



# **The Imaging Services Accreditation Scheme Standard: statements, rationales and criteria**

## **ISAS Standard v3.0, 2017**

### **Disclaimer**

While the College of Radiographers (CoR) and The Royal College of Radiologists (RCR) have taken reasonable steps to ensure that these accreditation standards are fit for the purpose of accrediting 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 accreditation 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.

### **1. Introduction**

The following Standard is designed to be applied within a service accreditation scheme. It articulates the expectations of good imaging, interventional radiology and teleradiology services; services not seeking accreditation may also find it helpful.

The Standard is the product of a rigorous development process and review and represents the judgements of panels of radiographers, radiologists and patients 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 and regulatory bodies. The Standard has been assessed for country-specific applicability.

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The Standard was first published in 2009 and was reviewed and revised in 2011–2012 and again in 2015–2016. The latest review process included consultation with stakeholders, including a number of accredited sites, ISAS assessors and Special Interest and Advisory Groups of the RCR and the CoR. The Review Team consulted also with UKAS Assessment Managers and the Joint Accreditation Scheme Committee (JASC). As part of the latest revision, the overall number of statements and criteria has been reduced. Several statements have been combined to improve clarity, an example being the inclusion of radionuclide imaging into the statement relating to ionising radiation. In addition, it is recognised that strong leadership and management together with clarity of roles and responsibilities are essential elements of a successful organisation. This is reflected in other recognised accreditation standards as well as being an important part of inspections by national bodies. As a consequence, a fifth Domain relating to Leadership and Management has been added. This has been created by moving statements which have been reworded from the other Domains.

The Standard is designed to:

be patient-focused;

cover the functions and systems of a whole diagnostic imaging and interventional radiology service (asymptomatic breast screening services are currently excluded from consideration); and

address quality in delivery and support quality improvement.

## 2. The domains

For convenience, the Standard is divided into the following five domains:

Leadership and Management (LM);

Clinical (CL);

Facilities, Resources and Workforce (FR);

Patient Experience (PE); and

Safety (SA).

Each domain has a description which explains its purpose, and each domain contains a number of standard statements. However, the domains cannot be considered in isolation and, for the purpose of accreditation, all domains and standard statements should be treated as an interlinked package.

## 3. The Standard

There is one service accreditation Standard which consists of 29 standard statements. The statements sit within a framework of two distinct sections.

**Section one** comprises the standard statement, rationale and criteria.

Each **standard statement** addresses one aspect necessary for the provision of an imaging service.

A brief **rationale** details why that standard statement is considered to be important.

A list of **criteria** indicates the structures and processes necessary to deliver the standard statement.

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This section of the framework is designed to be context-independent, fixed between editions and publicly available.

**Section two** provides commentary and references.

A commentary for each standard statement points services to the relevant evidence base, including current professional guidance and legislation. This section provides valuable guidance on the provision of evidence to support the application for accreditation and should be read carefully before preparing the submission.

This section is reviewed and updated regularly to reflect evolving best practice.

Section two of the framework is commercially sensitive and is embedded within the online assessment tool.

## 4. Assessment of the Standard

The Standard is primarily designed to be a benchmark against which service delivery can be evaluated to drive quality improvement. It can be used for the purpose of service improvement outside the formal accreditation process as well as forming the basis for formal accreditation. More detailed information on the conduct of assessment for accreditation against the Standard is available from the accreditation provider, the United Kingdom Accreditation Service ([www.ukas.com](http://www.ukas.com)).

## 5. Scope of the Standard

The Standard can be applied to any organisation performing radiological procedures or providing teleradiology regardless of the number of staff or the scope of activities, from large NHS or independent providers, to small independent services and services provided at community-based facilities.

The scope of the service to be assessed must be defined by the service before assessment begins. The scope specifies organisational details and includes a comprehensive description of all imaging modalities used, patient groups treated and the physical location of each service area to be accredited.

The Standard is designed to be applied to all current diagnostic imaging modalities and interventional radiology services: general x-ray; ultrasound; computed tomography (CT); interventional radiology (IR); magnetic resonance imaging (MRI); dual energy x-ray absorption (DEXA); radionuclide imaging (RNI); hybrid imaging; and symptomatic breast mammography. Non-imaging aspects of Nuclear Medicine (including radiopharmacy) and asymptomatic breast screening services are not currently included in the scope of this Standard: other quality review systems are available for these areas of practice.

A service will not be assessed against any standard statements or criteria that are not applicable to its defined scope. For example, a service that performs only MRI procedures will  
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not need to address SA1: *'The service implements and monitors systems to manage risks associated with ionising radiation, including ensuring pre-procedure safety checks for all patients'*. Similarly, a service that does not treat children will not need to provide evidence relevant to children in meeting a criterion such as SA1C2: *'Systems in place to ensure radiation doses are as low as reasonably practicable, for children and adults, consistent with the acquisition of diagnostic images'*.

Conversely, the service must ensure that it interprets the standard statements broadly to reflect the full range of modalities used and the requirements of its patient groups. For example, services which image children must consider their special requirements in relation to each modality used.

The Standard is not designed to reflect or check compliance with any specific national legislation and regulations. However, **no service can be accredited if it fails to meet all applicable statutory requirements.**

## Leadership and Management Domain

The Purpose of this Domain is to ensure appropriate leadership and managerial controls to support the staff to deliver the service. This is achieved through an effective leadership and management structure (senior, service and clinical) under the direction of a person or persons with the competence to define and delegate responsibilities for the activities provided and by working within an appropriately designed quality management system.

**LM1** The organisation has a management and leadership structure with identified roles, responsibilities, authorities and interrelationships

**LM2** The organisation has a quality management system to integrate and monitor all its processes

LM1	Roles, responsibilities, authorities and interrelationships.
<p><b>Rationale:</b> <i>The organisation must have an appropriate senior, service and clinical managerial structure with defined roles, responsibilities, authorities and interrelationships to deliver its imaging service operations, hereafter called 'the Service', whether at permanent facilities or when using mobile units or outsourced services. The organisation should ensure that the management of staff is effective, fair, consistent and supportive and complies with current legislation and best practice.</i></p>	
<p><b>Criteria</b></p>	
LM1C1	Defined organisational roles and responsibilities for the overall management, leadership and direction of the Service
LM1C2	Defined roles, responsibilities and interrelationships for senior clinical, professional and service management and leadership
LM1C3	Defined roles, responsibilities and interrelationships for each service delivery area/ modality, as appropriate
LM1C4	Systems in place to ensure clear definition and management of tasks for staff to deliver the service
LM1C5	Systems in place to ensure an appropriate complement of staff to deliver identified tasks
LM1C6	Systems in place to ensure agreed appraisals and/or personal development reviews are conducted for all staff
LM1C7	Systems in place to manage conflicts of interest and to ensure no involvement in any activities that would diminish the Service's competence, impartiality, judgment and operational integrity
LM1C8	Systems in place to define, document and communicate to staff the organisation's core values and objectives
LM1C9	Systems in place to communicate to staff the need to meet the needs and

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	requirements of users, as well as regulatory, professional and accreditation bodies
LM1C10	Systems in place to support staff in managing stress and achieving a work/life balance

<b>LM2</b>	<b>Quality Management System.</b>
<b>Rationale:</b> <i>The Service must have an appropriately designed quality management system that integrates all agreed processes and regular monitoring of effectiveness whether at its permanent facilities or when using mobile units or outsourced services.</i>	
<b>Criteria</b>	
LM2C1	Systems in place to manage all service documents
LM2C2	Systems in place for a clearly defined audit programme for all processes
LM2C3	Systems in place to identify and manage discrepancies when untoward events occur throughout the patient journey, including near-misses, and take preventative and / or corrective action(s)
LM2C4	Systems in place to maintain and continually review a register of all Service risks to include financial risks
LM2C5	Systems in place to implement actions necessary to achieve agreed quality objectives and continual improvement of all Service activities and processes
LM2C6	Systems in place to review the quality management system at planned intervals to ensure its continued suitability, adequacy and effectiveness

## Clinical Domain

The purpose of the Clinical domain is to promote the service's role in rapid and accurate diagnosis and treatment. This is achieved through: administrative and clinical practices appropriate to the patient population including children; effective management of risk and emergencies; and the review of existing and new clinical practice to develop and improve the service.

**CL1** The service implements and monitors systems to ensure delivery of the service from referral to discharge from the service.

**CL2** The service implements and monitors systems to ensure the acquisition of optimal diagnostic quality images.

**CL3** The service implements and monitors systems to ensure the clinical and technical quality of reports.

**CL4** The service implements and monitors systems to ensure the clinical and technical quality of interventional procedures.

**CL5** The service implements and monitors systems to manage drugs, contrast media and radioactive medicinal products, where relevant.

**CL6** The service implements and monitors systems to manage clinical records.

**CL7** The service implements and monitors systems to ensure that those who have professional contact with the service are able to give feedback on their experience.

**CL8** The service implements and monitors systems to review current and emerging clinical practice, implementing new practice as appropriate.

<b>CL1</b>	<b>The service implements and monitors systems to ensure delivery of the service from referral to discharge from the service.</b>
<b>Rationale:</b> <i>The service should work collaboratively with colleagues to agree and deliver appropriate imaging pathways to ensure diagnosis and/or treatment within specified timescales with minimal delays for all relevant patient groups.</i>	
<b>Criteria</b>	
CL1C1	Systems in place to manage imaging pathways from referral to discharge from the service, within specified timescales
CL1C2	Systems in place to ensure a collaborative approach to define and deliver imaging pathways and to maintain communication both within and outwith the service

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CL1C3	Systems in place to ensure clinically relevant information is received from referrers and patients
CL1C4	Systems in place to ensure vetting, prioritisation, justification and authorisation of individual referrals, as relevant
CL1C5	Systems in place to ensure communication of reports to referrers and multidisciplinary meetings within specified timescales. This must include systems to manage unexpected findings and potential medical emergencies.

<b>CL2</b>	<b>The service implements and monitors systems to ensure the acquisition of optimal diagnostic quality images.</b>
<b>Rationale:</b> <i>The service should ensure that all images in each service area within the scope for the organisation are acquired in accordance with agreed protocols by competent staff working within their defined scope of practice. Images should be of optimal diagnostic quality according to current best practice, and provide essential image characteristics.</i>	
<b>Criteria</b>	
CL2C1	Systems in place to develop, agree, maintain and apply image acquisition protocols for all examinations
CL2C2	Systems in place to ensure that image acquisition protocols are accessible and communicated to all imaging staff
CL2C3	Systems in place to assure diagnostic image quality
CL2C4	Systems in place to ensure analysis and feedback on imaging practice in all service areas is available and communicated to all relevant staff and colleagues to inform development of practice

<b>CL3</b>	<b>The service implements and monitors systems to ensure the clinical and technical quality of reports.</b>
<b>Rationale:</b> <i>The service should ensure that all images are reported in accordance with agreed local practice by competent staff working within their defined scope of practice to deliver accurate and effective radiological and clinical interpretation of images. Protocols should be agreed for reporting under outsourced contracts external to the service, including teleradiology arrangements.</i>	
<b>Criteria</b>	
CL3C1	Systems in place to develop and agree the structure and content of reports to meet local needs
CL3C2	Systems in place to ensure that agreed reporting formats are accessible and communicated to all reporting staff

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CL3C3	Systems in place to assure the quality and accuracy of reports and amendments
CL3C4	Systems in place to ensure that reporting staff are able to access a second opinion
CL3C5	Systems in place to ensure analysis and feedback on reporting practice is available and communicated to all relevant staff and colleagues to inform development of practice

<b>CL4</b>	<b>The service implements and monitors systems to ensure the clinical and technical quality of interventional procedures.</b>
<b>Rationale:</b> <i>The service should ensure that all interventional procedures are conducted in accordance with agreed protocols for children and adults by competent staff working within their defined scope of practice.</i>	
<b>Criteria</b>	
CL4C1	Systems in place to define, assess and manage risks related to interventional procedures
CL4C2	Systems in place to develop, agree, maintain and apply protocols for all interventional procedures
CL4C3	Systems in place to ensure that protocols for interventional procedures are accessible and communicated to interventional staff
CL4C4	Systems in place to ensure appropriate clinical and emergency support is available
CL4C5	Systems in place to ensure that staff are able to access a second opinion for complex procedures
CL4C6	Systems in place to ensure analysis and feedback of interventional practice is communicated to all relevant staff and colleagues to inform development of practice

<b>CL5</b>	<b>The service implements and monitors systems to manage drugs, contrast media and radioactive medicinal products.</b>
<b>Rationale:</b> <i>The service has a duty to ensure that drugs, including controlled drugs, contrast media and radioactive medicinal products are prescribed, prepared labelled and administered safely to reflect statutory requirements. Systems should reflect differences between adults and children. These agents should be stored appropriately and adverse reactions should be dealt with efficiently and effectively.</i>	
<b>Criteria</b>	
CL5C1	Systems in place to manage the prescription of these agents
CL5C2	Systems in place to ensure the identification and management of patients at risk of adverse reactions to these agents
CL5C3	Systems in place to manage the safe receipt, preparation, labelling and

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	administration of these agents
CL5C4	Systems in place to ensure the management and care of patients receiving these agents, including response to adverse reaction
CL5C5	Systems in place to ensure that these agents are securely and safely stored
CL5C6	Systems in place to ensure collaboration with relevant teams/departments/organisations regarding the administration of these agents to patients and patient aftercare
CL5C7	Systems in place to assure supply of these agents and response to shortages and interruptions in supply
CL5C8	Systems in place to schedule RNI procedures to ensure the efficient and effective use of these agents

<b>CL6</b>	<b>The service implements and monitors systems to manage clinical records.</b>
<b>Rationale:</b> <i>The service has a duty to manage, store and transfer all patient data in a secure manner to reflect statutory requirements and maintain patient confidentiality whether transfers are internal or external (e.g. outsourced services) to the organisation.</i>	
<b>Criteria</b>	
CL6C1	Systems in place to maintain patient confidentiality
CL6C2	Systems in place to ensure the secure and confidential storage, retrieval, transmission and transportation of patient records
CL6C3	Systems in place to manage sharing of patient data between organisations
CL6C4	Systems in place to ensure control and audit of access to patient data

<b>CL7</b>	<b>The service implements and monitors systems to ensure that those who have contact with the service are able to give feedback on their experience.</b>
<b>Rationale:</b> <i>The service should encourage those who have contact with the service in a formal or professional capacity to give feedback, and use the feedback to improve and develop services and foster relationships with colleagues.</i>	
<b>Criteria</b>	
CL7C1	Systems in place to develop, agree and maintain materials to support user feedback
CL7C2	Systems in place to ensure that users are able to give feedback, in confidence if appropriate
CL7C3	Systems in place to ensure results of user feedback are collated, analysed, and

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	findings disseminated, communicated to relevant parties and acted upon
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<b>CL8</b>	<b>The service implements and monitors systems to review current and emerging clinical practice, implementing as appropriate.</b>
<b>Rationale:</b> <i>The service should carry out audits to explore the effect of current clinical practice. Audit information should be used in collaborative review processes to develop practice. The service should review emerging developments in clinical practice and develop new clinical practices in line with current research and guidance.</i>	
<b>Criteria</b>	
CL8C1	Systems in place to ensure regular audit of current practice, review and dissemination of findings and appropriate action
CL8C2	Systems in place for reviewing emerging clinical practices and implementing new practice as appropriate
CL8C3	Systems in place to ensure governance arrangements to support introduction of new clinical practices
CL8C4	Systems in place to ensure governance arrangements to support medico-legal work
CL8C5	Systems in place to support active engagement in research and development activities

## Facilities, Resources and Workforce Domain

The purpose of the Facilities, Resources and Workforce domain is to ensure that resources are used effectively to provide a safe, efficient, comfortable and accessible service. This is achieved through appropriate and adequate facilities (rooms and equipment); motivated and competent staff; and the integration of sound business planning principles within the service.

**FR1** The service implements and monitors systems to ensure that facilities and environment support delivery of the service.

**FR2** The service implements and monitors systems for the procurement of equipment to deliver the service.

**FR3** The service implements and monitors systems to install and maintain equipment to deliver the service.

**FR4** The service implements and monitors systems to ensure that staff are competent to deliver the service.

**FR5** The service implements and monitors systems to engage in integrated service and workforce review, planning and development.

**FR6** The service implements and monitors systems to manage its budget and service contracts.

**FR7** The service implements and monitors systems to manage internal and external major incident situations.

<b>FR1</b>	<b>The service implements and monitors systems to ensure that facilities and environment support delivery of the service.</b>
<b>Rationale:</b> <i>The service should provide an environment and facilities which are safe, clean, comfortable and fit for purpose for staff, patients and others.</i>	
<b>Criteria</b> <i>A current report demonstrating compliance with statutory requirements from the recognised regulator will be deemed sufficient evidence for relevant criteria.</i>	
FR1C1	Systems in place to ensure that all areas used by the service meet the specific needs of the patient population (including children and those with particular needs) and staff
FR1C2	Systems in place to ensure the management of space to facilitate efficient working

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FR1C3	Systems in place to ensure all areas used by the service are well maintained
FR1C4	Systems in place to ensure access to particular areas is restricted including the provision of appropriate signage and hazard warning notices
FR1C5	Systems in place to ensure the management and control of environmental conditions

<b>FR2</b>	<b>The service implements and monitors systems for the procurement of equipment to deliver the service.</b>
<b>Rationale:</b> <i>The service has a duty to assure the appropriate procurement and replacement of all equipment, including software and ancillary equipment such as resuscitation equipment, protective clothing and consumables.</i>	
<b>Criteria</b> <i>A current report demonstrating compliance with statutory requirements from the recognised regulator will be deemed sufficient evidence for relevant criteria.</i>	
FR2C1	Systems in place for the procurement of all equipment and consumables
FR2C2	Systems in place to ensure that equipment is appropriate for patients, staff, children and those with particular needs
FR2C3	Systems in place to ensure that equipment replacement is planned

<b>FR3</b>	<b>The service implements and monitors systems to install and maintain equipment to deliver the service.</b>
<b>Rationale:</b> <i>The service has a duty to assure the appropriate installation, maintenance and quality assurance of all equipment, including software and ancillary equipment such as resuscitation equipment, protective clothing and consumables.</i>	
<b>Criteria</b> <i>A current report demonstrating compliance with statutory requirements from the recognised regulator will be deemed sufficient evidence for relevant criteria.</i>	
FR3C1	Systems in place to assure installation, calibration, operation and optimal performance of equipment
FR3C2	Systems in place to ensure maintenance of all equipment and corresponding records
FR3C3	Systems in place to ensure that equipment failures and faults are monitored and managed and that safety warnings, alerts and recalls are circulated and acted upon within specified timescales

<b>FR4</b>	<b>The service implements and monitors systems to ensure that staff are competent to deliver the service.</b>
<b>Rationale:</b> <i>The service has a duty to ensure that all staff, whether substantive appointments or locum/ agency, are competent, skilled and supported to maintain, improve and widen the scope of their competencies.</i>	
<b>Criteria</b>	
FR4C1	Systems in place to support the recruitment of staff
FR4C2	Systems in place to ensure that all staff are competent to undertake the role(s) to which they have been appointed, including relevant employment checks
FR4C3	Systems in place to check qualification and current registration of relevant staff
FR4C4	Systems in place to ensure that all staff are properly inducted into their roles, together with any additional education and training provided as necessary
FR4C5	Systems in place to ensure that any staff in a training position are adequately supervised
FR4C6	Systems in place to ensure that the service maintains competencies to address the requirements of patients, children and those with particular needs
FR4C7	Systems in place to ensure that all staff are supported to maintain necessary skills, knowledge and levels of competence, and to develop new competencies

<b>FR5</b>	<b>The service implements and monitors systems to engage in service and workforce review, planning and development.</b>
<b>Rationale:</b> <i>The service should review clinical and non-clinical practice and workforce deployment. All service improvement activities and workforce development should facilitate an effective diagnostic imaging and interventional radiology service in response to changing healthcare needs.</i>	
<b>Criteria</b>	
FR5C1	Systems in place to support service review, improvement and planned development with the involvement of patients, staff, users and others
FR5C2	Systems in place to ensure strategic service planning and workforce planning are integrated
FR5C3	Systems in place to assess, agree and implement workforce development initiatives to include appropriate skill mix
FR5C4	Systems in place to manage any and all out-of-hours service provision
FR5C5	Systems in place to support engagement with content and delivery of relevant education and training

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FR5C6	Systems in place to support and monitor staff retention and ensure succession planning arrangements
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<b>FR6</b>	<b>The service implements and monitors systems to manage its budget and service contracts.</b>
<b>Rationale:</b> <i>The service should manage its budgets and service contracts effectively and efficiently to ensure high-quality care for patients.</i>	
<b>Criteria</b>	
FR6C1	Systems in place to ensure arrangements to negotiate, agree, regularly report and monitor budgets
FR6C2	Systems in place to ensure that all staff are aware of budget management processes and the implications for their area of responsibility
FR6C3	Systems in place to ensure engagement with wider financial planning processes
FR6C4	Systems in place to procure, manage and monitor delivery of contracted services
FR6C5	Systems in place to ensure arrangements for dealing with income generated by commercial and/or research activities, and/or charitable donations

<b>FR7</b>	<b>The service implements and monitors systems to manage internal and external major incidents.</b>
<b>Rationale:</b> <i>The service has a duty to ensure that it is able to respond appropriately to any major incident by engaging in emergency planning to ensure service continuity and patient care.</i>	
<b>Criteria</b>	
FR7C1	Systems in place to ensure appropriate response to internal and/or external major incidents
FR7C2	Systems in place that ensure continuing delivery of services following an internal incident
FR7C3	Systems in place that ensure continuing delivery of services following an external incident
FR7C4	Systems in place to ensure external and internal incident plans are communicated, practised and reviewed
FR7C5	Systems in place to ensure that the response to a major incident is analysed and the findings disseminated

## Patient Experience Domain

The purpose of the Patient Experience domain is to ensure that service delivery is patient-focused and respectful of the individual patient and their specific requirements. This is achieved through provision of appropriate information and support for patients and carers with due regard to differences in culture, religion, age and other factors. Effective feedback systems for patients and carers are necessary.

**PE1** The service implements and monitors systems to ensure that patients are able to access patient-friendly information about what happens before, during and after specific examinations/procedures.

**PE2** The service implements and monitors systems to ensure that the privacy, dignity and security of patients are respected throughout contact with the service.

**PE3** The service implements and monitors systems to ensure informed patient consent.

**PE4** The service implements and monitors systems to ensure that service delivery is patient-focused.

**PE5** The service implements and monitors systems to ensure that patients are able to give feedback on their experience of the service.

<b>PE1</b>	<b>The service implements and monitors systems to ensure that patients are able to access patient-friendly information about what happens before, during and after all examinations/procedures.</b>
<p><b>Rationale:</b> <i>The service should provide clear, relevant and up-to-date information in a range of formats regarding the service and explaining the purpose and nature of planned examinations/procedures. The information should be sufficient to enable patients and their carers to make informed decisions about their care, reduce their anxiety and give them confidence in their examination/procedure.</i></p>	
<b>Criteria</b>	
PE1C1	Systems in place to ensure that patients receive general and examination/procedure-specific information within specified timescales to allow preparation for an appointment or examination/procedure
PE1C2	Systems in place to ensure that all patient groups and/or carers, as appropriate, are able to access information in relevant formats
PE1C3	Systems in place to ensure that patients know who is present at and performing their examination/procedure

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PE1C4	Systems in place to ensure that patients know how, when and by whom results/reports will be communicated to them
PE1C5	Systems in place to ensure that patient information materials are developed and reviewed with lay and/or patient representatives, and kept updated within specified timescales

<b>PE2</b>	<b>The service implements and monitors systems to ensure that the privacy, dignity and security of patients are respected throughout contact with the service.</b>
<b>Rationale:</b> <i>The service should actively promote patients' privacy, dignity and security. Due regard should be paid to differences in culture, religion, age and other factors with reference to equality and diversity legislation.</i>	
<b>Criteria</b>	
PE2C1	Systems in place to encourage and support staff to be welcoming and to act with discretion and respect towards patients and carers
PE2C2	Systems in place to ensure that patients' privacy, dignity and security are maintained
PE2C3	Systems in place to ensure that patients are able to secure personal effects while undergoing examinations/procedures

<b>PE3</b>	<b>The service implements and monitors systems to ensure informed patient consent.</b>
<b>Rationale:</b> <i>The service should ensure that all patient groups and/or carers, as appropriate, are involved in decisions about their examinations or procedures. Valid, informed consent to examinations/ procedures is central to patient involvement in their own care.</i>	
<b>Criteria</b>	
PE3C1	Systems in place to ensure that patients are able to discuss their examination/procedure options with an appropriate staff member
PE3C2	Systems in place to enable patients to give or withhold informed consent for all examinations/procedures
PE3C3	Systems in place to arrange taking of consent from children and patients with particular needs for all examinations/procedures
PE3C4	Systems in place to enable patients to give or withhold informed consent for access to and distribution of images and reports
PE3C5	Systems in place to enable patients to give or withhold informed consent for their data to be used for teaching and/or research purposes

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<b>PE4</b>	<b>The service implements and monitors systems to ensure that service delivery is patient-focused.</b>
<b>Rationale:</b> <i>The service should focus delivery on patients and their specific requirements. Due regard should be paid to differences in culture, religion, age and other factors, including vulnerability.</i>	
<b>Criteria</b>	
PE4C1	Systems in place to ensure that the service is accessible to all patients and carers
PE4C2	Systems in place to ensure that appointments are available to meet patient needs and circumstances and co-ordinated with other appointments where possible
PE4C3	Systems in place to ensure positive identification of patients, including appropriate form of address
PE4C4	Systems in place to ensure that specific requirements of patients and carers are identified and responded to
PE4C5	Systems in place to ensure that relevant information is communicated to individual patients during their contact with the service, including arrangements for transfer/continuity of care
PE4C6	Systems in place to provide support for patients who become distressed during their contact with the service including when the service fails to meet expectations

<b>PE5</b>	<b>The service implements and monitors systems to ensure that patients and others are able to give feedback on their experience of the service.</b>
<b>Rationale:</b> <i>The service should encourage patients, carers and others including staff to give feedback, either verbal or written, and use the feedback to improve and develop the service. The feedback may include complaints which should be managed effectively within specified timescales, and use the information to inform development of care and service delivery.</i>	
<b>Criteria</b>	
PE5C1	Systems in place to develop, agree and maintain materials to support feedback and complaints
PE5C2	Systems in place to ensure that patients, carers and others are able to give feedback in a variety of formats and in confidence
PE5C3	Systems in place to respond to and manage feedback and complaints within specified timescales
PE5C4	Systems in place to ensure results of patient feedback and complaints are collated, analysed and findings disseminated, communicated to relevant parties and acted upon

## Safety Domain

The purpose of the Safety domain is to ensure that services provide the highest level of safety for patients, staff and others who come into contact with the service. This is achieved through assessment and management of the risks associated with delivery of the service.

**SA1** The service implements and monitors systems to manage risks associated with ionising radiation.

**SA2** The service implements and monitors systems to manage risks associated with ultrasound.

**SA3** The service implements and monitors systems to manage risks associated with magnetic resonance imaging.

**SA4** The service implements and monitors systems to manage risks associated with the use of ablative technologies and therapeutic devices.

**SA5** The service implements and monitors systems to manage the risk of infection.

**SA6** The service implements and monitors systems to manage risks associated with hazardous substances and materials.

**SA7** The service implements and monitors systems to ensure the general health and safety of patients, staff and others.

<b>SA1</b>	<b>The service implements and monitors systems to manage risks associated with ionising radiation.</b>
<b>Rationale:</b> <i>The service has a duty to ensure that organisational arrangements and general radiation protection measures for staff, patients and others are in place to restrict exposure to ionising radiation and reflect statutory requirements. Any ionising radiation doses received by patients, staff and others should be as low as reasonably practicable.</i>	
<b>Criteria</b> <i>A current report demonstrating compliance with statutory requirements from the recognised regulator will be deemed sufficient evidence for relevant criteria.</i>	
SA1C1	Systems in place to define, assess and manage risks of medical exposure to ionising radiation, including ensuring pre-procedure safety checks for all patients
SA1C2	Systems in place to ensure that radiation doses are as low as reasonably practicable, for children and adults, consistent with the acquisition of diagnostic

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Next review date 2021

Page 19 of 29

	images
SA1C3	Systems in place to ensure recording of dose information/administered activity and justification and authorisation of variations from diagnostic reference levels
SA1C4	Systems in place to define, assess and manage risks of occupational exposure to ionising radiation
SA1C5	Systems in place to identify and monitor, as appropriate, other persons exposed to ionising radiation
SA1C6	Systems in place to classify and monitor environments where ionising radiation is used
SA1C7	Systems in place to ensure that those involved in post-procedural care and transport of patients are aware of radiation risks and their management, when radioactive materials have been used

<b>SA2</b>	<b>The service implements and monitors systems to manage risks associated with ultrasound.</b>
<b>Rationale:</b> <i>The service should ensure that the potential risks associated with the use of ultrasound are minimised to patients, staff and others.</i>	
<b>Criteria</b>	
SA2C1	Systems in place to define, assess and manage potential risks related to ultrasound
SA2C2	Systems in place to minimise acoustic output and exposure times

<b>SA3</b>	<b>The service implements and monitors systems to manage risks associated with magnetic resonance imaging.</b>
<b>Rationale:</b> <i>The service should ensure that risks associated with the use of magnetic resonance imaging (MRI) are minimised for patients, staff and others.</i>	
<b>Criteria</b>	
SA3C1	Systems in place to define, assess and manage risks related to the use of MRI
SA3C2	Systems in place to minimise exposure to different types of electromagnetic fields, radiofrequencies and noise
SA3C3	Systems in place to ensure pre-entry safety checks for all patients, staff and others
SA3C4	Systems in place to ensure that all ancillary equipment used in the MRI examination room are assessed and approved for use in the MRI environment

<b>SA4</b>	<b>The service implements and monitors systems to manage risks associated with interventional radiology including the use of ablative technologies and therapeutic devices.</b>
<b>Rationale:</b> <i>The service has a duty to ensure that the risks associated with the use of ablative and therapeutic devices such as radiofrequency probes, lasers, intussusception reduction and lithotripsy devices, are minimised.</i>	
<b>Criteria</b>	
SA4C1	Systems in place to define, assess and manage risks related to the use of all ablative and therapeutic devices
SA4C2	Systems in place to ensure that staff receive training to use specific ablative and therapeutic devices, to include laser safety training as appropriate

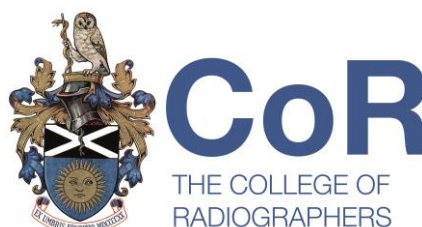
<b>SA5</b>	<b>The service implements and monitors systems to manage the risk of infection.</b>
<b>Rationale:</b> <i>The service has a duty to minimise infection by providing appropriate training and equipment and upholding rigorous standards of hygiene.</i>	
<b>Criteria</b>	
SA5C1	Systems in place to define, assess and manage the risk of infection
SA5C2	Systems in place to manage patients with contagious and communicable diseases, and/or suppressed immune systems
SA5C3	Systems in place to ensure the care of any individual exposed to contagious and communicable diseases
SA5C4	Systems in place to ensure decontamination of equipment and environment following their use as well as in the event of an incident

<b>SA6</b>	<b>The service implements and monitors systems to manage risks associated with hazardous substances and materials.</b>
<b>Rationale:</b> <i>The service has a duty to minimise the potential of harm from hazardous substances and materials by providing appropriate training and equipment.</i>	
<b>Criteria</b>	
<i>A current report demonstrating compliance with statutory requirements from the recognised regulator will be deemed sufficient evidence for relevant criteria.</i>	
SA6C1	Systems in place to define, assess and manage risks associated with hazardous substances and materials
SA6C2	Systems in place to ensure the management and disposal of waste, including

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	radioactive waste
SA6C3	Systems in place to ensure that appropriate protective equipment is available and maintained
SA6C4	Systems in place to ensure decontamination and care of people as well as of equipment and the environment, following an incident, including radioactive spillages

<b>SA7</b>	<b>The service implements and monitors systems to ensure the general health and safety of patients, staff and others.</b>
<p><b>Rationale:</b> <i>The service has a duty to promote a good health and safety culture, manage adverse healthcare events and minimise risk and failure. This is wide-ranging and includes the risk of fire, minimising the potential for harm from moving and handling patients and equipment by providing appropriate training and lifting aids, as well as violent or aggressive behaviour and supporting staff, patients and others involved in such incidents.</i></p>	
<p><b>Criteria</b></p> <p><i>A current report demonstrating compliance with statutory requirements from the recognised regulator will be deemed sufficient evidence for relevant criteria.</i></p>	
SA7C1	Systems in place to define, assess and manage health and safety risks
SA7C2	Systems in place to ensure that moving and handling aids are available and maintained
SA7C3	Systems in place to assure the safe transport of patients
SA7C4	Systems in place to manage adverse healthcare events
SA7C5	Systems in place to maintain staff awareness and training on general health and safety
SA7C6	Systems in place to ensure that health and safety equipment is available and maintained
SA7C7	Systems in place to ensure support for patients, staff and others who have been involved in an incident



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## Appendix A

### ISAS Standard

#### Record of Statement changes from Standard v2.1 January 2013 to Revised Standard January 2017

<i>Standard v2.1 January 2013</i>	<i>Where covered in the Revised Standard January 2017</i>	<i>Comments</i>
<b>Clinical domain</b>		
<b>CL1</b>		
CL1C1	Included in LM1C1 / C2	
CL1C2	CL1C1	
CL1C3	CL1C2	
CL1C4	CL1C3	
CL1C5	CL1C4	Minor reword
CL1C6	Included in PE4C4 / FR2C2	
CL1C7	Included in CL1C5	reword
<b>CL2</b>		
CL2C1	Included in LM1C2	
CL2C2	CL2C1	
CL2C3	CL2C2	
CL2C4	CL2C3	
CL2C5	CL2C4	
<b>CL3</b>		
CL3C1	Included in LM1C2	
CL3C2	CL3C1	
CL3C3	CL3C2	
CL3C4	CL3C3	Minor reword
CL3C5	Included in CL1C5	Minor reword
CL3C6	CL3C4	
CL3C7	CL3C5	
<b>CL4</b>		
CL4C1	Included in LM1C2	
CL4C2	CL4C1	
CL4C3	CL4C2	
CL4C4	CL4C3	
CL4C5	Included in LM2C5	Minor reword
CL4C6	CL4C4	
CL4C7	CL4C5	
CL4C8	CL4C6	
<b>CL5</b>		

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CL5C1	Included in LM1C2	
CL5C2	CL5C1	Minor reword
CL5C3	CL5C2	Minor reword
CL5C4	CL5C3	Minor reword
CL5C5	CL5C4	Minor reword
CL5C6	CL5C5	Minor reword
CL5C7	CL5C6	Minor reword
<b>CL6</b>		
CL6C1	Included in LM1C2 / LM1C2 / LM2C4	
CL6C2	Included in LM2C3 / LM2C4	Reword
CL6C3	Included in LM2C3	Minor reword
CL6C4	Included in CL1C4 / CL8C4 / CL8C5	Reword
CL6C5	Included in LM2C3	Reword
<b>CL7</b>		
CL7C1	Included in LM1C1 / C2	
CL7C2	CL6C1	
CL7C3	CL6C2	
CL7C4	CL6C3	
CL7C5	CL6C4	
<b>CL8</b>		
CL8C1	Included in LM1C1 / C2	
CL8C2	CL7C1	
CL8C3	CL7C2	
CL8C4	CL7C3	
<b>CL9</b>		
CL9C1	Included in LM1C1 / C2	
CL9C2	CL8C1	
CL9C3	CL8C2	
CL9C4	CL8C3	
CL9C5	CL8C5	
<b>CL10</b>		
CL10C1	Included in LM1C2	Minor reword
CL10C2	Included in CL2C1	
CL10C3	Included in CL2C2	
CL10C4	Included in CL2C3	
CL10C5	Included in CL1C4 / SA1C3	Reword
CL10C6	Included in CL5C7	Reword
CL10C7	Included in CL5C8	
CL10C8	Included in CL2C4	Minor reword
<b>Facilities, Resources and Workforce domain</b>		
<b>FR1</b>		
FR1C1	Included in LM1C1	Reword

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FR1C2	FR1C1	
FR1C3	FR1C2	
FR1C4	FR1C3	
FR1C5	FR1C4	Minor reword
FR1C6	FR1C5	
FR2		
FR2C1	Included in LM1C1 / C2	
FR2C2	FR2C1	
FR2C3	FR3C1	Minor reword
FR2C4	FR2C2	
FR2C5	FR3C2	
FR2C6	FR3C3	
FR2C7	FR2C3	
FR3		
FR3C1	Included in LM1C1 / C2	
FR3C2	LM1C4	
FR3C3	LM1C5	
FR3C4	LM1C6	
FR3C5	Included in LM1C8 / LM2C1	Reword
FR3C6	FR5C4	
FR3C7	LM1C10	
FR3C8	LM1C7	
FR3C9	Included in CL7C2 / CL7C3	Reword
FR4		
FR4C1	Included in LM1C1 / C2	
FR4C2	FR4C1	
FR4C3	FR4C2	
FR4C4	FR4C3	
FR4C5	FR4C4	Minor reword
FR4C6	FR4C5	
FR4C7	FR4C6	
FR4C8	FR4C7	
FR4C9	Included in LM2C1 / LM2C6	Reword
FR5		
FR5C1	Included in LM1C1 / C2	
FR5C2	FR5C1	
FR5C3	FR5C2	
FR5C4	FR5C3	Minor reword
FR5C5	FR5C5	
FR5C6	FR5C6	
FR6		
FR6C1	Included in LM1C1 / C2	

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Next review date 2021

Page 25 of 29

FR6C2	FR6C1	
FR6C3	FR6C2	
FR6C4	FR6C3	
FR6C5	FR6C4	
FR6C6	FR6C5	
FR7		
FR7C1	Included in LM1C1 / C2	
FR7C2	Included in PE5C2 / PE5C3	
FR7C3	Included in PE5C3	Minor reword
FR7C4	Included in PE5C4 / FR4C4	
FR7C5	PE5C4	Minor reword
FR8		
FR8C1	Included in LM1C1 / C2	
FR8C2	FR7C1	
FR8C3	FR7C2	
FR8C4	FR7C3	
FR8C5	FR7C4	
FR8C6	FR7C5	
Patient Experience domain		
PE1		
PE1C1	Included in LM1C1 / C2	
PE1C2	PE1C1	
PE1C3	PE1C2	Minor reword
PE1C4	PE1C3	
PE1C5	PE1C4	
PE1C6	PE1C5	
PE2		
PE2C1	Included in LM1C1 / C2	
PE2C2	PE2C1	
PE2C3	PE2C2	
PE2C4	PE2C3	
PE3		
PE3C1	Included in LM1C1 / C2	
PE3C2	PE3C1	
PE3C3	PE3C2	
PE3C4	PE3C3	
PE3C5	PE3C4	
PE3C6	PE3C5	
PE4		
PE4C1	Included in LM1C1 / C2	
PE4C2	PE4C1	
PE4C3	PE4C2	
PE4C4	PE4C3	
PE4C5	PE4C4	

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Next review date 2021

Page 26 of 29

PE4C6	PE4C5	
PE4C7	PE4C6	Minor reword
PE5		
PE5C1	Included in LM1C1 / C2	
PE5C2	PE5C1	
PE5C3	PE5C2	
PE5C4	PE5C4	
Safety domain		
SA1		
SA1C1	Included in LM1C2	
SA1C2	SA1C1	Minor reword
SA1C3	SA1C2	
SA1C4	SA1C4	
SA1C5	SA1C5	
SA1C6	SA1C6	
SA1C7	Included in FR3C1	
SA1C8	Included in FR1C4	
SA1C9	Included in LM2C3	
SA2		
SA2C1	Included in LM1C2	
SA2C2	SA2C1	
SA2C3	SA2C2	
SA2C4	Included in LM2C3	
SA3		
SA3C1	Included in LM1C2	
SA3C2	SA3C1	
SA3C3	SA3C2	Minor reword
SA3C4	SA3C3	
SA3C5	Included in FR4C4	Minor reword
SA3C6	SA3C4	
SA3C7	Included in FR1C4	
SA3C8	Included in LM2C3	
SA4		
SA4C1	Included in LM1C2	
SA4C2	SA4C1	
SA4C3	SA4C2	Minor reword
SA4C4	Included in FR1C4	Minor reword
SA4C5	Included in LM2C3	
SA5		
SA5C1	Included in LM1C1 / C2	

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Next review date 2021

Page 27 of 29

SA5C2	SA5C1	
SA5C3	SA5C2	
SA5C4	SA5C3	
SA5C5	SA5C4	Minor reword
SA5C6	Included in LM2C3	
SA6		
SA6C1	Included in LM1C1 / C2	
SA6C2	SA6C1	
SA6C3	SA6C2	Minor reword
SA6C4	SA6C3	
SA6C5	SA6C4	Minor reword
SA6C6	SA6C4	Minor reword
SA6C7	Included in LM2C3	
SA7		
SA7C1	Included in LM1C1 / C2	
SA7C2	Included in SA7C1	Reword
SA7C3	SA7C2	
SA7C4	SA7C3	
SA7C5	Included in LM2C3	
SA8		
SA8C1	Included in LM1C1 / C2	Minor reword
SA8C2	Included in SA7C1	Minor reword
SA8C3	SA7C7	
SA8C4	Included in LM2C3	
SA9		
SA9C1	Included in LM1C1 / C2	
SA9C2	SA7C1	
SA9C3	SA7C4	
SA9C4	SA7C5	Minor reword
SA9C5	SA7C6	
SA9C6	Included in FR1C4	Minor reword
SA9C7	Included in LM2C3	
SA10		
SA10C1	Included in LM1C2	
SA10C2	Included in SA1C1	
SA10C3	Included in SA1C1	
SA10C4	Included in SA1C2	
SA10C5	Included in FR3C1	
SA10C6	Included in SA1C4	
SA10C7	Included in SA1C5	
SA10C8	Included in SA1C6	
SA10C9	Included in FR4C4 / FR4C5	Reword
SA10C10	Included in FR1C4	
SA10C11	Included in CL5C3	Minor reword
SA10C12	Included in LM1C9	Minor reword

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SA10C13	Included in SA6C2	Minor reword
SA10C14	Included in SA6C4	Minor reword
SA10C15	SA10C7	Minor reword
SA10C16	Included in LM2C3	