



# IQIPS 1

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## **The Conduct of UKAS Assessments for the Improving Quality in Physiology Services (IQIPS) Accreditation Scheme**

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## Changes since last edition

Removal of self-assessment (SAIT) with Royal College of Physicians.

Pre-assessment now optional.

## 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 IQIPS, accreditation is independent verification of the physiology service provider's competence to provide services such that the users have confidence in the outcomes.

**UKAS Accreditation Managers** (ACMs) or Section Heads manage and take responsibility for accreditation decisions for a particular accreditation scheme or programme.

**UKAS 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 physiology service provider to add to their accredited activities and/or add to their service delivery locations and/or add another physiology discipline. This will require additional assessment by UKAS to determine competence of the service provider to conduct those new activities and/or to work at those new locations and/or deliver those new disciplines.

**UKAS Lead Assessors** take responsibility for leading and coordinating assessment teams. The IQIPS lead assessor will normally be the UKAS Assessment Manager or an experienced, trained and authorised UKAS Technical Assessor.

**Nonconformities** are when the physiology service is not able to provide evidence to demonstrate that it meets the requirements set out within the IQIPS Standard and/or fails to fulfil its own requirements. These will be raised as Findings requiring corrective/mandatory improvement actions within a specified timescale.

Quality Management System is a collection of processes focused on consistently meeting user needs and requirements. It is expressed as the organisational structure, policies, procedures, processes and resources needed to implement quality management.

Physiology Service Management is the identified management team for a single discipline or for a number of disciplines within the same organisation.

## 1. Introduction

### 1.1 Scope and Purpose

- 1.1.1 This publication gives general guidance on UKAS assessments and accreditation for organisations that provide physiology services. Accreditation is against the IQIPS Standard and covers activities undertaken by any of the following eight physiology discipline:
- Audiology
  - Cardiac physiology
  - Gastro-intestinal physiology
  - Neurophysiology
  - Respiratory and Sleep physiology
  - Ophthalmic and Vision Science
  - Vascular Science
  - Urodynamics
- 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 (optional)
  - Conduct of formal assessments – 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 physiology service to carry out specific physiology activities in accordance with the requirements defined within the IQIPS Standard and will subsequently ensure, by monitoring, that the same level of performance is maintained or improved.
- 1.1.5 A copy of the IQIPS Standard and details about how to apply for UKAS accreditation together with UKAS' terms and conditions for the scheme is publicly available on the UKAS website [www.ukas.com](http://www.ukas.com) or can be requested as hardcopies from [IQIPScustomerservice@ukas.com](mailto:IQIPScustomerservice@ukas.com)
- 1.1.6 Physiology services that are UKAS customers are also able to access the IQIPS Standard through the UKAS online system provided on application.

Note: It is recognised that some IQIPS standard statements and/or criteria may not be applicable to particular physiology 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 physiology service management (hereafter called service management) to define the full range of physiology disciplines and activities to be assessed and to give the UKAS assessment team access to information that demonstrates its competence as a Service for all disciplines and activities applied for.
- 1.2.2 The responsibility for **meeting** the IQIPS Standard rests with the service management. It is also the service management's responsibility to satisfy itself that each discipline's service provision 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 physiology service(s) is fully compliant with the requirements set out in the IQIPS 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 IQIPS standard statements. There may be a number of different ways in which a physiology service can demonstrate its competence and conformity. UKAS assessment teams will consider alternative approaches and innovative methods that the physiology service has implemented to ensure good quality outcomes for users.
- 1.2.5 UKAS accreditation will be granted to physiology services who have demonstrated that they fully meet the requirements set out in the IQIPS Standard.

## 1.3 Background to the IQIPS Standard

- 1.3.1 The IQIPS Standard has been specifically developed for UK physiology services by professionals who practise within physiological services in both the NHS and private healthcare sectors.
- 1.3.2 The IQIPS Standard describes the requirements to be met by any physiology service wishing to gain accreditation and is designed to be applicable to all eight physiology disciplines.

## 2. UKAS Assessment Tools and Techniques

- 2.1 A range of helpful tools and techniques is also available, on request, to support prospective UKAS customers prior to submission of a formal application for assessment and accreditation. This includes: a bespoke on-line self-assessment tool and preparation for accreditation workshops; online support and estimation of annual fees.
- 2.2 A range of assessment tools and techniques is available to support the UKAS assessment and accreditation process. During the early stages of the process UKAS will discuss with service management 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.
- 2.3 On receipt of an application for assessment and accreditation UKAS will make an online system available to the physiology service. The necessary detailed application information should be submitted by the service to UKAS via this online system.

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- 2.4 Physiology services can upload and submit documentary information for examination by their UKAS assessment manager and or team via the online system. Feedback from assessments will be provided in a written report and via the online system, as appropriate.
- 2.5 The pre-assessment stage is an optional part of the initial assessment process for new applicants and for any application for extension to scope in a new physiology discipline. 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.
- 2.6 For formal assessments, a UKAS assessment team must establish the physiology service's competence, as defined within the IQIPS Standard, by ensuring the proper evaluation of competence in all areas and activities for which the physiology 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 quality management information and records including databases, reports of mock inspections or other forms of external quality assurance activities;
  - Examination of objective evidence of monitoring and commitment to continuous quality improvements;
  - Interviews/discussions with management, patients, referrers and staff.
- 2.7 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.
- 2.8 This prior remote examination of documents is the first part of the formal assessment process for initial assessment, mid-cycle surveillance assessment, extension to scope and reassessment. The outcome of the examination of documents supports the assessment team's preparation for the on-site assessment visit. The recommendation by the assessment team to grant, extend or renew accreditation would not normally be based solely on the outcome of an examination of documents.
- 2.9 The on-site assessment is conducted on premises where the physiology 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.
- 2.10 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.
- 2.11 The outcome of both of the examination of documents and the on-site assessment is recorded on the UKAS Assessment Report Form. Any identified nonconformities and associated corrective / mandatory and or recommended actions arising from these assessments are recorded on the UKAS Improvement Action Form.

- 2.12 On occasions, UKAS may conduct unannounced visits as part or in place, of planned surveillance/reassessment activity or where an extra assessment visit is required e.g. as part of a complaint investigation. Any unannounced visit will be justified by the UKAS Accreditation Manager or Section Head.

### **3. The Accreditation Process**

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

#### **3.1 Application – Stage 1**

3.1.1 UKAS will accept an application from:

- A new physiology service not holding UKAS accreditation for any other physiology discipline;
- An existing accredited physiology discipline wishing to extend the scope of its accreditation to add new activities, and/or new service delivery location and/or another physiology discipline;
- A new legal entity applying for the transfer of accreditation from an existing UKAS accredited physiology discipline.

3.1.2 Application packs are accessible from the UKAS website [www.ukas.com](http://www.ukas.com) a senior management representative must complete, sign and return all relevant application information directly to the UKAS Applications Unit.

3.1.3 In submitting an application for initial assessment and accreditation, the service management is making a formal commitment to support the discipline(s) to achieve and maintain accreditation.

3.1.4 All new applications are vetted by a UKAS Accreditation Manager / Section Head who will check that any necessary eligibility criteria have been satisfied before it is passed to the UKAS Finance Department for legal identity and credit checking. Where concerns are raised regarding the financial viability of the physiology service, UKAS may proceed with the requested assessment activity but may require payment in advance.

3.1.5 On acceptance of an application, a letter of acknowledgment will be forwarded to the physiology discipline 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 customer login details to the IQIPS online system. The system includes user guidance within it.

3.1.6 The UKAS Assessment Manager would normally make contact with the named coordinator/representative within 10 working days of receipt of application to make introductions, clarify information requirements for the contract review and for the optional pre-assessment if requested. The Service can opt for the contract review process and the pre-assessment process to be jointly conducted by telecom or at a face to face-to face meeting.

3.1.7 The physiology discipline(s) is expected to upload the required contract review information into the 'About You' section of the on-line system and to make the information available to the UKAS assessment manager at its earliest opportunity.

### 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.

3.2.2 A contract review is conducted for:

- All new applications for initial accreditation;
- All applications for extension to scope;
- Any additional and/or unplanned assessment, such as, examination of further documents, extra on-site assessment visits;
- Re-assessment application.

3.2.3 The contract review is normally undertaken by the Assessment Manager and is then authorised by the Accreditation Manager / Section Head. 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 IQIPS Customers;
- The tools and techniques to be used to conduct the assessment including such things as:
  - Number of service delivery locations to be visited and distance between each;
  - Number of technical areas/modalities to be assessed and by whom.
- The skills mix and size of the assessment team needed to ensure competence within the team to be able to assess the entire scope and to conduct the on-site assessments visits over a consecutive two-day period;
- Potential conflicts of interest between the proposed team and the physiology service in order to ensure the independence and impartiality of the assessment team and that team members are acceptable to the physiology service;
- Factors such as past performance/assessment outcome and accreditation history, in particular how the physiology service responded to previous nonconformities 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 a contract review the Assessment Manager will calculate and issue the physiology 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 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 physiology 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 physiology 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, during each surveillance year and at re-assessment ensuring adequate coverage of the scope of accreditation over the 4-year cycle (See 'Assessment Coverage Requirements' at Annex 1);
  - Any activity that is not regularly performed should be assured by the assessment team and if necessary included on the forward plan for review at an appropriate surveillance assessment.
  - Whether specific identified physiology 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 Assessments occasionally do not cover the planned scope. In such instances, the Assessment Manager in conjunction with the assessment team and where appropriate, the service management, will consider the impact of the outcome of the assessment on future planned activities to be accredited and if necessary the Forward Plan will be revised.

### 3.4 The Assessment Team

- 3.4.1 At a minimum the assessment team will comprise a UKAS **Assessment Manager**, also acting as the lead assessor, plus at least one peer/technical Assessor and one lay/patient representative assessor. **At UKAS's discretion, technical experts may be invited to assist during an assessment.** The total size and skill mix of the team will vary as necessary to provide the expertise to adequately assess the competence of the physiology discipline(s) concerned.
- 3.4.2 All communication between UKAS and the physiology service being assessed should be via the UKAS Assessment Manager and or the UKAS Customer Support Team and the identified coordinator/representative. Physiology 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, UKAS contract and to formally declare any known conflict of interests.
- 3.4.4 The 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 physiology service concerned. UKAS will provide the physiology discipline(s) with details of each team member (name and current place of work) when the team has been assembled.
- 3.4.5 The physiology discipline(s) 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 participate in assessments as a peer/technical assessor. Assessment Managers are also available to provide advice on technical and policy matters related to the process of accreditation to both the physiology discipline(s) and the 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. These UKAS staff would normally ensure that both the customers and members of their assessment team are kept informed of progress and the next steps in the assessment and accreditation process.
- 3.4.8 **Peer Assessors**, also called technical assessors, are recruited from the ranks of practising senior physiologists and clinical scientists. Peer/technical assessors must satisfy the pre-defined Technical Competence Criteria for a particular IQIPS discipline to be accepted for UKAS training. All recruits receive training in the requirements of the IQIPS Standard and in assessment skills and techniques prior to being authorised as a UKAS assessor for that discipline. Recently retired individuals who are already authorised as UKAS assessors may continue in their role subject to them remaining on the relevant professional register.
- 3.4.9 **Technical Experts** will have in-depth knowledge of the specific technical area to be assessed and the requirements of the Standard. He / she will always work under the direction and supervision of an authorised peer/technical or Lead assessor who will be responsible for recording any Findings and agreeing improvement actions for nonconformities.

### **3.5 Pre-Assessment – Stage 3**

- 3.5.1 The pre-assessment stage is optional and can be requested by the customer on submission of the formal application for assessment and accreditation to UKAS. The outcome of the pre-assessment does not contribute to the accreditation recommendation but can be useful to the Service to gauge its readiness for formal assessments.
- 3.5.2 The expectation is that the discipline(s) would have conducted a detailed self-assessment prior to requesting a pre-assessment from UKAS.
- 3.5.3 Prior to the pre-assessment service management is expected to provide UKAS with information to demonstrate:
- That a detailed self-assessment against the Standard has been undertaken and that policies and procedures/processes have been defined for the majority of standard statements;
  - That an annual performance monitoring plan is in place and that specific audits are being regularly conducted to demonstrate quality outcomes across the standard;
  - That actions plans are available for any identified Service gaps and or weaknesses;
  - An agreed project plan to achieve accreditation in a timely manner.
- 3.5.4 The pre-assessment is undertaken by the UKAS Assessment Manager based on an examination of documentary information provided by the service in the 'About You' and 'Document Box' sections of the online system. The pre-assessment would normally be conducted off-site via the on-line system and the report issued in the same way. However, the customer can also request a face-to-face meeting to discuss the findings in the report.
- 3.5.5 For large multi-site organisations the Assessment Manager may request a review of the organisations quality manual and quality management system to make a preliminary assessment of interfaces and controls between multiple locations performing all or part of the work to be accredited.
- 3.5.6 Any pre-assessment must be completed within three months of submitting an application for formal assessment and accreditation to UKAS.

### **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 physiology discipline(s) is expected to provide the assessment team with access to comprehensive, convincing and unambiguous information to support its claim of conformity with the IQIPS Standard.
- 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, mid-term

surveillance and re-assessments this is normally set for approximately four to six weeks prior to the agreed date for the on-site assessment visit.

- 3.6.1.4 The entire assessment team will undertake a thorough examination of all documents, audits and records supplied by the physiology discipline(s) in order to evaluate the systems as documented, and to assess conformity within the IQIPS Standard.
- 3.6.1.5 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 normally communicated to the service within a Visit Plan (see 3.6.2 below).
- 3.6.1.6 For initial accreditation, extension to scope and re-assessment, any Findings and the recommendation for grant or renewal of accreditation is determined by the outcome of both the examination of documents and the on-site assessment. During surveillance years Findings and the decision to maintain accreditation may be determined by the outcome of an examination of documents only. However, the assessment team reserves the right to request an extra visit where the documentary evidence is deemed insufficient to justify the claim of continued conformity.
- 3.6.1.7 Following grant or renewal of accreditation and following each surveillance assessment the physiology service must update its documentary information as necessary and make them available for examination by the assessment team annually via the online system.

### **3.6.2 The Visit Plan**

- 3.6.2.1 The visit plan is prepared and a draft issued to the physiology 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 physiology service will be given the opportunity to raise queries with the visit plan prior to the on-site assessment visit. UKAS reserves the right to amend the visit plan at any time including during 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 but may be more dependent on the size and complexity of the Service. 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 and travel between locations;
- Confirm facilities required by the team to include a private meeting room, internet access and safe storage for valuable;
- 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 and expected behaviours.

3.6.5.2 Before the meeting is closed the physiology service is given an opportunity to disclose any known nonconformities and to ask relevant questions.

3.6.5.3 The on-site assessment would normally formally commence at all relevant locations 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 physiology discipline(s) is competent and conforms to the IQIPS 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 physiology discipline(s) 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 reviewed during both the off-site documentary review process and at 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 for the grant of accreditation to UKAS will be based.
- 3.6.7.3 Findings should be objective, unambiguous and where necessary further explanation should be provided to ensure understanding by the physiology discipline(s).
- 3.6.7.4 Any identified nonconformities should be discussed and appropriate improvement actions agreed with the service management at the earliest opportunity during the assessment.
- 3.6.7.5 All nonconformities 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 customer representative to propose improvement actions to address recordable findings as they arise, subject to the agreement of the service 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.

- 3.6.7.6 Any proposed improvement/corrective action to address a nonconformity must be formulated by the physiology discipline. This can be in discussion with the assessor as long as UKAS does not provide at any time any consultancy, e.g. offer specific solutions. The assessor may provide guidance on sources of information in helping address the non-conformity. They may also provide guidance on whether the proposed action is likely to be acceptable in effectively addressing the non-conformity subject to the outcome of the service management's own root cause analysis.

### 3.6.8 Private Meeting

- 3.6.8.1 The private meeting is normally scheduled for just prior to the Final meeting. At this meeting the assessment team will discuss the outcome of the assessment to agree overall conformity with IQIPS Standard, the recommendation to be put forward by the team and will also use the opportunity 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 physiology discipline(s) claim of conformity for the full scope of its activities and locations put forward for assessment;
- Sufficiency and adequacy of the information/evidence provided;
- The degree to which service management and staff demonstrated good knowledge and understanding of agreed systems and processes and how well this verified conformity with the standard statements and criteria;
- Validity of audits and how this demonstrated good quality outcomes for service users ;
- Feedback received from users and how these are acted upon by the service.

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- 3.6.8.3 The assessment team will co-ordinate, confirm and categorise nonconformities 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 IQIPS Standard and must be addressed by the physiology discipline(s), 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 a 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 extension to scope, the service can be given up to three months to address mandatory findings. During surveillance and re-assessment 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 IQIPS 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 Assessment Report will clearly indicate the scope of the service that has been satisfactorily assessed and will highlight all Findings to include areas of good practice, any nonconformities 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 physiology 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 physiology 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 physiology 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 physiology discipline(s) be offered a reduced scope of accreditation may be made. The options and implications of any deferment will be discussed fully with the 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 physiology discipline(s) has failed to demonstrate competence and conformity with the requirements of the IQIPS Standard, the recommendation will be that accreditation should **not** be offered. In such cases the service management will be advised to discuss its future options with UKAS.

### 3.6.9 Final Meeting

- 3.6.9.1 The on-site assessment visit normally concludes with a final meeting involving the assessment team and senior management from the physiology 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 physiology discipline(s). Physiology discipline(s) 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 nonconformities with the IQIPS Standard may exist within the physiology discipline(s) that has not been found by the assessment team.
- 3.6.9.4 Each assessor would normally summarise his or her identified nonconformities and the 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 a summary of the Assessment Report and would normally advise the service management to expect to receive a final copy of the report and IAR within five working days.
- 3.6.9.6 The assessment team should end by formally thanking the physiology discipline(s) for their assistance. The Service management should then be given 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 types (with the exception of surveillance assessments) prepare and submit the assessment information pack 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 Findings requiring improvement action evidence have been raised by the assessment team then 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 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 the recommendation;
- Whether UKAS' processes had been followed throughout the assessment;
- 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 developed and/or updated as appropriate.

3.7.6 In some circumstances, further information may be requested from the assessment team and/or physiology discipline(s) 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 physiology discipline(s), 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 physiology discipline(s) 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 physiology discipline(s) before accreditation can be granted. This provisional offer stage normally takes place while any mandatory improvement actions are being addressed by the physiology discipline(s).

### **3.8 Manage Improvement Actions – Stage 6**

3.8.1 The service management is required to respond to any mandatory improvement actions recorded on the Improvement Action Report Form within the agreed timescales. The service management 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 acknowledgement of Findings for those not requiring evidence.

3.8.2 UKAS will provide service management with confirmation of receipt of improvement action 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 remaining outstanding actions and in particular the risk to the physiology service. The Assessment Manager will consider and decide 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 findings raised during the assessment that required mandatory improvement actions 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 physiology 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 consistently miss timeframes for submissions of evidence for improvement actions, 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 physiology service.
- 3.9.2 The decision-maker will review the information provided to determine:
- Whether the physiology service meets the requirements for the IQIPS 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 physiology service;
  - Whether all relevant records of effort changes have been updated;
  - Whether there is a Forward Plan that adequately 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 physiology service. The grant letter will provide a web link to where the physiology service's Schedule of Accreditation is published. During surveillance years the Assessment Manager would normally

- arrange for maintenance 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 It is UKAS' policy to make public the full scope of each physiology 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 physiology activities and service delivery locations that have been assessed and accredited by UKAS.
- 3.9.6 Schedules for all accredited physiology services are published on the UKAS website [www.ukas.com](http://www.ukas.com)
- 3.9.7 Accredited physiology services will be eligible to use the UKAS Medical accreditation symbol and the IQIPS symbol. Copies of the symbols will be sent to the service at grant of accreditation
- 3.9.8 Rules on the use of the UKAS Medical symbol can be found in the UKAS terms and conditions of business for IQIPS customers document which is published at [www.ukas.com](http://www.ukas.com) 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 physiology 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 physiology service with the IQIPS Standard and to review effectiveness of implementation of improvements actions from previous assessments.
- 3.10.2 The first surveillance assessment is normally scheduled for approximately six 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 monitoring audits.
- 3.10.3 The physiology 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 normal surveillance assessment programme includes examination of documents in each year with a mid-term on-site surveillance on-site assessment visit by the Assessment Manager and part of the assessment team (See Appendix A).
- 3.10.4 In the fourth year of the accreditation cycle the physiology 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 physiology service and/or its accredited activities, these will be recorded by the Assessment Manager and/or assessment team.

## The Conduct of UKAS Assessments for the Improving Quality in Physiology Services (IQIPS) Accreditation Scheme

- 3.10.6 Following each surveillance assessment and re-assessment the physiology service must supply information to demonstrate how it has addressed any findings raised that require evidence of clearance 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 accredited scope.
- 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 visit to an accredited physiology service at any time to ensure that the service continues to conform to the requirements of the IQIPS Standard.
- 3.10.9 The UKAS Assessment Manager will monitor accreditation expiry dates and will notify the physiology 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 / Section Head.
- 3.10.11 It is the responsibility of the physiology service to notify UKAS of all significant changes to its status and or operation, e.g. change of name of legal identity, change of head office, changes to key personnel, significant equipment/kit and service delivery locations upgrades and or changes to accredited activities. The UKAS Assessment Manager will ensure that any new activities, service delivery locations and/or equipment are assessed at the earliest opportunity to confirm continued compliance with the requirements. Where the head office or legal identity has changed the physiology service must sign a new version of the UKAS Agreement, including any supplements, detailing the new information. UKAS will issue a new Accreditation Certificate where necessary, e.g. where the name of the Service and or its address has changed.

## 4. Extension / Reduction of Scope

- 4.1 Extension/reduction to scope application information is available from the UKAS website [www.ukas.com](http://www.ukas.com) and within the online system. 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 any assessment related to the extension to scope assessment with the physiology 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 the extension to scope assessment, nonconformities may be raised by the assessment team. All Findings requiring mandatory improvement actions must be satisfactorily addressed by the physiology 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**

The physiology service's accreditation can be suspended by UKAS. This will normally be due to serious concerns in relation to the physiology service's continued conformity with the IQIPS 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 physiology 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 physiology service withdraw from the accreditation process if it consistently fails to progress its application project and or any required actions, such as requests for improvement actions to be submitted or for an extra visit to be arranged within agreed timescales or due to unacceptable behaviours by Service staff.
- 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 physiology 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](http://www.ukas.com)

### **6.1 Complaints**

- 6.1.1 Any concerns/complaints regarding an accredited physiology 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 physiology service. Where the investigation and/or response from the accredited physiology 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 physiology 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.

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- 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 physiology 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 IQIPS which details the fee structure is available from the UKAS website [www.ukas.com](http://www.ukas.com)

## Annex 1

### Assessment Coverage Requirements

#### Initial Assessments

Physiology Service	Coverage
Locations visited	<p><b>Physiology services with less than 10 locations</b> 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><b>Physiology services with 10 or more locations</b> 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, high street outlets and hospital sites. Initial Grant of Accreditation may be limited to only those locations visited. For Extension to scope to include the entire organisation, the 4 year Forward Plan will specify arrangements for sampling of locations ranging from 60 per cent to 100 per cent. The determination of sample size to be visited for the ETS recommendation to be made by the Assessment Team based on the outcome of previous assessments.</p>
Business, technical and patient management system	All system requirements of the IQIPS Standard.
Clinical activities	Range of physiology examinations and or procedures and reports for each discipline to ensure key techniques, methods and competences are assessed.
Staff	Representative sample of key personnel for each examination and/or procedure and/or techniques and generally at all locations. The sample should provide assurance of competence in all examinations and/ or techniques.

## Re-assessments

Physiology Service	Coverage
Frequency	1 <sup>st</sup> Cycle 3.5 years, on-going 4 years
Locations visited	<p><b>Physiology services with less than 10 locations</b> As for initial assessment above</p> <p><b>Physiology services with 10 or more locations</b> As for initial assessment above. Locations not visited during 1<sup>st</sup> Cycle should be prioritised for inclusion in sampling. Consideration should be given to including previously visited locations unless justified not to on the basis of past performance and a determination of risks.</p>
Business, technical and patient management system	All system requirements of the IQIPS Standard.
Clinical activities	Range of physiology examinations and or procedures and reports from each discipline to ensure key techniques, methods and competences are assessed.
Staff	Representative sample of key personnel for each examination and/or procedure and/or technique and generally at all locations. The sample should provide assurance of competence in all examinations and/ or procedures and/or techniques.

**Appendix A – Schematic of 4-year cycle**

