



# 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

This document has been amended to reflect the revised initial assessment process based on learning from the Early Implementer sites. Note paragraphs 3.3, 6.0, 6.1.1, 6.1.2, 6.1.3, 6.1.4 and 6.3.

## Glossary

**Accreditation** is independent assessment that identifies the competence of an organisation to carry out specific tasks/activities.

**Accreditation Managers** manages and takes responsibility for accreditation decisions for a particular technical section or area.

**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.

**Lead Assessors** take responsibility for leading and coordinating assessment teams. The ISAS lead assessor will normally be the UKAS Assessment Manager who has satisfied defined competency requirements.

**Nonconformities** will arise 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 leading to mandatory improvement actions.

**Outcome measures** are performance measures that seek to quantify the level of change a service has or needs to achieve to reach desired outcomes. Outcome measures can be used to regularly monitor (frequency is set by the service) progress with relevant clinical processes/activities, clinical outcomes and or patient/staff/user reported outcomes. Outcome measures are most commonly expressed as 'percentage of' and 'rates of change'. ISAS customers are required to provide evidence to demonstrate performance against one outcome measure for each standard statement.

# 1 INTRODUCTION

## 1.1 Scope and Purpose

- 1.1.1 This publication gives general guidance on the conduct of UKAS assessments for services that provide diagnostic imaging and interventional radiology services, herein called imaging services.
- 1.1.2 UKAS will assess and accredit the imaging service in accordance with the Imaging Services Accreditation Scheme Standard (ISAS Standard) and other specified UKAS and ISAS requirements. The ISAS Standard includes 31 standard statements each supported by a list of criteria.
- 1.1.3 UKAS assessment and accreditation is conducted on the understanding that it is the responsibility of the imaging service to comply with relevant national legislative and regulatory health and safety requirements.

## 1.2 Background to the ISAS

Accreditation is based on the principle of external assessment of an organisation or service against a known standard. The ISAS Standard has been specifically developed for UK imaging services and 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). The ISAS Standard describes the requirements to be met by the imaging service and is designed to be applicable to all imaging modalities except nuclear medicine and non-symptomatic breast screening.

# 2 ASSESSMENT AND ACCREDITATION

- 2.1 UKAS will assess and accredit the imaging service to carry out specified imaging activities to defined performance levels, as defined within the ISAS Standard and other specified UKAS and ISAS requirements, and will subsequently ensure, by monitoring, that the requirements are maintained.
- 2.2 The imaging service must provide evidence of conformity with both the technical and quality criteria requirements of the ISAS Standard by providing documentary information via a web-based assessment tool. This imaging service is able to access the assessment function of the tool on application for accreditation.
- 2.3 The web-based assessment tool is primarily a mechanism for the imaging service to provide UKAS with appropriate information about how it meets, and will continue to meet, the ISAS Standard. The tool can also be used by the imaging service for the purpose of self-assessment and to track its own performance.
- 2.4 On receipt of a completed web-based assessment, a UKAS appointed Assessment Team will review the documentary information provided by the imaging service. Once they are satisfied that the information provided offers adequate evidence of the imaging service's competence and conformity with the ISAS Standard, an on site assessment visit will be conducted.

- 2.5 The on site assessment visit normally takes place over two consecutive days and will be conducted at the imaging service's primary service delivery site and, where appropriate, at other service delivery sites.
- 2.6 It is the responsibility of the imaging service to provide the Assessment Team with comprehensive and relevant information that covers the full breadth of its imaging activities. The responsibility for *meeting* the ISAS Standard rests with the imaging service; the role of the assessment team is to *verify* that they do.
- 2.7 Some standard statements and criteria may not be applicable to the imaging service. Assessors will expect to be provided with clear reasons why those standard statements and or criteria are considered not to be applicable.
- 2.8 Information obtained about an imaging service before, during, or after assessment, including the fact that the particular imaging service has applied for accreditation, or that an application for accreditation has been deferred or rejected, is treated as strictly confidential by UKAS and DIAL.
- 2.9 The procedures described in this publication apply to the use and evaluation of the web-based assessment tool, the conduct of on site assessment visits and to any visits after accreditation has been granted for the purposes of surveillance, reassessment, extension of scope, resolution of complaints or other purposes.

### 3 ASSESSMENT TEAM

A UKAS appointed Assessment Manager will take responsibility for managing the assessment of each imaging service. The size and skill mix of the Assessment Team will vary dependent on the imaging service's size, range of imaging activities performed and geographical locations to be assessed. UKAS uses both lay and peer/technical assessors to perform assessments. All assessors, including UKAS staff acting as assessors, are fully trained for their role and must satisfy UKAS criteria in terms of their technical expertise and experience. As a minimum, the team will include an Assessment Manager (also acting as the Lead Assessor), one Lay Assessor and one Peer/Technical Assessor.

#### 3.1 Assessment Managers

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. Assessment Managers will appoint and lead Assessment Teams and may also participate in assessments as an assessor. They will also be available to provide advice on technical and quality matters related to the process of accreditation to both the imaging service and Assessment Team. 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 Support Team are the main point of contact and are responsible for ensuring that imaging services and assessors are kept informed of progress and the next steps in the assessment and accreditation process.

### 3.2 Peer/Technical Assessors

UKAS will assign a minimum of one peer/technical assessor to each Assessment Team. Peer/technical assessors are recruited from the ranks of practising consultant radiologists, senior radiographers, medical physicists, radiology nurses and radiography managers. Recently retired individuals from these professional groups may also be recruited subject to them remaining on their relevant professional registers. Peer/technical assessors must meet defined Technical Competence Criteria and undertake the required UKAS training prior to being authorised to assess. They are also required to sign a UKAS Confidentiality Agreement, Code of Conduct and a Volunteer Agreement. Peer/technical assessors have no direct contact with the imaging service being assessed, except during the on site assessment visit.

### 3.3 Lay Assessors

UKAS will assign a minimum of one lay assessor to each Assessment Team. Lay assessors are drawn from the general public and will have experience as patient representatives, such as members of a recognised local, regional or national patient group, or will have an interest in healthcare delivery. Lay assessors must undertake the required UKAS training prior to being authorised to assess. They are also required to sign a UKAS Confidentiality Agreement, Code of Conduct and a UKAS contract. Lay assessors have no direct contact with the imaging service being assessed, except during the on site assessment visit.

## 4.0 ASSESSMENT APPROACH

- 4.1 Assessment teams will seek to establish that management and staff in the imaging service have a good understanding of the ISAS Standard and that they are able to demonstrate that the service meets all relevant standard statements and criteria.
- 4.2 Assessment teams will use a number of tools and techniques to gather evidence that the imaging service meets all relevant standard statements and criteria such as:
- Direct observations providing objective evidence of implementation of service's policies, procedures and processes.
  - Examination of interfaces (control, internal auditing and management review) between any multiple locations performing all or part of the accredited work.
  - Examination of records and contracts, interviews with management and staff, witnessing activities, results of participation in proficiency testing, mock inspections, internal and external peer review or other forms of external quality assurance activity.
- 4.3 Assessors must see **evidence** that organisational competence and conformity with all relevant standard statements and criteria is being achieved by the imaging service. There may be a number of different ways in which a service can demonstrate its competence and conformity with each standard statement and each criterion. Assessors will consider alternative approaches and innovative methods that the service has implemented to ensure good quality outcomes for users of the service.

## 5.0 DETERMINING CONFORMITY WITH THE ISAS STANDARD

- 5.1 Initially at least two members of the assessment team, one of whom must be the UKAS Assessment Manager, will make an individual judgment on each standard statement and criterion, before agreeing with regard to the imaging service's conformity with the standard statement.
- 5.2 Judgments about conformity will be made using the following principles:
- The availability of evidence to support the service's claim of conformity for the full scope of its services put forward for assessment
  - The adequacy of the information provided
  - The knowledge and understanding of the management and staff of the service of their systems and processes and how these demonstrate conformity with the standard statements and criteria
  - The validity of the outcome measures identified and fulfilled by the service
  - The feedback received by the service from users of the service
- 5.3 A holistic approach will be used by the Assessment Manager/Lead Assessor in determining overall conformity with the ISAS Standard, taking account of all of the findings and conclusions of the assessment team rather than considering each standard statement in isolation.
- 5.4 All assessment reports and associated information will be reviewed and evaluated by a UKAS decision-maker (this would normally be the Accreditation Manager), who is independent of the Assessment Team, to determine the adequacy of assessment and in particular for:
- Coverage of the scope of the imaging service's activities
  - Extent of the 'sampling' carried out
  - Breadth and depth of the assessment
  - Validity and consistency of findings and conclusions
  - Clarity of recommendations
- 5.5 Feedback will be provided to assessors where any inconsistency of judgment is identified.

## 6.0 ASSESSMENT AND ACCREDITATION PROCESS

Appendix A gives an overview of the accreditation cycle. There is an initial assessment period that includes pre-assessment review of a single standard statement by the Assessment Manager leading to formal review of the web-based assessment and on site assessment visit by the full Assessment Team. To maintain accreditation the imaging service is then required to update the information within the web-based assessment tool and submit the information annually for review by the Assessment Team. A mid-cycle on site surveillance visit will normally be undertaken by the Assessment Manager and if necessary other members of the Assessment Team. Renewal of accreditation involving a web-based assessment and an on site assessment visit will normally take place during Year 4.

## 6.1 Processing of applications

- 6.1.1 Any imaging service that registers an interest in becoming accredited will be provided with a login to the '*traffic light ready*' function of the web-based assessment tool and encouraged to attend a free, non-obligatory ISAS Preparatory Workshop. Those services wishing to make an application can access the relevant ISAS application documents directly from the ISAS website [www.isas-uk.org](http://www.isas-uk.org). The imaging service must complete, sign and return all application documents together with the specified non-refundable application fee to UKAS to initiate the formal application process.
- 6.1.2 On receipt of the fully completed application documents, the UKAS Customer Support Team will issue the imaging service with a login to the '*assessment function*' of the web-based assessment tool. The imaging service will then be instructed to complete and submit detailed information about itself and the scope of the imaging activities it wishes to have assessed in the 'About You' section of the tool. At the same time, the imaging service will also be asked to evidence a single standard statement and to submit this together with the 'About You' section to UKAS at its earliest convenience (normally within 28 days). During this time UKAS will assign an Assessment Manager who will contact the service to arrange a date for a Planning meeting.
- 6.1.3 At the Planning Meeting the Assessment Manager will discuss the previously submitted 'About You' information and the evidenced single standard statement with appropriate imaging service representatives.
- 6.1.4 The purpose of the Planning Meeting is to ensure that UKAS:
- Fully understands the customer's requirements;
  - Has made a realistic estimation of the size and complexity of the imaging service and the range of its imaging activities;
  - Can provide the imaging service with necessary assessment resource, in terms of numbers of lay and peer/technical assessors required to best support the imaging service through the assessment and beyond;
  - Has provided the imaging service with a good understanding of their role and responsibilities within the accreditation process and UKAS' expectations in this regard;
  - Supported the imaging service to make a realistic estimation of the resources it will need to put into place to progress to Grant of Accreditation in a timely manner.
- 6.1.5 Following the Planning Meeting, the Assessment Manager will undertake a detailed review of the 'About You' information to develop a quotation for the full assessment and accreditation fee in a process called *Contract Review*. This quotation will be issued to the imaging service together with a request for a purchase order for the first annual instalment of fees and also a letter of acceptance. The Service will be required to give a submission date for the web-based assessment at this stage.
- 6.1.6 Assessment and accreditation fees are normally payable in annual instalments. The first instalment of fees will be charged by issue of a formal UKAS invoice and should be paid within 30 days of the invoice date.
- 6.1.7 The Assessment Manager will then proceed to select the Assessment Team and to make provisional arrangements for review of the web-based assessment and the on site assessment visit.

- 6.1.8 Peer/technical and lay assessors are chosen for the Assessment Team on the understanding that they are impartial and independent of the imaging service concerned. The imaging service may object to the appointment of specific assessor(s) 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 the grounds for objection are considered to be unreasonable, UKAS reserves the right to appoint the assessors(s) originally selected.

## 6.2 Initial assessment

The first period of assessment following a new application is called *Initial Assessment*. It includes pre-assessment, a web-based assessment and an on site assessment visit. The objective of assessment is to establish by external review that the imaging service is competent and able to conform to the requirements set out in the ISAS Standard. The assessment will include:

- Thorough review of documentary information supplied as evidence;
- On site assessment of the imaging service at normal work to include witnessing and/or auditing of routine processes;
- Interview with imaging staff and or management to verify the information provided within the web-based assessment tool.

## 6.3 Pre-assessment

The imaging service must fully evidence one standard statement and submit it to UKAS for review by the Assessment Manager prior to the date of the Planning Meeting. Feedback from this review will be provided to the imaging service within the web-based assessment tool and will also inform some of the discussions at the Planning Meeting. The advice provided should help the imaging service to develop a clear understanding about the work it needs to do to prepare for formal assessment.

## 6.4 Web-based assessment

- 6.4.1 The imaging service must complete the ISAS web-based assessment and submit it to UKAS for review by the Assessment Team. The imaging service is expected to detail evidence for its claim by attaching relevant documentary information for each standard statement and criterion within the tool. A list of ways in which conformity with each criterion might be demonstrated is suggested within the web-based assessment tool as *Indicative Evidence*, but the list is neither exhaustive nor prescriptive. The imaging service is expected to cite whatever it considers to be the most appropriate information. It is essential that the imaging service responds to all relevant questions as comprehensively and unambiguously as possible. Incomplete or ambiguous information is likely to result in delay during review by the Assessment Team.
- 6.4.2 Guidance for the imaging service on how to demonstrate regular monitoring of performance for each standard statement is available within the web-based assessment tool as *Outcome Measures*. This list is neither exhaustive nor prescriptive. The imaging service is required to identify, set its own performance target for, and regularly monitor at least one outcome measure for each standard statement. The Assessment Team will expect the imaging service to justify the chosen outcome measure and the associated monitoring arrangement. This would normally be on the basis that the chosen outcome measure is aligned to a national performance measure, or has been agreed with local stakeholders, or is an accepted measure of good practice. The Assessment Team will encourage imaging services to continuously improve on current performance measures.

- 6.4.4 Once the completed web-based assessment has been received, the Assessment Team will review and make comment on the evidence supplied. The Assessment Team will then agree:
- Whether or not to proceed with the provisional plans for the on site assessment visit to the imaging service based on the preliminary review of documentary evidence provided.
  - Any further information required from the imaging service prior to or during the on-site visit.

*Note:* Repeated request for further information from the imaging service by the Assessment Team could cause delays in assessment and unplanned additional assessment effort for the Assessment Team. In such circumstances, particularly where it results in a re-scheduling of the previously planned on site assessment visit, the imaging service may be asked to pay a supplementary fee.

- 6.4.5 Once the Assessment Team is satisfied with the information provided via the web-based assessment tool, the Assessment Manager will contact the imaging service to confirm arrangements for the on site assessment visit.
- 6.4.6 The reviewed web-based assessment will then be returned to the imaging service with feedback from the Assessment Team. Any findings for specific improvement actions arising at that time will be forwarded separately via an Initial Web-based Assessment Report.

## **6.5 The on site assessment visit plan**

- 6.5.1 The Assessment Team will prepare a detailed visit plan indicating the imaging activities and locations to be assessed by each assessor during the on site assessment visit. The plan will specify particular individuals to be interviewed and specific imaging activities to be assessed and will also give approximate timings for each activity. All imaging services will be given the opportunity to raise queries with the visit plan.
- 6.5.2 UKAS will aim to distribute copies of the visit plan to the imaging service at least four weeks prior to the date of the on site assessment visit.

## **6.6 The on site assessment visit**

- 6.6.1 The on site assessment visit will normally focus on imaging activities undertaken during the imaging service's normal working day. However, the Assessment Team reserves the right to assess the imaging services' out-of-hours provision. It may also be necessary, on occasion, for the Assessment Team to ask the imaging service to provide a demonstration of some activities that are not ongoing during the on site assessment visit period in order to assess the range of imaging activities for which accreditation is being sought. This will normally be evident from the visit plan.
- 6.6.2 The on site visit begins with an Introductory Meeting between the Assessment Team and representatives of the imaging service. Each assessor will then begin their assessments as identified in the visit plan. The main focus for the assessors will be to assess service activities included within the scope at application and, in particular, those areas not amenable to being evidenced within the web-based assessment, and to interview specific members of staff. The Assessment Manager/Lead assessor will manage the Assessment Team to ensure that the relevant activities, sites and people are assessed and will provide support and advice as necessary. A member of the imaging service's staff

nominated by the management should normally be available to accompany each assessor at all times during the on site assessment visit.

- 6.6.3 The on site assessment visit normally ends with a Final Meeting involving the Assessment Team and senior management from the imaging service and the parent organisation, where appropriate. UKAS would normally expect those attending this meeting to have the necessary authority to deal with the range of findings and any improvement actions that may arise. At this meeting each assessor will present a summary of the areas examined/assessed, their findings and necessary improvement actions.

## 6.7 The introductory meeting

This short meeting is held on arrival on the first day of the on site visit to enable the Assessment Team and the imaging service's representatives to become acquainted. This meeting will normally be chaired by the Assessment Manager /Lead Assessor and will cover, but not necessarily in this order:

- An explanation of the purpose of the on site assessment visit, the functions of the assessors and confirmation that the imaging service's staff understand the procedure;
- Confirmation of the range of imaging activities covered by the imaging service's application and how this would be defined in the imaging service's Schedule of Accreditation;
- Confirmation of the visit plan and of the programme for the assessment of activities and any interviews;
- Confirmation that a representative of the imaging service has been assigned to accompany each assessor, and an explanation of the role of this representative in the assessment;
- Confirmation that the imaging service will receive a detailed report from the on site assessment visit through the web based assessment tool plus a Summary and Improvement Action Report, including an executive summary of the assessment, the recommendation to UKAS and all findings, within five working days;
- Confirmation that all findings will be treated in confidence;
- Arrangements for providing an office and any services needed by the assessors including access to internet facilities;
- Confirmation of the imaging service's normal working hours, luncheon breaks etc, within which UKAS will endeavour to work;
- An opportunity for the imaging service's management and staff to ask relevant questions.

## 6.8 Recording assessment findings

- 6.8.1 The imaging service will receive an Initial Web Based Assessment Report prior to the on site assessment visit.
- 6.8.2 During the on site assessment visit the Assessment Team will record a summary of discussion/interviews with imaging service representatives and any findings before the assessor leaves the area under assessment.
- 6.8.3 A summary of assessment findings, including nonconformities and agreed improvement actions will be reported back to the imaging service through an Executive Summary and Recommendation on Accreditation Report and an Improvement Action Report. Any

improvement actions previously identified within the Initial Web-based Assessment Report will be included in this report.

- 6.8.4 Findings can be categorised as either Mandatory Improvement Actions or Developmental Actions dependent on their nature. Mandatory Improvement Actions are nonconformities and must be addressed by the imaging service before accreditation can be granted. Developmental Actions identify the potential for nonconformity with the ISAS Standard and or opportunities for improvement. The Assessment Team will agree with the imaging service how Developmental Actions can to be addressed and the timescale for implementation.
- 6.8.5 Individual assessors will record which activities they have witnessed or assessed and a brief summary of any interviews/discussions with the imaging service's representatives. These records provide the objective evidence on which the recommendation on the grant of accreditation by UKAS will be based.

*Note:* It is appropriate for the accompanying imaging service's representative (or relevant section manager, for example) to propose actions that could address recordable findings as they arise, subject to the agreement of the imaging service's management. This may not apply to all findings, depending (for example) on the financial or resource implications, and some actions may need to be confirmed at the Final Meeting.

- 6.8.6 When the assessors have completed their assessment they will hold a private meeting to discuss and co-ordinate their findings and to draft the Executive Summary and Recommendation on Accreditation and Improvement Action Reports. The imaging service must provide a private room for this meeting.
- 6.8.7 The Improvement Action Report will clearly state the findings made during the on site assessment visit and, where appropriate, how the imaging service has agreed to address them. The Executive Summary and Recommendation on Accreditation report will indicate areas of good practice and may highlight areas for further improvement. The outcome of the entire assessment will be included in this report.

## 6.9 The Final Meeting

- 6.9.1 The final meeting is where the Assessment Team will present their findings to the imaging service's senior management/representatives.
- 6.9.2 The Assessment Manager /Lead Assessor will normally chair the Final Meeting. The following items will be addressed:
- A reminder of the purpose of the on site assessment visit and reiteration of confidentiality;
  - The possibility that non-conformity with ISAS Standard may exist within the imaging service that has not been found by the Assessment Team;
  - Where appropriate, each assessor will summarise his or her findings, and similarly, the Assessment Manager will present his or her own findings as an individual assessor;
  - Brief explanation of improvement actions;
  - A date by which mandatory improvement actions are to be implemented will be agreed in consultation with the imaging service. The timescale will depend on the nature of the improvement action. A period of up to three months is normally acceptable for mandatory improvement actions during initial assessment. The implications of any developmental actions will also be discussed;

- That the imaging service will receive the formal report and improvement actions via the web-based assessment tool;
- The imaging service will have an opportunity to discuss the assessment and to ask questions.

6.9.3 The Assessment Manager /Lead Assessor will inform the imaging service of the recommendation that will be made to UKAS.

## **7.0 FACTORS AFFECTING THE RECOMMENDATION**

7.1 The Assessment Team must make a recommendation based on its assessment of the imaging service's competence and conformity with the ISAS Standard.

7.2 Where there are no findings that require mandatory improvement actions, the Assessment Manager /Lead Assessor, acting on behalf of the Assessment Team will normally recommend that accreditation be granted to the imaging service without delay.

7.3 Where there are findings that require mandatory improvement actions, the recommendation will normally be that accreditation is offered to the imaging service subject to satisfactory clearance of all mandatory improvement actions within an agreed timescale, normally three months.

7.4 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 information for review through the web-based assessment tool, or until a repeat on site assessment visit 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 will be discussed fully with the service management.

7.5 Where the number and seriousness of the findings are such that, in the opinion of the Assessment Team, the imaging service has failed to demonstrate its 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.

## **8.0 POST ASSESSMENT**

8.1 As soon as possible after the assessment the Assessment Manager /Lead Assessor will submit the recommendation to UKAS for a decision on accreditation.

8.2 Further information may be requested from the imaging service and/or the Assessment Team in order for UKAS to proceed with a decision.

8.3 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. This Provisional Offer and draft Schedule need to 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.

8.4 The imaging service must provide UKAS with documentary evidence to demonstrate the actions it has taken to address all mandatory improvement actions within the specified timescale. The evidence will be reviewed by the Assessment Team who will report their findings to the Assessment Manager.

- 8.5 In exceptional circumstances, it may be necessary for a follow-up on site assessment visit to be made to the imaging service to verify the actions taken. Assessment at such a visit will be directed specifically to the confirmation of clearance of the improvement action(s) concerned.
- 8.6 Once all members of the Assessment Team are satisfied that all improvement actions have been satisfactorily addressed, the final decision on accreditation will be made.
- 8.7 Where the Assessment Team is unable to recommend accreditation for the full scope originally requested by the imaging service, UKAS will confirm the recommendation/decision in writing within one month of the on site assessment visit.
- 8.8 The Accreditation Manager, as the authorised decision-maker, takes responsibility for making the accreditation decision. During the first two years of operation of ISAS, the Joint Accreditation Service Committee (JASC) on behalf of the DIAL will review all decisions to assess consistency with the aims of the ISAS, and its underlying principles.

## **9.0 GRANT OF ACCREDITATION**

A Grant of Accreditation letter is sent to the imaging service together with an Accreditation Certificate and a reference to the link where the imaging service's Schedule of Accreditation can be found on the ISAS website [www.isas-uk.org](http://www.isas-uk.org).

## **10.0 SCHEDULE OF ACCREDITATION**

- 10.1 It is UKAS policy to define the scope of each imaging service's accreditation which is formally expressed in a Schedule of Accreditation. This, along with the Accreditation Certificate, provides an accurate and unambiguous description of the range of imaging activities that have been assessed and accredited by UKAS and will include the geographical locations covered by the scope.
- 10.2 Schedules for all accredited imaging services are published on the UKAS and ISAS website.

## **11.0 SURVEILLANCE AND REASSESSMENT**

- 11.1 Following the grant of accreditation, the imaging service is required to participate in a regular assessment programme in order to maintain accreditation. Year 1 assessment will normally comprise of the review of the updated web-based assessment by the Assessment Team. The first submission date for the updated web-based assessment during Year 1 of the accreditation cycle will normally be timetabled for six months, but no more than eight months, after the accreditation grant date. This date will apply annually thereafter. Year 2 assessment will normally consist of review of the updated web-based assessment and an on site surveillance visit. The full Assessment Team will participate in the review of the annual web-based assessment, as necessary. However, it is anticipated that the on site surveillance visit will normally only involve the Assessment Manager. Year 3 assessment comprises of a review of the further updated web-based assessment. Year 4 is a full reassessment requiring a review of the web-based assessment and an on site assessment visit by the full Assessment Team.
- 11.2 Where subsequent on site assessment visits are conducted, the purpose is to determine whether or not the imaging service continues to fulfil the requirements for accreditation. The general approach described previously in this publication will apply to all such visits. In addition the Assessment Manager will need to establish that all significant changes in

- the imaging service's status or operation have been notified to UKAS and will verify the effectiveness of previous improvement actions.
- 11.3 If an on site surveillance or reassessment visit identifies that there have been significant changes to the imaging service and its activities, these will be recorded by the Assessment Manager and/or Assessment Team.
- 11.4 Following an on site surveillance or reassessment visit the imaging service must supply evidence that it has addressed any mandatory improvement actions within one month. If mandatory improvement actions are not satisfactorily addressed within the specified time period it may be necessary to consider the suspension of all or part of the scope of accreditation.
- 11.5 At the conclusion of an on site reassessment visit, the Assessment Manager /Lead Assessor will, as with an initial assessment, make a recommendation to UKAS based on the team's findings. The Assessment Manager will arrange for renewal of accreditation based on the Assessment Team's findings.
- 11.6 Suspension or withdrawal of accreditation will be recommended to UKAS where the number and seriousness of the findings are such that, in the opinion of the Assessment Team, the imaging service can no longer meet the requirements of the ISAS Standard.
- 11.7 UKAS reserves the right to request an earlier submission of the web-based assessment and/or to make an unannounced on site assessment visit to an accredited imaging service at any time to ensure that the service continues to conform to the requirements of the ISAS Standard.

## **12.0 EXTENSION / REDUCTION OF SCHEDULE OF ACCREDITATION**

- 12.1 When an imaging service applies for an extension/reduction to its existing scope of accreditation UKAS will consult with relevant members of the Assessment Team. The team will consider whether the extension/reduction to scope can be recommended based on information provided within the web-based assessment tool only or if an on site assessment visit is necessary.
- 12.2 The Assessment Manager may arrange for an earlier than scheduled submission of the web-based assessment and/or extra on site visit. He or she may suggest combining the extension to scope assessment with the scheduled annual submission of the web-based assessment and/or on site assessment visit. For planning purposes and to minimise costs it is helpful if the application for extension of scope is submitted to UKAS at least three months before the next scheduled web-based assessment submission date.
- 12.3 The size and skill mix of the Assessment Team will be reviewed by UKAS to ensure that the Assessment Team is able to deal effectively with the extension/reduction to scope.
- 12.4 Where mandatory improvement actions are raised in relation to an extension/reduction to the existing scope of accreditation, it is expected that these will normally be addressed within three months of the on site visit. If the improvement actions are not addressed within three months, the extension of scope may not be granted.

## 13.0 SUSPENSIONS AND WITHDRAWALS

### 13.1 Suspension

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

### 13.2 Withdrawal and resignation of accreditation

13.2.1 The imaging service can choose to withdraw at any time before the Grant of Accreditation. If the imaging service chooses to terminate its contract with UKAS subsequent to the Grant of Accreditation, this will be regarded as resignation of accreditation.

13.2.2 Any imaging service wishing to obtain accreditation following a withdrawal or resignation will be required to commence the process with a new application.

## 14.0 COMPLAINTS AND APPEALS

A description of the UKAS complaints and appeals process is available on the UKAS website at [www.ukas.com](http://www.ukas.com)

### 14.1 Complaints

14.1.1 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.

14.1.2 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.

14.1.3 On receipt of the written complaint, UKAS will send an acknowledgment within 5 working days and will provide the name of the investigating officer as well as the date when UKAS will next make contact.

14.1.4 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.

### 14.2 Appeals

14.2.1 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.

14.2.2 Any decision that is the subject of an appeal will remain in force until the appeal process has been completed.

### Appendix A

