ISQuaEEA

International Society for Quality in Health Care
External Evaluation Association

Guidelines and Principles for the Development of Health and Social Care Standards

5th Edition Version 1.1, March 2022

Contents

Foreword and Acknowledgements

In 2018, the International Society for Quality in Health Care External Evaluation Association (ISQua EEA) was established, as a separate legal entity, by the International Society for Quality in Health Care to deliver external evaluation services. ISQua EEA commenced operations on 1st January 2019. This version of the 5th edition of the Principles (v1.1) has been updated to reflect that the International Accreditation Programme (IAP) is now delivered by ISQua EEA.

This, the 5th Edition of the Guidelines and Principles for the Development of Health and Social Care Standards (the Principles) is the result of an extensive review which commenced in March 2017. A literature review was undertaken at the outset by the IAP team to identify any new themes or changes in each of the Principle areas which should be considered in the revision of the Principles. Client and surveyor evaluations of the Principles were also collated and analysed and these together with the literature review were used to guide the revision of the Principles.

The Accreditation Council, on behalf of the ISQua EEA Board is responsible for advising on all standards developed by ISQua EEA. ISQua EEA would like to thank the following Accreditation Council members who worked closely with the IAP team to revise the Principles: Bruno Lucet, France; Carsten Engel, Denmark; and Linda O' Connor representing Lena Low, Australia. With the guidance of the working group a draft set of Principles was developed and circulated to stakeholders including client organisations and surveyors for consultation in Quarter 4 2017.

Using the RUMBA principles these standards were pilot tested by the Department for Communities and Social Inclusion, Australia and the Australian Council on Healthcare Standards (ACHS), Australia; and two of our peer review surveyors: Barbara Donaldson, New Zealand and Claudia Jorgenson, United States of America in Quarter 1 2018. RUMBA principles ensure the criteria are relevant, understandable, measurable, beneficial and achievable.

A change log outlining the differences between this, the 5th Edition and the 4th Edition can be found at the end of this document. A total of six new criteria have been introduced. These address the promotion of staff well-being, the identification and management of high risk aspects of care, support for patients / service users in improving and maintaining health, disaster recovery planning, staff education on person-centred care and the reporting of quality performance information to the governing body. The 4-point rating scale has also been revised based on feedback received through the IAP evaluation process to ensure that there is clearer differentiation between each numerical rating. The same rating scale will be used for all services within the International Accreditation Programme.

I would also like to acknowledge the work of the IAP team Nicola McCauley-Conlan, Gillian Conway and Caitriona Curran. A special word of thanks to Nicola McCauley-Conlan who project managed the Principles revision process to produce Principles which promote best practice in standards development.

I would like to thank our client organisations and surveyors who complete the post-survey evaluations and who contributed to the consultation process for the draft Principles. Your feedback and ongoing support has helped us to revise the Principles ensuring that they remain fit-for-purpose and a resource for standards developing bodies around the world.

This is Version 1.1 of the 5th Edition and will be available from March 2022. Minor changes have been made to the Guidelines but no changes have been made to the criteria.

Elaine O' Connor
Head of Operations
March 2022

Glossary

Accreditation	A self-assessment and external peer review process used by health and social care organisations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health or social care system.
Adverse Events	Unintended injuries or complications that are caused by the management of a patient/service user's care, rather than by the underlying disease. Such complications can lead to death, disability or a prolonged hospital stay
Appropriate	The degree to which something is suitable for a specific purpose.
Assessment	The process by which the characteristics and needs of patients/ service users, groups, communities or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for services or actions.
Audit	A systematic independent examination and review to determine whether actual activities and results comply with planned arrangements.
Capacity	Resources, assets, and ability of organisations or individuals to deliver services. Or The ability to use and understand information to make and communicate a decision.
Certification	Formal recognition of compliance with set standards validated by external evaluation.
Client	Individuals or organisations being served by the organisation.
Code of Behaviour	A documented set of agreed principles that informs all parties of responsibilities and expectations under the code.
Community	Individuals, families, groups and organisations that usually reside in the same locality.
Competency	The knowledge, skills, abilities, behaviours, experience and expertise to be able to perform a particular task and activity.
Complaint	Expression of a problem, an issue, or dissatisfaction with services that may be verbal or in writing.
Confidentiality	The right of individuals to keep information about themselves from being disclosed.
Consent	Voluntary agreement or approval given by an individual.
Data	Numbers, symbols, words, images, graphics that have yet to be organised or analysed.
Efficiency	The degree to which resources are brought together to achieve desired results most cost effectively, with minimal waste, re-work and effort.

Equity	The absence of avoidable, unfair or remediable differences in health among groups of people, whether those groups are defined socially, economically, demographically, geographically or by other means. Health equity is achieved when everyone can attain their full potential for health and well-being.
Ethics/Ethical	Acknowledged set of principles which guide professional and moral conduct.
Evaluation	A formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.
Expert	An expert is a person with extensive knowledge or ability based on education, research, experience, and occupation in a particular area of study.
Governing Body	Individuals or group with ultimate authority and accountability for the overall strategic directions and modes of operation of the organisation.
Health Professionals	Medical, nursing or allied health professional staff that provide clinical treatment and care to patients/service users, and, where required, have completed and maintained registration or certification from a statutory authority.
Human resources	The personnel requirements of the organisation.
Information	Data that is organised, interpreted and used. Information may be paper-based or electronic.
Information Management	The collection, management and distribution of information.
Licensing	The process by which a governmental authority grants permission to an individual practitioner or health and social care organisation to operate.
Mission	A broad written statement that articulates the organisation's purpose and scope.
Near miss	An incident that was prevented from occurring due to timely intervention or chance that did not result in injury, illness, or damage but had the potential to do so.
Operational plan	A plan which clearly defines the actions that the organisation will take within a defined timeframe to deliver its stated objectives and enable the organisation to meet its longer-term strategic objectives. The operational plan provides detailed information about how the organisation will achieve its stated objectives and identifies what activities must be undertaken; who has responsibility for undertaking each of the stated activities; the timeframes in which the activities must be completed; and the resources (financial, human and other) required to achieve the identified activities.
Orientation	The process by which staff are introduced to a new role and work environment.
Patient/Service User Safety Incident	Any unintended or unexpected incident which could have or did lead to harm for one or more patients/service users.
Performance evaluation	The continuous process by which a manager and a staff member review the staff member's performance, set performance goals, and evaluate progress towards these goals.

Policy	A written operational statement that formalises the approach to tasks that is consistent with the organisational objectives.
Procedure	A written set of instructions conveying the approved and recommended steps for a particular act or series of acts. Or The treatment or care of a patient/service user in a clinical or social care setting.
Process	A series of actions or steps taken in order to achieve a particular end.
Quality	The degree of excellence, or extent to which an organisation meets identified needs or objectives and exceeds expectations.
Quality improvement plan	A plan that outlines quality improvement initiatives including the proposed actions, timelines and responsible individual(s).
Research	Contribution to an existing body of knowledge through investigation, aimed at the discovery and interpretation of facts.
Risk	The probability of danger, loss or injury.
Risk management	A systematic process of identifying, assessing and taking action to prevent or manage clinical, administrative, property and occupational health and safety risks in the organisation.
Risk management framework	A set of components that provide the foundations and organisational arrangements for designing, implementing, monitoring, reviewing and continually improving risk management throughout the organisation.
Safety	The degree to which the potential risk and unintended results are avoided or minimised.
Scope	The range and type of services offered and any conditions or limits to service coverage.
Service user	A person who uses health or social care services.
Staff	Employees of the organisation including temporary and permanent staff.
Stakeholder	A person, group or organisation that has interest or concern in an organisation. Stakeholders can affect or be affected by the organisation's actions, objectives and policies.
Strategic plan	A formalised plan that establishes the organisation's overall goals.
Surveyor	An external peer reviewer of organisational performance against agreed standards.
Values	Principles, beliefs or statements of philosophy that guide behaviour, which may include social or ethical issues.
Vulnerable Populations	Individuals who are vulnerable are those who may be restricted in their capacity to guard themselves against harm or exploitation.

Part A – The Guide

Section 1
About ISQua EEA

1.0 Introduction

Part A of this document is a guide for organisations and surveyors using the ISQua EEA Principles for the Development of Health and Social Care Standards, 5th Edition. It describes the survey process; the different roles and responsibilities; how to complete the self-assessment tool; the rating scale; and how to achieve and maintain ISQua EEA accreditation.

1.1 The International Accreditation Programme (IAP)

The International Society for Quality in Health Care External Evaluation Association (ISQua EEA) provides third-party external evaluation services to health and social care external evaluation organisations and standards developing bodies around the world. ISQua EEA's primary programme is the International Accreditation Programme (IAP). The IAP delivers a unique global accreditation service to external evaluation organisations and standards developing bodies.

Since 1999, the IAP has provided these organisations with an independent third-party assessment process to validate existing systems and drive continuous quality improvement.

Operating in over 60 countries, the IAP offers three separate peer review assessment options:

- **Accreditation of Health and Social Care Standards;**
- **Accreditation of External Evaluation Organisations; and**
- **Accreditation of Surveyor Training Programmes.**

The survey process includes:

- self-assessment;
- peer review evaluation;
- written report with recommendations;
- award; and
- continuous assessment.

The IAP is a voluntary process and is entered by application via the ISQua EEA website (www.ieea.ch).

Evaluation services are provided on a voluntary basis by international surveyors.

1.1.1 Code of Conduct

ISQua EEA personnel, including surveyors will:

- act ethically;
- be responsive to the needs and interests of clients;
- avoid conflicts of interest;
- act professionally;
- respect confidentiality;
- be competent to undertake the work they are assigned; and
- ensure complaints about any of ISQua EEA's personnel or services are investigated promptly and fairly and resolved wherever possible.

1.1.2 Aim of the ISQua EEA Principles

The ISQua EEA Principles have been developed for the assessment and accreditation of the health and social care standards of external evaluation organisations (including accreditation, certification and inspection) and standards developing bodies.

This edition has been streamlined with new criteria building on: the promotion of staff wellbeing, the identification and management of high risk aspects of care, support for patients/service users in improving and maintaining health, disaster recovery planning, staff education on person-centred care and the reporting of quality performance information to the governing body.

1.2 Roles and responsibilities

1.2.1 Governance of the IAP

ISQua EEA is governed by a Board of Directors elected by and from its members. The External Evaluation Award Committee (EEAC) governs the IAP on behalf of the Board. The Board has delegated responsibility to the EEAC to approve accreditation awards. The EEAC makes the final award decisions.

1.2.2 Validation Reviewer

The Accreditation Council delegates its accreditation recommendation to a Validation Reviewer who will be either an experienced surveyor or a Council member with no conflict of interest. The Validation Reviewer is responsible for:

- reviewing the report to ensure it is clear and the comments will provide the organisation with the direction needed to continually improve in meeting the Principles;
- ensuring that the comments reflect that the appropriate rating has been applied;
- ensuring the report findings support any recommendations and/or opportunities for improvement;
- ensuring that the report supports the survey team's accreditation decision recommendation; and
- completing the Validation Review Form and submitting it to ISQua EEA.

The Validation Reviewer's recommendation goes to the External Evaluation Award Committee (EEAC), which makes the final decision regarding accreditation.

1.2.3 ISQua EEA accreditation staff

ISQua EEA staff work with each participating organisation and:

- train and allocate surveyors and Validation Reviewers;
- schedule the surveys and manage the critical path;
- complete technical reviews;
- perform quality assurance reviews of survey reports.

1.2.4 Participating organisations

All participating organisations should agree to abide by the terms and conditions of the IAP and adhere to the timescales as set in the critical path (see 2.1). As part of the application process they should nominate a contact for all correspondence with ISQua EEA. ISQua EEA should be updated with any changes to these details.

1.3 Surveyors

ISQua EEA has a consortium of experienced international professionals who work with health and social care external evaluation organisations in over 18 countries around the world. The ISQua EEA surveyors are recruited and trained to validate an organisation's self-assessment and assess their level of achievement against the ISQua EEA Principles and Standards.

1.3.1 Survey team composition

The survey team consists of two peer review surveyors, chosen by ISQua EEA, one of whom is appointed as the team leader. The role of the survey team is to validate the organisation's self-assessment and provide detailed feedback on whether compliance to each criterion is achieved.

The organisation is provided with the surveyors' biographies and has the opportunity to object to any surveyors who they consider to have a conflict of interest. The Accreditation Manager should be informed of reasons for the objection within 5 working days of the organisation receiving the biographies. ISQua EEA will review the reasons for the objection and make the final decision to remove or retain the surveyor on the team.

1.3.2 Survey team responsibilities

All team members are responsible for preparing for survey including:

- ensuring endorsement from their organisation for participating in the survey;
- reading pre-survey materials;
- leading on the Principles allocated;
- completing their section(s) of the report; and
- answering any queries that ISQua EEA may have.

1.3.3 Team leader responsibilities

The team leader is responsible for coordinating the survey; collating the findings; ensuring that there is a consensus of agreement on the ratings; and writing the executive summary. The team leader submits the report, rating matrix and award recommendation to ISQua EEA.

Section 2
Overview of the Process

2.1 Entry into the Programme

To be eligible for assessment, an organisation must be an external evaluation organisation or a standards developing body within the health or social care sector. Before an organisation can apply for accreditation of their organisation, ISQua EEA should first accredit at least one set of their standards using these Principles.

An application for accreditation of a set of standards may only be made by the organisation that owns the standards or by a third party with written endorsement from the establishment that owns the standards. To fully comply with the ISQua EEA Principles 1 and 2, the standards should have been tested and evaluated to enable feedback.

In certain circumstances, external evaluation organisations that use standards developed by another body can apply for ISQua EEA accreditation of their organisation. For example, an organisation could assess against standards developed by their Ministry of Health. Evidence must be provided to demonstrate the agreement which is in place between the external evaluation organisation and the standards developer.

All organisations must complete an application form prior to entry into the programme. Once this has been received and payment made to ISQua EEA for access to the survey resources, ISQua EEA will assign a critical path which includes dates for the following:

- submission of the completed self-assessment, standards and supporting evidence for technical review;
- submission of the final self-assessment and supporting evidence for survey;
- desktop standards survey;
- review of the survey report by the organisation for factual errors;
- informal notification of assessment by Validation Reviewer;
- award decision ratification at the next External Evaluation Award Committee (EEAC) meeting.

For organisations undergoing re-accreditation, the next survey will be scheduled at least two months prior to the current expiry date to prevent any lapses in accreditation.

2.2 Multiple standard sets

Generally, each set of standards must be accredited on an individual basis, however, if the organisation has a suite/set of standards it wishes to submit for assessment, and they are all based on the same model, but with service specific differences, a comparison of the differences should be provided to ISQua EEA. ISQua EEA will determine if a separate assessment is needed for each set, or if all sets can be assessed by assessing a core set and how the other sets differ.

Section 3
Working with the Principles

3.0 Introduction

The ISQua EEA international accreditation process is a mechanism for external evaluation organisations and standards developing bodies to assure themselves that their standards meet international best practice requirements and to demonstrate this to their clients, funders and other stakeholders. Organisations can guide the development of their standards through the implementation of the ISQua EEA Principles for the Development of Health and Social Care Standards.

These Principles have been developed as statements of outcomes that are necessary for the development of standards with the aim of patient safety, continuous quality improvement and person-centred care. They are supported by criteria that are the measurable components of the Principles.

3.1 Framework of the Principles

The ISQua EEA Principles address the development, measurement, structure and content of standards as follows:

Standards Development	The standards are planned, developed and evaluated through a defined and rigorous process.
Standards Measurement	There is a transparent measurement or rating methodology used by organisations and surveyors to aid consistent rating of achievement.
Organisational Role, Planning and Performance	The standards require the assessment of the capacity and efficiency of health and social care organisations.
Safety and Risk	The standards include processes to manage risk and to protect the safety of patients/service users, staff and visitors.
Person-Centred Approach	The standards are person-centred, reflect the continuum of care and encourage partnerships between patients/service users and professionals.
Quality Performance	The standards require service organisations to evaluate, monitor and improve the quality of services.

A comparative table of the extent to which criteria in the 4th edition Principles have been incorporated into the 5th edition is included in this document (page 56).

3.2 Structure of a Principle

1 **The standards are planned, developed and evaluated through a defined and rigorous process.**

2 **Criterion 1.1**

The rationale for developing new and/or revising standards is established taking into account:
a) environmental scanning of trends relevant to the specific standards area
b) feedback from surveyors, client organisations, professionals, patient/service user groups, governments and other stakeholders
c) using evaluation data collated from previous editions
d) the knowledge and advice of experts

3 **Guidance**

The expected impact of developing standards may be considered both to the organisation developing them and also to the client organisations.

Environmental scanning could take into account literature searches from national and international sources.

Element c) is only applicable for revised standards.

4 **Suggested Evidence**

To complete the self-assessment tool, describe how the need for developing or revising the standards was established. Include a description of how the views of each of the groups involved were obtained, e.g. consultation.

This is supported by further evidence of:

- Minutes of meetings
- Feedback information
- Evaluation data

1 **Overall principle statement** – this describes the high-level outcome for the Principle.

2 **Criterion** – this is mandatory, and organisations are required to self-assess against the criterion. If there are multiple elements within each criterion (e.g. a) to d)), these have equal weighting. Therefore, organisations are required to consider each of these when formulating their written response and the overall rating for the criterion and to outline how they are meeting each of the elements.

Surveyors will assess and report on whether each element has been met.

3 **Guidance** – this explains and expands on the concepts contained within the criterion. It provides guidance for organisations on factors to be considered when formulating their written response and overall rating for the criterion. The guidance is provided for explanatory purposes only and is not mandatory. Organisations may demonstrate their compliance with the criterion in ways other than those outlined.

4 **Suggested evidence** – these are illustrative examples of the type of evidence which organisations can provide to demonstrate their compliance with the criterion. Organisations may demonstrate their compliance with the criterion in various ways and may provide alternative or additional evidence other than that listed.

3.3 Completing the self-assessment tool

The first task is to complete an initial self-assessment of the standards to be surveyed using the self-assessment tool (SAT). It is recommended that a small team is tasked with working through the self-assessment process. They will be responsible for collating all the evidence, checking details and identifying any areas for particular attention. If the team has any problems with interpreting the Principles or deciding what, or how much evidence should be provided, ISQua EEA accreditation staff are available to provide advice. They can also assist with any questions that organisations may have about the survey process. At the end of this exercise, a gap analysis should be completed with identified actions where further work is required.

When completing the self-assessment tool, organisations are required to self-assess each criterion, including both a numerical rating and written response. If there are multiple elements within a criterion, care should be taken to ensure that these are all assessed. Many of the criteria have additional guidance to assist organisations when completing the self-assessment. This guidance is not mandatory. For Principles 1 and 2, suggested evidence is also included for each criterion. Please note that this is suggested evidence only and organisations may decide to present other evidence that demonstrates their compliance. Evidence should be provided for each criterion and must be in English. For Principles 3-6, organisations should include all the relevant extracts from their standards (including the criterion number and text) to demonstrate how they have met the requirements. If any actions are required to achieve better compliance, these should be clearly documented.

The overall rating for each Principle is calculated by adding the ratings and then dividing by the number of criteria. This overall rating should be rounded up or down. For example, Principle 2 has 4 criteria; if they are rated as a 3, 4 and two 2's, the total combined score is 11, this is divided by 4 (number of criteria) = 2.75, which is rounded up to 3 to give the overall score. An overarching statement regarding the level of compliance should be added for each Principle when each overall rating score has been calculated.

The SAT, including the text, is copyrighted and the property of ISQua EEA. It is designed for self-assessment and external surveyor reporting. The SAT must be completed in English, in Arial 10 font, should be focused and not excessive. Automatic numbering, bullet point systems or any type of additional formatting of the document should be avoided. This also applies to information that has been copied and imported from any other documents. Extra formatted headings, borders, graphics and colour elements should be avoided.

3.4 Rating scale

When applying a rating, use the following rationale and guidance to determine the level of compliance. If necessary, add details of the improvements that are required to achieve a higher rating.

Rating	Rationale	Guidance
4	Full achievement All elements addressed and no gaps in compliance (100%) No recommendation (but can have an opportunity for improvement)	If the organisation has exceeded the requirements this should be noted in the surveyor finding.
3	Good achievement Majority of the criterion elements addressed (more than 60%) Recommendation or opportunity for improvement required	The rationale for the recommendation or opportunity for improvement should be included in the surveyor finding.
2	Fair achievement Some of the criterion elements addressed (between 30 - 60%) Recommendation required Risk assessment required	The rationale for the recommendation and the risk assessment should be included in the surveyor finding.
1	Poor achievement Few or none of the criterion elements addressed (under 30%) Recommendation required Risk assessment required	The rationale for the recommendation and the risk assessment should be included in the surveyor finding.

If there are multiple elements within each criterion, please consider these to have equal weighting. For some criteria with only one measurable element, it may only be possible to have full or poor achievement (i.e. there is no option for partial achievement).

Recommendations must be provided when one or more elements of the criterion have not been met i.e. where there is a gap in compliance. Recommendations are mandatory and must be addressed by the organisation. They are required to submit progress reports 12 and 30 months post award demonstrating how the recommendations have or will be addressed. Recommendations should only relate to elements of the criterion which have not been met (i.e. gaps in compliance).

Opportunities for Improvement (OFIs) identifying areas that organisations could consider improving or strengthening can also be provided. They can be provided with any rating and are not considered mandatory.

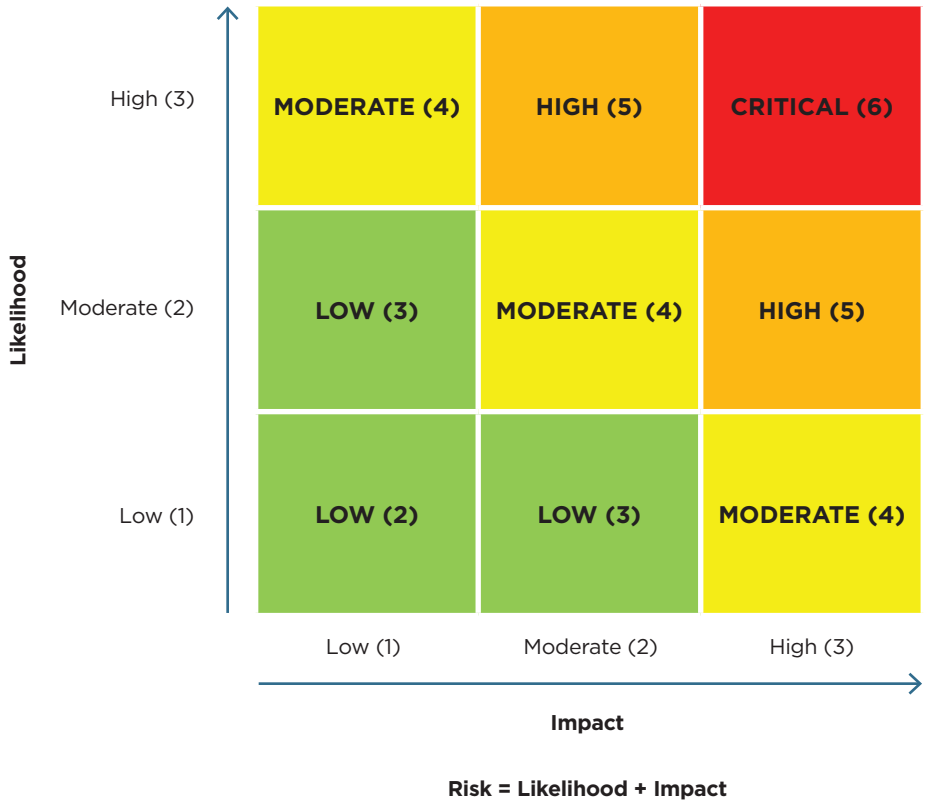
3.5 Risk assessment

When a rating of 1 or 2 is given to any criterion during self-assessment, or by the survey team, a risk assessment must be carried out.

With a rating of 1 or 2, there is a potential risk for the organisation as some or many of the specific criterion elements are not in place. A risk assessment involves describing what the risk is in relation to the missing elements of the criterion and then quantifying this risk by assigning a numerical score using the following risk matrix.

The risk matrix allows one to determine how likely it is that the identified risk will actually happen or materialise (the likelihood) and the impact on the organisation if the risk does materialise or happen (the impact).

The numerical risk assessment score (the overall score) is calculated by adding the score for the likelihood of the risk occurring with the score for the impact of the risk if it did occur. Or more simply, Risk = Likelihood + Impact.



3.6 Core criteria

A number of criteria have been identified as core to the Principles; these are listed below and relate to clinical and corporate responsibilities, processes with immediate impact on patient/service user safety and clinical effectiveness, the requirement for evaluated and formally approved evidence based standards and a defined measurement system.

Core criteria should achieve a rating 3 or higher for the Principle to reach compliance. However, a core criterion rating of 2 may be acceptable, if the risk associated with the criterion is low or moderate as calculated using the ISQua EEA risk matrix and the necessary action can be achieved within 3-6 months post award.

Core Criteria					
Principle 1	Principle 2	Principle 3	Principle 4	Principle 5	Principle 6
1.5	2.1	3.4	4.2	5.10	6.1
1.8	2.2	3.5	4.3	5.11	6.2
1.11		3.8	4.6		
1.12		3.9	4.7		
		3.10	4.8		
		3.13	4.10		
			4.12		

In total, there should be no more than **four core criteria achieving a rating of 2 or lower**, and the risk associated with these criteria must be low or moderate.

3.7 Not applicable criteria

It is recognized that not all criteria may be applicable for all sets of standards. For some criteria, the guidance identifies when a criterion should be considered not applicable. Any further criteria which organisations consider to be not applicable should be discussed with ISQua EEA staff in advance of the technical review. If agreed, the self-assessment should clearly state the date of the agreement with ISQua EEA and the reason the specific criterion, or elements of it, are not applicable. For example, a criterion may not apply due to national, legal, environmental or cultural factors. If the survey team determine that the criterion should be applicable, this will be noted in the report and a rating will be provided.

3.8 Technical Review

The self-assessment tool must be fully completed in English and all supporting evidence translated into English and submitted to ISQua EEA for technical review eight weeks in advance of the survey start date. The date for the technical review submission is included in the critical path. An ISQua EEA Accreditation Manager then reviews the draft self-assessment tool and supporting evidence to ensure that the self-assessment has been completed in accordance with ISQua EEA requirements and that relevant evidence has been provided for each criterion. A report is sent to the organisation commenting on any areas which may need to be addressed; no comments are made on compliance. The organisation then has time to make any necessary changes to the self-assessment tool prior to submission to the survey team. This process ensures that the self-assessment tool is suitable for assessment and helps streamline the survey. The technical review report is also made available to the survey team.

3.9 Submitting the final self-assessment tool and required documentation

The completed self-assessment tool, a copy of the standards and any remaining supporting evidence must be submitted in English to ISQua EEA four weeks prior to the survey start date.

Section 4
Post Survey - Award and Maintenance of Accreditation

4.1 Achievement of Accreditation

For a set of standards to achieve ISQua EEA accreditation, an overall compliance rate of 70% must be achieved. Each individual Principle must also achieve a 70% compliance rate and the following rules must be met:

- there should be no more than two criteria within each Principle rated as a 2 or lower, and the risk associated with these criteria must be low or moderate;
- there should be no more than four core criteria in total with ratings of 2 or lower, and the risk associated with these criteria must be low or moderate;
- there should be no high or critical risk ratings for any criteria;
- recommendations from previous accreditation cycles (if applicable) must have been considered and/or implemented.

Award with consideration: If **one Principle** does not meet the above rules, but the surveyors' recommendations can be achieved within 3 or 6 months, accreditation can be recommended, with the completion of an Action Plan within 3 or 6 months of award outlining how and when the specific report recommendations will be addressed, or have been addressed (the survey team will specify the timeframe i.e. 3 or 6 months). Failure to address the recommendations may result in an award being revoked.

Deferred award: If **two Principles** do not meet the above rules, depending on the scenario, a recommendation on the individual report can be made to defer an award for 3 or 6 months, subject to the submission of an action plan from the organisation.

Overall compliance rate = 184.8/264 = 70%					
Principle 1 44.8/64 = 70%	Principle 2 11.2/16 = 70%	Principle 3 42/60 = 70%	Principle 4 33.6/48 = 70%	Principle 5 39.2/56 = 70%	Principle 6 14/20 = 70%
1.1	2.1 (Core)	3.1	4.1	5.1	6.1 (Core)
1.2	2.2 (Core)	3.2	4.2 (Core)	5.2	6.2 (Core)
1.3	2.3	3.3	4.3 (Core)	5.3	6.3
1.4	2.4	3.4 (Core)	4.4	5.4	6.4
1.5 (Core)		3.5 (Core)	4.5	5.5	6.4
1.6		3.6	4.6 (Core)	5.6	
1.7		3.7	4.7 (Core)	5.7	
1.8 (Core)		3.8 (Core)	4.8 (Core)	5.8	
1.9		3.9 (Core)	4.9	5.9	
1.10		3.10 (Core)	4.10 (Core)	5.10 (Core)	
1.11 (Core)		3.11	4.11	5.11 (Core)	
1.12 (Core)		3.12	4.12 (Core)	5.12	
1.13		3.13 (Core)		5.13	
1.14		3.14		5.14	
1.15		3.15			
1.16					

4.2 Decision process

Following the survey, the survey team submits the draft report and the ratings matrix with award recommendation to ISQua EEA. To ensure fairness and consistency of the process, the following steps occur:

- ISQua EEA staff perform a quality assurance review of the survey report;
- the survey team reviews any queries from ISQua EEA and submits their final report and award recommendation to ISQua EEA;
- the organisation undertakes a factual review of the report to ensure that the surveyors have not misinterpreted evidence or missed information. Any comments raised from the factual accuracy review are discussed with the survey team and the report finalised as appropriate;
- the final report is sent to a Validation Reviewer with the survey team award recommendation; and
- the final report, including any changes suggested by the Validation Reviewer and agreed by the survey team, and the completed Validation Review Form are sent to the External Evaluation Award Committee (EEAC) which make the final award decision.

4.3 The award

In making their decision the EEAC considers the achievement of accreditation guidelines as outlined in 4.1 and the recommendations of the survey team and the Validation Reviewer. They also consider the organisation's overall performance across all Principles and the overall number of recommendations recorded as part of the survey.

It is the right of the EEAC to confer a different award than that recommended by the survey team and the Validation Reviewer if they consider it appropriate in light of the overall performance and number of recommendations recorded. Following the EEAC meeting, ISQua EEA will advise of the accreditation award decision. If the standards are successfully accredited, they will be accredited for four years with effect from the date of the EEAC meeting at which the decision was made.

The award will be issued once confirmation is received from the ISQua EEA Finance Department that all accreditation-related fees have been paid.

Following approval, ISQua EEA will send a final report, issue a Certificate of Accreditation and provide the ISQua EEA Accreditation logo and the policy that sets out the conditions of its use. ISQua EEA will also publish details of the award on its website.

4.4 Post-survey evaluation

ISQua EEA is committed to improving its services and each organisation and survey team are asked to complete an online questionnaire on their experience of the survey. The summation of the evaluation results is published in an annual report which is distributed to stakeholders.

4.5 Maintaining the award

Continuing accreditation status will be subject to the completion of a Progress Report within 12 months of award outlining how and when the report recommendations will be addressed, or have already been addressed. A second Progress Report showing these changes is required 30 months post award. Recommendations relating to Principles 3 – 6 (i.e. the content of the standards) should be addressed as part of an organisation's normal revision process (unless otherwise specified).

ISQua EEA awards are specific to the edition which is submitted at the time of survey. In order to maintain ISQua EEA accreditation, an organisation must report any significant changes, such as new or updated versions of the standards. If there are any concerns about lack of progress or if the standards have been changed significantly, the External Evaluation Award Committee (EEAC) will be informed and may request an independent review. The independent review will be undertaken by an ISQua EEA senior surveyor who will review the progress report and evidence provided and will make a recommendation to the EEAC regarding the appropriateness of the action undertaken and any further action required by the organisation. An ISQua EEA accreditation award can be removed by the EEAC, depending on the result of this review.

4.6 Appeal

If there is dissatisfaction with the accreditation decision, the organisation has the right to appeal within 28 days of receiving their final accreditation decision, clearly outlining the grounds on which they disagree with the decision. The appeal will be independent of any other process.

Grounds for appeal are that:

- relevant and significant evidence was not properly considered, or was incorrectly interpreted;
- inappropriate weighting was given to the evidence; or
- the original decision-making process was inconsistent with the published criteria for accreditation.

The appeal will be considered within one month of the written request being received by the ISQua EEA Chief Executive Officer. The appeal panel will consist of three members:

- A member of the Board who will chair the appeal panel;
- Two independent experts, not involved in the survey.
- The CEO and Chair of the appeal panel shall decide on a fourth member of the panel, if required.

The appeal panel's decision is reviewed and communicated to the Board. If the appeal results in a recommended change in accreditation status, the decision must be endorsed by the External Evaluation Award Committee (EEAC).

Part B – The Principles

Principle 1
Standards Development

The standards are planned, developed and evaluated through a defined and rigorous process.

Criterion 1.1

The rationale for developing new and/or revising standards is established taking into account:

a) environmental scanning of trends relevant to the specific standards area

b) feedback from surveyors, client organisations, professionals, patient/service user groups, governments and other stakeholders

c) using evaluation data collated from previous editions

d) the knowledge and advice of experts

Guidance

The expected impact of developing standards may be considered both to the organisation developing them and also to the client organisations.

Environmental scanning could take into account literature searches from national and international sources.

Element c) is only applicable for revised standards.

Suggested Evidence

To complete the self-assessment tool, describe how the need for developing or revising the standards was established. Include a description of how the views of each of the groups involved were obtained, e.g. consultation.

This is supported by further evidence of:

- Minutes of meetings
- Feedback information
- Evaluation data

Criterion 1.2

Any relationships with the standards of other organisations, and professional and regulatory requirements are identified and considered.

Guidance

Links or overlap with regulatory requirements or other standards may be identified within the standards or in a separate guide to aid implementation of the standards and avoid duplication where possible.

Suggested Evidence

To complete the self-assessment tool, describe any relationships with the standards/ requirements of other organisations and describe how these help minimise duplication.

This is supported by:

- reference to 3-4 criteria from your standards that demonstrate the alignment of these standards with the standards of other organisations, and professional and regulatory requirements.

Criterion 1.3

There is a process for the development or revision of standards which is supported by a plan that includes clearly defined activities, resources and timeframes.

Guidance

This relates specifically to the edition of the standards which has been submitted for assessment.

Suggested Evidence

To complete the self-assessment tool, describe how these standards were developed and/or revised.

This is supported by:

- The standards development/revision plan
- The standards development/revision policy or process

Criterion 1.4

The documented standards development process for new and/or revised standards is made publicly available.

Guidance

The process may be made available by being posted on the organisation's website.

This relates specifically to the edition of the standards which has been submitted for assessment.

See criterion 1.3 relating to the standards development process.

Suggested Evidence

To complete the self-assessment tool, describe how the standards development process is made publicly available.

This is supported by:

- Evidence of how the standards development process is made publicly available.

Criterion 1.5 CORE

Standards are based on:

a) current available research, evidence and experience

b) internationally recognised guidelines

c) recommendations/standards from WHO and other national/international professional organisations

d) input from technical experts

Guidance

Legal requirements are addressed in criterion 3.6.

Suggested Evidence

To complete the self-assessment tool, identify any research or evidence of good practice on which the standards have been based.

Describe how technical experts contributed to the standards development process.

This is supported by:

- reference to a number of criteria that demonstrate the incorporation of WHO, internationally recognised guidelines and/or professional organisation recommendations.

Criterion 1.6

Stakeholders, including governmental bodies, client organisations, surveyors, professionals and patients/service users, are provided with opportunity for input into the standards development and/or revision process through direct or indirect representation and formal consultation.

Guidance

As part of the consultation process, draft standards may be made available to interested parties for comment (e.g. standards could be posted online).

Suggested Evidence

To complete the self-assessment tool, describe what groups were represented in the standards development process, how they were involved, the methodology, e.g. web-based, workshops, and what consultation processes took place with which groups.

This is supported by:

- Details of consultation
- Feedback
- Minutes of meetings

Criterion 1.7

The scope of the standards is clear in terms of:

a) the type of health or social care organisation/service to which they apply

b) whether they are designed for use by the whole organisation or a specific service

c) the range of services covered

Suggested Evidence

To complete the self-assessment tool, reference or provide appropriate extracts from the standards introduction or manual that explain the scope of the standards.

Criterion 1.8 CORE

The purpose of the standards is clearly documented.

Guidance

The standards could be used for accreditation, certification, licensing, insurance or public funding eligibility, setting a level of acceptable performance or facilitating quality improvement (or a combination of these).

Suggested Evidence

To complete the self-assessment tool, reference or provide appropriate extracts from the standards introduction or manual that explain the purpose of the standards.

Criterion 1.9

The standards have been designed and evaluated to ensure that there is a clear framework that makes them easy for client organisations and surveyors to use.

Guidance

The framework may include:

i. standards being grouped logically, e.g. by function or system

ii. standards being labelled, and pages identified so that their content can be easily located

iii. the use of a numbering or alphabetical system for the standards and their criteria or elements enabling them to be easily identified

Suggested Evidence

To complete the self-assessment tool, describe how the standards framework has been designed and evaluated to ensure it is appropriate for users.

This is supported by:

- Feedback
- Minutes of meetings

Criterion 1.10

The standards have been evaluated to ensure the wording of the standards is clear and unambiguous.

Guidance

Clear wording may be achieved by:

i. sentences having clear subjects and objects so it is clear what is required or who is responsible

ii. avoiding words that may have more than one meaning or interpretation e.g. adequate, good, well or sufficient

iii. a formal review process to identify and clarify wording that is ambiguous or not clear

iv. material being available to assist users in the interpretation of the standards

v. minimising the use of acronyms, and if used, providing an explanation

Suggested Evidence

To complete the self-assessment tool, describe how the language of the standards was evaluated before approval, and how the results were used to ensure the wording is appropriate for users.

This is supported by:

- Evaluation data

Criterion 1.11

CORE

The standards have been evaluated by client organisations and surveyors prior to approval to ensure that each standard is relevant, understandable, measurable, beneficial and achievable (RUMBA). The outcomes are used to identify required changes to the standards and the assessment methodology.

Guidance

It is anticipated that a systematic evaluation is undertaken to ensure that each standard is relevant, understandable, measurable, beneficial and achievable (RUMBA).

However, it is recognised that the extent of the evaluation may vary depending on whether this is a new or revised set of standards and that this will be determined by the organisation.

For ISQua EEA re-accreditation surveys, it is recognised that the RUMBA principles may be evaluated by client organisations and surveyors on an ongoing basis.

Types of evaluation could include field testing, interviews or desktop exercises.

In the case of a new set of standards, it is recognised that a specific surveyor workforce may not necessarily be in place for this external evaluation programme. In such instances it is anticipated that the standards would be evaluated by those with surveying experience and who have worked on other external evaluation programmes, those with surveyor skills or potential surveyors for the new external evaluation programme.

Suggested Evidence

To complete the self-assessment tool, describe how the standards were evaluated before approval, and how the evaluation results were used to make changes to the standards.

This is supported by:

- Instructions for participants
- The evaluation plan including timescale, numbers and types of participants
- Examples of feedback
- Examples of changes that were made to the standards following evaluation

Criterion 1.12

CORE

There is a process for the approval of new and/or revised standards before implementation.

Suggested Evidence

To complete the self-assessment tool, describe the approval process.

This is supported by:

- Evidence to show that the standards were approved before implementation

Criterion 1.13

There is a process to:

a) determine the requirements under which the standards could be used by an independent assessment organisation, other than the body that developed the standards

b) establish a formal agreement between the different bodies in relation to their use

c) collect feedback from the assessment organisations using the standards

Guidance

If the standards can only be used by the applicant organisation, rate this criterion as Not Applicable (N/A).

Suggested Evidence

To complete the self-assessment tool, describe the process.

This is supported by:

- Evidence of any defined process and agreement for allowing another organisation to use the standards

Criterion 1.14

There is a plan for the implementation of new and/or revised standards which includes: activities, responsibilities, timeframes and any transitional arrangements.

Guidance

Requirements could include the revisions of standards being publicised and distributed to client organisations and surveyors in sufficient time for them to develop an understanding of the standards before the date of implementation.

The implementation plan could be included within the overall standards development or revision plan.

Suggested Evidence

To complete the self-assessment tool, describe the activities, timeframes and transitional arrangements, and how client organisations and surveyors are made aware of them.

This is supported by:

- The plan for implementation

Criterion 1.15

Information and education are provided to client organisations and surveyors on the new and/or revised standards to enable understanding and implementation.

Guidance

The changes to the standards may be outlined in a statement and/or an index/change log.

Suggested Evidence

To complete the self-assessment tool, describe how client organisations and surveyors are educated about new and/or revised standards.

This is supported by:

- Examples of education activities
- Examples of how client organisations and surveyors are made aware of the changes made

Criterion 1.16

Feedback (including satisfaction of client organisations, surveyors and stakeholder groups) on the standards is obtained, documented and monitored on an ongoing basis.

The data are analysed and evaluated to assist with improving the standards.

Guidance

This criterion relates to the ongoing collection and evaluation of feedback about the standards from client organisations, surveyors and stakeholder groups.

For a new set of standards, a planned process for the collection and evaluation of feedback could be outlined in the self-assessment tool.

Suggested Evidence

To complete the self-assessment tool, describe how feedback is collected and evaluated.

This is supported by:

- Feedback tools
- Results of feedback
- Summary of relevant analysis and evaluation of data
- Examples of how the data have been used in the development of the standards

Principle 2
Standards Measurement

There is a transparent measurement or rating methodology used by organisations and surveyors to aid consistent rating of achievement.

Criterion 2.1

CORE

There is a process for measuring or rating an organisation's performance on each standard, criterion or element.

Suggested Evidence

To complete the self-assessment tool, describe the measurement or rating process for the standards and the criteria or elements.

This is supported by:

- Evidence of the measurement or rating process

Criterion 2.2

CORE

There is a documented methodology for measuring overall achievement of a set of standards.

Guidance

The methodology could include:

i. achievement on all compulsory criteria/standards

ii. all criteria/standards being achieved at a defined level

iii. no criterion/standard being rated below a defined level

A risk assessment may be required when a criterion or standard receives a low rating.

The methodology may be used by organisations to assess their overall achievement of the standards as part of a self-assessment process.

The methodology may be included in the guidelines (see criterion 2.3).

Suggested Evidence

To complete the self-assessment tool, describe the methodology for measuring the overall achievement of the standards, e.g. numeric rating system, scoring, or voting.

This is supported by:

- Evidence of the overall measurement or rating methodology and how it is made available to client organisations and surveyors

Criterion 2.3

Guidance on the measurement or rating methodology is provided to:

a) enable client organisations to assess their own performance against the standards

b) assist surveyors to rate standards

Guidance

Guidance could relate to the weighting of criteria/standards, the role of compulsory criteria/standards, or the use of risk assessments if there are identified risks or safety issues.

Specific situational examples could be included to help guide surveyors.

Suggested Evidence

To complete the self-assessment tool, describe the guidance available.

This is supported by:

- Guidelines, measurement tools or other information provided to assist consistent rating

Criterion 2.4

Feedback on the measurement or rating methodology is collected from client organisations and surveyors to ensure that it is clear and understandable. The data are evaluated, and results are used to make improvements.

Guidance

This criterion relates to both the initial testing of the measurement or rating methodology and the ongoing collection and evaluation of feedback from client organisations and surveyors.

Suggested Evidence

To complete the self-assessment tool, describe how the measurement or rating methodology is evaluated. Describe how the results have been, or will be, used to make improvements to the methodology.

This is supported by:

- Feedback forms
- Examples of results
- Examples of improvements

Principle 3
Organisational Role, Planning and Performance

The standards require the assessment of the capacity and efficiency of health and social care organisations.

Criterion 3.1

The standards require organisations to define their:

a) mission

b) values

c) ethics or code of behaviour

d) strategic objectives within a plan

Guidance

A strategic plan sets the long-term objectives of an organisation to address major changes or improvements.

It is recognised that not all services will develop their own mission, values, code of behaviour and strategic objectives, however, the standards should require that such services adhere to those developed by the wider organisation.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 3.2

The standards require organisations to:

a) have an operational plan with identified service objectives

b) measure progress in achieving these objectives

Guidance

Service objectives could relate to the number and type of planned service activities.

The plan may include links to other plans within the organisation, for example, human resources, risk, communication and financial plans.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 3.3

The standards require organisations to have a process to develop, authorise, review and update their plans, policies and procedures within defined timeframes for the organisation's key functions.

Guidance

The key functions relate to both operational and clinical procedures. Key functions are determined by organisations.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.4 CORE

The standards require organisations to have formalised corporate and clinical governance arrangements with clearly defined roles and responsibilities.

Guidance

Corporate governance responsibilities may relate to determining the organisation's direction, setting objectives and developing policy to guide the organisation in achieving its mission, monitoring the achievement of those objectives and the implementation of policy.

Clinical governance refers to a systematic approach to maintaining and improving the quality of care. Clinical governance may include clinical audit, risk management, quality improvement, education and training, information management, and research and development. It is recognised that not all of these may be relevant.

It is recognised that the governance arrangements will vary depending on the scope of the standards and some of these responsibilities may be delegated to an identified individual(s).

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.5 CORE

The standards require organisations to define the responsibilities, with any required delegation, within an organisation for:

a) operational management

b) financial management

Guidance

Operational management responsibilities may relate to implementing policy, setting targets or goals for the future through planning and budgeting for the organisation's range of services, establishing processes for achieving those targets, allocating resources to accomplish those plans and ensuring that plans are achieved.

Financial management is defined as the planning, monitoring, organising and controlling of the monetary resources of an organisation.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 3.6

The standards are consistent with the current legal and health and/or social care policy requirements of the environment in which they apply.

Guidance

Common legal and regulatory requirements that may be referenced relate to:

i. employment e.g. equal opportunities
ii. disability
iii. health and safety
iv. building and fire safety
v. environmental protection
vi. reportable diseases
vii. waste management
viii. food safety
ix. health professional registration
x. health information
xi. medicine and healthcare products
xii. technical standards e.g. information technology

It is recognised that the standards may not address all the above and that further examples could be provided.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Evidence may also be provided to demonstrate when certain legal and regulatory requirements are addressed by another national or regional body.

Criterion 3.7

The standards require that organisations use a planning process, taking into account any professional practice recommendations, to determine the level of staffing and skill mix required to meet the needs of the services provided.

Guidance

Professional bodies may have requirements or standards for the numbers of qualified staff required to ensure a safe service.

There may also be regulatory requirements at a national or regional level.

See operational plan in criterion 3.2.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.8 CORE

The standards require that staff, independent practitioners and volunteers, have relevant and current:

a) education

b) skills and competencies

c) experience

d) orientation and training

Guidance

If volunteers are not applicable, please ensure this is clearly stated within the self-assessment.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 3.9 CORE

The standards require that the health and/or social care practitioners permitted by law and by the organisation to practice, including independent practitioners:

a) are credentialed; and

b) have their scope of practice defined.

Guidance

Credentialing relates to the process of verifying education, training and proven skills of health and/or social care practitioners.

The scope of practice relates to the range and type of procedures that a health and/or social care practitioner is permitted to perform within the organisation.

It is recognised that credentialing may be undertaken by another body and if so, it is expected that the standards will reflect the organisation's role in this process.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 3.10 CORE

The standards require organisations to have processes to regularly evaluate the continued competency and ongoing performance of all staff in line with their job descriptions.

Guidance

The process(es) could include reviews of scope of practice, competency assessments, performance evaluations, and any training or education requirements being documented and shared with the staff member involved.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.11

The standards require that organisations have arrangements for relevant on-going education (courses and training sessions) that is necessary to acquire and maintain the required level of performance and competency.

Guidance

Education opportunities may be formalised, or they may be integrated into the working environment.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.12

The standards require that organisations have arrangements for the:

a) promotion of staff well-being

b) resolution of workplace issues

Guidance

The promotion of staff well-being may involve:

i. procedures to promote well-being, e.g. stress management, workload monitoring, management of work-life balance, healthy lifestyle programmes

ii. staff being provided with appropriate supervision, support and advice

The resolution of workplace issues may involve:

i. measures to protect staff against violence, bullying and harassment

ii. clear procedures for the effective management of underperformance

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 3.13 CORE

The standards require staff to use current accepted evidenced-based standards, protocols and guidelines.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.14

The standards require that the planning for the provision of services is informed by patients/ service users, their families, staff and where possible the wider community

Guidance

This may relate to the range of services offered by an organisation and how and where the services are delivered.

This criterion does not relate to individual care plans (see criterion 5.11).

Where the organisation has no influence on the range of services they provide (e.g. when it is politically determined) this should be noted in the self-assessment.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 3.15

The standards require that there is a framework to support coordination within and between departments and with relevant external services.

Guidance

The framework could be supported by cooperation agreements, shared protocols and/or committees for shared planning of care for individual service users.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Principle 4
Safety and Risk

The standards include processes to manage risk and to protect the safety of patients/service users, staff and visitors.

Criterion 4.1

The standards require organisations to manage risk through a risk management framework which must include both reactive and proactive processes.

Guidance

Proactive risk management is essential to quality and safety and is applicable to all organisations.

A risk management framework could include:

i. scope, objectives and criteria for assessing risk
ii. risk management responsibilities and functions
iii. staff training
iv. a list of identified risks – strategic, operational and financial
v. processes for reporting risks to the governing body
vi. a summary of risk plans for major risks
vii. processes for communicating with stakeholders

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 4.2 CORE

The standards require organisations to support the risk management framework with a:

a) risk management plan

b) risk management policy (or policies)

c) risk register

Guidance

A risk management plan describes the responsibilities and timeframes for the reporting, reviewing and monitoring of risks.

A risk register is a live record of all prioritised risks and is updated on a regular basis. The identified risks may be rated in accordance with their severity, probability and/or potential impact to the organisation.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.3 CORE

The standards require organisations to assess patients/service users:

a) to identify those that are at high risk of harm; and

b) to have processes in place to mitigate these risks

Guidance

The types of risk assessments will be determined by the scope of the standards.

This criterion relates to the identification of patient/service user characteristics that may render care to be higher risk for a particular patient/service user compared to the general population.

Risk assessments could relate to:

i. medication management
ii. falls
iii. infection susceptibility
iv. nutrition
v. risks resulting from long-term conditions
vi. risks relating to the care of vulnerable patients/service users

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.4

The standards require organisations to:

a) identify procedures, treatments or aspects of care that are high risk; and

b) have arrangements in place to mitigate these risks

Guidance

The risks could be relevant to patients/service users and/or staff.

For an acute care service, these could include:

i. surgical and invasive procedures
ii. management and use of blood and blood products
iii. use of ionising radiation, radioactive isotopes and nuclear medicine
iv. use of cytotoxic drugs and controlled drug management
v. research and clinical trials
vi. equipment risks, e.g. fire/injury risks from use of lasers

For a social care service, these could include:

i. medication management including polypharmacy
ii. use of equipment and medical devices
iii. transfer of patients/service users

For a primary care service, these could include:

i. management of blood
ii. identification and transfer of biological samples

For a laboratory service, these could relate to:

i. procedures which require the use of personal protective equipment
ii. waste disposal techniques
iii. sample identification procedures

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.5

The standards require organisations to have processes for:

a) reporting, investigating and taking action in response to safety incidents including adverse events and near misses that affect patients/service users, staff or visitors

b) using findings to make improvements

c) communicating with patients/service users about adverse events they are affected by

Guidance

The processes could include:

i. training for staff in the reporting, investigation and communication methods

ii. means for documenting and reporting incidents/events

iii. root cause analysis

iv. support for staff affected by adverse events

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.6 CORE

The standards require that organisations identify and implement evidence-based patient/service user safety strategies appropriate to the care or services provided.

Guidance

Patient/service user safety strategies could include medication management, patient identification, supply chain efficiency strategies using when appropriate information technology such as barcoding, safe surgery checklists, laboratory sample identification procedures, hand hygiene practices and safeguarding strategies for vulnerable populations (e.g. children and older people).

For social care standards, this could include counselling, community involvement strategies and positive behaviour support.

Further information on patient safety strategies/solutions may be found on the WHO website.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 4.7 CORE

The standards require organisations to:

a) have a programme for the prevention and control of infections which includes at least hand hygiene

b) provide staff education about the programme

c) collect, analyse and report programme results

Guidance

It is recognised that the infection control programme will vary depending on the scope of the standards.

Other requirements may include, as appropriate to the care or services provided:

i. use of isolation and precaution techniques

ii. antimicrobial stewardship

iii. management of nosocomial infections

iv. sterilisation and decontamination procedures

v. monitoring of infection rates

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.8 CORE

The standards require organisations to protect the health and safety of staff, taking into consideration any current government or legal requirements.

Guidance

A health and safety programme for staff could include:

i. protective clothing and equipment for staff

ii. workplace assessments

iii. staff vaccination

iv. prevention from manual handling injuries

v. prevention from needlestick injuries

vi. protection from occupational hazards, for example radiation, chemicals and substances

vii. management of violence and aggression

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 4.9

The standards require organisations to:

a) train staff on the safe operation of equipment, including medical devices; and

b) ensure only trained and competent people handle specialised equipment

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.10 CORE

The standards require organisations to ensure that:

a) relevant safety laws and regulations are met

b) the buildings, space, equipment and supplies necessary for the stated services are provided

c) facilities and equipment are inspected, tested, maintained and updated or replaced in a planned and systematic way

Guidance

It is important for organisations to ensure they are able to carry out treatment and care in an environment which has sufficient space; the correct equipment; and has systems in place to ensure supplies are available and patient/service user safety will not be compromised.

Local legal requirements for health and safety may also give further guidance.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 4.11

The standards require that organisations develop, review and test a disaster recovery plan.

Guidance

The disaster could be natural (e.g. floods, earthquakes, hurricanes, disease outbreaks), or manmade (e.g. urban fires, industrial accidents, bioterrorism).

The disaster recovery plan may also be referred to as an emergency or contingency plan.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 4.12

CORE

The standards require patient/service user records to be:

a) current, complete and accurate

b) confidential and secure

c) retained and/or destroyed in accordance with any relevant legislation

Guidance

In the case of both electronic and hard copy records, requirements may include, as relevant to the service provided:

i. legible, dated, timely and signed entries

ii. alert notations

iii. progress notes, observations, consultation reports, diagnostic results

iv. all significant events such as alterations to patients'/service users' conditions and responses to treatment and care

v. any safety incidents including near misses and adverse events

vi. use of only recognised abbreviations

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Principle 5
Person-Centred Approach

The standards are person-centred, reflect the continuum of care and encourage partnerships between patients/service users and professionals.

Criterion 5.1

The standards require organisations to:

a) identify and inform patients/service users of their rights and responsibilities; and

b) ensure staff respect those rights

Guidance

It is recognised that patient/service user rights may be defined in national or regional legislation where available.

Rights could include privacy, dignity, respect, confidentiality of information, personal safety and access to all information about their care.

Responsibilities could include providing accurate information to care providers, facilitating the delivery of care and respecting the rights of staff.

Patient/service user rights and responsibilities could be included in a Patient's Charter or equivalent.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 5.2

The standards require processes to receive and resolve ethical dilemmas in a defined timeframe.

Guidance

This criterion relates to the need for a structured process for the management of any ethical dilemma that may arise in the service.

Ethical dilemmas could arise when there are conflicting decisions regarding the provision or withdrawal of treatment. This could involve different professionals, the patient/service user and/or families/carers.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.3

The standards require staff to involve patients/service users in shared-decision making about their own care by:

a) discussing their options for care and treatment

b) identifying and respecting their preferences or choices

Guidance

Shared decision-making could include the discussion of benefits and risks and may involve the use of decision aids. Information could be available in different languages and formats to facilitate the shared decision-making process.

Choices could include the type of treatment, who they want involved in their care or service and end of life wishes.

Preferences may relate to

i. how individuals are addressed
ii. their care and treatment options
iii. their personal effects
iv. their clothing and self-care routines
v. drinks and meals
vi. activities, interests, privacy, visitors

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 5.4

The standards require organisations to:

a) obtain informed consent from patients/service users

b) respect when a patient/service user declines care or treatment

Guidance

It is recognised that standards relating to consent will be based on national or regional legislation where available.

The standards may reference arrangements which are in place for minors or individuals who do not have the capacity to make informed decisions.

The standards may specify how consent is obtained and recorded for activities such as:

i. participation in research or experimental procedures
ii. operative and invasive procedures, anaesthesia and moderate/deep sedation
iii. where there is a significant risk of adverse effects
iv. photographs and promotional activities, for which the consent could be for a specific time or purpose

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact. It is also recognised that explicit consent may not be required for certain services (e.g. primary care).

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.5

The standards require that services educate and support patients/service users to maintain and improve their own health and wellbeing.

Guidance

This could include requirements relating to smoking cessation programmes, stress management advice, diet and exercise guidance and substance abuse management.

It is recognised that the requirements will vary depending on the scope of the standards.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.6

The standards require that the cultural context and spiritual preferences of patients/service users are recognised.

Guidance

The standards may require processes to:

i. provide access to spiritual care or advice that meets patients'/service users' needs

ii. where culturally appropriate, provide separate facilities and services for women and men

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.7

The standards require that staff are educated about person-centred care.

Guidance

Education could relate to the provision of integrated care, patient/service user rights, complaint management, shared decision-making, communication skills, informed consent, and the cultural beliefs, needs and activities of different patient/service user groups.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.8

The standards require that patients/service users are provided with information on:

a) admission or entry processes

b) the range of services provided by the organisation/service

Guidance

Information could be provided in different languages and formats depending on the needs of the community and diversity of the population.

Information could be adapted to the age and ability of the person.

Information could be made publicly available via the organisation's website.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 5.9

The standards require that all patients/service users can physically access and use the service.

Guidance

The physical accessibility of the building could relate to wheelchair accessible entrances and facilities and clear signage.

Assistive technologies (e.g. hearing loops) may also be used.

The arrangements in place could be based on national or regional legislation or best practice guidance.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.10 CORE

The standards require that the assessments of patients/service users:

a) involve relevant disciplines

b) are performed by qualified individuals

c) are completed and documented as required by organisation policy

Guidance

Assessments could relate to medical, physical, mental health and/or social care needs.

For laboratory standards, this could relate to the assessment of patient/service user samples.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 5.11

CORE

The standards require that individual treatment or care plans are prepared and documented:

a) based on the assessment of patient/service user needs, including the results of diagnostic tests where relevant

b) using evidence-based care guidelines or pathways where appropriate

c) involving the patient/service user

d) including the goals or desired results of the treatment or care

Guidance

Families/carers are included in the development of the care plan when appropriate.

It is recognised that some care plans are based on national or regional pathways or guidelines and customisation may be limited.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 5.12

The standards require that:

a) treatment or care plans are followed

b) the progress of patients/service users in achieving the goals or desired results of treatment, care or service is monitored

c) patients'/service users' needs are reassessed when indicated

d) the treatment or care plan is revised according to reassessment results

Guidance

The standards may also set expectations as to who participates in care planning, the documentation of care plans in the patient record, the frequency of monitoring and reassessment and care plan modification.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each element of this criterion is met.

Criterion 5.13

The standards require organisations to include patients/service users in the planning of their discharge or referral to internal and/or external services.

Guidance

Requirements could relate to planning for the transfer of care between primary and secondary healthcare providers, the provision of homecare services, palliative care, rehabilitative care and/or residential care.

If death is the expected outcome, planning could include the preparation of patients/service users and their families for death, the management of pain and symptoms, linkage with support groups, counselling, and addressing spiritual and cultural needs.

This criterion would be not applicable for laboratory standards/standards with no direct patient/service user contact.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 5.14

The standards require services to:

a) have processes in place to receive feedback from patients/service users

b) have processes in place to investigate and resolve patient/service user complaints within a defined timeframe

c) make the complaints process publicly available

Guidance

It is recognised that standards relating to complaints will be based on national or regional legislation where available.

Feedback could include concerns, compliments and formal complaints.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Principle 6
Quality Performance

The standards require organisations to evaluate, monitor and improve the quality of services.

Criterion 6.1

CORE

The standards require organisations to collect information relating to the performance of the service.

Guidance

The information collected could include:

i. complaints
ii. compliments and concerns
iii. audit information
iv. findings from risk assessments
v. patient/service user safety incidents including adverse events
vi. patient/service user reported outcome measures
vii. patient/service user satisfaction
viii. staff satisfaction
ix. other performance measures appropriate to the care or service delivered

Organisations may participate in national or regional programmes which require that defined performance measures are collected.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 6.2

CORE

The standards require that the performance data collected is evaluated and used to guide quality improvement.

Guidance

Performance data can be trended and used to identify areas of excellence or opportunities for improvement. This may involve benchmarking against other departments or organisations.

The data can be used by those responsible and/or involved in the delivery of that service to enable improvements to be made.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Criterion 6.3

The standards require organisations to have quality improvement plans which:

a) are formalised with clearly defined goals, objectives and allocated responsibilities

b) identify the specific activities to be undertaken to meet the stated goals and objectives

c) are regularly updated

d) are communicated to relevant stakeholders

Guidance

A quality improvement plan is a detailed and overarching work plan for an organisation's clinical and service quality improvement activities and identifies specific areas of focus for the timeframe of the plan.

Performance data informs the development of the quality improvement plan. It is a live document which is regularly updated to reflect the organisation's progress in addressing the stated goals and objectives.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 6.4

The standards require organisations to report to the governing body on:

a) performance data

b) quality improvement activities

Guidance

The reporting frequency may be defined in the standards.

It is recognised that the governing body may differ depending on the scope and size of the service.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how each measurable element is met.

Criterion 6.5

The standards require organisations to make their performance results/data publicly available.

Guidance

If there are any reasons why certain performance results/data cannot be published, the rationale could be included within the self-assessment tool.

Suggested Evidence

The self-assessment should include examples from the standards that demonstrate how this criterion is met.

Comparative Table

5th Edition to 4th Edition

The table below shows the current criterion number and its comparative in the 4th Edition. Where the criterion is new to the 5th Edition the reference to the 4th is noted as New.

Principle/Criterion 5th Edition	5th Edition Reference	4th Edition Reference
Principle 1 – Standards Development		
Establishing rationale for new and/or revised standards	1.1	1.1
Relationships with other standards and regulatory requirements	1.2	1.2
Standards development plan	1.3	1.3
Public availability of standards development process	1.4	1.16
Standards based on research, guidelines, national/international recommendations and technical input	1.5	1.4
Stakeholder engagement	1.6	1.5
Scope of standards	1.7	1.6
Purpose of standards	1.8	1.7
Standards framework	1.9	1.8
Wording of standards	1.10	1.9
Testing/piloting of standards	1.11	1.10
Approval of standards	1.12	1.11
Use of standards by an independent assessment organisation	1.13	1.12
Plan for implementation	1.14	1.14
Information and education provided to clients and surveyors	1.15	1.13
Ongoing collection and analysis of feedback	1.16	1.15
Principle 2 - Standards Measurement		
System for rating performance on each standard, criterion or element	2.1	2.1
Documented methodology for measuring overall achievement	2.2	2.3
Guidance on using the measurement/rating system	2.3	2.2
Collection and analysis of feedback on the measurement/rating system	2.4	2.4
Principle 3 - Organisational Role, Planning and Performance		
Defined mission, values, ethics, strategic objectives	3.1	3.1
Operational plan, measurement in achieving objectives	3.2	3.2
Plans, policies and procedures, document control	3.3	6.5
Corporate and clinical governance responsibilities	3.4	3.3
Operational and financial management responsibilities	3.5	3.3
Integration of legal and health and/or social care policy requirements	3.6	3.4
Staff planning, staffing levels, skill mix	3.7	3.5
Education, skills, experience, orientation, training	3.8	3.6
Credentialing, defined scope of practice	3.9	3.7
Performance/competency evaluation	3.10	3.8
On-going education	3.11	3.9
Staff well-being, workplace issue resolution	3.12	**New**

Principle/Criterion 5th Edition	5th Edition Reference	4th Edition Reference
Use of evidence-based standards, protocols and guidelines	3.13	3.10
Involvement of patients/service users and staff in planning	3.14	3.11
Coordination within and between departments and external services	3.15	3.12
Principle 4 - Safety & Risk		
Risk management framework	4.1	4.1
Risk management plan, risk management policy, risk register	4.2	4.2
Risks to patients/service users, mitigation of these risks	4.3	4.3
High risk procedures and treatments, mitigation of these risks	4.4	**New**
Safety incident investigation, reporting and communicating	4.5	4.4
Evidence-based patient/service user safety strategies	4.6	4.8
Prevention and control of infection	4.7	4.9
Staff health and safety protection	4.8	4.5
Staff training on equipment	4.9	4.6
Safety law, building and equipment safety	4.10	4.7
Disaster recovery planning	4.11	**New**
Patient/service user records	4.12	4.10
Principle 5 – Person-Centred Approach		
Patient/service user rights and responsibilities	5.1	5.1
Processes to receive and resolve ethical dilemmas	5.2	5.3
Discussing options for care, respecting choices	5.3	5.4
Informed consent	5.4	5.4
Support for patients/service users in improving and maintaining health	5.5	**New**
Cultural and spiritual sensitivity	5.6	5.5
Staff education on person-centred care	5.7	**New**
Information on admission processes and range of services	5.8	5.6
Access to care or services	5.9	5.6
Patient/service user assessment	5.10	5.7
Patient/service user treatment or care plans	5.11	5.8
Following, monitoring progress, revising treatment or care plans	5.12	5.9
Discharge, referral	5.13	5.10
Patient/service user feedback, complaint management	5.14	5.2
Principle 6 – Quality Performance		
Collection of information relating to service performance	6.1	6.3
Evaluation and use of performance data	6.2	6.4
Quality improvement plans	6.3	6.2
Reporting of quality information to governing body	6.4	**New**
Publication of performance data	6.5	6.1

Change in Scale

	5th Edition	4th Edition
Principles	6	6
Criteria	66	57

Review Committee

Carsten Engel (IKAS), Bruno Lucet (HAS), Linda O'Connor (ACHS), Elaine O' Connor (ISQua EEA), Gillian Conway (ISQua EEA) and Nicola McCauley-Conlan (ISQua EEA)

Change Log

Date	Vers #	Summary of changes made
March 2022	1.1	■ International Society for Quality in Health Care (ISQua) replaced with International Society for Quality in Health Care External Evaluation Association (ISQua EEA). ■ Board Accreditation Committee (BAC) replaced with External Evaluation Award Committee (EEAC). ■ Glossary – new definition of equity added ■ Section 4.3 The Award – additional text added regarding role of the EEAC ■ Part B; Criterion 1.11 guidance updated ■ Part B; Criterion 2.2, guidance iii) - Criteria replaced with criterion.

ISQua EEA

International Society for Quality in Health Care
External Evaluation Association

International Society for Quality in Health Care
External Evaluation Association (ISQua EEA),
Multifiduciaire Genève,
Carrefour de Rive 1,
Case postale 3369,
1211 Genève 3
Switzerland

www.ieea.ch