Clinical Service Accreditation Alliance: Work stream 1

Requirements and guidance for the accreditation of Certification Bodies providing clinical service certification schemes

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Version 1

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About the Clinical Service Accreditation Alliance

This guidance is one of six resources created by the Clinical Service Accreditation Alliance (CSAA). The CSAA is a collection of professional bodies, which came together in 2013 with the aim of standardising and improving the quality of healthcare service accreditation, ensuring patient focus, improvements in standards of care and minimal administrative burden on the healthcare system.

CSAA outputs: Tools, guidance and resources

As part of its two-year collaboration, the Alliance has developed a suite of resources to support professional bodies who wish to develop professionally-led and patient-centred clinical accreditation schemes. These will publish in late November 2016 and comprise:

- Work stream 1: Requirements and guidance for accreditation of Certification Bodies (in conjunction with UKAS – this document)
- Work stream 2: Sharing and improving accreditation methodologies
- Work stream 3: A map of clinical services for clinical services accreditation schemes
- Work stream 4: A generic framework of standards for accrediting clinical services (*Healthcare – Provision of clinical services – Specification*[1] or PAS 1616 – produced by BSI)
- Work stream 5: Requirements for clinical services accreditation IT systems
- Work stream 6: Developing accreditation schemes for clinical services

The Alliance's work culminated in November 2016 with the first publication of these guidance documents and this work is now housed with the Healthcare Quality Improvement Partnership (HQIP) with oversight from the CSAA Sponsor Group, whose members are drawn from the Royal College of Nursing, Royal College of Physicians, Royal College of Surgeons, Royal Pharmaceutical Society, Allied Health Care Professionals and the Academy for Healthcare Science. More information can be found here: *www.hqip.org.uk/national-programmes/accreditation-of-clinical-services/*

About this guidance

Healthcare Quality Improvement Partnership (HQIP) is working in partnership with the United Kingdom Accreditation Service (UKAS), in order to achieve a system which demonstrates competence and equivalence between various clinical service assurance schemes.

There is some important nomenclature to note in relation to this document. UKAS operates in accordance with the national Accreditation Regulations and EC Regulation 765/08, which recognise accreditation by the national accreditation body within the conformity assessment chain (*see diagram 1*). To avoid any confusion of terms, bodies accredited by UKAS cannot use the term 'accreditation' in their corporate or trading name or otherwise hold themselves out as providing accreditation services.

In this document the terms are used as follows:

Accreditation is the recognition by UKAS of various bodies such as medical royal colleges or other institutions, who in this document are referred to as Certification Bodies.

Certification is the recognition by a certification body (e.g. a royal college or other institution) that a clinical service has achieved agreed defined standards.

Introduction

Many clinical service providers choose to demonstrate the quality and suitability of the service they provide by subscribing to certification schemes. These schemes are operated in a variety of different ways and by a number of different professional bodies. Terminology to describe existing certification schemes varies, however over time greater consistency in terminology is likely to be achieved.

The CSAA recognised that certification schemes need to demonstrate that they are effective and are delivered with competence, integrity and impartiality. This is necessary to ensure that the various schemes that are developed are of comparable high quality and add value to the service and the service user. There is also demand from organisations providing clinical services that Certification Bodies become more consistent in their practices, share information and become more transparent in their operations.

This document provides the requirements and guidance that can be used for the accreditation of Certification Bodies that operate clinical service certification schemes.

It sets out requirements and relevant guidance to assist Certification Bodies and UKAS, where a Certification Body seeks accreditation. The accreditation award will be ISO/IEC 17065:2012.

The requirements contained within this document can also be used to inform decisions by regulators or other health improvement institutions.

As well as HQIP and UKAS, this guidance is further underpinned by the International Society for Quality in *Health Care (ISQua) Guidelines and Standards for External Evaluation Organisations*[2] and *Guidelines and Principles for the Development of Health and Social Care Standards*.[3]

ISQua has extensive experience of improvement in the quality and safety of healthcare worldwide, supported through external evaluation and other mechanisms. This guidance does not seek to replicate any part of the standards developed by ISQua but acknowledges their expertise in the healthcare arena and specifically their standards.

Terms and definitions

- **Certification Body:** An independent, impartial body that operates one or more certification schemes to certify clinical services

  - **Note 1:** The term **'certification'** is used here to enable differentiation from any accreditation that might be awarded by UKAS to the Certification Body in recognition of its competence to certify clinical services
  - **Note 2:** A certification scheme is a certification system related to specified services, to which some specified requirements, specific rules and procedures apply
  - **Note 3:** A Certification Body may operate a single scheme, operate a number of schemes or host a scheme on behalf of another organisation

- **Certify:** Officially recognise as possessing certain qualifications or meeting certain standards
- **Clinical service:** Describes a system within or across healthcare provider(s) delivering prevention, diagnostics, treatment and/or care or rehabilitation to service users. Most clinical services involve more than one healthcare provider and have a role in prevention and promotion of self-care where appropriate. Within this document this term is generally referred to as a 'service'
- **Certification scheme:** a certification scheme can provide confidence in clinical services in different ways, for instance confidence:
  - That the clinical service meets defined standards/requirements
  - That the service continues to meet the scheme requirements (and the standards/requirements therein)

Note 4: The clinical service so defined must be meaningful to clinicians, service users and representatives. It might:

- Be a dedicated clinical service, such as endoscopy or pulmonary rehabilitation
- Be a single healthcare facility such as a ward or a primary care centre
- Comprise a group of staff and facilities that work together, as a 'virtual team' to provide care to a common group of service users, such as people who have had a stroke or those being assessed and investigated for memory problems. The staff and facilities that make up this virtual team might either be co-located within a particular setting, such as a general hospital, or be distributed across a number of settings or be employed by more than one institution
- Provide care to service users at a particular time-point and level of care, such as anaesthetic practice within a general hospital, or provide care to service users over time and across the boundaries between health and social care and between primary and secondary care, such as liver services

- **Lay members (on Boards or committees):** A lay member is defined, for the purposes of this document, as someone who ensures the public voice of the local population is heard and that opportunities are available for public and patient engagement in the scheme. They will have direct or indirect experience of the clinical service that is the focus of certification. The term 'lay member' includes service users (defined below). Lay members have a unique contribution to make in the sense that they are experts by experience. This is in addition to any other skills, qualities, knowledge and experience they have
- **Lay assessors:** A lay assessor is defined, for the purposes of this document, as someone who has some knowledge of healthcare, may have used the clinical service that is the focus of certification or have experience of it through a family member or other personal contact
- **Service user:** A service user is defined, for the purposes of this document, as someone who is using, or has used the clinical service. It includes patients and may include their carers or other representatives

Accreditation of Certification Bodies that provide clinical service certification schemes

ISO/IEC 17065:2012 is an international standard, which sets out criteria for bodies operating certification of services and will be used to assess and accredit those Certification Bodies that certify clinical services described in Note 3. This document will be used to supplement and interpret the general criteria contained in ISO/IEC 17065:2012.

Diagram 1: Summary of how UKAS accreditation can underpin the certification schemes for clinical services

Criteria and guidance

The requirements in the following sections apply to Certification Bodies that provide certification for clinical service certification schemes and support the achievement of ISO/IEC 17065:2012. The requirements to achieve the standard are categorised as those that relate to three broad areas as follows:

1. Leadership and governance	2. Operational delivery	3. Assessment management
1.1. General requirements 1.1.1 Legal and contractual matters 1.1.2 Management of impartiality 1.1.3 Liability and financing 1.1.4 Non-discriminatory conditions 1.1.5 Confidentiality **1.2. Structural requirements** 1.2.1 Risk management	**2.1 Resource requirements** 2.1.1 Certification body personnel **2.2 Process requirements** 2.2.1 Certification schemes 2.2.2 Client application and management 2.2.3 Certification standards 2.2.4 Clinical service assessment and assessment team 2.2.5 Certification decision and reporting 2.2.6 Certification process 2.2.7 Surveillance 2.2.8 Records	**3.1 Management System requirements** 3.1.1 General management system

Each area and its criteria are described in more detail in the next section. There are some examples of suggested evidence requirements in *Appendix 1*. The word 'shall' implies a key requirement that must be met. Additional guidance is provided with some examples of suggested evidence although these are meant as a guide. It is accepted that a clinical service can meet a requirement in many ways.

1. Leadership and governance	
1.1. General requirements	**Criteria**
1.1.1 Legal and contractual matters	**i.** The lead roles and responsibilities of the Certification Body and any advisory structures shall be defined and documented.
	ii. The Certification Body shall ensure that there is a documented agreement between the various clinical and non-clinical professional associations whose members make a contribution to the clinical service that is the focus of certification.
	iii. The Certification Body shall ensure that the agreement is reviewed at least annually to ensure its effectiveness.
	iv. The Certification Body shall have an agreed set of principles that it operates to. ***Note:*** *The principles should, as a minimum:* – *Put the service user first* – *Be peer-led* – *Be outcomes focused* – *Promote improvement* – *Be supportive (as opposed to punitive)* – *Be educative, including sharing of best practice* – *Encourage, reward and celebrate excellence* – *'Practice what they preach' in relation to continuous improvement* – *Require learning from feedback*
	v. Members of the Certification Body and its committees shall be assisted in fulfilling their responsibilities through clear terms of reference, which include roles, membership and lines of reporting.
	vi. The Certification Body shall define its governance structure and how its management structure interacts with it.
	vii. The Certification Body shall have a clear vision statement for all its activities that provide the basis for operational planning and direction.
	viii. There shall be documented agreements with professional societies and service user groups defining how they recognise and support the certification scheme, how they are involved in the governance, development and delivery of the certification scheme, and how they promote participation.
	ix. Clinical service shall be represented on relevant committees and advisory/working groups.
	x. Lay members shall be full members of governance groups. **xi.** The Certification Body shall be a stand-alone legal entity, or part of a legal entity, and document its governance arrangements and responsibilities. ***Note:*** *A legal entity may be a college, Trust, partnership, proprietorship or any structure that has* ***legal*** *standing in the eyes of law. The provider organisation can enter into agreements or contracts, assume obligations, incur and pay debts, sue and be sued in its own right, and to be held responsible for its actions.*

	xii. The Certification Body shall have clear policies and agreements for any contracted work related to the delivery of the clinical certification scheme. ***Note:*** *A provider may have a number of contracted activities or none. These relate directly to the provision of certification activities and may apply to assessors who are contracted to support certification schemes operated by the Certification Body. They may also apply to external contractors providing professional and technical expertise to the delivery of the Certification Scheme (for example, trainers) and where assessments might be carried out on behalf of the Certification Body by another organisation.*
	xiii. The Certification Body shall ensure the competence and effectiveness of any external organisations or individuals that are contracted provide services to the Certification Body through monitoring and reviews.
1.1.2 Management of impartiality	**i.** The Certification Body shall seek to operate impartially so that its certification activities are not adversely influenced. The Certification Body shall have formal rules for the appointment and operation of any committees that are involved in the certification process. Such committees shall be free from any commercial, financial and other pressures that might influence decisions. The Certification Body shall retain authority to appoint and withdraw members of such committees.
	ii. Members of the governing committees and groups shall have information and training on the Certification Body's specific policies related to individual certification schemes. ***Note:*** *The following documents and policies should be made available for all members:* – *Clinical standards* – *Code of conduct* – *Confidentiality* – *Impartiality*
	iii. Members of the governing body shall have the information and training to assist them in fulfilling their role.
	iv. The effectiveness of the governance of the scheme delivery shall be evaluated using indicators and other measures of performance. ***Note:*** *indicators and measures of performance might include but are not limited to:* – *Board meeting participation and satisfaction* – *Achievement of annual objectives and work plan* – *Effectiveness of induction and training processes* – *Managing conflicts of interest*

	v. The Certification Body shall have policies in place in order to ensure effective and efficient delivery of its certification scheme(s). As a minimum the following policies shall be included: – **Impartiality:** to ensure that all decisions are independent and objective. There shall be clear arrangements in place to ensure impartiality in all its activities and avoidance of any conflicts of interest – **Code of conduct:** the set of rules outlining the responsibilities of, or proper practices for, all staff, contractors, members of committees and assessors to operate to – **Complaints:** there shall be a documented process with timescales in place to support client organisations, assessors and stakeholders – **Appeals:** there shall be a clear process in place related to certification decisions – **Serious personal and professional issues:** to clarify and manage issues about individuals including reporting advice and arrangements to professional organisations
1.1.3 Liability and financing	**i.** The Certification Body shall have documented arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.
	ii. The Certification Body shall make the required performance level to support its activities clear to any external contractors. ***Note:*** *Examples may include IT services and human resource administration.*
	iii. There shall be documented agreements and monitoring arrangements with all key suppliers. ***Note:*** *A key supplier is an independent company or body contracted to provide services e.g. an IT provider or training company.*
	iv. The Certification Body shall have the financial stability and resources required for its operations.
	v. The Certification Body shall state clearly the costs to participate in a scheme and this shall be periodically reviewed and transparent to all scheme participants and stakeholders.
	vi. The financial accounts of the Certification Body shall be transparent and available. ***Note:*** *The Certification Body shall publish a summary of annual financial accounts.*
	vii. The Certification Body shall have processes for financial planning and budgeting, and policies for delegation of financial responsibility.
	viii. There shall be internal and independent systems of financial and asset control that protect the Certification Body's assets.
	ix. Financial systems shall be well managed including monitoring, tracking and review systems. ***Note:*** *A well-managed system is one that operates in an **efficient, fair** and **resilient** manner. To achieve this one would expect to see clear documented procedures for budget control and auditing, clear lines of responsibility and accountability and robust processes to support all procedures.*
1.1.4 Non-discriminatory conditions	**i.** Non-discrimination: the procedures under which the Certification Body operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants.

1.1.5 Confidentiality	**i.** The Certification Body shall have policies in place in order to ensure effective and efficient delivery of its certification scheme(s) including: – **Confidentiality:** *to manage all information obtained or created during the performance of certification activities*
1.2 Structural requirements	Criteria
1.2.1 Risk Management	**i.** The Certification Body shall have a risk management framework that is used to identify and manage all known risks and learn from unexpected events.
	ii. The Certification Body shall identify all potential risks for its operations including those specific to certification schemes. ***Note:*** *Risks might include but are not limited to: reputation, engagement in the scheme, impartiality, financial, human resources, IT systems, environmental, quality assurance, and operation of the scheme.*
	iii. The Certification Body shall consult with stakeholders; lay representatives, staff members, contract staff and clinical services to ensure that recorded risks are relevant and comprehensive.
	iv. The Certification Body shall establish processes to mitigate the identified risks and define metrics to monitor the known risks.
	v. The Certification Body shall review the risks on a regular basis to determine whether the processes to mitigate risk have been effective and, if not, design and implement new processes to reduce risk.

2. Operational delivery	
2.1 Resource requirements	Criteria
2.1.1 Certification body personnel	**i.** The human resource strategy of the Certification Body shall reflect the requirements of the strategic and operational plans.
	ii. All employment policies and procedures shall be developed in accordance with local law and legislation and cover all aspects from recruitment to end of service.
	iii. The Certification Body shall have policies and systems in place to ensure it has sufficient competent staff with the mix of skills to enable delivery of the certification scheme(s).
	iv. The Certification Body shall have a description of its staff, and the responsibilities of both its staff and the wider team. ***Note:*** *The wider team includes but is not exclusive to: contractors, professionals providing specialist advice and assessors.*
	v. Peer and lay assessors shall be appointed to represent the requirements of the clinical service and the delivery of the scheme.
	vi. Assessors shall have documented roles, competencies and agreements.
	vii. Lay people who are experts by experience shall participate as full members of assessment teams.
	viii. The Certification Body shall have policies and systems in place to meet the induction requirements of staff, including any additional service specific education and training.
	ix. The Certification Body shall have policies and systems in place to ensure the workforce, including assessors, are properly trained and competent.
	x. A training needs analysis shall support all new staff that support the certification scheme.
	xi. New assessors shall have a structured training pathway and shall be evaluated for their competence in the role. ***Note:*** *The training pathway should as a minimum include:* – *Mock survey processes* – *Legal and survey requirements* – *Standards and their interpretation* – *Survey techniques* – *Communication skills* – *Performance expectation* – *Evaluation systems* – *Handling serious issues and escalation*

	xii. The Certification Body shall have an effective appraisal system for all staff.
	xiii. All training programmes shall be evaluated to ensure that they are achieving agreed learning outcomes.
	xiv. There shall be on-going development of staff skills. Assessors shall be supported to update skills and knowledge proportionate to the needs of the scheme. ***Note:*** *Assessors may have annual or as-needed face to face refresher training, remote updates or a combination of both.*
	xv. The Certification Body shall seek and evaluate feedback from services and assessors to inform the performance of assessors and staff.
2.2 Process requirements	Criteria
2.2.1 Certification schemes	**i.** The certification scheme(s) shall be developed in response to a defined service need. ***Note:*** *There should be a recognised need for a scheme and its feasibility considered through a wide range of external bodies. There should be objectives about what the scheme might achieve and how it will improve the service user experience.*
	ii. The Certification Body shall consult with key stakeholders to ensure that the certification scheme is viable and supported.
	iii. The Certification Body shall consider the clinical service that is the focus of a certification scheme from the perspective of service users and the workforce.
	iv. The Certification Body shall keep an up to date register of clients and their certification status.
	v. The Certification Body shall have an operating plan that reflects the overall vision for the scheme(s) and the resources required to achieve this.
	vi. When the Certification Body is a defined part of a legal entity, the operational structure shall include the line of authority and the relationship to other parts of the same legal entity.
	vii. The Certification Body shall define its management and Board structure, making it clear who the personnel are and their responsibilities. ***Note:*** *This should include responsibility for the following:* – *Development of policies relating to the operation of the Certification Body*
2.2.2 Client application and management	**i.** Requirements shall be documented and publicised.
	ii. The Certification Body shall ensure that all applicants for certification are aware of and understand the entry criteria before agreeing their entry to the certification scheme. ***Note:*** *Applicants should provide as a minimum details of their organisation and the scope of their clinical service on application.*
	iii. The Certification Body shall actively promote the certification scheme to clinical services to encourage participation.
	iv. The Certification Body shall offer the scheme to the full range of clinical services managed by independent and voluntary sector providers, encompassing health and social care where appropriate.
	v. The Certification Body staff shall have an agreed mission statement that defines the etiquette and values of the Certification Body and is made clear to all clients.

	vi. The Certification Body shall have a database of all participating clinical services that includes their status and monitoring and assessment dates.
	vii. Services being assessed shall be provided with relevant information about the clinical service certification scheme.
	viii. The Certification Body shall have an individual agreement with each clinical service. ***Note:*** *The agreement with each service should include:* *a. Mechanisms for addressing serious concerns about service user safety, potential abuse of or other serious matters relating to service user care identified during the course of assessment of a clinical service.* *b. Mechanisms for the client to inform the Certification Body in a timely way, of changes that may affect its ability to conform with the certification requirements, including:* – *Legal, commercial, organisational status or ownership* – *Changes to the clinical service, its structure and delivery* – *Major changes to the quality and safety of the clinical service* – *Major changes to the leadership of the clinical service and personnel*
	ix. There shall be defined resources available to assist a clinical service to achieve the standards.
2.2.3 Certification standards	**i.** The Certification Body shall ensure that its certification schemes operate to agreed standards for provision of a clinical service. The standards and other performance measures shall be based on national guidance, guidelines developed by professional associations, current research evidence, consensus agreements and/or recommendations from the World Health Organisation and take full account of current legislation relating to quality and safety to regulate providers. ***Note:*** *The* BSI PAS 1616[1] *provides a framework for clinical services to operate to and be assessed against,it does not provide the specifics for all services and these will need to be supplemented with specific guidance for each clinical speciality. Pre-existing standards should be mapped to the BSI PAS 1616 and any deficits risk assessed.*
	ii. The scope and purpose of the standards and underpinning criteria shall be clear in terms of: – *The type of clinical service to which they apply* – *The contribution made by all professional groups and sectors (including social care) to the delivery of care by that service* – *The range of services that are covered* – *The reason the standards are needed and used*
	iii. The Certification Body shall provide information and education to staff and assessors of standards to support effective assessments.
	iv. The standards and criteria to certify a clinical service shall be made available in a format that is accessible to key stakeholders and service users.
	v. The need for new or revised underpinning criteria and other performance measures shall be established by seeking the views of stakeholders and service users.

	vi.	Service users shall have explicit opportunity for input into the process of development and revision of standards and other performance measures through direct representation and formal consultation.
	vii.	The standards shall specify service user outcomes whenever possible.
2.2.4 Clinical service assessment and assessment team	i.	The Certification Body shall actively plan the assessment in collaboration with the service involved.
	ii.	The Certification Body shall communicate all assessment information to the clinical service, including special requirements, assessors in training and observers.
	iii.	There shall be an effective mechanism for avoiding conflicts of interest when peer assessors are selected to undertake a review of a clinical service.
	iv.	The Certification Body shall ensure that the clinical service has an opportunity to raise any conflicts of interest it has identified.
	v.	The Certification Body shall ensure that all pre documentation and preparation materials are communicated to the clinical service through authorised individuals.
	vi.	The Certification Body shall ensure that all information is provided ahead of the site assessment for the assessment team to review.
	vii.	The Certification Body shall support assessments through an IT system or manual systems to support evidence review, feedback, communication and production of an assessment report. ***Note:*** *whilst IT systems are not mandated, modern schemes should be working toward implementing IT systems to support efficient and effective delivery of schemes.*
	viii.	The Certification Body shall agree a timetable with the clinical service for completion of evidence preparation, review and attendance on site.
	ix.	The Certification Body shall make it clear who from the clinical service is required for attendance on the day of a site visit.
	x.	All assessors shall have clear means of identifying who they are, including photographic ID.
	xi.	The Certification Body shall ensure security policies for those attending a site visit are complied with.
	xii.	The Certification Body shall ensure that a clear and consistent verbal feedback process to the clinical service on the day of the site visit is followed.
	xiii.	There shall be methodology for consistently assessing the achievement of a standard.
	xiv.	Assessments shall be conducted by assessors and clinical services to a structured timeline from application to the achievement of the award.
	xv.	There shall be methods of data collection and sample sizes to support valid assessments for quality indicators, service user outcome measures, service user satisfaction scales and staff survey questionnaires collected as part of the assessment process.
	xvi.	The assessment shall be conducted using agreed guidelines and assessment tools.
	xvii.	The level of performance expected shall match or exceed that expected by regulators or heath inspectorate bodies.

	xviii. The Certification Body shall have a clear policy to determine the circumstances where safety issues in a clinical service may need escalation.
	xix. The Certification Body shall ensure that there is two way, on-going communication with clinical services regarding outstanding actions for certification.
	xx. The planning of the assessment shall be transparent and timely.
	xxi. The assessment team shall be selected to provide a balance of skills and experience to match the needs of the participating clinical service.
	xxii. The Certification Body shall make all guidelines for assessments available to all assessors who will assess the clinical service.
	xxiii. The Certification Body shall ensure that regular checks are conducted of assessment activity including timescales to ensure compliance with assessment protocols.
2.2.5 Certification decision and reporting	**i.** The Certification Body shall have a clear policy and procedures to determine the outcome of an assessment. ***Note:*** *The policy should state who is responsible for determining the outcome of the assessment including the assessment team's responsibility and what is expected on the day of the assessment.*
	ii. The certificate shall include the period/date for review so that any external organisations will be aware not only of the date of issue, but when a formal review is due.
	iii. The Certification Body shall ensure that the certification award follows an agreed format. ***Note:*** *The certification award should include, as a minimum, the name of the clinical service, organisation, the scope of the clinical service and certification and the date and term of issue.*
	iv. The Certification Body shall have agreed rules about the uses of certificates, logos and references to the certification scheme.
	v. The Certification Body shall have a clear policy to determine the circumstances where a clinical service may be suspended or withdrawn from a certification scheme resulting in the loss of certification. ***Note:*** *The certification decision policy should state the changes in circumstances a clinical service needs to advise the Certification Body about and the associated timescales.*
	vi. The Certification Body shall have a clear and consistent process to feedback information about the assessment to the clinical service. The policy for recommendations of certification and the achievement of key actions and recommendations shall be communicated to the service.
	vii. The Certification Body shall ensure that the results of the assessment are documented in a written report that is independently quality assured and that there are clear timescales for the communication of the report.
	viii. The Certification Body shall require clinical services to develop and submit an action plan to address any weaknesses identified by the assessment. **ix.** The Certification body shall have a policy and process on how the final results of a certification assessment are displayed and communicated. ***Note:*** *Outcomes may result in 'key actions' (to comply with) or recommendations for improvement (not mandatory). All services should receive a summary of areas of high achievement.*

2.2.6 Surveillance	**i.** The Certification Body shall have a documented policy and process for surveillance of certified clinical services, including agreement of areas monitored and safety parameters. ***Note:*** *It is usual for there to be some interaction/audit activity on an annual basis.*
	ii. The Certification Body shall require clinical services to develop and submit an action plan to address any weaknesses identified by the assessment.
	iii. There shall be agreed timescales for review and rectification of areas of non-compliance by the clinical service.
2.2.7 Records	**i.** The Certification Body shall ensure effective management of all information, which defines and describes the types of information generated, collected, used and delivered as part of its certification activities.
	ii. The Certification Body shall have clear policies and systems to support information management to ensure accuracy, integrity, confidentiality, reliability, timeliness, security and retention. ***Note:*** *The compliance evidence for clinical services should be retained for the duration of the clinical service certification cycle e.g. five years*
	iii. The information collected and held shall meet all statutory and professional requirements. ***Note:*** *The following are examples of information for clinical service certification schemes:* – *The clinical service to be certified and the general features of the client, including its name and the address of its physical location(s)* – *General information concerning the service, relevant to the field of certification for which the application is made, such as its activities, its human and technical resources, and its functions and relationship in a larger corporation, if any* – *All other information needed in accordance with the relevant certification requirements, such as information for initial evaluation including clinical data and surveillance activities. The Certification Body shall operate clear processes for information requests related to clinical services and their assessment outcomes* – *Information applications/tools/programmes shall have ongoing maintenance and development to ensure integrity and reliability* – *All quality improvement and training resources provided for clinical services and assessors shall be maintained and reflect up to date practice* – *Staff shall be trained on how to run operational systems correctly and shall be aware of information management policies*

3. Assessment management	
3.1 Management system requirements	Criteria
3.1.1 General management system	**i.** There shall be a document management system with mechanisms in place to ensure that all policies and procedures are up to date and reviewed.
	ii. The Certification Body shall have an agreed framework for improving the quality and performance of its services.
	iii. The Certification Body shall have internal systems to monitor, review and act on: – *Performance against accepted standards (including timeliness of planning and delivery of peer assessment visits and of delivery of the report of the results of assessment)* – *Performance on defined indicators and other relevant measures* – *Compliance with policies, procedures and guidelines* – *Progress against the quality improvement plan* Results of the above shall be reported and communicated to staff.
	iv. The Certification Body staff and clinical services participating in the certification scheme shall be surveyed formally at least once per year about their perceptions of the certification scheme and for areas to be improved.
	v. The Certification Body shall actively seek and evaluate feedback after each assessment and act promptly upon any improvements required.
	vi. The evaluation of the performance of the Certification Body shall include a defined approach to measure the impact of the certification scheme in bringing about improvements in the quality of care provided by participating services.
	vii. Identified staff, assessors, advisors and contractors shall participate actively in audits and research about the effectiveness of the Certification Body in bringing about improvements in clinical services.
	viii. Improvement activities and projects shall be planned and documented to enable continuous improvement to processes and services using a defined improvement model.
	ix. The quality improvement framework shall be regularly evaluated and the results reported by management to the governing group.
	x. The Certification Body shall make public the results of all the accreditation assessments it undergoes, including indicators and other measures of its performance.

Appendix 1: Suggested evidence for criteria

The evidence requirements are not meant to be exhaustive but serve as a guide for providers of schemes. It is appreciated that a provider will have its own unique structures and processes and the evidence requirements must reflect this.

	Criterion	Suggested evidence
Legal and contractual matters	**1.1.1 i**	An organogram or equivalent documenting the roles and responsibilities of the Certification Body and any advisory structures. A supporting description of how the roles function and relate to the scheme.
	1.1.1 ii	Documented agreement process/document between the clinical and non-clinical professional associations who make a contribution to the clinical service that is the focus of certification.
	1.1.1 iii	A description of the annual review process for a scheme and supporting meeting output notes and any actions.
	1.1.1 iv	A summary of the documented Certification Body principles and values that it operates to.
	1.1.1 v	All committee and working groups actively support the development and delivery of the scheme including terms of reference and membership (cross reference to 1.1.1 ix and 1.1.1 x).
	1.1.1 vii	Written vision statement for the Certification Body or evidence to support activities that provide the basis for operational planning.
	1.1.1 viii	Documented agreements with professional societies and service user groups defining support, involvement and promotion of the certification scheme.
	1.1.1 xi	Statement on legal status of the provider organisation. Provide a description of the type of entity it is.
	1.1.1 xii	Policy for outsourcing contract work and whom the provider outsources to and a description of the process for monitoring this.
	1.1.1 xiii	A description of the process for service level agreements and monitoring review process with external organisations or individuals that provide services to the certification scheme.
Management of impartiality	**1.1.2 i**	Impartiality and conflict of interest policy.
	1.1.2 ii	Copies of standards pertaining to certification schemes, code of conduct, confidentiality policy, impartiality policy.
	1.1.2 iii	The communications and training plan to support members of the governing body.
	1.1.2 iv	Summary of indicators used to evaluate governance performance.
	1.1.2 v	Impartiality policy, statement on consultancy, code of conduct, conflict of interest policy, complaints policy, appeals policy.

Liability and financing	**1.1.3 i**	A copy of the provider's liability insurance cover or alternative arrangements.
	1.1.3 ii	Examples of external contracts, performance levels required and review arrangements (also meets1.1.3 iii).
	1.1.3 iv	Budget planning and approval process, financial summary reports or annual reports.
	1.1.3 v	Scheme's participation costs and a summary of what the service gets for this payment/licence fee.
	1.1.3 vi	Budget tracking systems, financial audit, and financial reports (also meets 1.1.3 iv, ix).
	1.1.3 vii	Documented policies for financial responsibility and processes for financial planning, budgeting.
	1.1.3 viii	Process for internal and independent systems of financial and asset control.
Non-discriminatory conditions	**1.1.4 i**	Non-discriminatory procedures and application processes.
Confidentiality	**1.1.5 i**	Confidentiality procedures and application processes.
Risk management	**1.2.1 i**	Risk management strategy and process, minutes of meetings to support reviews of risks and supporting policies.
	1.2.1 ii	Risk plan including those specific to certification schemes including mitigation strategies (also meets 1.2.1 iii).
	1.2.1 iv	Sample meeting minutes that show monitoring, review and actions taken to reduce risk (also meets 1.2.1v).
Certification body personnel	**2.1.1 i**	The human resource strategy for the Certification Body.
	2.1.1 ii	Employment policies and procedures to support the operational delivery of the scheme.
	2.1.1 iii	The establishment and skill mix for the Certification Body including schemes.
	2.1.1 iv	Role descriptions for all assessor roles including lay representatives.
	2.1.1 v	Application process and pack for all assessors.
	2.1.1 vi	Assessors contracts or agreements, competencies and agreements.
	2.1.1 vii	Documented process for how lay assessors participate in the assessment process.
	2.1.1 viii	Induction programmes for staff, including service specific education and training.
	2.1.1 ix	Training pathways including competency assessments and evaluations of these for assessors and staff (also covers 2.1.1 xi).
	2.1.1 x	Training needs analysis examples for new staff that support the certification scheme.
	2.1.1 xi	A structured training pathway for new assessors and a process for evaluation of their competence in the role.
	2.1.1 xii	A description of appraisal system for all staff. A summary/matrix of staff appraisals.

	2.1.1 xiii	Evaluation for training programmes and examples of results.
	2.1.1 xiv	Systems and process for on-going development of staff and assessor skills and knowledge.
	2.1.1 xv	Feedback from services and assessors relating to the performance of assessors and staff.
Certification schemes	**2.2.1 i**	Operational plan, minutes of meetings with stakeholders (also covers 2.1.1 ii).
	2.2.1 iii	List of schemes operating and descriptions of scheme and their objectives.
	2.2.1 iv	Register of clients and their certification status for schemes.
	2.2.1 v	The operating plan for the scheme(s).
	2.2.1 vii	Organogram and description of governance and management.
Client application and management	**2.2.2 i**	Publically available information about the scheme requirements.
	2.2.2 ii	Policy and process for application and suitability.
	2.2.2 iii	Marketing and communications plan for schemes(s).
	2.2.2 iii	The range and type of services participating in the scheme(s).
	2.2.2 v	Team etiquette and values policy.
	2.2.2 vii	Summary of information or pack provided to applicants about the clinical service certification scheme.
	2.2.2 vii	Relevant information about the clinical service certification scheme for the services being assessed.
	2.2.2 viii	Copies of agreements for clinical services participating in certification schemes.
	2.2.2 ix	Escalation policy and process for addressing serious concerns about service user care, safety and abuse (also covers 2.2.4xx).
	2.2.2 x	Policy and process for the client to inform the Certification Body of changes that may affect its ability to conform with the certification requirements.
Certification standards	**2.2.3 i**	The process for developing the standards, underpinning criteria and evidence requirements.
	2.2.3 ii	Copies of up to date standards and requirements for certification schemes.
	2.2.3 iii	Processes to provide education and information to staff and assessors of standards to support effective assessments.
	2.2.3 iv	The systems and processes for services to access the standards and criteria for assessment.
	2.2.3 v	Methodology for review and update of the standards.
	2.2.3 vi	Evidence of feedback on standards, this includes feedback from clinical services, professional and patient groups.
	2.2.3 vii	Examples of where user outcomes are included in the standards used for individual schemes.

Clinical service assessment and assessment team	**2.2.4 i**	Policies and process for planning assessments in collaboration with the service involved.
	2.2.4 ii	The policy and processes for communicating the full assessment process to the clinical service. Services Handbooks and guidance (also covers 2.2.4 v, vi).
	2.2.4 iii	Conflicts of interest policy and process (also covers 2.2.4 iv).
	2.2.4 vii	Process for review of service evidence ahead of the site assessment.
	2.2.4 viii	Assessment timetable examples and process for agreeing it with a service with the clinical service.
	2.2.4 ix	Policy for assessor identification, security and etiquette on site assessments (also covers 2.2.4 x, 2.2.4 xi).
	2.2.4 xii	The process for verbal feedback to the clinical service and how this is monitored for consistency.
	2.2.4 xiii	Methodology for assessing the achievement of a standard.
	2.2.4 xiv	Process for checks of assessment activity including timescales to ensure compliance with assessment protocols (also covers 2.2.4 xxiii).
	2.2.4 xv	Description of methods of data analysis and outcomes to support assessments.
	2.2.4 xvi	Assessor guidelines/handbook for assessments (also covers 2.2.4 xxii).
	2.2.4 xix	The communication processes with service and assessors regarding outstanding actions for certification.
	2.2.4 xxii	Selection process for assessment teams.
	2.2.4 xxiii	Process for checks of assessment activity including timescales to ensure compliance with assessment protocols.
Certification decision and reporting	**2.2.5 i**	Policy and procedures to determine the outcome of an assessment.
	2.2.5 ii	Examples of certificates including process for management and review (also covers 2.2.5 iii, 2.2.5 ix).
	2.2.5 iv	Policy for use of certificates, logos and references to the certification scheme.
	2.2.5 v	Policy for suspension or withdrawal from a certification scheme resulting in the loss of certification.
	2.2.5 vi	Policy and processes for certification decisions and examples, performance level for achievement of standards.
	2.2.5 vii	Quality assurance of reports policy and process.
	2.2.5 viii	Policy and processes for ingoing submission of actions plans and the review process to achieve certification.
Surveillance	**2.2.6 i**	Policy and description of processes for all surveillance activities including timescales (covers 2.2.6 i, 2.2.6 ii and 2.2.6 iii).

Records	**2.2.7i**	Effective management of all information, which defines and describes the types of information generated, collected, used and delivered as part of its certification activities.
	2.2.7ii	Clear policies and systems to support information management to ensure accuracy, integrity, confidentiality, reliability, timeliness, security and retention.
	2.2.7iii	The information collected meets all statutory and professional requirements.
General management system	**3.1.1 i**	Description of quality management approaches to schemes, evidence of reviews and feedback to staff.
	3.1.1 ii	Strategy and plans for improving the quality and performance of It's services.
	3.1.1 iii	Internal monitoring, review and audit systems to assess performance and quality of services provided. Evidence of feedback to staff.
	3.1.1 iv	Feedback surveys from Certification Body staff and clinical services participating in the certification scheme and for areas to be improved.
	3.1.1 v	Methodology and summary of clinical service with action plans for any improvements required.
	3.1.1 vii	Research involvement, effectiveness of scheme reports.
	3.1.1 viii	Summary of improvement activities projects and reviews to support improvements in the scheme (also covers 3.1.1 ix).
	3.1.1 x	The policy and description of the process to make public the results of all the accreditation assessments.

Appendix 2: ISO/IEC 17065 and ISQua clause reference information

This table can be used to relate the requirements of this scheme to the ISO/IEC 17065:2012 Standard – Conformity assessment – requirements for bodies certifying products, processes and services and *ISQua Guidelines and Standards for External Evaluation Organisations* 2014.[1]

	Criterion	ISO/IEC 17065 Clause	ISQua Criterion
Legal and contractual matters	**1.1.1 i**	5.1.2 & 5.2	
	1.1.1 ii	4.1.2.1 & 4.1.2.2	
	1.1.1 iii	8.5.1.1	
	1.1.1 iv	5.1.3 (a)	*ISQua Criterion 1.2, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	1.1.1 v	5.1.2 & 5.1.3	
	1.1.1 vi	5.1.4 & 6.1	
	1.1.1 vii	5.1.2	*ISQua Criterion 1.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	1.1.1 viii	8.2.1 & 5.1.4	
	1.1.1 ix	5.2.2. (a)	
	1.1.1.x	6.1.1.1	
	1.1.1 xi	4.1.1	*ISQua Criterion 1.4, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	1.1.1 xii	6.2.2	*ISQua Criterion 2.3, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	1.1.1 xiii	6.2.2.2 & 6.2.2.4	

Management of impartiality	**1.1.2 i**	4.2	
	1.1.2 ii	5.2.1	
	1.1.2 iii	6.1.2.1 & 5.1.4	
	1.1.2 iv	5.2	*ISQua Criterion 1.14, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	1.1.2 v	5.1.2, 4.2, 5.2 & 7.1.3	
Liability & financing	**1.1.3 i**	4.3.1	
	1.1.3 ii	6.2.2.3 & 6.2.2.4	
	1.1.3.iii	6.2.2.4 (c)	
	1.1.3 iv	4.3.2	
	1.1.3 v	4.4.1	
	1.1.3 vi	4.3.2	
	1.1.3 vii	5.1.3 (c)	*ISQua Criterion 2.7, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
Non-discriminatory conditions	**1.1.4 i**	4.4.1- 4.4.4	
Confidentiality	**1.1.5 i**	4.5.1	
Risk management	**1.2.1 i**	5.2.1 & 5.2.2.	
	1.2.1 ii	4.2.3	*Against the associated note, ISQua Criterion 3.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	1.2.1 iii	4.2.1	
	1.2.1 iv	4.2.4	
	1.2.1 v	4.2.4	
Certification body personnel	**2.1.1 i**	6.1.1, 6.1.2, 6.1.3, 6.2.1	*ISQua Criterion 4.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.1.1 ii	6.1.1, 6.1.2, 6.1.3, 6.2.1	*ISQua Criterion 4.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]

	2.1.1 iii	6.1.1, 6.1.2, 6.1.3, 6.2.1	
	2.1.1 iv	6.1.1.1	
	2.1.1. v	6.1.2.2	
	2.1.1 vi	6.1.2.1	
	2.1.1 vii	6.1.2.1 (a)	
	2.1.1 viii	6.1.2.1 (b)	
	2.1.1 ix	6.1.2.2 (f)	
	2.1.1. x	6.1.2.1 (b)	
	2.1.1.xi	6.1.2.1 (e)	*Against the associated note, ISQua Criterion 6.4, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.1.1.xii	6.1.2.2 (f) & 6.1.2.1 (e)	
	2.1.1.xiii	6.1.2.1	
	2.1.1.xiv	6.1.2.1	
	2.1.1 xv	6.1.2.1 (e)	
Certification schemes	**2.2.1 i**	7.1.1, 5.2.2 (a) & 5.2.4	*ISQua Criterion 7.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.1 ii	5.2.2 (a) & 5.2.2 (b)	
	2.2.1.iii	6.2, 7.4.1, 7.1.1, 5.1.2 & 5.1.3	
	2.2.1.iv	5.2.4	*ISQua Criterion 7.4, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.1 v	4.6 (a)	*ISQua Criterion 2.6, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.1 vi	5.1.2	
	2.2.1 vii	5.1.3	Against the associated note, *ISQua Criterion 1.8, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]

Client application and management	**2.2.2 i**	7.2, 7.3, 7.8, 7.9 & 7.10	
	2.2.2 ii	7.2	*ISQua Criterion 7.2, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.2 iii	4.4	
	2.2.2 iv	4.4	
	2.2.2 v	5.1.4	*ISQua Criterion 1.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.2 vi	7.8	
	2.2.2 vii	4.6 (a-d)	
	2.2.2 viii	4.1.2.1	
	2.2.2 ix	4.1.2.2	
	2.2.2 x	4.1.2.2	
	2.2.2 xi	7.2	
Certification standards	**2.2.3 i**	7.3.1 (e)	
	2.2.3 ii	7.4.1	*ISQua Criterion 1.6, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.3 iii	6.1.3 (c)	
	2.2.3 iv	4.6	
	2.2.3 v	5.2.4 & 5.1.3	
	2.2.3 vi	5.2.4	
	2.2.3 vii	7.1.2	
Clinical service assessment and assessment team	**2.2.4 i**	7.4 – general	
	2.2.4 ii	4.6 (a)	
	2.2.4 iii	4.2.3	
	2.2.4 iv	4.2.3	

	2.2.4 v	7.4.3	
	2.2.4 vi	7.2 & 7.4.3	
	2.2.4 vii	7.12 & 8.4.2	
	2.2.4 viii	7.4.1	
	2.2.4 ix	7.4.1	
	2.2.4 x	7.4.1	
	2.2.4 xi	7.4.1	
	2.2.4 xii	6.1.1.2	
	2.2.4 xiii	7.1.2	
	2.2.4 xiv	4.6	
	2.2.4 xv	7.4.1	
	2.2.4 xvi	7.4.1	
	2.2.4 xvii	7.4	
	2.2.4 xviii	7.4.3 & 7.4.6	
	2.2.4 xix	7.4.7	
	2.2.4 xx	7.4.1	*ISQua Criterion7.10, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.4 xxi	7.4.2	*ISQua Criterion 7.9, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.4 xxii	7.4.3	
	2.2.4 xxiii	6.1.2.1 (e)	
Certification decision and reporting	**2.2.5 i**	7.6	
	2.2.5 ii	7.1.1	
	2.2.5 iii	7.7.1, 7.7.2 & 7.7.3	Against the associated note, *ISQua Criterion 8.2, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]

	2.2.5 iv	4.1.3	*ISQua Criterion 8.7, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.5 v	7.11	
	2.2.5 vi	7.6, 7.7, 7.8, 7.10, 7.11 & 7.13	
	2.2.5 vii	7.7.1	
Surveillance	**2.2.6 i**	7.9	
	2.2.6 ii	7.9	
	2.2.6 iii	7.9	
Records	**2.2.7 i**	7.12	*ISQua Criterion 5.1, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.7 ii	7.12	*ISQua Criterion 5.3, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
	2.2.7 iii	7.12	*ISQua Criterion 1.5, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2] Against the note, *ISQua Criterion 5.9 & 5.10, Guidelines and Standards for External Evaluation Organisations, 4th Edition Version 1.1 July 2014.*[2]
General management system	**3.1.1 i**	8.0, 8.5.3 (a) & (b) & 8.6.4	
	3.1.1 ii	8.5.1.1	
	3.1.1 iii	8.5.1	
	3.1.1 iv	8.5.2 (b) & 7.13	
	3.1.1 v	7.13	
	3.1.1 vi	7.13	
	3.1.1 vii	8.7 & 8.8	
	3.1.1 viii	8.7 & 8.8	
	3.1.1 ix	8.5	
	3.1.1 x	N/A	

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