



ISAS 1

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The Conduct of UKAS assessment for the Imaging Services Accreditation Scheme (ISAS)

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Changes since last edition

Reference to V2.1 of the ISAS standard has been removed from section 1.1.1.

Glossary

Accreditation

ISO/IEC 17000 defines accreditation as ‘third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks’. Conformity assessment is defined as a ‘demonstration that specified requirements relating to a product, process, system, person or body are fulfilled’.

For ISAS, accreditation is independent verification of an organisation’s competence to provide diagnostic imaging services such that the users have confidence in the outcomes.

Accreditation Managers manage and take responsibility for accreditation decisions for a particular accreditation scheme or programme.

Assessment Managers (AMs) have overall responsibility for managing the relationship with Customers and the assessment process. The AM is responsible for ensuring UKAS retains a full record of the assessment and accreditation activities for each of their allocated Customers.

Extension to scope is defined as a request from the imaging service to add to their accredited activities and/or add to their service delivery locations. This will require additional assessment by UKAS to determine competence of the service to conduct those new activities and or to work at those new locations.

Lead Assessors take responsibility for leading and coordinating assessment teams. The ISAS lead assessor will normally be the UKAS Assessment Manager.

Nonconformities are when the imaging service is not able to provide evidence to demonstrate that it meets the requirements set out within the ISAS Standard. These will be raised as findings that will require corrective/mandatory improvement actions.

Outcome measures or performance measures are used to monitor regularly (targets and frequency are set by the service) progress with service processes, clinical outcomes and patient/staff/user satisfaction. They are also effective tools for demonstrating good management controls and a commitment to continuous quality improvements. Outcome measures are most commonly expressed as ‘percentage of’ and ‘rates of change’. Imaging services are expected to report relevant and meaningful outcome measures for each standard statement.

1. Introduction

1.1 Scope and Purpose

- 1.1.1 This publication gives general guidance on UKAS assessments and accreditation for organisations that provide diagnostic imaging services. The scope for diagnostic imaging services, herein called imaging services, to be covered by UKAS accreditation is defined within the ISAS Standard.

1.1.2 The procedures described within this document apply to all the stages of the UKAS accreditation process, including:

- Application – Stage 1
- Contract review – Stage 2
- Pre-assessment – Stage 3
 - First pre-assessment
 - Second pre-assessment for staged pathway only
- Conduct of formal assessment – Stage 4
 - Examination of documents
 - On-site assessment visit
- Provisional decision – Stage 5
- Manage improvement actions – Stage 6
- Final decision and Grant of Accreditation – Stage 7
- Surveillance and re-assessment – Stage 8

1.1.3 The document covers all the stages listed above as well as extensions to scope and assessments conducted for other purposes such as complaint resolution.

1.1.4 UKAS will assess and accredit the imaging service to carry out specific imaging activities in accordance with the requirements defined within the ISAS Standard and will subsequently ensure, by monitoring, that the same level of performance is maintained or improved.

1.1.5 A copy of the ISAS Standard and details about how to apply for UKAS accreditation together with UKAS' terms and conditions for the scheme is publicly available via the ISAS website www.isas-uk.org or in hard copy. Imaging services that are UKAS customers are also able to access the ISAS Standard via the UKAS web-based assessment tool provided on application.

Note: It is recognised that some ISAS standard statements and/or criteria may not be applicable to particular imaging services. UKAS will expect to be provided with clear justification for why those standard statements and/or criteria are considered not to be applicable.

1.2 Responsibilities in Accreditation

1.2.1. It is the responsibility of the imaging service to define the full range of imaging activities to be assessed and to give the UKAS assessment team access to information that demonstrates competence for those activities.

1.2.2 The responsibility for **meeting** the ISAS Standard rests with the imaging service. It is also the service's responsibility to satisfy itself that the service being provided is fit-for-

purpose and legally compliant, i.e. in compliance with relevant applicable national legislative and regulatory requirements

- 1.2.3 The role of the UKAS assessment team is to **verify** that the imaging service is fully compliant with the requirements set out in the ISAS Standard.
- 1.2.4 To make a recommendation on accreditation the UKAS assessment team must see evidence of organisational competence and conformity with all relevant ISAS standard statements. There may be a number of different ways in which an imaging service can demonstrate its competence and conformity. UKAS assessment teams will consider alternative approaches and innovative methods that the imaging service has implemented to ensure good quality outcomes for users.
- 1.2.5 UKAS accreditation will be granted to imaging services who have demonstrated that they fully meet the requirements set out in the ISAS Standard.

1.3 Background to the ISAS Standard

- 1.3.1 The ISAS Standard has been specifically developed for UK imaging services. It is licensed for use by UKAS from Diagnostic Imaging Accreditation Ltd, DIAL, a jointly-owned entity established by The College of Radiographers (CoR) and The Royal College of Radiologists (RCR).
- 1.3.2 The ISAS Standard describes the requirements to be met by an imaging service wishing to gain accreditation and is designed to be applicable to all imaging modalities, including tele-radiology and radionuclide imaging. The standard does not cover asymptomatic breast screening and non-imaging aspects of Nuclear Medicine including radio pharmacy.
- 1.3.2 A Joint Accreditation Scheme Committee, JASC, established by DIAL is responsible for maintenance of the ISAS Standard which is revised on a five-yearly basis. The underlying standard guidance material which includes Commentaries, reference lists and example evidence, monitoring outcome measure lists are reviewed and updated on an annual basis.

2. UKAS Assessment Tools and Techniques

- 2.1 A range of assessment tools and techniques is available. During the early stages of the accreditation process UKAS will discuss with the imaging service the various 'tools and techniques' that are available for assessment and will determine in conjunction with the service the most effective and efficient assessment approach to enable verification of compliance.

- 2.2 Prior to application, UKAS, working with the CoR and RCR, will make pre-application engagement and preparation information and support available to imaging services who are considering accreditation.
- 2.3 Prospective UKAS customers may wish to attend a UKAS preparation for accreditation training workshop to gain information to support early preparations against the ISAS Standard. Imaging services are also encouraged to undertake gap analyses and to project plan using bespoke Traffic Light Ready self-check tools.
- 2.4 On receipt of an application for accreditation, UKAS will make an online web-based assessment tool available to the imaging service. The necessary detailed application information should be submitted by the service to UKAS via this online tool.
- 2.5 During the assessment stages, imaging services can upload and submit documentary information for examination by the UKAS assessment team and also receive feedback from the team directly via the online tool.
- 2.6 If an imaging service wishes to provide documents and information for examination during their assessment via a means other than the online tool, UKAS would be willing to consider reasonable alternatives.
- 2.7 A pre-assessment stage is necessary as part of the initial assessment process for all new applicants and for an application for extension to scope in a new imaging modality. The purpose of pre-assessment is to help the service and UKAS determine and prepare for the next steps. Pre-assessment is not a formal assessment and will not provide any recommendation on accreditation. Imaging services that opt for the staged assessment pathway will have the option of a second pre-assessment.
- 2.8 For formal assessment, a UKAS assessment team must establish the imaging service's competence as defined within the ISAS Standard by ensuring the proper evaluation of competence in all areas and activities for which the imaging service seeks or holds accreditation. This normally involves:
- Examination of objective evidence of service management intentions;
 - Examination of interfaces and controls between multiple locations performing all or part of the accredited work;
 - Examination of records including databases, reports of mock inspections or other forms of external quality assurance activities;
 - Examination of objective evidence of monitoring and a commitment to continuous quality improvements;
 - Interviews/discussions with management, patients, referrers and staff.
- 2.9 A significant amount of objective evidence is acceptable in the form of documents and records. Examination of this documentary information would normally be undertaken off-site prior to an on-site assessment of other evidence that is not amenable to being documented.

- 2.10 This prior remote examination of documents is the first part of the formal assessment process for initial assessment, extension to scope and reassessment. The outcome of the examination supports preparation for the on-site assessment visit. Where necessary, it also provides an opportunity for the service to continue to develop. The recommendation on accreditation would not normally be based solely on the outcome of the examination of documents. The exception is the year one and year three annual surveillance assessments.
- 2.11 The on-site assessment is conducted on premises where the imaging service operates. This type of assessment normally involves:
- Direct observations of staff performing technical duties;
 - Review of the suitability of service delivery, accommodation and environment;
 - Review of records and documentation, in particular those documents that are not amenable to being submitted electronically and/or are confidential;
 - Interviews and discussions with key personnel/staff, patients and other users.
- 2.12 For large multi-site organisations an additional on-site assessment may be conducted at the head office location to allow the assessment team to properly examine interfaces and controls between multiple locations performing all or part of the work to be accredited.
- 2.13 The outcome both of the examination of documents and of the on-site assessment are recorded on the UKAS Assessment Report Form. Any corrective/mandatory or recommended actions arising from these assessments are recorded on the UKAS Improvement Action Form. Imaging services that choose to submit documentary information via the UKAS web-based assessment tool will receive additional separate feedback within the tool.
- 2.14 On occasions, UKAS may conduct unannounced visits as part of, or in place of, planned surveillance/reassessment activity or where an extra visit is required e.g. as part of a complaint investigation. Any unannounced visit will first be justified by the Accreditation Manager.

3. The Accreditation Process

The accreditation process for imaging services is detailed in the sections below.

3.1 Application – Stage 1

3.1.1 UKAS will accept an application from:

- A new imaging service not holding any existing accreditation from UKAS;

- An existing accredited imaging service wishing to extend the scope* of their accreditation to add new activities, and/or modalities, and/or service delivery locations;
 - A new legal entity applying for the transfer of accreditation from an existing UKAS accredited imaging service.
- 3.1.2 Application packs are accessible from the ISAS website www.isas-uk.org. A senior management representative must complete, sign and return all relevant application information directly to the UKAS Applications Unit. All applications for initial assessment should be accompanied by the specified UKAS application fee minus any agreed discount or by a purchase order.
- 3.1.3 In submitting an application for initial accreditation, the senior management team is making a formal commitment to achieve accreditation within a maximum timescales of 24 months. UKAS expects all applications for initial assessment to be accompanied by a plan that confirms timescales and the availability of resources to support the project.
- 3.1.4 Imaging services making an application for initial accreditation can choose from two different assessment pathways, direct or staged. The service's preferred assessment approach (direct or staged pathway) must be clearly indicated on the application form.
- 3.1.5 Those services that opt for the staged initial assessment pathway will have their , 'status' publicly acknowledged at three different attainment levels as they proceed along the pathway provided that they formally waive the right to anonymity that is normally afforded to all UKAS customers. This must be indicated clearly on the application form.
- 3.1.6 The status of imaging services that have opted for the direct assessment pathway will not be published until final accreditation is granted. Imaging services applying for the direct pathway may choose to switch to the staged pathway should this subsequently prove to be a more suitable approach. Appendix A gives an overview of both the direct and staged pathways.
- 3.1.7 All new applications are vetted by a UKAS Accreditation Manager who will also conduct a preliminary review of the application documents in order to determine how to proceed with the application.
- 3.1.8 The application will then be passed to the UKAS Finance Department for legal identity and credit checking. Where concerns are raised regarding the financial viability of the imaging service, UKAS may proceed with the requested assessment activity but may require payment in advance.
- 3.1.9 On acceptance of an application, a letter of acknowledgment will be forwarded to the imaging service confirming that UKAS has accepted and is processing the application. This acknowledgment letter would normally provide the name and contact details of the appointed UKAS Assessment Manager together with unique login details to the ISAS web-based assessment tool. The tool includes user guidance within it.

- 3.1.10 The UKAS Assessment Manager would normally make contact with the named imaging service representative within 10 working days of receipt of application to make introductions, clarify information requirements for both the contract review and the first pre-assessment stages and to arrange for a joint contract review and pre-assessment meeting at UKAS' head office. For an extra charge, imaging services may request that this joint meeting be hosted at a different location.
- 3.1.11 The imaging service is expected to upload the required contract review information into the 'About You' section of the ISAS web-based assessment tool and to make the information available to the UKAS assessment manager at least 10 working days prior to the date of the scheduled joint meeting.

3.2 Contract Review – Stage 2

- 3.2.1 The purpose of the contract review is for UKAS to determine the resource needed to complete the assessment both in terms of technical expertise and time. The contract review normally covers the resource needed to assess the scope concerned for the entire four-year accreditation cycle. Additional contract reviews will be necessary for unplanned one-off event such as further examination of documents and or an extra on-site assessment visit.
- 3.2.2 A contract review is conducted for:
- All new applications for initial accreditation;
 - All applications for extension to scope;
 - Any additional assessment event;
 - Re-assessment application.
- 3.2.3 The contract review is normally undertaken by the Assessment Manager and is then authorised by the Accreditation Manager. A previously authorised contract may be reviewed, and revised and re-authorised, as necessary, where a change to the contract is identified. For example:
- The scope of the applicant changes;
 - The accredited scope requires amendment;
 - The previously identified team members are changed;
 - UKAS identify a need to change the allocated effort.
- 3.2.4 For the contract review the Assessment Manager takes into consideration all information provided by and agreed with the service such as:
- UKAS Terms and Conditions of Business for ISAS Customers
 - The tools and techniques to be used to conduct the assessment including such things as:

- Number of service delivery locations to be visited;
- Number of technical areas/modalities to be assessed and by whom;
- The agreed arrangements for examination of documents.
- The skills mix and size of the assessment team needed to ensure competence within the team to assess the entire scope and to conduct the on-site assessments visits over a maximum consecutive two-day period;
- Potential conflicts of interest between the proposed team and the imaging service in order to ensure the independence and impartiality of the assessment team and that team members are acceptable to the imaging service;
- Factors such as past performance/assessment outcome and accreditation history, in particular how the imaging service responded to findings raised;
- For extensions to scope and re-assessments, the impact on the existing four-year Forward Plan (see section 3.3 below).

3.2.5 On completion of the initial contract review the Assessment Manager will calculate and issue the imaging service with a formal written quotation for accreditation fees together with an acceptance letter for signing and return to UKAS. The Assessment Manager will normally begin to identify the Assessment Team at this point although no assessment work can be progressed until the service has confirmed acceptance of the quotation.

3.2.6 During the contract review for re-assessment, the composition of the assessment team will be reviewed. The technical assessors on the team may be changed to ensure that the effectiveness of the assessment is maintained. In order to ensure continuity, a phasing process may be employed to achieve this change in personnel.

3.3 Forward Plan

3.3.1 A Forward Plan covering the entire four-year assessment cycle is created for every imaging service. The purpose of the Forward Plan is for UKAS to document and record the plans to conduct assessments that ensure proper evaluation of the competence of the imaging service over the 4-year cycle. The plan relates directly to the information recorded during the contract review.

3.3.2 The Forward Plan should provide sufficient detail to demonstrate that UKAS has identified and assigned a competent team to conduct the assessment activities and that the team has adequate effort assigned to them in order to conduct the planned activities over the four-year cycle. As a minimum the Assessment Manager will consider the following when producing the Forward Plan:

- The assessment activities that will need to be assessed at initial assessment and each surveillance and re-assessment to ensure coverage of the scope of accreditation over the 4-year cycle (See ' Assessment Coverage Requirements' at Annex 1);
- Whether specific imaging staff need to be witnessed and or interviewed;
- For multi-location organisations; which locations are to be visited;

- The management system activities to be assessed at initial assessment and during surveillance and reassessment;
- The technical competencies required (including the identity of the proposed assessor with that competence) to assess the specific activities.

3.3.3 For new applicants a Forward Plan is normally drafted at the initial contract review and is revised as appropriate ready to be submitted with the provisional decision.

3.3.4 As assessments occasionally do not cover the planned scope, the Assessment Manager in conjunction with the assessment team and the imaging service as necessary will consider the impact of the outcome of the assessment on the future planned activities and revise the Forward Plan where necessary.

3.4 The Assessment Team

3.4.1 At a minimum the assessment team would comprise a UKAS **Assessment Manager** also acting as the lead assessor plus at least one lay Assessor and one peer/technical Assessor. The total size and skill mix of the team will vary as necessary to provide the expertise to adequately assess the competence of the imaging service.

3.4.2 All communication between UKAS and the imaging service being assessed should be via the UKAS Assessment Manager and or the UKAS Customer Support Team. Imaging services should not make direct contact with individual members of their assessment team.

3.4.3 All members of the assessment team, including UKAS staff acting as assessors, are fully trained for their role by UKAS and are required to satisfy UKAS criteria in terms of their expertise, experience and continuing competence. All assessors are also required to sign a UKAS Confidentiality Agreement, Code of Conduct, a Volunteer Agreement/contract and to formally declare any conflict of interests.

3.4.4 A UKAS Assessment Manager takes responsibility for appointing the assessment team. Each assessor is chosen on the understanding he /she is impartial and independent of the imaging service concerned. UKAS will provide the imaging service with details of each team member (name and current place of work) when the team has been assembled.

3.4.5 The imaging service may object to the appointment of an assessor by providing justifiable reasons for non-acceptance. In such cases, UKAS will endeavour to offer an alternative. In the event that a suitable alternative cannot be identified, or that the grounds for objection are considered to be unreasonable, UKAS reserves the right to appoint the assessors(s) originally selected.

- 3.4.6 Assessment Managers are permanent employees of UKAS with continuing responsibility for the assessment of a group of customers. Their primary responsibility is to ensure consistent, impartial and timely assessments. In addition to leading the assessment team, the Assessment Manager may also participate in assessments as a peer/technical assessor. Assessment Managers are also available to provide advice on technical and quality matters related to the process of accreditation to both the imaging service and assessment team.
- 3.4.7 Assessment Managers are supported by an office based Customer Support Team of Customer Liaison Officers and Customer Account Co-ordinators. The Assessment Manager and Customer Liaison Team are the main point of contact with UKAS. Together these UKAS staffs ensure that both the Service and assessors are kept informed of progress and the next steps in the assessment and accreditation process.
- 3.4.9 **Peer Assessors**, also called technical assessors, are recruited from the ranks of practising consultant radiologists and senior radiographers, sonographers, medical physicists, medical physics technicians and radiography managers. Peer/technical assessors must satisfy pre-defined Technical Competence Criteria to be accepted for training. Recently retired individuals from the above professional groups who are already authorised as assessors may continue in their role subject to them remaining on the relevant professional register.
- 3.4.10 **Lay Assessors** are drawn from the general public and would normally have experience as a patient representative, or have an interest in healthcare delivery.

3.5 Pre-Assessment – Stage 3

3.5.1 First Pre-assessment (Direct and Staged Pathways)

- 3.5.1.1 The nature and conduct of the first pre-assessment is the same for imaging services that opt for the direct or staged assessment pathway.
- 3.5.1.2 The pre-assessment incorporates a significant element of self-assessment by the imaging service as confirmed by the senior team and limited sampling by the UKAS Assessment Manager.
- 3.5.1.3 Senior management is expected to provide UKAS with information:
- To confirm that a self-assessment against the Standard has been undertaken and that policies and procedures/processes have been defined for the majority of standard statements;

Note: the above can be achieved in a variety of ways, for example, a service could fully address approximately 75% of the standard statements or partially

address all of the standard statements. In addition, there is no expectation that a separate policy will be provided for every standard statement.

- To demonstrate examples of defined policies and procedures/processes;
- To confirm that an annual performance monitoring plan with specific outcome measures have been defined for the majority of the standard statements;
- To demonstrate examples of defined outcome measures.

3.5.1.4 The pre-assessment is undertaken by the UKAS Assessment Manager based on an examination of documentary information provided by the service and further verification during the joint contract review and pre-assessment meeting.

3.5.1.5 The Assessment Manager will assess the content (as opposed to the number) of policies and procedures and outcome measures to make a determination about how to proceed with the process.

3.5.1.6 The outcome of the pre-assessment is recorded and fed back to the service using a UKAS Pre-assessment Report Form. Services that have opted for the staged assessment pathway receive a formal *Attainment level 1* acknowledgement from UKAS on satisfactory completion of the first pre-assessment.

3.5.1.7 All new applicants are expected to complete the first pre-assessment stage within three months of submitting an application to UKAS.

3.5.2 Second Pre-assessment (Staged Pathway only)

3.5.2.1 A second pre-assessment is available for applicants for initial assessment that opt for the staged assessment pathway.

3.5.2.2 The second pre-assessment incorporates a further significant element of self-assessment by the imaging service as confirmed by the senior team and limited sampling by the UKAS assessment manager and a peer assessor.

3.5.2.3 Senior management is expected to provide UKAS with information:

- To confirm that policies and procedures/processes have been defined for all standard statements;
- To confirm that an annual performance monitoring plan identifying outcome measures for all standard statements have been defined;

- To demonstrate defined policies, procedures/processes plus implementation and monitoring for all applicable standard statements within the Safety domain.

3.5.2.4 The UKAS Assessment Manager and a peer/technical assessor will assess the information to make a determination about how to proceed with the process.

3.5.2.5 The outcome of the second pre-assessment is recorded and fed back to the service using a UKAS Pre-assessment Report Form. On satisfactory completion of this second pre-assessment the service will receive a formal *Attainment level 2* acknowledgement from UKAS.

3.5.2.6 The second pre-assessment should normally take place three to six months after the first pre-assessment.

3.6 Conduct of Formal Assessments – Stage 4

3.6.1 Examination of Documents

3.6.1.1 This is a necessary part of the formal assessment for all applicants for initial assessments, surveillance assessments, extensions to scope and re-assessments. The outcome of this assessment together with the outcome of the on-site assessment visit, where appropriate, will determine the recommendation for accreditation.

3.6.1.2 The imaging service is expected to provide the assessment team with access to comprehensive, convincing and unambiguous information to support its claim of conformity with the ISAS Standard. Incomplete and/or ambiguous information is likely to result in requests for further information from the assessment team resulting in possible delays and may incur extra charges.

3.6.1.3 All documentary information must be made available to the assessment team by the date previously agreed with the Assessment Manager. In the case of initial assessments and re-assessments this is normally set for approximately ten to twelve weeks prior to the agreed date for the on-site assessment. For surveillance assessments this is normally set for four to six weeks prior to the date of the on site assessment.

3.6.1.4 A list of ways by which conformity with each criterion might be demonstrated using documentary information is available to imaging services as *Show Examples* and *Show Key Outcomes* within the web-based assessment tool. These lists are neither exhaustive nor prescriptive.

3.6.1.5 The entire assessment team will undertake a thorough examination of all documents and records supplied by the imaging service in order to evaluate its systems as documented, and for conformity within the ISAS Standard. Documents and records for each standard statement will be evaluated by a minimum of two assessors.

3.6.1.6 During initial assessments, extension to scope and re-assessments, the assessment team will use the outcome of the examination of documents to make a determination about how to proceed with the on-site assessment. This is communicated to the service within a Visit Plan (see 3.6.2 below).

3.6.1.7 For initial accreditation, and re-assessment, any findings and the recommendation for grant of accreditation is determined by the outcome of both the examination of documents and the on-site assessment. However, during surveillance years one and three, findings and the recommendation for maintenance of accreditation may be determined by the outcome of an examination of documents only.

3.6.1.8 Following grant of accreditation the imaging service must update documentary information as necessary and make them available for examination annually.

3.6.1.9 Imaging services that have opted for the staged pathway will receive their formal Attainment Level 3 acknowledgement from UKAS at the same time as the visit plan is issued.

3.6.2 The Visit Plan

3.6.2.1 The visit plan is prepared and issued to the imaging service by the Assessment Manager at least four weeks prior to the date of the on-site assessment visit.

3.6.2.2 The visit plan will detail the activities and locations to be assessed by each assessor during the on-site assessment. Where necessary, the plan will also identify particular individuals to be interviewed and may include a request for an informal lunch with referrers/professional users of the service and, if appropriate, patients.

3.6.2.3 The imaging service will be given the opportunity to raise queries with the visit plan prior to the on-site assessment visit.

3.6.3 On-site Assessment

For initial assessments and re-assessments the on-site visit period is normally two consecutive days. For surveillance assessments the visit period is normally only one day but may be more depending on the number of activities and/or locations to be assessed.

3.6.4 Prior to Arrival

The UKAS Assessment Manager will generate all necessary related forms and ensure that the assessment team has all required documentation and is properly briefed.

3.6.5 Opening / Introductory Meeting

3.6.5.1 The opening/introductory meeting is chaired by the Assessment Manager / Lead Assessor in order to:

- Make introductions;
- Explain the purpose and process;
- Clarify and confirm the assessment criteria and scope under assessment;
- Confirm the agreed visit plan to include availability of individuals for interview, travel between locations;
- Confirm facilities required by the team to include a private meeting room, internet access and lockers;
- Confirm the service's normal working hours within which the assessment team will endeavour to work;
- Confirm escort arrangements for each assessor to be available throughout the visit;
- Confirm reporting arrangements for the final meeting;
- Confirm confidentiality undertaking.

3.6.5.2 Before the meeting is closed the imaging service is given an opportunity to disclose any known non-conformities and to ask relevant questions.

3.6.5.3 The on-site assessment will formally commence on completion of the opening/introductory meeting.

3.6.6 On-site Assessment

3.6.6.1 The Assessment Manager/Lead assessor will manage the assessment team to ensure that all relevant activities, locations and people are assessed in accordance with the visit plan and will provide support and advice, as necessary.

3.6.6.2 Each assessor will conduct his/her assessment in order to gather objective evidence that the imaging service is competent and conforms to the ISAS Standard for the scope of accreditation applied for/held.

3.6.6.3 The focus of the assessment will normally be activities undertaken during the normal working day. However, it may be necessary to assess some activities out-of-hours and this would normally be evident from the visit plan.

3.6.6.4 In certain circumstances the assessors may request the imaging service to provide a demonstration of activities that are not on-going during the visit period. This would normally be evident from the visit plan.

3.6.6.5 During the visit, the plan may be revised to enable the team to review the impact of significant issues raised by members of the assessment team.

3.6.7 Analysis, Recording of Findings and Reporting

3.6.7.1 The assessment team will analyse all relevant information and evidence gathered during their review of documents and records and on the on-site assessment visit.

3.6.7.2 Assessors will maintain appropriate records of activities they have assessed and any interviews with individuals. These records provide the objective evidence on which the recommendation of the grant of accreditation to UKAS will be based.

3.6.7.3 Identified findings are discussed and agreed with the imaging service at the earliest opportunity during the assessment. Findings are recorded on the UKAS Improvement Action Report Form, IAR, and classified as Mandatory (nonconformity) or Recommended (opportunity for improvement).

Note: It is appropriate for the accompanying imaging service's representative to propose improvement actions to address recordable findings as they arise, subject to the agreement of the imaging service's management. This may not apply to all findings, for example those with significant financial and/or human resource implications. Consequently, some improvement actions may need to be confirmed at the final meeting.

3.6.7.4 Any proposed improvement/corrective action to address a finding must be formulated by the imaging service. However, it is permissible for the assessor to provide guidance on sources of information that may help in addressing the findings and to populate the IAR with the agreed action.

3.6.8 Private Meeting

3.6.8.1 The private meeting is normally set for the end of the on-site assessment and before the final meeting. At this meeting the assessment team will discuss the outcome of the assessment to agree overall conformity with ISAS Standard, the recommendation to be put forward by the team and to draft the Assessment Report and Improvement Action Report.

3.6.8.2 Judgments about conformity will be made using the following principles:

- Availability of evidence to support the imaging service's claim of conformity for the full scope of its services put forward for assessment;
- Adequacy of the information provided;
- Demonstrated knowledge and understanding of the management and staff of their systems and processes and how this demonstrated conformity with the standard statements and criteria;
- Validity of the outcome measures identified and fulfilled by the service;
- Feedback received from users and how these are acted upon by the service.

- 3.6.8.3 The assessment team will co-ordinate, confirm and categorise their assessment findings and any previously agreed improvement actions (corrective actions) before transferring them onto the electronic UKAS Improvement Action Report form.
- 3.6.8.4 Mandatory improvement actions are nonconformities with the ISAS Standard and must be addressed by the imaging service, normally via documentary evidence, before accreditation can be granted.
- 3.6.8.5 In exceptional circumstances, the assessment team may determine that it is necessary for a follow-up on-site assessment visit to verify the actions taken to address nonconformity. In such instances, the assessment will be directed specifically to the confirmation of clearance of the improvement action(s) concerned. This is an additional assessment and will be charged separately.
- 3.6.8.6 For initial assessments and re-assessments, the service can be given up to three months to address mandatory findings. During surveillance years this is one month only.
- 3.6.8.7 Recommended/developmental improvement actions are normally associated with issues where, in the opinion of the assessment team, there is potential for nonconformities to arise and/or opportunities for improvements to service delivery.
- 3.6.8.8 The Assessment Team chaired by the Assessment Manager will determine overall conformity with the ISAS Standard, taking account of all of the findings and conclusions of the entire assessment rather than considering each standard statement in isolation.
- 3.6.8.9 The Accreditation Report will clearly indicate the scope of the service that has been satisfactorily assessed and will highlight areas of good practice and areas for further improvement and will outline the recommendation from the assessment team to UKAS.
- 3.6.8.10 In circumstances where there are no findings that require mandatory improvement actions, the recommendation will be that accreditation be granted to the imaging service without delay.
- 3.6.8.11 Where there are findings that require mandatory improvement actions, the recommendation will be that accreditation is offered to the imaging service subject to confirmation from the assessment team that they had seen information of satisfactory clearance of all mandatory improvement actions within the agreed timescale.
- 3.6.8.12 If there are one or more activities where the extent of nonconformity is not acceptable, a recommendation may be deferred until the imaging service can provide further documents for examination by the assessment team or until a repeat on-site assessment has been carried out. Alternatively, a recommendation that the imaging service be offered a reduced scope of accreditation may be made. The options and implications of any deferment will be discussed fully with the imaging service management.

3.6.8.13 Where the number and or seriousness of the findings are such that, in the opinion of the assessment team, the imaging service has failed to demonstrate competence and conformity with the requirements of the ISAS Standard, the recommendation will be that accreditation should not be offered. In such cases the imaging service will be advised to discuss its future options with UKAS.

3.6.9 Final Meeting

3.6.9.1 The on-site assessment normally concludes with a final meeting involving the assessment team and senior management from the imaging service and/or the parent organisation, as appropriate.

3.6.9.2 The purpose of the final meeting is for the assessment team to present their findings and recommendation(s) to senior management from the imaging service. Imaging service representatives attending this meeting should have the necessary authority to deal with the range of findings and any improvement actions that may arise.

3.6.9.3 The final meeting is chaired by the Assessment Manager/Lead Assessor who will commence by acknowledging the possibility that specific non-conformity with ISAS Standard may exist within the imaging service that has not been found by the assessment team.

3.6.9.4 Each assessor will summarise his or her findings and agreed improvement actions.

3.6.9.5 The Assessment Manager will then:

- Agree any outstanding improvement actions with senior management;
- Agree the date for receipt of information to address findings that have been categorised as requiring mandatory improvement actions. A period of up to three months is normally acceptable during initial assessment;
- Discuss the implications of any recommended/developmental actions;
- Present the summary Assessment Report and would normally advise the imaging service to expect to receive a final copy of the report and IAR within five working days.

3.6.9.6 The assessment team will formally thank the imaging service for their assistance and then give the service an opportunity to discuss the assessment and to ask questions.

3.7 Provisional Decision – Stage 5

3.7.1 As soon as possible after the assessment the Assessment Manager/Lead Assessor will for all assessment activities (with the exception of surveillance assessments) prepare and submit the assessment information for a provisional decision.

3.7.2 The assessment information must contain a full explanation of the decision being requested and full justification of the recommendation.

- 3.7.3 The provisional decision request is normally submitted prior to receipt of improvement action evidence. However, where no improvement actions requiring evidence have been raised by the assessment team the provisional decision is normally requested at the same time as the final decision.
- 3.7.4 An authorised decision maker, normally a UKAS Accreditation Manager or UKAS Specialist Support Assessment Manager who is independent of the assessment team, will take responsibility for making the accreditation decision.
- 3.7.5 The decision-maker will review the information to determine:
- Whether the assessment had adequate coverage and depth and was conducted in accordance with the contract review;
 - Whether the conclusions of the assessment team support the recommendation;
 - Whether there are adequate records retained to support the recommendation;
 - Clarity of recommendation;
 - Whether UKAS processes have been followed;
 - Where the assessment has not been conducted in accordance with the contract review the decision maker will need to determine that the assessment has been conducted by a competent and appropriate team;
 - The suitability of the draft schedule of accreditation;
 - That the four-year Forward Plan has been reviewed and updated as appropriate.
- 3.7.6 In some circumstances, further information may be requested from the assessment team and/or imaging service for UKAS to proceed with a decision.
- 3.7.7 Feedback will be provided to the assessment team where any inconsistency of judgment is identified.
- 3.7.8 Where the assessment team was unable to recommend accreditation for the full scope of activities originally requested by the imaging service, UKAS will confirm the recommendation/decision, in writing, within one month of the on-site assessment.
- 3.7.9 Where a recommendation to grant accreditation is agreed by UKAS, the imaging service will receive a Provisional Offer letter which will also include a draft Schedule of Accreditation as soon as the decision has been made.
- 3.7.10 The Provisional Offer and draft Schedule of Accreditation must be accepted by the imaging service before accreditation can be granted. This provisional offer stage normally takes place while any mandatory improvement actions are being addressed by the imaging service.

3.8 Manage Improvement Actions – Stage 6

- 3.8.1 The imaging service is required to respond to any mandatory improvement actions recorded on the Improvement Action Report Form within the agreed timescales. The service will be provided with an Improvement Action Summary Form to summarise details of the evidence provided together with the evidence itself and/or to confirm completion of improvement actions for those not requiring evidence.
- 3.8.2 UKAS will provide imaging services with confirmation of receipt of evidence. At the same time the received evidence will be distributed to the assessment team for review.
- 3.8.3 Each assessor is expected to complete an Improvement Action Assessor Feedback Form within 10 working days detailing whether the mandatory finding is satisfactorily cleared or requesting further evidence as appropriate.
- 3.8.4 The UKAS Assessment Manager will collate all returns from the assessors requesting further evidence if required.
- 3.8.5 Where the further evidence fails to address the mandatory finding for the second time the Assessment Manager will consider the impact of the actions remaining outstanding and the risk to the accreditation of the imaging service. The Assessment Manager will consider whether an on-site visit is required to review the actions and or whether a sanction should be imposed.
- 3.8.6 Where an additional visit is conducted to determine the implementation of mandatory improvement actions, the Assessment Manager will provide a separate Assessment Report to confirm whether the findings from the assessment to which it relates have been cleared.
- 3.8.7 All Mandatory Findings raised during the assessment must be satisfactorily addressed before the Final Decision is requested or, in the case of surveillance assessments, maintenance of accreditation is confirmed.
- 3.8.8. UKAS monitors the timely submission of evidence by imaging services. Where timeframes are not met, the Customer Liaison Team will contact the service and/or assessor in question to determine the reason for the delay. Depending on the outcome of the discussion the Assessment Manager may extend the timeframe for submission.
- 3.8.9 Where a service and/or assessor continue to miss timeframes for submissions of evidence or improvement action review reports, the Customer Liaison Team will escalate the issue.

3.9 Final Decision & Grant of Accreditation – Stage 7

- 3.9.1 The Assessment Manager will provide the decision-maker with all necessary information to confirm that the assessment team are satisfied that all mandatory improvement actions have been satisfactorily addressed by the imaging service.
- 3.9.2 The decision-maker will review the information provided to determine:
- Whether the imaging service meets the requirements for the ISAS Standard and the scope being offered in the Schedule of Accreditation;
 - Whether all mandatory actions raised at the assessment have been satisfactorily addressed in accordance with UKAS requirements;
 - Where Schedule changes are required that these are appropriate;
 - Whether the offer of accreditation has been accepted by the imaging service;
 - Whether all relevant records of effort changes have been updated;
 - Whether there is a Forward Plan that covers the scope being offered.
- 3.9.3 Once satisfied the decision-maker will complete the final decision to grant accreditation by issuing an initial grant of accreditation letter and signed Certificate of Accreditation to the imaging service. The grant letter will provide a web link to where the imaging service's Schedule of Accreditation is published. During surveillance years the Assessment Manager would normally arrange for renewal of accreditation and will advise the service of continuation of accreditation direct.
- 3.9.4 Initial grant of accreditation will be for a period of four years, subject to satisfactory annual surveillance assessments by the assessment team.
- 3.9.5 UKAS has undertaken to issue an embargoed notice of Grant of Accreditation decisions to the Joint Accreditation Service Committee (JASC) at least three to five days prior to the final decision. This short notice period provides the Colleges an opportunity to flag any apparent inconsistency with the aims of the ISAS and its underlying principles without causing undue delay to the publication of the decision.
- 3.9.6 It is UKAS policy to make public the full scope of each imaging service's accreditation. This is formally expressed in a Schedule of Accreditation. This schedule along with the Accreditation Certificate with the unique customer number provides an accurate and unambiguous description of the range of imaging activities and service delivery locations that have been assessed and accredited by UKAS.
- 3.9.7 Schedules for all accredited imaging services are published on the UKAS website www.ukas.com with additional access link via the ISAS website www.isas-uk.org
- 3.9.8 Accredited imaging services are provided with information on how to access and use the UKAS Medical accreditation symbol and the ISAS Symbol.
- 3.9.9 Information on the use of the UKAS Medical symbol can be found in the UKAS terms and conditions of business for ISAS document at www.isas-uk.org with more detailed

information set out in “URN 11/673”, a current copy of which is available from UKAS or is accessible on the web-site at www.ukas.com under “Information Centre/Publications List”. Users of the Medical symbol must comply with the current conditions set out in this document.

3.10 Surveillance and Reassessment – Stage 8

- 3.10.1 Following the grant of accreditation, the imaging service is expected to participate in an annual surveillance assessment programme in order to maintain accreditation. The purpose of surveillance is to monitor the continued conformity of the accredited imaging service with the ISAS Standard and to review effectiveness of implementation of improvements actions.
- 3.10.2 The first surveillance assessment is normally be scheduled for approximately six to eight months following the grant of accreditation. This surveillance date/profile date will then apply annually thereafter. The focus of the first surveillance will normally be assessment of updated policies, processes and relevant audits.
- 3.10.3 The imaging service will be advised of the details of its surveillance assessment programme at grant of accreditation. Surveillance assessment is normally undertaken by the entire assessment team as set out in the Forward Plan. The standard programme includes examination of documents in each year with a mid-term on-site surveillance assessment on-site visit by the Assessment Manager and at least one peer assessor (See Appendix A).
- 3.10.4 In the fourth year the imaging service will undergo re-assessment by a refreshed assessment team. Following successful completion of the re-assessment a renewal letter is issued and accreditation extended for a further four years again subject to satisfactory annual surveillance.
- 3.10.5 If the on-site surveillance assessment or re-assessment identifies significant changes to the imaging service and/or its accredited activities, these will be recorded by the Assessment Manager and/or assessment team.
- 3.10.6 Following the on-site surveillance assessment or re-assessment the imaging service must supply information to demonstrate how it has addressed any resultant mandatory improvement actions within one month.
- 3.10.7 Mandatory improvement actions that are not satisfactorily addressed within the specified time period could lead to the suspension of all or part of the scope of accreditation.
- 3.10.8 UKAS reserves the right to request an earlier submission of documents for examination and/or to make an unannounced on-site assessment to an accredited imaging service at any time to ensure that the service continues to conform to the requirements of the ISAS Standard.

- 3.10.9 The UKAS Assessment Manager will monitor accreditation expiry dates and will notify the imaging service that their accreditation is due to expire at least three months before this happens.
- 3.10.10 Exceptionally, the expiry date may be extended up to a maximum of six months with the authorisation of the Accreditation Manager.
- 3.10.11 It is the responsibility of the imaging service to notify UKAS of all significant changes to its status and or operation, e.g. change of name and legal identity, change of head office and activities, and service delivery location. The UKAS Assessment Manager will ensure that any new activities and service delivery locations are assessed at the earliest opportunity to confirm continued compliance with the requirements. Where the head office or legal identity has changed the imaging service must sign a new version of the UKAS Agreement, including the supplements, detailing the new information. UKAS will issue a new Accreditation Certificate where necessary, e.g. where the name of the organisation has changed.

4. Extension / Reduction of Scope

- 4.1 Extension/reduction to scope application information is available from the ISAS website www.isas-uk.org. All extension to scope applications should be forwarded to the UKAS applications Unit.
- 4.2 On receipt of the extension/reduction to scope application UKAS will consult with the assessment team who will determine the extent of the assessment necessary to grant the extension/reduction to scope. In some instances both examination of documents and on-site assessment may be required.
- 4.3 Where possible UKAS will endeavour to combine the extension to scope assessment with the imaging service's next scheduled surveillance assessment to minimise costs.
- 4.4 It may be necessary to review the size and skill mix of the assessment team in order to assess effectively the extension/reduction to scope application.
- 4.5 Following assessment, findings may be raised by the assessment team. All mandatory improvement actions must be satisfactorily addressed by the imaging service within three months of the assessment for grant of the requested extension/reduction to scope to be granted.

5. Suspension, Withdrawal and Resignation

5.1 Suspension

An imaging service's accreditation can be suspended by UKAS. This will normally be due to serious concerns in relation to the imaging service's conformity with the ISAS

Standard or as a result of repeated failure to satisfactorily address mandatory improvement actions and/or failure to comply with the UKAS Agreement e.g. at an assessment or following an investigation of a complaint.

5.2 Withdrawal and Resignation

- 5.2.1 The imaging service can choose to withdraw from the accreditation process at any time before the Grant of Accreditation.
- 5.2.2 Additionally, UKAS may request that the imaging service withdraw from the accreditation process if it consistently fails to progress within agreed timescales.
- 5.2.3 Termination of the contract with UKAS subsequent to the Grant of Accreditation is regarded as resignation of accreditation.
- 5.2.4 Any imaging service wishing to obtain accreditation following a withdrawal or resignation will be required to commence the process with a new application.

6. Complaints and Appeals

A description of the UKAS complaints and appeals processes is available on the UKAS website at www.ukas.com

6.1 Complaints

- 6.1.1 Any concerns/complaints regarding an accredited imaging service's ability to comply with accreditation requirements will be investigated by UKAS. Complainants should in the first instance address their complaint to the accredited imaging service. Where the investigation and/or response from the accredited imaging service is not considered acceptable, the complainant may then direct their complaint to UKAS. Details of the complaint should be provided ideally in documentary form.
- 6.1.2 If any applicant or accredited imaging service has cause for complaint about any aspect of the UKAS assessment or accreditation service, they may formally register a complaint in writing to UKAS.
- 6.1.3 On receipt of the written complaint, UKAS will send an acknowledgment within five working days and will provide the name of the investigating officer as well as the date when UKAS will next make contact.
- 6.1.4 All complaints are fully investigated by UKAS and the complainant will be kept informed of progress. On completion of the investigation, the complainant will be informed of the outcome of the investigation and any actions taken.

6.2 Appeals

- 6.2.1 An applicant or accredited imaging service may formally request UKAS to reconsider any adverse decision UKAS has made related to its desired accreditation status by submitting an appeal in writing to UKAS' Accreditation Director within one month of receipt of notification of the decision.
- 6.2.2 Any decision that is the subject of an appeal will remain in force until the appeal process has been completed.

7. Accreditation Fees

- 7.1 Accreditation fees are charged for the assessment effort required to verify compliance to grant and maintain accreditation.
- 7.2 A copy of UKAS terms and conditions of business for ISAS which details the fee structure is available from the ISAS website www.isas-uk.org

Annex 1

Assessment Coverage Requirements

Initial Assessments

Imaging Service	Coverage
Locations visited	<p>Imaging services with less than 10 locations</p> <p>The main service delivery location and all locations where accredited work will take place i.e. satellite sites, normally up to a maximum of six locations. Sampling is allowed where there is more than six and less than 10 locations depending on their nature. Any locations not visited during initial assessment will be visited prior to or during the mid-term surveillance assessment. This will be reflected in the 4 year Forward Plan.</p> <p>Imaging services with 10 or more locations</p> <p>The main service delivery location or central head office location and a minimum of 10 locations covering, as far as possible, the breadth of the different types of locations where the accredited work will take place e.g. mobile units, GP clinics, hospital sites. The 4 year Forward Plan will specify arrangements for annual sampling of locations ranging from 40 per cent to 100 per cent during the first four years of accreditation. Sample size to be visited is determined by the Assessment Team based on the outcome of previous assessments.</p>
Business, technical and patient management system	All system requirements of the ISAS standard.
Clinical activities	Range of imaging examinations and or procedures and reports from each modality to ensure key techniques, methods and competences are assessed.
Staff	Representative sample of key personnel for each examination and/or procedure and/or modality and for reporting and generally at all locations. The sample should provide assurance of competence in all examinations and/ or procedures and in reporting.

Re-assessments

Imaging Service	Coverage
Frequency	1 st Cycle 3.5 years, on-going 4 years
Locations visited	<p>Imaging services with less than 10 locations</p> <p>As for initial assessment.</p> <p>Imaging services with 10 or more locations</p> <p>As for initial assessment. Locations not visited in previous initial and surveillance assessment should be prioritised for inclusion in sample. Consideration should be given to including previously visited locations unless justified not to based on performance and risk assessment.</p>
Business, technical and patient management system	All system requirements of the ISAS standard.
Clinical activities	Range of imaging examinations and or procedures and reports from each modality to ensure key techniques, methods and competences are assessed.
Staff	Representative sample of key personnel for each examination and/or procedure and/or modality and for reporting and generally at all locations. The sample should provide assurance of competence in all examinations and/ or procedures and in reporting.

Appendix A – Schematic of 4-year cycle

