowledgement of receipt         d. Management of alerts when reporting out of hours         e. Communication with the patient should include location, method and next steps.         • Reports should be clear and the critical elements of the report emphasised, along with, where appropriate, the actions the referrer needs to take.         • There should be a process in place for the operator to alert the reporter of untoward findings noted at the time of imaging.         Notes:         1. Recommendations: Parliamentary and Health Service Ombudsman Unlocking Solutions in Imaging: working together to learn from failings in the NHS (2021).
	<ol> <li>Guidance published by the Academy of Medical Royal Colleges <u>Recommendations on alerts and notifications of</u> <u>imaging reports 2022</u>.</li> </ol>

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-511	Pathway and Condition-specific Protocols
	Statement
	Pathway and condition-specific protocols are in use.
	Outcome measure
	The service can demonstrate an improvement in imaging and care pathways through an audit of the implementation and use of protocols.
	Indicative inputs
	• The protocols may cover but are not limited to (relevant to the service being provided):
	a. Trauma (adults and children)
	b. Stroke c. Cancer
	d. Venous thromboembolic disease
	e. Acute abdomen pathway
	f. Suspected acute aortic syndromes
	g. Acute chest pain of possible cardiac origin.
	Protocols should be available for forensic imaging where this is provided.
	The protocols should be based on national guidelines.
	<ul> <li>The service should regularly audit ongoing compliance with these protocols, which should be cross-referenced to any incidents or non-compliance reported.</li> </ul>
	Notes: 1. Examples of other pathway- and condition-specific guidelines include: chronic obstructive pulmonary disease (COPD), diabetes, dementia, heart failure, abdominal aortic aneurysm, peripheral vascular disease, upper gastrointestinal (GI) bleeding, lower GI bleeding, kidney disease and acute kidney injury, renal vascular access, liver disease and uterine disease including post-partum haemorrhage.
	<ol><li>Reviewers will want to be assured that the pathway- and condition-specific guidelines are relevant to the service(s) being provided. They should be sufficient to cover at least all the areas commonly provided by the service.</li></ol>
	3. Compliance with this standard may be part of a wider MDT audit rather than a service-specific audit. When this occurs, reviewers will want to ensure the service has considered the imaging elements of the audit results.
	4. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that, among other elements, there has been communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	5. Reviewers will want to ensure that MDT attendance and feedback is used for improvements in the service.

### **Guidelines, Protocols** and Clinical Safety

Ref	Standard
XR-512	Forensic Imaging
	Quality statement
	A protocol for the provision of forensic imaging is in place.
	Outcome measure
	The service complies with national and professional body standards and guidance on the use of forensic imaging.
	Indicative inputs
	All examinations for suspected physical abuse should be treated as forensic examinations.
	<ul> <li>Protocols should differentiate in the role and processes of forensic imaging between patients still living and deceased cases.</li> </ul>
	Deceased patients should be treated with the same level of respect as that afforded to living patients.
	A protocol should cover at least:
	a. The collection of evidence and its use in a court of law
	b. Continuity of evidence
	c. Authorised referrers
	d. Requirements of particular care pathways, for example care of the elderly, child protection
	<ul> <li>e. Safeguarding</li> <li>f. Risks and benefits of the procedure (including clinical and radiation risk)</li> </ul>
	g. Cultural and religious sensitivities
	h. Privacy and dignity
	i. Infection prevention and control
	j. Out-of-hours' service provision.
	• Radiographers undertaking forensic radiography should have agreed competences in this specialist field (see XR-204).
	<ul> <li>Management of consent must be clearly and explicitly set out for both living and deceased patients, and relate to the provider's consent policy. Reference should be made to consent for minors.</li> </ul>
	The process to follow when consent is withheld should be set out in the protocol.
	<ul> <li>Forensic imaging is part of a multidisciplinary pathway, and the development of the protocol should be in agreement with other stakeholders, for example the coroner's office.</li> </ul>
	<ul> <li>When examinations of deceased patients are carried out within an imaging department during a time when other patients are in the department, the protocol should detail how this will be managed sensitively.</li> </ul>
	• Communication Aids (XR-106) and Information (XR-102) will also apply in relation to this QS.
	The service should regularly audit compliance with this QS.
	Notes:
	<ol> <li>The guidance from the SoR provides the definitive approach to forensic imaging: <u>Society-of-Radiographers-Forensic-and</u> <u>Post-Mortem-Radiography-Guidance_Final (sor.org)</u>. RCR and ScoR joint guidance for <u>The radiological investigation of</u> <u>suspected physical abuse in children (2017)</u>.</li> </ol>
	<ol><li>Infection prevention and control, consent, safeguarding and other elements within the protocol should be consistent with the wider organisation's policy in those areas.</li></ol>
	3. The protocol should specify whether participation in forensic imaging is optional for staff.

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-513	Management of Medicines and Contrast Media
	Quality statement
	A policy on the management of medicines and contrast media is in use.
	Outcome measure
	The service can demonstrate compliance with its management of medicines and contrast media policy, through an audit of compliance.
	Indicative inputs
	Guidelines should cover at least:
	a. Roles, responsibilities and scope
	b. Security, storage and stock control
	c. Checking of controlled and emergency drugs
	<ul> <li>d. Prescription, mechanisms of administration and supply including unlicensed medicines, Patient Group Direction (PGD), (see note 3) and Patient Specific Direction (PSD)</li> </ul>
	e. Identification and management of extravasation
	f. Process for cleaning contrast media spills
	g. Disposal and mixing of contrast media
	h. Identification and management of patients at risk of adverse reactions
	i. Management of adverse reactions
	j. Reporting of adverse reactions as appropriate
	k. Aftercare of patients
	I. Processes for managing medicines that are administered off-label.
	<ul> <li>The policy and PGDs must have been agreed by the provider's formal medicines management forum (for example the Drugs and Therapeutics Committee).</li> </ul>
	• Training in PGDs and medicines management should be provided for all staff covered by this QS.
	HCPC regulator annotations should be checked for non-medical prescribers.
	The service should regularly audit compliance with this QS.
	<ul> <li>An individual trained in recognising and treating severe contrast reactions, including anaphylaxis and extravasation should be identified for all areas of contrast agent delivery and all times of service provision.</li> </ul>

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-513	Notes:
	1. This QS also links to modality-specific measures (Renal Function Protocol, CT-802, MR-807 and IR-805).
	<ol><li>The guidelines should link with the employer's medicines management policy and must have been agreed by the chief pharmacist and/or the provider's Drug and Therapeutics Committee.</li></ol>
	3. Template examples of PGD for contrast media can be found at www.sps.nhs.uk/articles/contrast-agent-pgd-templates.
	<ol> <li>When the service has a nominated lead for medicines management, this person must be named in the compliance evidence for XR-202.</li> </ol>
	<ol> <li>SoR Improving Patients' Access to Medicines: A Guide to Implementing Diagnostic Radiographer and Therapeutic Radiographer Prescribing within the NHS in the UK (Second Edition), 2023 and Practice Guidance for Radiographer Independent and /or Supplementary Prescribers, 2023.</li> </ol>
	6. Roles and responsibilities of registered professionals are defined in the Human Medicines Regulations 2012 and vary by profession. The nonregistered workforce including the support workforce can in some circumstances support medicines supply, preparation and administration when there is a PSD or prescription in place. For non-legislative requirements such as second checking of medicines this will be defined by employer level policy.
	<ol><li>Reviewers will want to check that staff are aware of the process for reporting of reactions such as MHRA yellow card, internal reporting and <u>Medicines Management</u>.</li></ol>
	8. Local governance processes should be in place for occasions where medicines are being administered off label for example saline bags are licensed for single use only, and sometimes are being used in multidose injectors outside of their marketing authority. In these circumstances, local governance processes should come in to play this should include a full risk assessment and acceptance by the employer within the medicines management policy for its off-label use.

## Guidelines, Protocols and Clinical Safety

XR-514	Ionising Radiation Safety
	ionion gradation outory
	Quality statement The service is compliant with national regulations regarding the use of ionising radiation.
	Outcome measure
	The service has regulatory audits demonstrating compliance with Ionising Radiation (Medical Exposure) Regulations, Ionising Radiation Regulations (2024)/the Ionising Radiation (Medical Exposure) Regulations (NI) (2018) and Environmental Permitting (England and Wales) Regulations 2016/Radioactive Substances regulations currently in place.
	Indicative inputs
	The audits should cover at least the following areas:
	a. Ionising Radiation (Medical Exposure) Regulations – IR(ME)R
	i. Employer's IR(ME)R procedures/protcols
	<ul> <li>ii. Administration of Radioactive Substances Advisory Committee (ARSAC) licensing (employer and practitioner)</li> <li>iii. Staff competency training and entitlement</li> </ul>
	iv. Equipment
	<ul> <li>v. Diagnostic exposure optimisation and reference levels</li> <li>vi. Accidental/unintended exposures</li> </ul>
	vii. Clinical and IR(ME)R audits
	b. Ionising Radiation Regulations – IRR
	viii. HSE authorisation
	ix. Radiation protection management
	x. Radiation protection training
	xi. Risk assessments
	xii. Area designation
	xiii. Local rules
	xiv. Staff dose records and requirements for classified workers xv. Contamination monitoring
	xvi. Radioactive source management.
	• The role of the MPEs, RPA, RPS and RWA should be clearly defined in line with regulations.
	<ul> <li>The staffing level of MPEs should be compliant with the recommendations from ARSAC.</li> </ul>
	<ul> <li>The role of the employer, as set out in the IR(ME)R and IR(ME)R (NI) regulations, should be clearly defined, along with clear delegation.</li> </ul>
	• The radiation protection committee should have multidisciplinary membership relevant to the service(s) provided.
	• The provider's radiation safety committee (or equivalent) should consider reports of compliance and confirm their findings.
	<ul> <li>Where the radiation safety committee (or equivalent) deems the service non-compliant with national regulations, an action plan with clear timescales and named individuals should be in place along with a date for expected compliance.</li> </ul>
	<ul> <li>The service should ensure that it liaises with other employers as appropriate to ensure that any employee who has more than one employer has dose limits applied across organisations.</li> </ul>
	Compliance with this QS should be audited regularly.

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-514	Notes:
	1. The audits demonstrating compliance should as a minimum include input from:
	The medical physics expert (MPE) for diagnostic radiology or nuclear medicine, as appropriate
	The radiation protection adviser (RPA)
	The relevant radiation protection supervisors (RPS)
	The radioactive waste adviser (where appropriate) (RWA)
	<ol><li>This QS will demonstrate how the service has assured itself, the employer and the provider organisation that it remains compliant with national radiation safety regulations.</li></ol>
	3. The service should have radiation protection and safety groups at a local and provider level with clearly defined terms of reference and membership details. Any area(s) of non-compliance should be raised at an appropriate level with escalation processes in place. Robust action plans including responsibilities and timescales should be drawn up to fulfil regulatory requirements.
	4. Procedures should be in place covering the use of ionising radiation. Reviewers will want to know that staff are aware of these and know how to access them. These should include a radiation safety policy (may be at provider level), employer's procedures, and local rules.
	5. Reviewers should be assured that roles and responsibilities are clearly identified.
	<ol><li>IR(ME)R confers a legal responsibility on the employer. Reviewers should be able to identify a clear accountability structure from the service leads to the employer, such that this legal duty can be discharged.</li></ol>
	7. Reviewers should identify the appropriate processes and extent of entitlement under IR(ME)R.
	8. The report from the MPE may incorporate the RPA report or other records, but these should be separately identified.
	9. The named individuals in this QS should also be identified within the documents required for XR-202.
	10. Reviewers will want to check that staff are aware of the processes for reporting unintended or accidental exposures and that services have processes in place for preliminary investigation as required by regulation.

## Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-515	Hazardous Substances
	Quality statement
	The service is compliant with national regulations regarding the presence and use of hazardous substances.
	Outcome measure
	The service has an up-to-date report showing compliance with Control of Substances Hazardous to Health (COSHH) Regulations.
	Indicative inputs
	COSHH assessments should be in place.
	• There should be a lead person in the service responsible for COSHH compliance.
	Notes:
	<ol> <li>Compliance with COSHH will not be subject to detailed review. Compliance with this QS will demonstrate that the service has assured itself, the employer and the wider organisation that it remains compliant with national regulations.</li> </ol>
	<ol><li>Reviewers should note that in many organisations, compliance with these regulations is managed centrally by the wider organisation rather than at service level. Reviewers will want to understand how the service receives assurance of compliance.</li></ol>
	3. Where compliance is managed at wider organisation level, reviewers will want to understand the role of the named person within this QS in assuring that compliance.
	<ol> <li>This QS will have a specific relevance to MR phantoms and nuclear medicine and molecular imaging. Reviewers will want to be assured that these specific areas are compliant.</li> </ol>

### Guidelines, Protocols and Clinical Safety

Ref	Standard
XR-516	Health and Safety
	Quality statement
	The service is compliant with the Health and Safety at Work Act.
	Outcome measure
	The service has an annual report showing compliance with Health and Safety Regulations.
	Indicative inputs
	• The provider's health and safety policy should be in use, with specific references to the service being provided.
	There should be a nominated lead person responsible for health and safety compliance.
	<ul> <li>The service should display information about health and safety in an accessible place.</li> </ul>
	The policy should include reference to lone working and homeworking.
	<ul> <li>The service should have a forum in place for reviewing risk assessments and reported incidents. This may be part of a wider organisational or service level process.</li> </ul>
	Mandatory training in health and safety should be up to date.
	• Information on a) actions in the event of a fire, and b) access to first aid, should be clearly identified and visible.
	Risk assessments should be in place and should include (but not be limited to):
	a. Moving and handling
	b. Work-related musculoskeletal disorders (especially in relation to ultrasound (US-801))
	c. Display screen equipment
	d. Ergonomics
	e. Lone working
	f. Remote/home working
	g. Electrical safety
	h. Stress
	i. Physical and verbal aggression
	j. Slips, trips and falls
	k. Specific risks associated with imaging procedures.
	<ul> <li>Formal risk assessments should have been undertaken by staff trained in their use.</li> </ul>
	<ul> <li>There should be a process for updating formal risk assessments following service change or undertaking new assessments on the introduction of a new service.</li> </ul>
	Compliance with this QS should be audited regularly.
	Notes:
	<ol> <li>Compliance with health and safety regulations will not be subject to detailed review. Compliance with this QS will demonstrate how the service has assured itself, the employer and the wider organisation that it remains compliant with national regulations such as <u>HSE: Information about health and safety at work</u>.</li> </ol>
	2. This QS may be met by a separate imaging department policy so long as this is consistent with the provider's health and safety policy.
	3. Homeworking is also included in XR-208 and XR-401. The health and safety requirements should be consistent with the staff wellbeing and governance requirements in these QSs.

### **Guidelines, Protocols** and Clinical Safety

Ref	Standard
XR-517	Artificial Intelligence/Machine Learning
	Quality statement
	All departments have a strategy for development, implementation, auditing, discrepancies, training and education in relation to machine learning algorithms.
	Outcome measure
	The service demonstrates that it has a strategy for planning the implementation and use of machine learning algorithms, including a discrepancy workflow and feedback process.
	Indicative inputs
	<ul> <li>The service should be able to demonstrate that it has a policy in place to support staff in the correct use of, and reference to, machine learning algorithms.</li> </ul>
	<ul> <li>Policies should be developed with local interpretation of guidance taken from 'NHS Digital Recommendations and hospital IT Teams.'</li> </ul>
	<ul> <li>Policies should show local application of <u>NHS recommendations for machine learning algorithms</u>.</li> </ul>
	The performance of algorithms should be regularly audited.
	Notes:
	1. Reviewers should ask about the frequency of the review of local policies.
	<ol> <li>Further information is available from the SoR guidance <u>Artificial intelligence: Guidance for clinical imaging and</u> <u>therapeutic radiography workforce professionals (2021) https://www.sor.org/learning-advice/professional-body-</u> <u>guidance-and-publications/documents-and-publications/policy-guidance-document-library</u>.</li> </ol>
	3. RCR guidance on AI deployment fundamentals for medical imaging.
	4. Reviewers will want to review:
	NHSX <u>A Buyer's Guide to AI in Health and Care</u> .
	DoH Code of conduct for data-driven health and care technology.

### Service Organisation and Liaison with Other Services

Ref	Standard
XR-601	Operational Policy
	Quality statement An Imaging Service operational policy is in place.
	Outcome measure
	The service regularly reviews key performance indicators (KPIs) to assure itself that its operational policy is effective.
	Indicative inputs
	The service should demonstrate that there is an operational policy in place that covers all the areas provided by the service.
	<ul> <li>The operational policy should be accessible by staff working within the service.</li> </ul>
	• The policy may cover (relevant to the services being provided):
	a. Availability of services (including 24/7 availability) (XR-206)
	b. Capacity and escalation plan to ensure imaging timescales are achieved (XR-602)
	c. Availability of staffing and competences to maintain service (XR-203 and XR-204)
	d. Cleaning schedules and IPC arrangements (XR-507)
	e. Timely access to support services (XR-304)
	f. Protocol for non-medical referrers (XR-501)
	g. Contribution to all multidisciplinary team meetings as appropriate
	h. Arrangements for non-medical imaging
	<ul> <li>Arrangements for staff feedback about the imaging service and for involving staff in decisions about the organisation of the service</li> </ul>
	<ul> <li>Arrangements for obtaining feedback from referring clinicians, and for involving them in decisions about the organisation of the service</li> </ul>
	k. Response to a major incident
	I. Processes for investigation following a serious untoward incident or never event
	m. Business continuity plan
	<ul> <li>n. Duty of Candour or similar arrangements (Putting Things Right: Wales) where they are covered by legislation (XR-104)</li> </ul>
	o. Outsourcing arrangements, for example teleradiology.
	• If the service provides forensic imaging, key elements should be recognised in the operational policy.
	• When services are provided between or across different providers, the operational policy should make clear a common approach to partnership working through dual policies or a single agreed system.
	The service should regularly audit compliance with this QS.

### Service Organisation and Liaison with Other Services

Ref	Standard
XR-601	Notes:
	<ol> <li>Compliance with parts of this QS will be cross-referenced to the response to meeting IR(ME)R requirements. Reviewers may want to check for consistency.</li> </ol>
	<ol><li>Compliance with this QS may sit within several documents; however, for compliance with this QS, where multiple documents are in use there should be a single document setting out how these individual documents relate to each other to ensure the effective operation of the service.</li></ol>
	3. The service's response to a major incident should be consistent with the wider organisation's major incident plan. It may be part of the service's operational policy, or the wider organisation's major incident plan, or both. The response should consider the role of imaging in internal and external major incidents.
	<ol> <li>The operational policy should be consistent with the arrangements for emergency services (QS XR-206), guidelines on referral to network and more specialist services, and pathway- and condition-specific guidelines (XR-511).</li> </ol>
	5. Compliance with this QS has links with compliance with many other QS. Reviewers should consider whether compliance has been achieved in other linked QS when assessing compliance with this QS.
	6. Reviewers should enquire how arrangements are detailed in the operational policy when, for example, a third-party provider is contracted to provide additional activity for the service.

### Service Organisation and Liaison with Other Services

Ref	Standard
XR-602	Imaging Timescales
	Quality statement Imaging timescales are defined and agreed.
	Outcome measure The service is able to demonstrate that modality-specific KPIs are being met for imaging timescales as defined by national guidelines or by locally agreed timescales where these exceed national guidelines, or there are no national guidelines in place.
	<ul> <li>Indicative inputs</li> <li>A dashboard of performance against agreed timescales should be regularly considered by the service for the following: <ul> <li>a. Receipt of referral</li> <li>b. Referral to examination</li> <li>c. Examination to report</li> <li>d. Initial reports issued</li> <li>e. Timescales for imaging in clinical pathways including (but not limited to) emergency, cauda-equina syndrome (CES), cord compression, stroke, transient ischaemic attack (TIA) and cardiac imaging</li> <li>f. Other timescales agreed locally.</li> </ul> </li> <li>The service should be able to demonstrate a policy and process setting out how it will meet these requirements.</li> </ul>
	<ul> <li>The service should regularly audit compliance with this QS.</li> <li>Notes: <ol> <li>The collection of the data for monitoring of agreed timescales is covered in XR-702.</li> <li>The service should show how it is monitoring and managing waiting times for patients.</li> <li>NHS England: Changes to cancer waiting times standard from 1 October 2023 should be implemented.</li> <li>This QS links to XR-206, XR-509 and XR-702.</li> <li>Where reviewers consider 'other timescales agreed locally', these should be credible and consistent with recognised good practice.</li> <li>Clinical Imaging Board (CIB) guidance on MRI provision for cauda equina syndrome.</li> </ol> </li> </ul>

### Service Organisation and Liaison with Other Services

Ref	Standard
XR-603	Risk Management
	Quality statement The service identifies and manages risks to the service delivery.
	Outcome measure The service is able to demonstrate effective risk management.
	<ul> <li>Indicative inputs</li> <li>A risk management policy should be in place (this may be the wider organisation's policy).</li> </ul>
	A system of risk assessment and risk management should be in use.
	Risks and actions should be recorded in an up-to-date risk register.      The risk register about the formal language of the risk register.
	<ul> <li>The risk register should be formally reviewed in line with the wider organisation's risk policy timeframes.</li> <li>The risk management system should cover at least:         <ul> <li>a. Risks associated with technical imaging service delivery</li> <li>b. Risks associated with delivery of clinical care</li> <li>c. Feedback to staff about risks identified, action taken and learning.</li> </ul> </li> </ul>
	<ul> <li>Examples of risks include:</li> <li>d. Staffing availability</li> <li>e. Patient misidentification</li> <li>f. Sufficient competences</li> <li>g. Equipment availability and uptime</li> <li>h. Business continuity</li> <li>i. Information governance</li> <li>j. Patient confidentiality</li> <li>k. Finance</li> <li>l. Health and safety.</li> </ul>
	Notes:
	<ol> <li>The risk assessment and management system should link with the wider organisation's risk management arrangements.</li> <li>Reviewers should recognise that each service must manage its risk in line with the wider organisation's risk policy. Compliance with this QS requires effective understanding and management of risk rather than a specific model or approach.</li> </ol>
	3. Response to clinical incidents, including unintended or excessive exposures, is covered in XR-514.
	4. The risk register may exist in one single document, or in location-specific registers.
	<ol><li>Reviewers will want to ask about the frequency of review and actions for risks that have remained on the register for some time.</li></ol>
	6. Reviewers should check that risks given a higher rating have been considered for inclusion on the wider organisation's risk register. The process for escalation should be clear.

### Service Organisation and Liaison with Other Services

Ref	Standard
XR-604	Service Improvement
	Quality statement
	The service regularly reviews the quality of the services provided.
	Outcome measure
	The service can demonstrate, through the records of the service level governance meetings, a sustainable improvement in care or patient outcomes through its approach to service improvement.
	Indicative inputs
	A service improvement plan should be in place for the service.
	• The service should be able to demonstrate a policy and process for regular review of the service improvement plan.
	<ul> <li>The service should be able to demonstrate how the QSs that measure patient experience, performance, delivery of KPIs and outcomes of audits have a link to the service improvement plan.</li> </ul>
	• The service should demonstrate how the patient partnership described in XR-109 has informed the development of the improvement plan.
	<ul> <li>The service should have systems for ongoing review and improvement of quality, safety and efficiency, including at least:         <ul> <li>a. Room utilisation</li> <li>b. Staff utilisation</li> </ul> </li> </ul>
	c. Review of clinical pathways with referring GPs and hospital clinicians
	d. New and emerging clinical practice and interventions.
	<ul> <li>The service improvement plan should be formally reviewed by the senior management team of the service at least annually.</li> </ul>
	The service should regularly audit compliance with this QS.
	Notes:
	1. Reviewers will want to ensure that there are clear links to at least XR-109, XR-702 and XR-707.
	2. For compliance with this QS, it is not sufficient to reference other QS, but the service should show how the data and information from those QS influence the service improvement plan.
	3. In the context of this QS, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	4. The service improvement plan may be contained in a document such as a service business plan but it should be able to be identified within that business plan.
	5. Within this QS, 'regular review' means that a review takes place at least annually.

### Service Organisation and Liaison with Other Services

Ref	Standard
XR-605	Service Development Plan
	Quality statement
	The service has a development plan or strategy that brings together the staffing, training, equipment and facilities plans for the next five years in support of the wider organisation's business plans.
	Outcome measure
	The service is able to demonstrate an improvement in service provision through an integrated service level forward plan with clear goals.
	Indicative inputs
	<ul> <li>The service should be able to demonstrate a service development plan that sets out its plans for the next five years and is consistent with the wider organisation's vision for the service.</li> </ul>
	<ul> <li>The service should be able to demonstrate how the five-year plan is aligned with the wider organisation's long-term delivery plan.</li> </ul>
	The service development plan should be aligned to the service improvement plan.
	• Where a service is part of a clinical imaging network, the service should demonstrate how this forward plan relates to this imaging network.
	Notes:
	1. This QS relates to the long-term plan for the service. XR-604 relates to the short- to medium-term improvement of the service.
	2. Reviewers should ask about the process for developing this plan.
	3. Reviewers should ask about the engagement of patients and their carers in the development of the plan.
	4. Reviewers should ask about the process for disseminating the plan to staff and stakeholders.
	5. Reviewers should ask about the relationship to the network.

## Governance\_

Ref	Standard
XR-701	Quality Management System
	Quality statement
	The imaging service has a quality management system (QMS) in place with a structured approach towards managing the quality assurance of the service.
	Outcome measure
	The service is able to demonstrate an annual review of the QMS in use, including a review against quality standards.
	Indicative inputs
	The service should demonstrate that there is a QMS in place.
	<ul> <li>There should be designated individuals to manage the QMS.</li> </ul>
	A quality manual should be in place to describe the service's QMS.
	A quality policy should define the service's quality objective and KPIs.
	• The QMS should define how risks, incidents, complaints, nonconformities and clinical records are managed.
	A document management system should be in place.
	<ul> <li>All policies, procedures, guidelines and formally issued instructions should comply with the wider organisation's document control policy; this should include but not be limited to:</li> </ul>
	a. Review dates and authorisation of use
	b. An agreed list of who can write, change, amend, approve and issue protocols, procedures and instructions.
	<ul> <li>Standardisation of protocols should be in place across the service. Protocols should have clear review dates and authorisation for use, and be part of a QMS. The service should have clear systems setting out who can make and authorise amendments to protocols.</li> </ul>
	<ul> <li>The service should show how it differentiates between governing the QMS and a collective service responsibility for quality promotion and ownership.</li> </ul>
	Improvements in the service should be linked to a review of the QMS.
	• The service should be able to demonstrate a process for feedback of the analysis from the QMS.
	• The service should be able to demonstrate the process used to analyse the QMS.
	• The service should show how people who work in the service are engaged in the review of quality.
	• Where services are provided between or across different providers, the governance system should make clear a common approach to partnership working through dual policies or a single agreed system. Reporting and accountability should be clarified.
	• The service should regularly audit compliance with this QS; this should include an annual self-assessment against the QSI
	Notes:
	1. Reviewers will want to ensure that the QMS is owned by the service and not seen as the responsibility of a small number of nominated individuals.
	2. Reviewers will want to check that protocols are only approved and issued by those who are on the authorised list.
	3. Reviewers should enquire about version control, distribution and communication to staff of updated documents.
	<ol> <li>Reviewers should enquire how arrangements are detailed in the operational policy (XR-601) when, for example, a third-party provider is contracted to provide additional activity for the service.</li> </ol>

# Governance

Ref	Standard
XR-702	Data Collection
	Quality statement
	The service collects data and monitors provision of the service.
	Outcome measure
	The service can demonstrate sustainable improvements in the service that have been driven by the data collected in compliance with this QS.
	Indicative inputs
	<ul> <li>The service should be able to demonstrate that data collection processes are in place, along with a system for monitoring and using those data.</li> </ul>
	A clear policy should be in place for data sharing for research and innovation purposes.
	<ul> <li>The service should have defined key data items for collection and analysis, including as a minimum the following monitoring of agreed imaging timescales (XR-602):</li> </ul>
	a. Recording of date of referral
	b. Time of image capture
	<ul> <li>c. Time of report dictation</li> <li>d. Time of report verification</li> </ul>
	e. Time of report issue.
	<ul> <li>Key data items should also be collected for the wider organisations and national delivery standards, such as (but not limited to):</li> </ul>
	f. Cancer two-week wait
	g. Referral to treatment times
	h. Pathway-specific performance measures.
	<ul> <li>The impact of and delays to access for third-party support services on waiting times and clinical uptime should be analysed.</li> </ul>
	The service should participate in regular benchmarking through information sharing and analysis.
	A regular forum or meeting where these data are discussed should be in place.
	Notes:
	1. Reviewers will want to enquire about the process for selecting other data items for monitoring.
	2. Reviewers will want to enquire about the frequency of monitoring.
	3. Reviewers will want to enquire about how actions are identified and monitored when the data identify issues.
	4. This QS links to XR-602 and XR-604.

# Governance

Ref	Standard
XR-703	Audit
	Quality statement
	A rolling programme of audit of compliance with guidelines, protocols and clinical best practice is in place.
	Outcome measure
	The service can demonstrate sustainable improvements in care and outcomes as a result of ongoing audit.
	Indicative inputs
	The rolling programme should ensure that action plans are developed following audits, and that implementation is monitored.
	<ul> <li>The service should have appointed designated lead(s) for audit (see XR-202).</li> </ul>
	Operational audits of local processes should also be included.
	<ul> <li>Action plans should be in place where non-compliance is identified. Action plans should have named individuals and timescales for remedial action.</li> </ul>
	• The service should hold regular audit programme events that all staff are encouraged to participate in.
	Notes:
	1. Audit tools and resources are available on the <u>RCR website</u> .
	2. Reviewers will want to ensure that the range and scope of audits reflect the range of services provided.
	3. Reviewers will want to ensure that both clinical audits and process audits are carried out.
	<ol> <li>Reviewers will want to enquire how audit topics are selected. Reviewers should expect to see a link between (at the very least) XR-109, XR-206, XR-402, XR-503, XR-506, XR-508, XR-509, XR-511, XR-515 and XR-602.</li> </ol>
	5. Reviewer will want to ensure that the sustainability of changes made following audit is evaluated.
	6. Reviewers will want to enquire about the multidisciplinary nature of audit programmes.
	<ol><li>Reviewers will want to test whether staff who cannot attend the audit presentations can access the results and learning from those meetings.</li></ol>

## Governance\_

Ref	Standard
XR-704	Radiology Events and Learning Meetings
	Quality statement
	Multidisciplinary radiology events and learning meetings are held.
	Outcome measure
	The service can demonstrate changes in clinical or operational practice as a result of analysis and feedback to individual clinicians and teams.
	Indicative inputs
	The service should demonstrate that meetings are held at least every two months.
	• All consultant radiologists should attend at least 50% of the meetings held (see note 7).
	<ul> <li>Reporting radiographers, reporting sonographers and consultant radiographers should attend at least 50% of the parts of these meetings that are relevant to their role, or a meeting of the equivalent learning.</li> </ul>
	Reporting staff should be encouraged to submit both discrepancies and good spots for discussion.
	<ul> <li>The service should be able to demonstrate attendance records for meetings and meeting frequency, including a schedule of future dates.</li> </ul>
	<ul> <li>The meetings should have a formal process of recording the outcome for each case, learning and action points, and confidential feedback.</li> </ul>
	• There should be a process in place for the management of discrepancies that have the potential to cause patient harm.
	An annual report on radiology events and learning meetings should be produced.
	<ul> <li>In addition, clinicians should participate in morbidity and mortality (M&amp;M) meetings relevant to the MDT or clinical pathway. Learning from M&amp;M meetings should be shared with colleagues within the service pathways.</li> </ul>
	Notes:
	1. Additional guidance on radiology events and learning meetings is given in the RCR <u>Standards for Radiology Events</u> and Learning Meetings (2020).
	2. Radiology discrepancy meetings should be part of the quality management system (XR-701).
	<ol><li>Reporting radiographers, reporting sonographers, consultant radiographers and trainees should participate in attending these meetings.</li></ol>
	4. Radiographers and student radiographers should be able to attend.
	5. Reviewers should also enquire about learning from M&M meetings and changes that have occurred.
	<ol> <li>Reviewers should enquire, in specialties where M&amp;M participation is more relevant (such as interventional radiology), whether all clinicians participate (see also IR-801).</li> </ol>
	7. Current guidance is that consultants should attend at least 50% of the meetings. The service should reflect the latest published guidance in its response to this QS.
	8. The 2021 Ombudsman report <u>Unlocking Solutions in Imaging: working together to learn from failings in the NHS</u> provides recommendations on learning from past events.

# Governance

Ref	Standard
XR-705	Monitoring of Key Performance Indicators (KPIs)
XR-705	<ul> <li>Monitoring of Key Performance Indicators (KPIs)</li> <li>Quality statement The service regularly reviews KPIs, including timescales for imaging and reporting. </li> <li>Outcome measure The service can demonstrate achievement and improvement against the KPIs agreed between the provider and the commissioners. Indicative inputs <ul> <li>The service should be able to demonstrate a range of KPIs relevant to the service.</li> <li>KPIs, including timescales for imaging and reporting (XR-508, XR-602, XR-702), should be reviewed regularly with the provider's management and with commissioners. </li> <li>The service should be able to demonstrate records of a review of KPIs and a log of agreed actions.</li> <li>The service should regularly audit compliance with this QS. </li> </ul> </li> </ul>
	<ol> <li>This QS cannot be met if timescales for imaging and reporting (XR-602) have not been agreed.</li> <li>Please note that this QS is wider than the KPIs in XR-602.</li> </ol>

# Governance

Ref	Standard
XR-706	Research
	Quality statement
	The service actively participates in research.
	Outcome measure
	A portfolio of research, including clinical trials if applicable, is held by the service. There is active participation in a range of clinical audits and research.
	Indicative inputs
	The service demonstrates a local strategy for research is in place.
	All services should carry out appropriate clinical audits.
	A culture of research is embedded in the service.
	• A list of trials in which the service has participated in the last three years, if appropriate.
	There should be a named research lead (Link to XR-202).
	<ul> <li>Where research has been carried out the service should demonstrate the potential impact on patient care and outcomes and/or service delivery.</li> </ul>
	Notes: 1. Reviewers will want to enquire about how the service embeds a culture of research, taking into consideration guidance from RCR and SoR:
	• The <u>RCR clinical radiology curriculum 2021</u> provides guidance on research, audit and quality improvement for trainees
	SoR research strategy
	2. Research activities extend beyond formal research and publication.
	<ol> <li>As a minimum services should be participating in clinical audits, for example the RCR clinical audit programme. Full information and current audits can be found on the <u>RCR website</u>.</li> </ol>
	4. <u>SoR Developing a Research Strategy</u> (June 2023)
	5. The service should be able to identify imaging examinations which are part of a research or clinical trial and show that they have ethics and local approval with appropriate MPE/CRE involvement.
	6. Research portfolios may be held at wider organisational level or by a part of the services not directly managed by imaging. In this case, the service should be able to demonstrate how it is involved in these research studies.
	7. The QSs that relate to clinical delivery of imaging, regulation and good practice also apply to research and clinical trials.
	8. Reviewers will want to enquire about how the service supports staff, trainees and students to initiate and participate in research.
	9. Research and clinical trials involving ionising radiation should comply with IR(ME)R regulation 12.
	10. Research in nuclear medicine will need ARSAC approval: <u>How and when to submit research applications to</u> <u>ARSAC - GOV.UK (www.gov.uk)</u>

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## Governance

Ref	Standard
XR-707	Review and Learning
	Quality statement
	The service can demonstrate changes made as a result of review and learning.
	Outcome measure
	The service has multidisciplinary arrangements for the review of, and the implementation of learning from:
	<ul> <li>a. Positive feedback, complaints, outcomes, incidents and 'near misses'</li> <li>b. Published scientific research and guidance relating to imaging services</li> </ul>
	c. Other service level governance measures.
	Indicative inputs
	<ul> <li>Planned review and learning meetings should be held regularly.</li> </ul>
	<ul> <li>A record of review and learning meetings should include minutes and attendance lists.</li> </ul>
	<ul> <li>The service should be able to demonstrate a clear process for review of these measures.</li> </ul>
	• There should be a link to the improvement processes in XR-604.
	Notes:
	<ol> <li>The review of feedback may take place at a different time and place from the review of scientific research and guidance. The process for obtaining this is not subject to review, but reviewers will want to ensure that, collectively, review and learning are used to improve care and outcomes.</li> </ol>
	<ol><li>These arrangements should include feedback to operational staff and should link with the wider organisation's governance arrangements.</li></ol>
	3. NHS guidance for developing and maintaining effective systems and processes for responding to patient safety incidents can be consulted for the purpose of learning and improving patient safety.
	4. This QS is about staff within the service learning together. Uni-disciplinary meetings or management meetings are not sufficient for compliance with this QS.

The CT Service is expected to meet, where applicable, all the XR-\*\*\* quality statements. In addition, specific quality statements for CT are set out below. Each of these QS is applicable where the service provides a clinical pathway relevant to all or part of the QS. Where the pathway is not provided, the QS is 'not applicable' rather than 'not met'.

Where the service provides additional pathways to those set out in the statements below, it is expected to follow the generic principles contained within these pathway statements.

Use of CT scanning as a part of molecular imaging (for example PET CT) is included in the nuclear medicine and molecular imaging quality statements.

Ref	Standard
CT-801	CT Specific Training
	Quality statement
	All staff using CT equipment are adequately trained.
	Outcome measure
	Systems of work are in place to ensure individuals are fully trained and competent for practice within CT.
	Indicative inputs
	All staff should have sufficient training to maintain competence in CT.
	• The service should be able to demonstrate how, collectively, the competence of all staff links to the needs of the service. This may take the form of a competence matrix (see also XR-204).
	• A training and development programme should ensure that all staff have, and are maintaining, these competences.
	<ul> <li>A programme of training for staff working in the CT unit, in whatever role, should be provided (see XR-204). Systems of work should be in place to avoid people who are not trained in CT undertaking any examinations for which they are not fully trained for example cardiac imaging or CT colonography.</li> </ul>
	Records of additional training should be available.
	Notes:
	1. See also XR-202.
	2. There should be evidence of adequate training to provide the service, including on-call requirements, see also XR-206.
	3. Reveiwers should enquire how the service supports post graduate training and careet development within this speciality.

Ref	Standard
CT-802	Contrast Media and Renal Function Protocol
	Quality statement
	The service has a process for managing the risk of renal impairment and the use of contrast media.
	Outcome measure
	The CT referral protocol identifies patients at increased risk from contrast. When necessary, renal function (creatinine or eGFR) is recorded. An audit demonstrates that appropriate actions are taken before investigations using contrast media.
	Indicative inputs
	• The referral protocol should clearly define the use of contrast media and the assessment of renal function.
	• The refearral protocol should clarify the processes for identifying and managing the risks of renal impairment.
	• There should be evidence of an audit of whether the referral protocol requirements are implemented.
	Notes:
	<ol> <li>In certain circumstances, the responsible clinician may agree to proceed with the examination before renal function is fully assessed. Reviewers will want to be assured that this is on a case-by-case basis and that the decision is fully recorded.</li> </ol>
	2. This QS links to XR-513.
	3. Guidance on Iodinated Contrast is available from RANZCR
	<ol> <li>The MHRA has published the following guidance Prescribing medicines in renal impairment: using the appropriate estimate of renal function to avoid the risk of adverse drug reactions (2019).</li> </ol>
	<ol><li>The RCR and SoR have published a joint statement on 'patients who are breast-feeding or pregnant who require a CT or MR with contrast.'</li></ol>

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Ref	Standard
CT-803	Trauma Management
	Quality statement
	The service is compliant with national and professional guidance for trauma management.
	Outcome measure
	The service has evidence that it has reviewed the guidelines and has assessed its ability to comply with the requirements identified, with an action plan for non-compliance.
	Indicative inputs
	• The service should have reviewed the guidelines and updated the local processes, as required.
	An action plan should be in place for addressing any gaps in compliance.
	The service should regularly audit compliance with this QS.
	Notes:
	1. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	2. NICE guidelines 'Major trauma: assessment and initial management.'
	3. Regular comparison of benchmarking data from similar organisations should be undertaken in determining effective response times.
	4. Where locally derived KPIs are in place there should be radiology service input. The value of the KPIs in themselves is not subject to review, other than to check that they ensure compliance with the national pathway standards and commissioner expectations.
	5. XR-601 should define the key elements of this pathway.
	6. RCR 'Major Adult Trauma Radiology Guidance' (2024).

Ref	Standard
CT-804	Clinical CT Pathways and Protocols
	Quality statement
	Pathway and condition-specific protocols specific to the CT service are in use.
	Outcome measure
	The service has reviewed national and professional guidelines and evidenced-based practice to inform its pathways and protocols. It has evidence that its protocols comply with the requirements for the pathways it provides. Audits show that these protocols and pathways are being followed and reviewed.
	Indicative inputs
	<ul> <li>The service should have reviewed clinical CT guidelines and pathway-specific protocols, and updated its local processes, as required.</li> </ul>
	Key pathways and clinical conditions include:
	a. CT colonoscopy
	b. Head injury
	<ul><li>c. CT coronary angiography</li><li>d. Stroke management</li></ul>
	e. Suspected aortic syndromes
	f. Cancer.
	NICE Guidelines should be regularly reviewed and included.
	• Key performance indicators (KPIs) for this QS should be locally agreed.
	<ul> <li>The service should regularly audit compliance with the protocols and have an action plan to address any areas of non-compliance.</li> </ul>
	<ul> <li>The service should have clear processes and protocols in place in line with IR(ME)R if justification and or reporting takes place remotely.</li> </ul>
	Notes:
	<ol> <li>Services not providing the pathways listed above (a–f) should evaluate and substitute their equivalent list of key pathways or conditions.</li> </ol>
	2. For services that do not image adult patients, CT-805 applies.
	3. Regular comparison of benchmarking data from similar organisations would be beneficial in determining effective response times.
	4. All guidelines should be based on legal and regulatory requirements, RCR and SoR guidance, and other national standards and guidance, along with evidence-based peer-reviewed sources. Each country in the United Kingdom has its own agreed legal framework and guidance.
	5. Guidelines and protocols may have different names; one protocol may cover several quality statements, and several protocols may cover one QS. The naming and organisation of guidelines and protocols is for local determination so long as, taken together, they cover the areas identified in this QS. Protocols should comply with the requirements of IR(ME)R regulations 6(4).
	6. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	7. Reviewers will want to be assured that staff working in the unit are familiar with the content of these documents.
	8. Reference should be made to XR-503, XR-504 and XR-511.

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Computerised Tomography (CT)

Ref	Standard
CT-805	Paediatric CT Protocols
	Quality statement
	Children and young people are imaged in line with national and professional guidance.
	Outcome measure
	Specific and evidence-based protocols are in place for CT scanning of children and young people. Audits show compliance with these protocols.
	Indicative inputs
	<ul> <li>National guidance should be used to inform local protocols.</li> </ul>
	<ul> <li>Image optimisation for the imaging of children and young people should be set out in the protocols.</li> </ul>
	The protocols in this QS should be consistent with those in XR-505.
	• The paediatric lead named in XR-202 should be involved in the approval of the protocols in this QS.
	Paediatric CT procedures should only be undertaken by designated, trained clinicians.
	Paediatric interventions should be undertaken in facilities designated for that purpose.
	Where possible, paediatric patients should be imaged on a designated list.
	Notes:
	1. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	2. Guidance will include, but is not restricted to:
	a. RCR paediatric trauma protocols
	b. 'The Radiological Investigation of Suspected Physical Abuse in Children' (2018), SoR
	c. 'Imaging Children: Immobilisation, Distraction Techniques and Use of Sedation' (2012), SoR.
	<ol><li>'The Image Gently Alliance is a coalition of healthcare organisations dedicated to providing safe, high-quality paediatric imaging worldwide. Their guidance is available to support services in paediatric imaging.</li></ol>
	4. These protocols are required under IR(ME)R 12(8)(a).
	5. Reviewers will want to ensure that dose optimisation for children is in line with 'DH Expert Working Party Response to the Committee on Medical Aspects of Radiation in the Environments 16th report 'Patient dose issues resulting from the use of CT in the UK'.
	6. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	7. Reference should be made to XR-503, XR-504 and XR-511.

The Interventional Radiology Service is expected to meet, where applicable, all the XR-\*\*\* quality statements and the CT, MR and ultrasound modalities.

In addition, specific quality statements for interventional Radiology are set out below. Interventional radiology relies on multidisciplinary team (MDT) working between the imaging service and a range of other specialties such as nursing and anaesthetics. The service should demonstrate how this MDT working can be achieved effectively. These quality statements relate to the provision of an overall IR service and not just the element of the service provided by staff working in the imaging service.

Each of these QS is applicable where the service provides a clinical pathway relevant to all or part of the QS. Where the pathway is not provided the QS is 'not applicable' rather than 'not met'.

Where the service provides additional pathways to those set out in the quality statements below, it is expected to follow the generic principles contained within these pathway quality statements.

Ref	Standard
IR-801	Interventional Radiology Safety Systems
	Quality statement
	Systems are in place to ensure high-quality and safe outcomes.
	Outcome measure
	Audits to show compliance with the range of IR standard operating procedures and systems of safe working practice by the service will demonstrate improvements in practice.
	Indicative inputs
	Protocols should be in use covering:
	a. Roles, responsibilities and scope of IR Staff
	b. Use of national and local safety standards for invasive procedures (NatSSIPs and LocSSIPs)
	c. Agreed World Health Organization (WHO) Surgical Safety Checklist for appropriate procedures
	d. Arrangements for accessing a second opinion for complex procedures
	e. Arrangements for clinical support in an emergency
	f. Use of sedation.
	<ul> <li>Interventional procedures should be undertaken by clinicians trained in that technique.</li> </ul>
	There should be arrangements to access additional specialist input (for example anaesthetic expertise).
	The service should participate in registry schemes, national benchmarking and comparative data and audits.
	<ul> <li>Clinicians undertaking interventional procedures should take part in regular morbidity and mortality reviews either within the imaging service or with colleagues from the relevant pathway (see also XR-704).</li> </ul>
	There should be a protocol for recognising multiple high dose procedures on the same patient.
	There should be a protocol for high patient dose follow up.
	• A process should be in place for the regular review of national safety guidance and the updating of protocols accordingly.
	The service should audit regularly against the use of these protocols.

Ref	Standard
IR-801	<ul> <li>Notes:</li> <li>1. Meeting this QS may be achieved with one or several protocols. Reviewers should ensure that, when more than one protocol is in place, it is clear where the information is to be found, and that when the protocols are read together they provide a comprehensive response.</li> </ul>
	<ol> <li>This QS overlaps with XR-510. Information on accessing second opinions and referral for more specialist advice or procedures may be covered in XR-509 or XR-510 or both.</li> </ol>
	3. The service director is responsible for agreeing which clinicians are able to provide each clinical intervention. Reviewers should see that this list is understood by those within the service.
	<ol> <li>Documented evidence of training for all staff should be available for review, for radiologists specialist IR training certificate.</li> </ol>
	5. A high patient dose system similar to that described by the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) will be a useful reference for services and reviewers.

Ref	Standard
IR-802	Access to Interventional Radiology Procedures
	Quality statement Patients have timely 24-hour access, seven days a week, to consultant-directed IR procedures.
	Outcome measure A rota is available for all the procedures offered by the service, including those provided 24/7.
	<ul> <li>Indicative inputs</li> <li>The standard operating procedure should list which procedures are available in hours and which are available out of hours.</li> </ul>
	<ul> <li>There should be a system in place to provide a 24/7 IR service; this may be through a Service Level Agreement with another organisation in the region.</li> </ul>
	<ul> <li>If some procedures cannot be provided (either in or out of hours), an agreed pathway of referral should be in place and communicated to those who refer to the service.</li> </ul>
	Notes:
	<ol> <li>When there are staff on this rota who are not part of the imaging establishment, reviewers will want to be assured that there are robust communication and planning arrangements in place (see also XR-203 and XR-514).</li> </ol>
	2. See XR-501 for the referral management protocol.
	3. The QS links to XR-203, XR-204 and XR-206, but not all the staff providing this pathway of care will be part of the imaging service establishment.
	<ol><li>Reviewers will want to ensure that there is an agreement in place with the receiving organisations in which they agree their role in the pathway.</li></ol>
	5. The aim of this QS is to provide certainty on the referral pathway, rather than to comment on the type of agreement or contract in place.

Ref	Standard
IR-803	Admissions
	Quality statement
	There is an effective admissions process in place.
	Outcome measure
	Effective management of patients who require admission before or after their procedure is demonstrated through an audit of the pathway.
	Indicative inputs
	<ul> <li>When a patient requires admission (either as a day case or as an inpatient), the responsible clinician at each stage of the pathway or procedure should be clearly identified. Handover of responsibility should be clear.</li> </ul>
	• Pre-admission and discharge procedures should be identified and agreed in the pathway.
	A procedure should be in place for patients who require urgent admission.
	• A protocol for the transfer of care between teams should be in place.
	<ul> <li>Agreement should be in place with the ward for the timely assessment and preparation of the patient prior to their procedure. This should be evidenced through an audit of delays.</li> </ul>
	Out-of-hours' emergency transfer for patients between services (either within one provider or between multiple providers) should have been agreed, including clinical criteria and other circumstances.
	Notes:
	1. The process of care as an inpatient is not subject to review.
	2. Reviewers will want to be assured that agreements are understood by all parties.

Ref	Standard
IR-804	Facilities
	Quality statement
	The clinical facilities are appropriate for the service provided.
	Outcome measure
	The service is provided in an environment that meets national and professional standards.
	Indicative inputs
	<ul> <li>The service should meet the current guidance on the provision of IR facilities for the range of procedures being performed.</li> </ul>
	There is a protocol for access to stock for IR procedures.
	• When required by the clinical procedures, IR rooms should be constructed to theatre standard (in relating to air exchange, handwashing, hygiene, flooring and so on).
	Notes:
	1. This QS relates to XR-107 and XR-401.
	2. The latest health building notes should guide the provision of facilities.
	3. Current guidance for facilities is the <u>Department of Health: Health Building Notes HB6</u> ; <u>Health Facilities Scotland (HBN) 6</u> .
	4. Not all rooms undertaking interventional procedures will require a theatre standard environment.
	<ol><li>Reviewers should note that theatre standards may need to recognise the constraints of having ceiling mounted equipment.</li></ol>
	<ol><li>All equipment should be appropriately optimised for the imaging investigation being undertaken. Reviewers should explore how this is achieved, with special emphasis on paediatric optimisation (see also XR-505).</li></ol>

Ref	Standard
IR-805	Contrast Media and Renal Function Protocol
	Quality statement
	The service has a process for managing the risk of renal impairment and the use of contrast media.
	Outcome measure
	The IR referral protocol identifies patients at increased risk from contrast media. When necessary, renal function (creatinine or eGFR) is recorded. An audit demonstrates that appropriate actions are taken before investigations using contrast media.
	Indicative inputs
	• The referral protocol should clearly define the use of contrast media and the assessment of renal function.
	• The referral protocol should clarify the processes for identifying and managing the risks of renal impairment.
	• There should be evidence of auditing whether the referral protocol requirements are implemented.
	Notes:
	<ol> <li>In certain circumstances, the responsible clinician may agree to proceed with the examination before renal function is fully assessed. Reviewers will want to be assured that this is on a case-by-case basis and that the decision is fully recorded.</li> </ol>
	2. This QS links to XR-513.
	3. Guidance on Iodinated Contrast is available from RANZCR.
	<ol> <li>The MHRA has published the following guidance <u>Prescribing medicines in renal impairment: using the appropriate</u> <u>estimate of renal function to avoid the risk of adverse drug reactions (2019)</u>.</li> </ol>

Ref	Standard
IR-806	Clinical IR Pathways and Protocols
	Quality statement
	Pathway and condition-specific protocols specific to the IR service are in use.
	Outcome measure
	The service has reviewed national and professional guidelines and evidenced-based practice to inform its pathways and protocols. It has evidence that its protocols comply with the requirements for the pathways it provides. Auditing shows that these protocols and pathways are being followed and reviewed.
	Indicative inputs
	• The service should be able to demonstrate that it has reviewed clinical IR guidelines and pathway-specific protocols, and updated local processes as required. Protocols should comply with the requirements of IR(ME)R regulation 6(4).
	An action plan should be in place for addressing any gaps in compliance.
	Key performance indicators (KPIs) for this QS should be locally agreed.
	<ul> <li>The service should regularly audit compliance with this QS to demonstrate that guidelines have been reviewed before their scheduled review date (see XR-701).</li> </ul>
	The service should regularly audit compliance with the protocols.
	Notes:
	1. For services that do not image adult patients, IR-507 applies.
	<ol><li>All guidelines should be based on legal and regulatory requirements, RCR, SoR and other national standards and guidance, along with evidence-based peer-reviewed sources. Each country in the United Kingdom has its own agreed legal framework and guidance.</li></ol>
	3. Regular comparison of benchmarking data from similar organisation would be beneficial in determining effective response times.
	4. Guidelines and protocols may have different names; one protocol may cover several QS and several protocols may cover one QS. The naming and organisation of guidelines and protocols is for local determination so long as, taken together, they cover the areas identified in this QS.
	5. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	6. Reviewers will want to be assured that staff working in the unit are familiar with the content of these documents.
	7. Reference should be made to XR-503, XR-504 and XR-511.

Ref	Standard
IR-807	Paediatric IR Procedures
	Quality statement
	Children and young people are imaged in line with national and professional guidance.
	Outcome measure
	Specific and evidence-based protocols are in place for IR procedures of children and young people. Audits show compliance with these protocols.
	Indicative inputs
	• Paediatric IR procedures should only be undertaken by designated clinicians trained in paediatric IR.
	Paediatric IR should be undertaken in facilities designated for that purpose.
	• Where clinical networks are in place to provide the required range of expertise, these will be clearly documented.
	Notes:
	1. Network relationships may vary depending on the imaging procedures. Not all pathways will be to the same provider.
	<ol> <li>Reviewers should expect to see specific paediatric optimisation, for example specific acquisition protocols (see also XR-505).</li> </ol>
	3. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	4. Reference should be made to XR-503, XR-504 and XR-511.

The MR service is expected to meet, where applicable, all the XR-\*\*\* quality standard. In addition, specific quality statements for MR are set out below. In the context of these quality statements, the use of the term 'MR unit' refers to a specific MR scanner as a unique piece of equipment.

Each of these QS is applicable where the service provides a clinical pathway relevant to all or part of the QS. Where the pathway is not provided, the QS is 'not applicable' rather than 'not met'.

Where the service provides additional pathways to those set out in the quality statements below, it is expected to follow the generic principles contained within these pathway quality statements.

Use of MR as a part of molecular imaging (for example PET MR) is included in the nuclear medicine and molecular imaging quality statements.

Ref	Standard
MR-801	Staffing
	Quality statement Named individuals are responsible for the key areas of service provision.
	Outcome measure The service has a named MR responsible person, MR safety expert and MR authorised person(s) and named MR operators.
	Indicative inputs <ul> <li>There should be an organisational chart.</li> </ul>
	Roles, responsibilities and scopes should be set out.
	• The staff named above should have appropriate education and training relevant to their role (see note 3).
	Categories of staff who can access an MR controlled access area and MR environment should be clearly defined.
	• Procedures for removing dedicated access to controlled areas should be in place when staff leave the service.
	Notes:
	1. See also XR-202. This QS reflects the additional requirements of an MR unit.
	<ol><li>Reviewers will want to ensure that those working in the MR service are aware of the name of each lead and the person's role.</li></ol>
	3. The responsible person is typically the lead MR Radiographer and the MRSE is typically an MR physicist. Details regarding roles, responsibilities and competencies are outlined in the following publications: MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use; SoR and BAMRR Safety in Magnetic Resonance Imaging; SoR Position statement Education and Training for Diagnostic Radiographers working in MRI; IPEM MRSE Certificate of Competence.
	4. The content of the role description is not subject to review other than to assure reviewers that the individual has clear responsibilities and that collectively the descriptions cover the full remit of the service.
	5. SoR has published information on the 'role of the radiographer in MRI'.
	<ol><li>Organisational charts should detail all those in roles that ensure effective delivery of the service, including support staff such as radiology department assistants.</li></ol>
	7. Certification for the MRSE is not currently a requirement but is now available by IPEM for radiographers and radiologists 'MRSE Certificate of Competence'.
	8. MRSE does not need to be an employee of the organisation and can be on a consultancy basis.

Ref	Standard
MR-802	MR Specific Training
	Quality statement
	All staff using MR equipment are adequately trained.
	Outcome measure
	Systems of work are in place to ensure individuals are fully trained and competent for practice within MR.
	Indicative inputs
	<ul> <li>The service should be able to demonstrate that there is a competence framework in place for all staff using MR equipment (see XR-204).</li> </ul>
	<ul> <li>All staff should have sufficient training to maintain competence in MR safety awareness where MR services are provided with the imaging service.</li> </ul>
	<ul> <li>The service should be able to demonstrate how, collectively, the competence of all staff links to the needs of the service. This may take the form of a competence matrix (see also XR-204).</li> </ul>
	• A training and development programme should ensure that all staff have, and are maintaining, these competences.
	<ul> <li>A programme of training for staff working in the MR unit, in whatever role, should be provided (see XR-204).</li> <li>Systems of work should be in place to avoid people who are not trained in MR or MR safety being allowed within MR controlled access areas.</li> </ul>
	Records of additional training should be available.
	Notes:
	<ol> <li>Reviewers should ensure that the requirement of XR-204 relating to MR safety awareness for all staff accessing the MR area is met when assessing compliance with this QS.</li> </ol>
	2. MR specific training can be organisational dependent and can include formal, in house or online training. The College of Radiographers recognise that there are many opportunities and programmes available to achieve the competence required for any role. A list of CoR approved programmes and CPD endorsed courses is available on the CoR website.
	3. Skills for Health, MRI competency <u>Competence Details – Skills for Health Tools</u> : MHRA <u>Magnetic resonance imaging</u> equipment in clinical use: safety guidelines - GOV.UK.
	4. The service should be able to evidence post graduate training and career development within this speciality.

Ref	Standard
MR-803	MR Governance
	Quality statement The MR service has established a governance process to ensure safe working practices.
	Outcome measure Policies and procedures have been developed and agreed, and are maintained and applied to all examinations and procedures using MR to ensure the safety of people (staff and patients) in the MR unit.
	<ul> <li>Indicative inputs</li> <li>The service should have policies and procedures in place based on current national guidance.</li> </ul>
	Justification requirements for referrals for MR should be clearly set out.
	<ul> <li>Procedures for the use of MR scanning in volunteers should be clearly set out and include, for example, informed consent and management of incidental findings.</li> </ul>
	<ul> <li>An annual MR safety audit should be undertaken, and the results of the audit formally considered by the MR safety committee or other appropriate governance meeting.</li> </ul>
	<ul> <li>Relevant staff should be aware of the protocols and how to access them, and any changes should be communicated to them.</li> </ul>
	<ul> <li>The procedures identified in MR-804 and MR-805 should be agreed by the service lead, MRRP and MRSE. A process for annual review should be clearly set out.</li> </ul>
	Notes:
	1. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	2. The following guidelines have been published:
	MHRA <u>Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use</u> (2021)
	SoR <u>Safety in Magnetic Resonance Imaging</u> (2019).
	3. Reviewers will want to be assured that staff working in the unit are familiar with the content of these documents.
	<ol> <li>Annual MR safety audit should include but not be limited to incidents, (including burns and contrast reactions), near misses, non-compatible equipment, recall and training.</li> </ol>

Ref	Standard
MR-804	Quality Assurance
	Quality statement
	A quality assurance (QA) process is in place specifically for the MR service.
	Outcome measure
	Quality control tests are performed on image quality, safety and environmental conditions. The results of the tests are reported and acted upon.
	Indicative inputs
	Image quality assurance tests should be undertaken according to an agreed schedule.
	• Oxygen monitoring, helium levels and humidity should be checked according to a predetermined schedule.
	Parameters for tolerances should be agreed before checks are undertaken.
	• A process for feeding back results should be in place. The outcome of decisions on these tests should be recorded.
	There should be documented mechanisms of escalation if parameters are out of tolerance.
	• Minutes of the meetings where these QA results are considered should be available.
	• Where specialist imaging is undertaken, any standards or constraints appropriate to that pathway should be met in addition to any other QA test.
	Notes:
	1. Professional reports and guidance should be used to support the QA processes in place.
	2. Reference should also be made to XR-303.
	<ol><li>Reviewers should be aware that these tests may be undertaken remotely by manufacturers but would expect to see evidence/documentation of tests and escalation process for any tests outside of tolerance.</li></ol>

Ref	Standard
MR-805	Environment and Equipment
	Quality statement
	Suitable arrangements are in place to ensure that the MR unit is safe for patients and staff.
	Outcome measure
	The service is provided in an environment that meets national and professional standards through clearly identified processes and procedures.
	Indicative inputs
	<ul> <li>Local rules should govern the safe operation of the service.</li> </ul>
	<ul> <li>Risk assessments of electromagnetic fields and the impact of the hazards in the MR unit should be undertaken please see <u>CEMFAW regulations</u>.</li> </ul>
	The MR controlled access area of each MR unit should be clearly identified, and access secured.
	• When services are required to utilise relevant MR conditional equipment within the MR environment, the projectile zone should be identified (see notes 6 and 7).
	<ul> <li>Equipment in use in the MR service should be labelled (and staff should have a clear understanding of the difference between the labels) with one of the following:</li> </ul>
	a. MR safe
	b. MR conditional
	c. MR unsafe d. See Note 2.
	Adequate, clearly visible signage should be in place at the entrances to the MR controlled access area and the MR environment.
	<ul> <li>A list of equipment marked MR conditional should be held in the control room that identifies the constraints that led to the conditional labelling.</li> </ul>
	• There should be a clear process for the identification of MR conditional devices and of how these conditions are met.
	<ul> <li>When MR equipment produces noise which might cause damage, appropriate hearing protection should be supplied for patients, staff and other people in the noisy environment. Special care should be taken with neonates, paediatric patients, those who are unconscious and those who have special sensitivity to noise. Note that this QS is linked to XR-506.</li> </ul>
	<ul> <li>Temperature, oxygen levels and humidity should be regularly monitored.</li> </ul>
	• Systems must be in place to ensure that checks are made before entry to MR rooms for ferromagnetic objects and any active or passive implanted devices such as pacemakers (see also MR-806).
	<ul> <li>Processes should be in place to deal with incidents in which unanticipated ferromagnetic foreign bodies are detected during the examination or procedure.</li> </ul>
	<ul> <li>A procedure for MR Quench should be in place. Staff should be familiar with the contents and their responsibilities within the procedure.</li> </ul>
	Notes:
	<ol> <li>Reviewers will want to be assured that MR authorised staff are fully conversant with the requirements of this QS.</li> <li>MR Unlabelled: The latest update to the MHRA Guidance now includes the term MR Unlabelled. The term 'MR Unlabelled' was added to guidance in Feb 2021 but note it is not a recognised term by the ASTM or internationally.</li> </ol>
	<ol> <li>International standard IEC60601-2-33 provides the latest updates on defining controlled areas in relation to magnet strength.</li> </ol>
	<ol> <li>The Control of Electromagnetic Fields at Work Regulations 2016 are monitored by the Health and Safety Executive.</li> <li>The projectile zone for each MR unit may be shown by a map in the local rules.</li> </ol>
	<ol> <li>The projectile zone for each MR unit may be shown by a map in the local rules.</li> <li>Relevant MR conditional equipment is any equipment that needs to enter the MR environment with a condition linked to static field strength. For example: dedicated MR anaesthetic machines and dedicated MR infusion pumps.</li> </ol>
	<ul> <li>7. The MHRA has published the following guidance <u>Safety guidelines for Magnetic Resonance Imaging equipment in</u> <u>clinical use, 2021</u>.</li> </ul>

Ref	Standard
MR-806	Safety Screening
	Quality statement
	Appropriate safety screening of patients, visitors and staff takes place.
	Outcome measure
	A protocol is in place and is audited to ensure that safety screening prior to examination and/or visit is completed thoroughly and effectively.
	Indicative inputs
	<ul> <li>Safety screening should be applied to the patient, staff conducting the examination, and carers or others who may enter the MR department.</li> </ul>
	Specific safety screening processes must be applied to unconscious or uncommunicative patients.
	• Safety screening of MR staff should take place annually or earlier if there is a relevant change.
	• Safety screening of patients should begin at referral, or at the earliest stage possible.
	<ul> <li>The referral form for MR should clarify the responsibility of the referrer in safety screening, especially with regard to implanted devices.</li> </ul>
	<ul> <li>Referrers to MR should identify other safety critical issues for the patient (such as claustrophobia or heightened sensitivity to noise) which may have an impact on their ability to undergo examination safely.</li> </ul>
	A feedback process for education and learning should be available for referrers.
	<ul> <li>There must be a system of work in place for the management of implanted devices, including the process for obtaining information on the implanted device and the identification of MR conditional devices (see MR-805). This includes communication with other healthcare professionals.</li> </ul>
	• A system or process for onward referrals of patients who cannot be managed locally by the service should be in place.
	<ul> <li>The service should have a protocol in place for dealing with cases of implants/devices where there is no assurance of MR safety from the manufacturers.</li> </ul>
	A safety screening questionnaire/checklist should be in regular use.
	<ul> <li>There should be evidence that staff and patients are aware of the process.</li> </ul>
	• The process should be regularly audited, with evidence of actions taken in response to audit findings being produced.
	<ul> <li>Incident reporting and management analysis should be in place.</li> </ul>
	Notes:
	1. Reviewers will want to enquire about the practical application of the protocol.
	<ol><li>Reviewers should enquire how the feedback to the referrer from the safety screening process happens and whether it has led to improvements.</li></ol>
	<ol><li>Reviewers should enquire about how the MR referrer's duty to supply relevant safety considerations (for example implants) is managed.</li></ol>
	4. Reference should be made to XR-501.
	5. Reviewers should enquire that both staff and patients are aware of the screening questionnaire/checklist and its purpose.
	6. Reviewers will want to see that space for private conversations when screening patients is available.

Ref	Standard
MR-807	Contrast Media and Renal Function Protocol
	Quality statement
	The service has a process for managing the risk of renal impairment and the use of contrast media.
	Outcome measure
	The MR referral protocol identifies patients at increased risk from contrast media. When necessary, renal function (creatinine or eGFR) is recorded. Audits demonstrate that appropriate actions are taken before investigations using contrast media.
	Indicative inputs
	• The referral protocol should clearly define the use of contrast media and the assessment of renal function.
	• The referral protocol should clarify the processes for identifying and managing the risks of renal impairment.
	There should be evidence of an audit of whether the referral protocol requirements are implemented.
	• The service should consider adapted protocols to minimise the use of Gadolinium contrast agents, with regard to evidence of Gadolinium deposition in the body.
	Notes:
	1. The QS relates to the specific contrast media used in MR. Reviewers should also ensure that the service meets XR-513.
	<ol><li>Frequency of audit is not stated but audits should be sufficiently frequent to provide assurance for the service and no more than a year apart.</li></ol>
	3. In certain circumstances, the responsible clinician may agree to proceed with the examination before renal function is fully assessed. Reviewers will want to be assured that this is on a case-by-case basis and that the decision is fully recorded. The MHRA has published the following guidance <u>Prescribing medicines in renal impairment: using the appropriate estimate of renal function to avoid the risk of adverse drug reactions (2019)</u> .
	4. A joint RCR and SoR statement provides guidance for patients who are breastfeeding who require a CT or MRI with contrast.
	5. The RCR has published the following guidance on <u>Gadolinium-based contrast agent administration to adult</u> <u>patients, 2019</u> .

Ref	Standard
MR-808	Clinical MR Pathways and Protocols
	Quality statement Pathway and condition-specific protocols specific to the MR service are in use.
	Outcome measure The service has reviewed national and professional guidelines and evidenced-based practice to inform its pathways and protocols. It has evidence that its protocols comply with the requirements for the pathways it provides. Audits show that these protocols and pathways are being followed and reviewed.
	<ul> <li>Indicative inputs</li> <li>The service should be able to demonstrate that it has reviewed clinical MR imaging guidelines and pathway-specific protocols, and updated local processes as required.</li> </ul>
	• Key performance indicators (KPIs) for this QS should be locally agreed.
	• The service should regularly audit compliance with this QS to demonstrate that guidelines have been reviewed before their scheduled review date (see XR-701).
	• The service should regularly audit compliance with the protocols and have an action plan to address any areas of non-compliance.
	Notes:
	1. For services that do not image adult patients, MR-809 applies.
	<ol><li>All guidelines should be based on legal/regulatory requirements for RCR, SoR and other national standards and guidance, along with evidence-based peer-reviewed sources. Each country in the United Kingdom has its own agreed legal framework and guidance.</li></ol>
	3. Regular comparison of benchmarking data from similar organisations would be beneficial in determining effective response times.
	4. Guidelines and protocols may have different names; one protocol may cover several quality statements and several protocols may cover one QS. The naming and organisation of guidelines and protocols is for local determination so long as, taken together, they cover the areas identified in this QS.
	5. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	6. Reviewers will want to be assured that staff working in the unit are familiar with the content of these documents.
	7. Reference should be made to XR-503, XR-504 and XR-511.

Ref	Standard
MR-809	Paediatric MR Protocols
	Quality statement
	Children and young people are imaged in line with national and professional guidance.
	Outcome measure
	Specific and evidence-based protocols are in place for MR scanning of children and young people. Audits show compliance with these protocols.
	Indicative inputs
	<ul> <li>Professional guidance should be used to inform local protocols.</li> </ul>
	The protocols in this QS should be consistent with the protocols in XR-505.
	• The paediatric lead named in XR-202 should be involved in the approval of the protocols in this QS.
	Paediatric MR procedures should only be undertaken by designated, trained clinicians.
	Paediatric interventions should be undertaken in facilities designated for that purpose.
	Where possible, paediatric patients should be imaged on a designated list.
	<ul> <li>A named consultant anaesthetic lead who is responsible for ensuring that the requirements for anaesthesia in MR are met should be identified.</li> </ul>
	<ul> <li>Paediatric MR may require the transfer of the patient to another facility or provider unit. Arrangements and responsibilities should be agreed in advance between providers. Where possible, the service should have consistent network arrangements.</li> </ul>
	Notes:
	1. Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS.
	2. Reviewers will want to be assured that staff working in the unit are familiar with the content of these documents.
	3. Network relationships may vary depending on the imaging procedures. Not all pathways will be to the same provider.
	4. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	5. Reference should also be made to XR-503, XR-504 and XR-511.

#### Nuclear Medicine and Molecular Imaging (NM)

This section also incorporates hybrid molecular imaging modalities such as SPECT/CT, PET/CT and PET/MR.

Where CT and MR are used in combination with nuclear medicine and molecular imaging, the CT and MR elements of that approach will be covered by the CT and MR quality statements, to avoid duplication. The use of hybrid technology will require determination of which quality statements are applicable to the service.

Non-imaging aspects of nuclear medicine are not within the scope of these quality statements.

Ref	Standard
NM-801	Service Delivery
	Quality statement
	The service defines its operating arrangements and procedures.
	Outcome measure
	A policy that describes the way the service operates is in routine use.
	Indicative inputs
	• The service should have an organogram that sets out its governance and working relationships within the provider organisation for:
	a. Imaging services
	b. Pharmacy/Radiopharmacy
	c. Clinical scientific services.
	An operational policy should define the governance arrangements.
	<ul> <li>There should be arrangements for relationships with other nuclear medicine and molecular imaging services when a network or mutual support arrangement is in place.</li> </ul>
	Response times should be agreed and reporting processes clearly defined.
	Out-of-hours' and urgent referrals processes should be agreed and documented.
	Notes: 1. Where the service sits outside the clinical imaging governance, reviewers will want to be assured that the service adequately meets the requirements of XR-601 for compliance with this QS.

# Nuclear Medicine and Molecular Imaging (NM)

Ref	Standard
NM-802	Facilities
NM-802	Facilities         Quality statement         Facilities for the use of radiopharmaceuticals for the patient groups being imaged are compliant with current guidance.         Outcome measure         The service has assessed compliance against national and professional standards and guidance on design of facilities.         Indicative inputs         • The service should meet the current guidance on the provision of nuclear medicine and molecular imaging facilities.         • If services are provided in non-compliant facilities, risk management should be agreed by the service leadership and include an action plan with timescales, and named responsible individuals should be produced.         • A regular audit of compliance should be carried out by th e service lead, the MPE, RPA and RWA.         • A dedicated area to prepare and draw up radiopharmaceuticals should be available (see note 2).         • Compliance with radiopharmacy standards should be ensured by regular QA and mandatory inspections by the MHRA.         Notes:         1. This QS relates to XR-107. Reviewers will want to ensure that the view of the patient has also influenced the design elements that relate to the patient experience and patient journey, in line with XR-109.
	2. Current guidance for facilities includes <u>Department of Health: Health Building Notes HB6</u> or <u>Health Facilities Scotland</u> ( <u>HBN) 6</u> . Services should ensure they are referring to the latest guidance.
	3. Reviewers should see that the UK Radiopharmacy Group reference for drawing up of doses has been considered.

# Nuclear Medicine and Molecular Imaging (NM)

Ref	Standard
NM-803	Use of Radiopharmaceuticals and Radioactive Materials
	Quality statement National standards for the use of radiopharmaceuticals and radioactive materials are followed within the service.
	Outcome measure The service can provide evidence of compliance with national regulations on the use of radioactive materials and radiopharmaceuticals.
	<ul> <li>Indicative inputs</li> <li>Suitably experienced and certificated regulatory experts should be appointed in writing (MPE, RPA, RWA).</li> </ul>
	<ul> <li>A report assessing regulatory compliance should be provided at least annually.</li> </ul>
	<ul> <li>The report should be considered by the service radiation safety meeting/governance meeting, and action plans to achieve compliance agreed where required.</li> </ul>
	<ul> <li>Reporting may include but not be limited to:         <ul> <li>Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017</li> <li>Employer's IR(ME)R procedures</li> <li>ARSAC licensing (employer and practitioner)</li> <li>Staff competency training and entitlement</li> <li>Equipment</li> <li>Diagnostic exposure optimisation and reference levels</li> <li>Accidental/unintended exposures</li> <li>Clinical and IR(ME)R audits</li> </ul> </li> </ul>
	<ul> <li>b. Ionising Radiation Regulations (IRR)</li> <li>HSE authorisation</li> <li>Radiation protection management</li> <li>Radiation protection training</li> <li>Risk assessments</li> <li>Area designation</li> <li>Local rules</li> <li>Dose records</li> <li>Contamination monitoring</li> <li>Radioactive source management</li> </ul>
	<ul> <li>c. Environmental Permitting Regulations</li> <li>Environmental permits</li> <li>Best available techniques</li> <li>Radioactive waste management</li> <li>Delivery and receipt of radioactive materials</li> <li>Security of radioactive sources</li> <li>d. Carriage of Dangerous Goods Regulations</li> </ul>
	<ul> <li>Carriage of Dangerous Goods Regulations</li> <li>Receipt of consignments</li> <li>Consignment (for example waste for incineration off-site)</li> <li>Quality control and regular maintenance of packaging</li> <li>Return of packaging.</li> </ul>

### Nuclear Medicine and Molecular Imaging (NM)

Ref	Standard
NM-803	Notes: 1. Appropriate national regulations for each country should be followed. These include, without limitation: the <u>lonising</u>
	Radiation (Medical Exposure) Regulations 2017 (IR(ME)R), Ionising Radiation (Medical Exposure) Regulations 2018 (NI), the Ionising Radiation Regulations 2017 (IRR), the Environmental Permitting (England and Wales) Regulations 2016 (EPR), the Environmental Authorisations (Scotland) Regulations 2018 (EASR), the Radioactive Substances (Modification of Enactments) Regulations (Northern Ireland) 2018, and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.
	<ol><li>This QS relates to XR-514 and where the nuclear medicine department is not a stand-alone service there will be some overlap.</li></ol>
	3. The report to demonstrate compliance is not specified and may be the report of another agency in so far as it meets the requirements of the outcome measure.

### Nuclear Medicine and Molecular Imaging (NM)

Ref	Standard
NM-804	Receipt, Storage and Transport of Radioactive Materials
	Quality statement
	Radioactive materials are transported and delivered safely.
	Outcome measure
	Procedures are in place for the receipt and storage of radiopharmaceuticals, and for their safe transport where applicable.
	Indicative inputs
	A standard operating procedure for radiopharmaceuticals should set out:
	a. How they are ordered
	b. Arrangements for their transport
	<ul> <li>c. Procedures for their receipt (including a dedicated receiving point and authorised personnel to accept receipt and return)</li> </ul>
	d. Procedures for their storage
	e. Out-of-hours' arrangements
	f. Procedures for their consignment (for example waste for off-site incineration).
	The service should regularly audit compliance with this QS.
	Notes:
	<ol> <li>This QS is to cover arrangements for an imaging facility that is supplied with radiopharmaceuticals by an off-site radiopharmacy, not for a complete transport operation.</li> </ol>
	2. When a service takes responsibility for the transport of radiopharmaceuticals (across site, between sites or to another site), procedures for safe transport will apply. Aspects of transport by a third-party provider (other than reporting when these are outside the legislative framework) are outside the scope of these QS.
	3. Reviewers will want to understand how the arrangements for receipt are understood by those delivering the radiopharmaceuticals.
	4. The <u>Carriage of Dangerous Goods Regulations 2009</u> also apply here. Reviewers will want to see that an appropriate assessment has been undertaken.
	5. This QS relates to NM-803.

# Nuclear Medicine and Molecular Imaging (NM)

Ref	Standard
NM-805	Clinical Nuclear Medicine and Molecular Imaging Pathways and Protocols
	Quality statement
	Pathway and condition-specific protocols specific to nuclear medicine and molecular imaging are in use.
	Outcome measure
	The service has reviewed national and professional guidelines and evidenced-based practice to inform its pathways and protocols. It has evidence that its protocols comply with the requirements for the pathways it provides. Audits show that these protocols and pathways are being followed and reviewed.
	Indicative inputs
	• When developing clinical protocols, the service should refer to clinical guidelines issued by the relevant professional body. Protocols should comply with IRMER regulation 6(4).
	Guidelines should include the use of medicines and adjuncts.
	• The service should regularly audit against these protocols, and the audits should be cross-referenced to any incidents or non-compliance reported.
	An action plan should be in place for addressing any gaps in compliance.
	Key performance indicators (KPIs) for this QS should be locally agreed.
	Notes:
	<ol> <li>Reviewers will want to be assured that the pathway- and condition-specific guidelines are relevant to the service(s) being provided. They should be sufficient to cover at least all the areas commonly provided by the service.</li> </ol>
	<ol><li>Reviewers should expect to see that relevant guidance has been considered in the context of local delivery and adapted for use within the service. This QS cannot be met by generic reference to national guidelines without local consideration</li></ol>
	3. Regular comparison of benchmarking data from similar organisations would be beneficial in determining effective response times.
	4. An audit of compliance may be part of a wider MDT audit rather than a service-specific audit. When this occurs, reviewers will want to ensure that the service has considered the imaging elements of the audit results. Reviewers will want to ensure that MDT attendance and feedback is used for improvements in the service.
	5. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	6. See also XR-503, XR-504 and XR-511.
	7. For hybrid services see CT-8 to ensure all audits are aligned.

# Nuclear Medicine and Molecular Imaging (NM)

Ref	Standard
NM-805	Paediatric Nuclear Medicine and Molecular Imaging Protocols
	Quality statement
	Children and young people are imaged in line with national and professional guidance.
	Outcome measure
	Specific and evidence-based protocols are in place for nuclear medicine and molecular imaging of children and young people. Audits show compliance with these protocols.
	Indicative inputs
	• When developing clinical protocols, the service should refer to clinical guidelines issued by the relevant professional bodies. Protocols should comply with IR(ME)R regulation 6(4) and 12(8).
	<ul> <li>The service should regularly audit against these protocols, and the audits should be cross-referenced to any incidents or non-compliance reported.</li> </ul>
	Notes:
	<ol> <li>Reviewers will want to be assured that the pathway- and condition-specific guidelines are relevant to the service(s) being provided. They should be sufficient to cover at least all the areas commonly provided by the service.</li> </ol>
	2. Reviewers should expect to see that relevant guidance has been considered in the context of local delivery and adapted for use within the service. This QS cannot be met by generic reference to national guidelines without local consideration.
	3. An audit of compliance may be part of a wider MDT audit rather than a service-specific audit. When this occurs, reviewers will want to ensure the service has considered the imaging elements of the audit results.
	4. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	5. Reviewers will want to ensure that MDT attendance and feedback is used for improvements in the service.

The ultrasound service, whether managed within the imaging service or as a stand-alone service, is expected to meet, where applicable, all the XR-\*\*\* quality statements. In addition, specific quality statements for US are set out below.

Each of these QS is applicable where the service provides a clinical pathway relevant to all or part of the QS. Where the pathway is not provided, the QS is 'not applicable' rather than 'not met'.

Where the service provides additional pathways to those set out in the statements below, it is expected to follow the generic principles contained within these pathway statements.

In the following QS the term ultrasound practitioner has been used to mean anyone undertaking an ultrasound examination for which they have been deemed competent.

Ref	Standard
US-801	Ultrasound Environment and Safety
	Quality statement Systems of work protect the ultrasound practitioner and the patient undergoing an ultrasound examination.
	Outcome measure The operator is protected from avoidable work-related musculoskeletal disorders through reviews of working practices and safe operating procedures.
	Indicative inputs
	• Working practices should be reviewed in line with current regulations and guidance from the Health and Safety Executive.
	<ul> <li>Designated ultrasound operators should undertake risk assessments of all procedures in line with the employer's agreed protocols.</li> </ul>
	<ul> <li>Equipment for the operator, facilities and the structure of the clinical lists should be designed to reduce risks of the occurrence of musculoskeletal disorders and/or staff burnout.</li> </ul>
	<ul> <li>Equipment for managing imaging of patients with a high BMI should be available where required (see also XR-404) and additional staffing resource should be available for the operator who requires extra support when imaging patients with particular needs such as high BMI or limited mobility.</li> </ul>
	<ul> <li>Ultrasound equipment should be inspected for damage on a regular basis to ensure the safety of the operator and the patient. Any damage should be reported and appropriate action taken.</li> </ul>
	• Appropriate individuals are available to act as a chaperone for intimate examinations (see also XR-105 and XR-203).
	<ul> <li>There should be staff training in risk assessment and ergonomics and other factors affecting work-related musculoskeletal disorders.</li> </ul>
	Notes:
	1. In this context, the term operator is used to mean both the ultrasound practitioner and any other healthcare professional taking part in the imaging examination.
	2. Reviewers should enquire about the support offered to staff who report that they have developed a work-related musculoskeletal disorder.
	3. This QS relates to XR-204 (Moving and handling and mandatory training) and XR-516 (Health and Safety).
	4. <u>SoR Guidance for intimate examinations and the use of chaperones</u> (May 2023).

Ref	Standard
US-802	Ultrasound Specific Training
	Quality statement
	All staff using ultrasound equipment are adequately trained.
	Outcome measure
	Systems of work are in place to ensure individuals are fully trained and competent for practice within ultrasound.
	Indicative inputs
	<ul> <li>A scope of practice which sets out the qualification and competences for ultrasound practitioners should be assessed and approved by the head of the ultrasound service.</li> </ul>
	The list of competences should be regularly reviewed and updated.
	<ul> <li>The service should be able to demonstrate that there is a competence framework in place for all staff operating ultrasound equipment (see XR-204). The competence framework and training plan should cover all staff identified in XR-203 and include competences relating to ultrasound safety.</li> </ul>
	• The service should be able to demonstrate how, collectively, the competence of all staff links to the needs of the service. This may take the form of a competence matrix (see also XR-204).
	<ul> <li>The service should audit regularly to assure itself that practitioners are undertaking only examinations for which they have approved competences.</li> </ul>
	• Arrangements should be set out for the supervision of sonographers and doctors in training undertaking ultrasound.
	<ul> <li>Arrangements should be set out for the supervision of newly-qualified sonographers throughout their preceptorship period.</li> </ul>
	<ul> <li>Ultrasound operators should be trained in the ergonomic use of ultrasound equipment in order to minimise work-related musculoskeletal disorders.</li> </ul>
	<ul> <li>Ultrasound operators should be trained in the use of products and devices for decontaminating ultrasound transducers and equipment.</li> </ul>
	Records of additional training should be available.
	Notes:
	1. This QS relates to XR-204.
	<ol><li>The term 'regularly reviewed' is not subject to exact definition but the reviews should be sufficiently frequent to provide assurance of continuing competence.</li></ol>
	<ol> <li>The Consortium for the Accreditation of Sonographic Education (CASE) defines standards for sonographic education and learning outcomes for ultrasound practitioners, and provides mapping to <u>National Occupational Standards</u>. Reviewers will want to ensure these have been considered in assessing competences.</li> </ol>
	4. SoR and British Medical Ultrasound Society (BMUS) have published <u>Guidelines for Professional Ultrasound Practice</u> (2023).
	<ol><li>RCR and BMUS guidance Recommendations for specialists practising ultrasound independently of radiology departments: safety, governance and education, 2023.</li></ol>
	<ol><li>Reviewers will want to ensure that safeguarding and responsibilities regarding female genital mutilation (FGM) are clearly understood by all staff working within gynaecology ultrasound.</li></ol>
	7. BMUS <u>Guidelines for the Management of Safety when using Volunteers &amp; Patients for Practical Training and Live</u> <u>Demonstration in Ultrasound Scanning and Consent</u> (2018) should be followed.

Ref	Standard
US-803	Clinical Ultrasound Pathways and Protocols
	Quality statement
	Pathways and conditions-specific protocols specific to ultrasound are in use.
	Outcome measure
	The service has reviewed national and professional guidelines and evidenced-based practice to inform its pathways and protocols. It has evidence that its protocols comply with the requirements for the pathways it provides. Audits show that these protocols and pathways are being followed and reviewed.
	Indicative inputs
	• The service should have considered national practice to reflect the local delivery of the service, including but not limited to the guidance from BMUS, SoR, RCR, Foetal Anomaly screening programme, the Society for Vascular Technology of Great Britain and Ireland and the NICE.
	• An action plan should be in place for addressing any gaps in compliance. The service should regularly audit against these protocols, and the audits should be cross-referenced to any incidents or non-compliance reported.
	• Key performance indicators (KPIs) for this QS should be locally agreed.
	<ul> <li>Audits of compliance with this QS should be able to demonstrate a link to the relevant MDT audit programme and the MDT annual report.</li> </ul>
	Notes:
	<ol> <li>Reviewers will want to be assured that the pathway- and condition-specific guidelines are relevant to the service(s) being provided. The guidelines should be sufficient to cover at least all the areas commonly provided by the service.</li> </ol>
	2. Reviewers should expect to see that all guidance has been considered in the context of local delivery and adapted for use within the service. This QS cannot be met by generic reference to national guidelines without local consideration.
	3. Regular comparison of benchmarking data from similar organisations would be beneficial in determining effective response times.
	4. Reviewers should note that the current SoR and BMUS guidance is helpfully summarised by pathway.
	5. An audit of compliance may be part of a wider MDT audit rather than a service-specific audit. When this occurs, reviewers will want to ensure that the service has considered the imaging elements of the audit results.
	6. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.

Ref	Standard
US-804	Paediatric Ultrasound Protocols
	Quality statement
	Children and young people are imaged in line with national and professional guidance.
	Outcome measure
	Specific and evidence-based protocols are in place for ultrasound scanning of children and young people. Audits show compliance with these protocols.
	Indicative inputs
	• The service should have considered national practice to reflect the local delivery of the paediatric service, including but not limited to the guidance provided by the British Medical Ultrasound Society, SoR, RCR and NICE.
	<ul> <li>The service should regularly audit against these protocols, and the audit should be cross-referenced to any incidents or non-compliance reported.</li> </ul>
	Notes:
	<ol> <li>Use of national guidance without consideration of local implementation is not sufficient for compliance with this QS and reviewers should expect to see that all guidance has been considered in the context of local delivery and adapted for use within the service.</li> </ol>
	<ol><li>Reviewers will want to be assured that the paediatric pathway- and condition-specific guidelines are relevant to the service(s) being provided. The guidelines should be sufficient to cover at least all the areas commonly provided by the service.</li></ol>
	3. Reviewers should note that the current SoR and BMUS guidance is helpfully summarised by pathway.
	<ol> <li>Reviewers will want to ensure that safeguarding and responsibilities regarding FGM are clearly understood by all staff working within the paediatric clinical protocols (see US-802 note 5).</li> </ol>
	5. An audit of compliance may be part of a wider MDT audit rather than a service-specific audit. When this occurs, reviewers will want to ensure the service has considered the imaging elements of the audit results. Reviewers will want to ensure that MDT attendance and feedback is used for improvements in the service.
	6. SoR Recommendations for education and training of specialist paediatric sonographers (June 2023).
	7. Reviewers will want to ensure that changes to pathways as a result of compliance with this QS are sustainable. In this context, 'sustainable' means that there is, among other elements, communication and agreement to change with the key stakeholders, consideration of the impact of change and a process for review once implemented.
	8. See also XR-505 and XR-511.

#### **Reference Sources** L

Glossary of Terms and	Abbreviations
Advocacy	Advocacy means to speak up for someone. It is about making things change because people's voices are heard and listened to. It's about making sure that people can make their own choices in life and have the chance to be as independent as they want to be.
Artificial Intelligence (AI)	The use of computer programs to perform tasks or reasoning processes that are related to medical services and care delivery.
ARSAC	Administration of Radioactive Substances Advisory Committee. ARSAC advises the licensing authorities on applications from practitioners, employers and researchers who want to use radioactive substances on people.
BMUS	British Medical Ultrasound Society.
Carer	Throughout the quality statements the term 'carer' applies to both family carers and paid carers or support workers.
CNR	Case note review or clinical observation. (Identified evidence sources within the QSI).
COR	College of Radiographers. The professional arm of the Society and College of Radiographers.
CQC	The Care Quality Commission is the independent regulator of health and social care in England.
DEXA	Dual-energy X-ray absorptiometry. A bone density scan using X-rays.
DoH	Department of Health.
Doc	Documentation should be available. Documentation may be in the form of a website or other social media. (Identified evidence sources within the QSI).
EASR	Environmental Authorisations (Scotland) Regulations 2018.
eGFR	Estimated glomerular filtration rate. A test to measure renal function.
Freedom To Speak Up Guardian	Independent support and advice to staff who want to raise concerns.
НСРС	Health and Care Professions Council. The HCPC has four main functions. In the context of this document, the main function is to keep a register of professionals, known as 'registrants' who meet the required standard.
HSIB	Healthcare Safety Investigation Branch. Conducts independent investigations of patient safety concerns in NHS-funded care across England.
IPEM	Institute of Physics and Engineering in Medicine.
IR(ME)R	The Ionising Radiation (Medical Exposure) Regulations 2017 and the Ionising Radiation (Medical Exposure) Regulations (NI) 2018.
IRR	Ionising Radiation Regulations.
Machine Learning	Machine learning is a subset of AI that uses algorithms and technologies to enable systems to identify patterns, make decisions, and improve themselves through experience and data.
MDT	Multidisciplinary Team.
MP&S	Meeting patients, carers and staff. (Identified evidence sources within the QSI).
MPE	Medical physics expert. An individual having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to medical exposure.
MHRA	The Medicines and Healthcare products Regulatory Agency. It regulates medicines, medical devices and blood components for transfusion in the UK.

#### **Reference Sources** L

Glossary of Terms and Abbreviations		
MHRA	The Medicines and Healthcare products Regulatory Agency. It regulates medicines, medical devices and blood components for transfusion in the UK.	
MRRP	Magnetic resonance responsible person. Day-to-day responsibility for safety. Provides continuity and consistency for the ongoing safe working practices of the department.	
MRSE	Magnetic resonance safety expert. Provides scientific advice to MR units including advising and monitoring of local safety procedures. Usually a medical physicist who is a HCPC registered clinical scientist.	
Network	A group of organisations working together and sharing experiences and learning for a common purpose. Each organisation remains independent from each other for its accountability and corporate governance.	
NICE	National Institute for Health and Care Excellence.	
PACS	Picture archiving and communication system. At its basic level, it is a system for storing and managing digital images. See also RIS.	
PGD	Patient group direction. Written instructions for a qualified healthcare professional to supply or administer medicines to patients.	
Projectile zone	An area around a magnet within the MR unit where there is a risk arising from ferromagnetic portable objects becoming attracted by the magnet.	
Provider	A health or social care organisation which provides services to patients.	
QRS	Quality review service.	
QS	Quality statement.	
RCR	Royal College of Radiologists	
RIS	Radiology information systems. A networked software system for managing medical images and associated data. See also PACS.	
RPA	Radiation protection adviser. Competent to advise employers on the safe and compliant use of Ionising Radiations. The post is a legally recognised position and is a requirement of the Ionising Radiations Regulations 2017.	
RWA	Radioactive waste adviser. A specialist in radioactive waste disposal and environmental radiation protection.	

