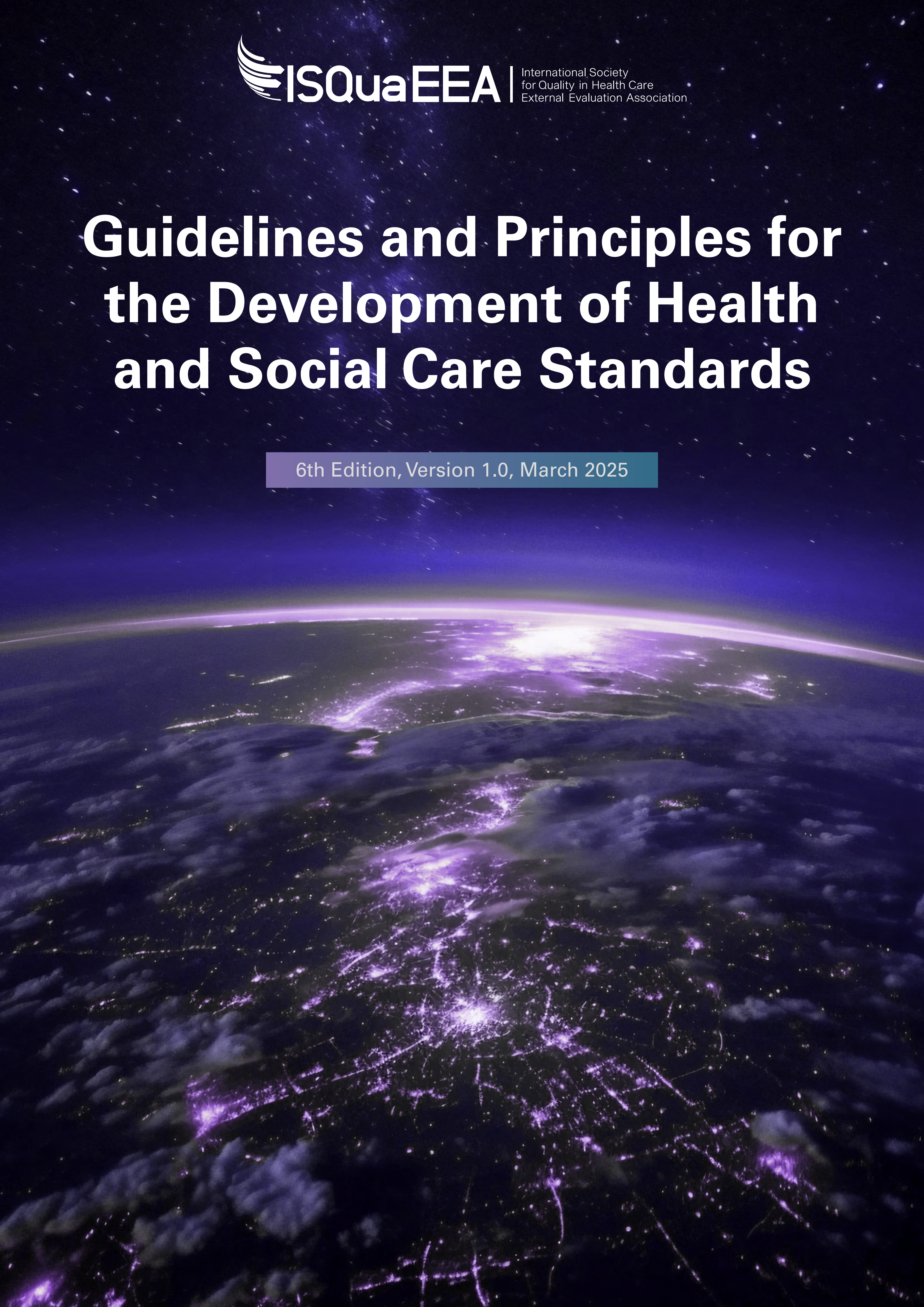

Guidelines and Principles for the Development of Health and Social Care Standards

6th Edition, Version 1.0, March 2025

ISQuaEEA | International Society for Quality in Health Care External Evaluation Association

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Foreword

The International Society for Quality in Health Care External Evaluation Organisation (ISQua EEA) is committed to ensuring that all Standards and Principles which underpin the International Accreditation Programme (IAP) are regularly revised to ensure that they remain current and reflect considered best practice and recommendations from research to support external evaluation organisations in developing their standards.

This 6th Edition of the ISQua EEA Guidelines and Principles for the Development of Health and Social Care Standards (the Principles) is the result of an extensive review and revision project which commenced in January 2023. We would like to thank our Project Manager Helen Crisp for her skilful management of this process and for her good humour and patience throughout.

The process included in-depth discussion with the members of the ISQua EEA Accreditation Council to review the purpose and intent of the Principles, followed by a literature review and interviews with those with expertise in quality and patient safety to identify emerging issues of importance for the quality and safety of health and social care services which needed to be included in the revised Principles. This was followed by surveys with client organisations and ISQua EEA surveyors to capture their views on the updates and improvements needed for the next Edition of the Principles. This identified three new areas to be addressed in the next Edition of the Principles namely:

- Sustainability of healthcare and social care services;
- Digital care and the use of artificial intelligence (AI) systems; and
- The need to support the care workforce.

Working groups comprising content or subject matter experts, ISQua EEA client organisations and ISQua EEA surveyors were then convened to develop the content for the updated Principles. The members of the working groups are listed in Appendix B and we would like to thank all those who participated for their valuable contributions.

The ISQua EEA Accreditation Council advised on the revision, which was overseen by a Steering Committee of Ellen Joan van Vliet, the Netherlands and Salma Jaouni, Jordan, with Carsten Engel, ISQua EEA CEO. A consultation was held on the draft revised Principles with stakeholders including ISQua EEA client organisations and surveyors. The consultation elicited a wide range of responses with many useful insights on interpretation, potential ambiguity and applicability of the Principles to the wide range of contexts in which they are used. Many thanks to all those who provided such thorough and thoughtful input to aid the revision process.

During the same period the draft Principles were pilot tested by three ISQua EEA client organisations namely: Agencia de Calidad Sanitaria de Andalucía (ACSA) the Andalusian agency for healthcare quality, Spain, Organização Nacional de Acreditação (ONA) National accreditation organisation, Brazil and the Brazilian Society of Clinical Pathology/Laboratory Medicine (SBPC/ML), Brazil; and three of our peer review surveyors: Anne Chenoweth, United States of America, Danielle Dorschner, Canada and Ed Mantler, Canada. The pilot testing enabled better understanding of how well the Principles could be applied in practice, highlighting where further revisions and guidance were necessary.

The 6th Edition of the Principles marks a major change from the 5th Edition. The table in Appendix A outlines the changes between the 5th and 6th Edition of the Principles and sets out where equivalent criteria to those in the 5th Edition are located in the 6th Edition. The 4-point rating scale has also been revised, based on feedback received throughout the revision process, and this is now a 3-point rating scale with clearer differentiation between the levels.

This edition will be available from March 2025 and all standards will be assessed against the 6th Edition from July 2026 onwards. Organisations with survey dates from July 2025 – June 2026 may elect to be surveyed against either the 5th or 6th Edition of the Principles.

We would like to thank and acknowledge all who took the time to contribute and participate in the various stages of the revision process as we would not have the document we have today without such valuable and insightful feedback. The details of those who formally contributed may be found in Appendix B but all contributions received including through the consultation process shaped the content of the final document. The 6th Edition Principles will provide a clear framework for those looking to develop or revise health or social care standards. They address and will ensure that due attention is paid to key quality issues including sustainability in health and social care organisations, digital care and the use of artificial intelligence (AI) and supporting the care workforce. We look forward to working with and supporting both our existing and new ISQua EEA clients to develop and/or revise their health or social care standards in line with the 6th Edition Principles.

Elaine O' Connor
Head of Operations
March 2025

Glossary

Note:
Only terms which have a specific meaning within the context of the ISQua EEA Guidelines and Principles for the Development of Health and Social Care Standards and the process of assessment against the Principles have been included in this glossary. Standard dictionary definitions should be checked to clarify the meaning of any other words or terms in the document.

Term	Definition
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 event	An unintended or unexpected event which resulted in harm for one or more patients/service users.
Audit	A systematic independent examination and review to determine whether actual activities and results comply with planned arrangements.
Award making body	An organisation which reviews the results of assessment of an organisation against quality standards and decides whether it is demonstrated that the standards are met and an award of accreditation or certification can be made and, where relevant, what level of award.
Certification	Formal recognition of compliance with set standards validated by external evaluation.
Criterion	A factor on which something is judged or decided. Within quality standards the criterion is usually a sub-statement beneath the level of the standard statement, which enables an assessment to be made on whether the standard is met.
Core criterion	Within the ISQua EEA Principles certain criteria under each Principle are denoted as 'Core', relating to key aspects of quality in the development of care standards, or to quality and safety requirements for the delivery of care services.
Decision rules	A predetermined set of propositions which aid consistent decision making. Within the context of making accreditation awards, the decision rules determine the level of achievement of the standards necessary to make an award.

Evaluation	A formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.
Evidence-based care	Care, treatment and support decisions and actions are undertaken based on published research and best practice guidance, to reduce subjective opinion, unfounded beliefs, or bias.
External evaluation organisation	An organisation which carries out an external, independent assessment of a health or social care organisation against standards, guidelines, indicators or other measures. The external evaluation organisation is not affiliated with the service being assessed.
Governance	Accountability for the way in which an organisation is managed at the highest level, and the systems for doing this. Within healthcare and social care this is interpreted as being accountable for continuously improving the quality of services and ensuring safe standards of care.
Governing body	The group with ultimate authority and accountability for the overall strategic direction and mode of operation of an organisation.
Holistic care	An approach to care that focuses on the whole person, taking into account their physical, mental, emotional, and spiritual wellbeing.
Information management	The appropriate and optimised capture, storage, retrieval, and use of information.
Informed consent	Consent is the voluntary agreement or approval given by an individual. In the context of healthcare, informed consent means that the patients/service users have given their voluntary agreement for treatment or care after having been provided with information on the precise nature of the care or treatment, together with the intended benefits and any associated risks.
Measurable element	Within quality standards, the statements which must be assessed to determine whether or not the standard is met.
Mission	What an organisation exists to achieve at the highest level.
Open disclosure	An honest, empathic, and timely approach to communicating with patients/service users and their families when things go wrong in the course of their individual care.
Operational objectives	A set of short-term goals that an organisation expects to achieve with its currently available resources.
Participating organisation	An organisation that is working within an externally run programme. In the ISQua EEA context, an accreditation, certification or regulatory programme of assessment.
Person-centred care	Care which is responsive to an individual's personal circumstances, values, needs and preferences.

Quality standards	Predefined, objective statements setting out requirements for services to be fit for purpose in delivering their key activities.
Risk	The probability of danger, loss or injury.
Risk management	Organisational arrangements for monitoring, reviewing and taking action to reduce risk in the provision of services.
Risk mitigation	The practice of reducing the impact of potential risks, which an organisation is unable to take action to eradicate, by developing plans to manage the risk and reduce the impact of harm.
Safety culture	How a healthcare or social care organisation supports the provision of safe care through its values, management style, expectations for staff behaviour and resourcing of safety.
Safety incidents	Any unintended or unexpected incident which could have or did lead to harm for one or more patient(s)/service user(s).
Self-assessment	A participating organisation's review of their own performance against standards.
Shared decision making	The involvement of the patient/service user in decisions about their care and treatment in a collaborative process with members of the care team.
Stakeholder	A person, group or organisation that has interest in, or influence on an organisation or service. Stakeholders can affect or be affected by the organisation's actions, objectives and policies.
Standards developing body	An organisation which develops quality standards for the provision of healthcare and/or social care services.
Strategic goals	A set of high-level objectives to further an organisation in achieving its mission.
Strategic priorities	The areas of activity that are deemed the most important for an organisation in line with its overall mission.
Substitute decision maker	A person who has been appointed (usually by the patient or service user but may be appointed by another party in the case of incapacity), to make decisions with care staff in the best interests of the patient/service user.
Surveyor	An external peer reviewer of organisational performance against agreed standards.
Values	Guiding principles for organisations that direct the overall approach of management and set the tone for its interactions with its service users, staff and other stakeholders.
Vision	An aspirational statement that describes what an organisation wants to achieve as it works to its mission, inspiring and motivating staff and stakeholders to work towards a common goal.

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 Guidelines and Principles for the Development of Health and Social Care Standards, 6th 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.

The International Society for Quality in Health Care (ISQua) is a not-for-profit, independent, health care quality organisation with members and contacts in over 100 countries. ISQua works to provide services to guide health professionals, providers, researchers, agencies and policy makers to achieve excellence in healthcare delivery and to continuously improve the quality and safety of care. ISQua works closely and is in 'Official Relations' with the World Health Organization.

ISQua EEA is a separate legal entity established in 2018 to provide external evaluation services. ISQua EEA manages the International Accreditation Programme (IAP) which conducts assessments of the organisations who in turn assess health and social care providers, ensuring that those who provide external evaluation services are themselves meeting quality standards and focused on improving the services they provide.

1.1
The International Accreditation Programme (IAP)

The International Accreditation Programme (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 their existing systems and drive continuous quality improvement.

Operating in over 35 countries, the IAP offers four separate peer review assessment options:

- Accreditation of Health and Social Care Standards
- Accreditation of External Evaluation Organisations
- Accreditation of Surveyor Training Programmes
- Accreditation of Quality and Patient Safety Training Programmes

The survey process includes the following stages:

- Self-assessment
- Peer review evaluation
- Production of a written report with recommendations
- Award
- Continuous assessment

More information about applying for the IAP can be found on the ISQua EEA website: **https://ieea.ch/**

1.2 Roles and responsibilities

1.2.1 | Governance of the IAP

ISQua EEA is governed by a Board of Directors. A subcommittee of the Board, the External Evaluation Award Committee (EEAC) is responsible for the governance and policy development of ISQua EEA's external evaluation programmes. This Committee is responsible for approving all external evaluation awards. It also approves the standards for the ISQua EEA programmes when new editions are released, along with any updated assessment methodologies for the individual programmes.

The Accreditation Council provides advice and recommendations to the ISQua EEA Board on matters relating to the International Accreditation Programme (IAP) and other external evaluation and accreditation-related issues.

1.2.2 | Validation Reviewer

The final accreditation recommendation for ISQua EEA surveys is made as part of the Validation Review. The Validation Reviewer is an experienced surveyor with no conflict of interest. The Validation Reviewer is responsible for:

- reviewing the report produced by the survey team 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 opportunities for improvement; recommendations; and/or Requirements for Action;
- ensuring that the report supports the survey team's accreditation decision recommendation; and
- completing the Validation Review Form and submitting it to the EEAC.

The Validation Reviewer's recommendation goes to the EEAC, which makes the final decision regarding the accreditation award.

1.2.3 | ISQua EEA 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; and
- perform quality assurance reviews of survey reports.

1.2.4 | Participating organisations

All participating organisations agree to abide by the terms and conditions of the ISQua EEA and adhere to the timescales as set in the critical path. As part of the application process, a contact for all correspondence with ISQua EEA should be nominated.

1.3 Surveyors

ISQua EEA has a consortium of experienced international professionals with external evaluation experience from over 20 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.

The survey team typically consists of three 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 whom they consider to have a conflict of interest. The ISQua EEA 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.

Section 2
Working with the Principles

2.0 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 Guidelines and Principles for the Development of Health and Social Care Standards (the Principles).

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.

2.1
Framework of the Principles

2.1.1 | The nine Principles

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

No.	Principle	Principle statement
1	**Standards Development and Rating Methodology**	Standards development and revision are planned and executed through a defined and rigorous process which includes a transparent rating methodology to aid consistent rating of achievement.
2	**Organisational Governance, Leadership and Management**	Within the standards there are requirements through which the governance, leadership and management of healthcare and/or social care organisations can be assessed.
3	**Person-Centred Care**	The standards are person-centred and encourage partnerships between patients/service users and healthcare and social care professionals, with involvement of family members (or other appointed substitute decision maker) as appropriate.
4	**Patient/Service User Safety and Organisational Risk Management**	The standards include requirements for a planned approach to patient safety, with processes to protect the safety of patients/service users, staff, contractors and visitors, take action when there has been harm and manage risk to reduce likelihood of harm.
5	**Process of Care Delivery**	The standards reflect the continuum of care and set out the expected steps for delivery of high-quality care.
6	**Sustainable Care**	The standards support environmentally sustainable healthcare and social care, including actions for providers to mitigate their environmental impact and increase their sustainability along with greater resilience in the face of environmental, climate and societal stressors.
7	**Digital Care and Artificial Intelligence Systems for Care**	The standards require systems for governance, security and monitoring of digital care (which includes telehealth and virtual consultations) and artificial intelligence (AI) systems to assess their effectiveness to support delivery of safe care.
8	**Supporting the Care Workforce**	The standards require healthcare and social care organisations to support the mental and physical wellbeing and professional development of their workforce and keep people safe at work.
9	**Quality Performance**	The standards require organisations to use a range of data sources to monitor, analyse and improve the quality of the service provision.

2.1.2 | The focus of each Principle

Principle 1: Relates to the way in which the standards developing body manages the processes to develop, revise (as appropriate) and issue the standards which have been submitted for accreditation.

Principles 2 through to 9: These Principles are all focused on the content of the standards set which has been submitted for accreditation.

2.1.3 | Major revisions and new content

The 6th Edition has been extensively revised from the 5th Edition, including 3 new areas of content in Principles 6 – 8:

Principle 6: Sustainable Care

Principle 7: Digital Care and Artificial Intelligence Systems for Care

Principle 8: Supporting the Care Workforce

Other major changes to the structure of the document include combining the content of what was Principle 1 and Principle 2 in the 5th Edition into one section in the 6th Edition, Principle 1: Standards Development and Rating Methodology. In addition, the criteria relating to person-centred care and the processes for delivery of care have been split into two separate Principles in the 6th Edition, namely: Principle 3: Person-Centred Care and Principle 5: Process of Care Delivery.

A table to show where criteria from the 5th Edition Principles have been incorporated into the 6th Edition is included in this document (Appendix A).

2.2 Structure of a Principle

01

Principle 1: Standards Development and Rating Methodology

Standards development and revision are planned and executed through a defined and rigorous process which includes a transparent rating methodology to aid consistent rating of achievement.

General guidance for Principle 1:
This Principle sets out requirements for how an organisation developing quality standards for healthcare and/or social care services plans, manages and delivers this work. The criteria relate to the workings of the organisation, not to the content of the standards.

02	1.1	**Criterion:** The organisation has a documented process for the development of new standards and the revision of existing standards which takes account of the context of the health or social care sector in which they will be applied.	Core
03		**Guidance:** The process set out for standards development may take account of emerging issues relevant to the specific services to which the standards are applied and may include, for example, how the organisation responds to new national or regional laws or regulations, updated professional guidance and sector-wide changes while developing standards content.	
04		**Suggested evidence:** To complete the self-assessment tool, describe how the organisation decided to develop or revise the standards being put forward for accreditation and the steps taken to gain information, input and feedback on the current context to inform the standards content. This is supported by further evidence of: • Minutes of meetings • Formal requests to stakeholders for input and feedback • Where the standards are a revised (rather than first) edition, evaluation data from use of the previous edition.	

01 **Number, title and description** of the Principle – this sets out the topic it covers.

02 **Criterion** – This is the level of assessment. Organisations are required to self-assess against the criterion. If there are multiple elements within each criterion 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.

The example 1.1 is a 'Core' criterion.

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

03 **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.

04 **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 for Principle 1.

For Principles 2 – 9 the suggested evidence is always examples from the standards submitted for accreditation, to demonstrate how the criterion is met.

2.3 Completing the self-assessment tool

We strongly recommend that sets of standards are developed or revised in line with the Principles to ensure that the requirements can be fully achieved. Organisations should complete an initial self-assessment of the standards being submitted for accreditation using the ISQua EEA 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 Principle 1 a range of suggested evidence is 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 2-9, organisations should include 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 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.

Organisations should self-rate their level of compliance for each criterion using the guidance on the rating methodology in this document on page 14. Please note: There is no requirement for an overall rating per Principle. This is a change from previous editions. Likewise, the surveyors will rate at the criterion level and accreditation decisions will be based on consideration of the criteria which are not fully met and how critical these are for developing high quality standards and/or for the high quality assessment of care provision.

2.4 Rating scale

<table>
<tr><th>Rationale</th><th>Rating</th><th>Guidance</th></tr>
<tr><td>Fully met- All elements addressed with no gaps in compliance</td><td>3</td><td>No recommendations – but it is still possible to have an Opportunity for Improvement.

If the organisation has exceeded the requirements this should be noted in the surveyor finding.</td></tr>
<tr><td colspan="3">If the criterion is not fully met, a risk assessment is required.

Surveyors must make an assessment on the risk the identified gap presents to
• The development of high-quality standards or
• High-quality assessment of care
The risk can be low, medium or high.

The gap is classified as minor (2) or major (1) based on the risk assessment and whether the criterion is core or non-core. While a gap including a larger proportion of the criterion will often be associated with a higher risk, it is the impact, not the extent, of the gap which determines the risk.

The rationale for the risk assessment should be included in the survey report.</td></tr>
<tr><td>In a non-core criterion: a gap with low or medium risk

In a core criterion: a gap with low risk</td><td>2 – minor gap</td><td>A recommendation (REC) must be provided outlining the action required to address the gap and fully meet the requirements of the criterion. These should be addressed by the time of the next accreditation survey.

Additionally, the surveyors may suggest an Opportunity for Improvement.</td></tr>
<tr><td>In a non-core criterion: a gap with high risk

In a core criterion: a gap with a medium or high risk

Any criterion that has not been addressed at all</td><td>1 – major gap</td><td>Surveyors must draft a Requirement for Action (RFA) outlining the action required to address the gap and fully meet the requirements of the criterion.

The extent to which the RFA must be completed in order to reduce the gap to a minor gap (what needs to be actioned) should be documented. This will have to be completed within six months. The remainder will have to be completed by the time of the next accreditation survey.

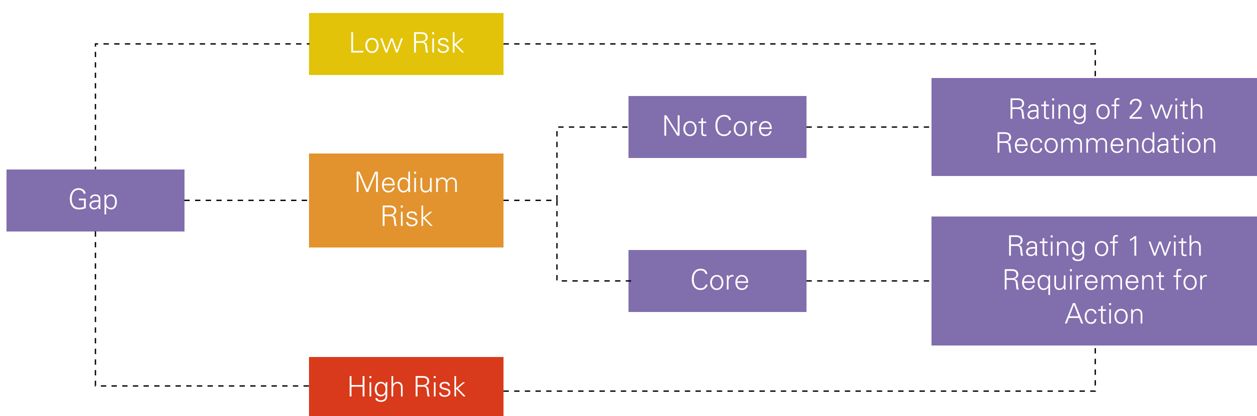
Additionally, the surveyors may suggest an Opportunity for Improvement.</td></tr>
</table>

Opportunities for Improvement (OFIs) identify areas that the surveyors suggest that the organisation could consider improving or strengthening. They can be provided with any rating and are not considered mandatory to be addressed.

Recommendations must be provided when there is a minor, low-risk gap for any criterion or a minor, medium-risk gap for a non-core criterion. It is mandatory to address recommendations, by providing progress reports 12- and 30-months post award, demonstrating how the recommendations have been, or will be, addressed.

Requirements for Action are required for all criteria rated as a 1 (medium or high risk for a core criterion and high risk for any criterion). The Requirement for Action needs to include clear guidance on the minimum level of improvement needed.

Requirements for Action are mandatory and must be addressed by the organisation.



2.5 Risk assessment

Risk assessments are required for all criteria that are not fully met. Risks may be rated as low, medium or high.

For Principle 1, a risk assessment involves describing what the risk is in relation to the missing elements of the criterion and then considering the extent that the missing elements prevent the possibility of developing high quality standards and/or the possibility of consistently measuring and rating achievement of the standards. For Principles 2 – 9, the risk relates to the extent to which the missing elements in a set of health or social care standards would prevent the assessment of the safety and/or quality of the care services.

2.6 Core criteria

A number of criteria have been identified as 'core' to the Principles; relating to aspects of standards development and rating methodology that are critical for the development of high quality standards (Principle 1) or to the assessment of aspects of care delivery which are critical for safe, high-quality care (Principles 2 – 9). The numbers for the core criteria within each Principle are listed below.

Please note that if a core criterion is rated as a 1 with a medium (or high) risk, a Requirement for Action is required.

Principle	Core criteria
Principle 1	1.1, 1.3, 1.4, 1.6, 1.7, 1.8, 1.9, 1.10, 1.11
Principle 2	2.3, 2.6, 2.7
Principle 3	3.1, 3.3, 3.7
Principle 4	4.2, 4.5, 4.7, 4.8, 4.9, 4.11
Principle 5	5.3, 5.4, 5.5, 5.8, 5.12
Principle 6	6.4, 6.7
Principle 7	7.2
Principle 8	8.1, 8.2, 8.4
Principle 9	9.1, 9.3

2.7 Not applicable criteria

It is recognised 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. All participating organisations are advised to liaise with ISQua EEA staff at an early stage of participation to discuss any criteria which they consider to be not applicable. The not applicable criteria should be agreed early, and in advance of the technical review. A date for these decisions will be incorporated into the critical path. If agreed, the self-assessment should clearly state the date of the agreement on non-applicability with ISQua EEA staff and the reason the specific criterion, or elements of it, are not applicable. A criterion will not apply if it addresses a process that does not occur in the setting in which the standards are intended to be used or if the criterion is adequately addressed and assessed by a national regulatory body in the jurisdiction where the standards will be used. In addition, a criterion may not apply if there are legal or other compelling obstacles to its use.

2.8 Technical Review

A technical review of the draft self-assessment tool, standards and supporting evidence is carried out by an ISQua EEA Accreditation Manager and the date of this is included in the critical path for the survey agreed with the participating organisation. The aim of the technical review is to ensure that the self-assessment tool (SAT) 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 their SAT submission and to upload additional evidence prior to the survey start date. This helps to streamline the assessment process by facilitating the organisation to submit a thorough and comprehensive SAT. The technical review report is also made available to the survey team.

2.9 Submitting the final self-assessment tool and required documentation

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

Section 3
Post Survey - Award and Maintenance of Accreditation

3.1
Achievement of Accreditation

Accreditation Award: For a set of standards to achieve ISQua EEA accreditation:

- There should be no more than one Requirement for Action (RFA).
- There can be no high-risk assessments for core criteria.
- Recommendations and Requirements for Action from previous surveys must have been addressed.
- If there are four or more criteria with ratings of 2 in the same Principle and if they relate to similar issues, the survey team can make a recommendation for a deferred award.

Deferred Award: If the requirements set out above are not met, the award will be deferred until there can be an assessment of a completed Action Report.

The organisation will be required to submit this with supporting evidence within 6 months of the accreditation decision. The report must outline:

- How any remaining Recommendations and Requirements for Action from previous surveys have been addressed.
- How the Requirements for Action identified during the current survey have been addressed to a satisfactory level.

The completed Action Report will be assessed by a member of the original survey team to determine whether or not accreditation can be recommended. The surveyor's review of the Action Report and associated accreditation recommendation will go to the EEAC who will make the final accreditation decision. If awarded, accreditation will date from the date of the initial, deferred decision, not the date of the EEAC meeting where the reviewed Action Report was presented.

3.2 Decision process

Following the survey, the survey team submit 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 review any queries from ISQua EEA and submit their final report and award recommendation to ISQua EEA;
- the organisation undertakes a factual accuracy 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 lead 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 (including an award recommendation from the Validation Reviewer) are sent to the External Evaluation Award Committee (EEAC) which makes the final award decision.

3.3 The award

If the standards meet the requirements as outlined in 3.1, the standards will be awarded accreditation status for four years with effect from the date of the ISQua EEAC meeting when the result is formally approved. The award is also dependent on confirmation 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 the ISQua EEA website and promote awards via its social media platforms.

3.4 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 themes arising from the evaluation responses are published in an annual report which is distributed to stakeholders.

3.5 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 and any outstanding Requirements for Action (RFA) will be addressed, or have already been addressed. A second Progress Report showing these changes is required 30 months post award. Recommendations (and if applicable, one RFA) relating to Principles 2- 9 (i.e. the content of the standards) should be addressed as part of an organisation's normal revision process (unless otherwise specified). Additional evidence may be requested to validate that the actions stated in the action report have been undertaken.

ISQua EEA awards are specific to the edition of standards 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 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 ISQua EEA. An ISQua EEA accreditation award can be removed by the EEAC, depending on the result of this review.

3.6 Appeal

If the participating organisation is dissatisfied 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 recommendation is reviewed and communicated to the Board.

The decision is made by the Board, and this decision is final. The outcome of the appeal process is communicated to the appeal applicant and all other relevant stakeholders.

Part B – The Principles

Principles for the Development of Health and Social Care Standards

General note on websites referenced in guidance: These are provided for information purposes only, as a possible source for further guidance on the issues addressed. The internet links in the text were correct and working at the point of publication.

Principle 1
Standards Development and Rating Methodology

Standards development and revision are planned and executed through a defined and rigorous process which includes a transparent rating methodology to aid consistent rating of achievement.

General guidance for Principle 1:
This Principle sets out requirements for how an organisation developing quality standards for healthcare and/or social care services plans, manages and delivers this work. The criteria relate to the workings of the organisation, not to the content of the standards.

1.1	**Criterion:** The organisation has a documented process for the development of new standards and the revision of existing standards which takes account of the context of the health or social care sector in which they will be applied.	Core
	Guidance: The process set out for standards development may take account of emerging issues relevant to the specific services to which the standards are applied and may include, for example, how the organisation responds to new national or regional laws or regulations, updated professional guidance and sector-wide changes while developing standards content.	
	Suggested evidence: To complete the self-assessment tool, describe how the organisation decided to develop or revise the standards being put forward for accreditation and the steps taken to gain information, input and feedback on the current context to inform the standards content. This is supported by further evidence of: • Minutes of meetings • Formal requests to stakeholders for input and feedback • Where the standards are a revised (rather than first) edition, evaluation data from use of the previous edition.	

1.2	**Criterion:** The organisation defines and documents the responsibilities, the timeframe and resources needed for standards development and revision. **Guidance:** The responsibilities and resources defined could include any externally contracted input to support the standards development/revision work. The information on timeframe and resources relates specifically to the edition of the standards which has been submitted for assessment. **Suggested evidence:** To complete the self-assessment tool, give a description of the responsibilities for standards development within the organisation and the roles of any external contractors, where relevant. This is supported by further evidence of: • The standards development/revision plan • The standards development/revision policy or process	
1.3	**Criterion:** The type of healthcare or social care organisation(s)/service(s) to which the standards apply is documented. **Guidance:** The organisation determines whether the standards apply to healthcare or social care and within these broad sectors for what type of organisation or service, for example, acute hospital care, healthcare laboratory services, primary health care, domiciliary social care, social care advice providers (these are provided as examples for guidance not as an exhaustive list). The organisation may also state whether the standards are to be applied to the whole of a provider organisation or a specific service/services within an organisation, or a group of collaborating services within a health system. This information may be set out in the introduction to the standards or other information provided for participating organisations. **Suggested evidence:** To complete the self-assessment tool, provide an extract from the information given to participating organisations, such as from the introduction to the standards manual or other guidance. The information to include: the type of healthcare or social care providers where the standards will be applied, whether the standards apply to a whole organisation or health/social care system or whether they would be applied to specific services within a wider organisation.	**Core**
1.4	**Criterion:** The purpose of the standards and how they are to be used is documented. **Guidance:** Standards can be used, for example, for inspection, registration, certification, mandatory accreditation, or voluntary accreditation. **Suggested evidence:** To complete the self-assessment tool, provide an extract from the information given to participating organisations, such as from the introduction to the standards manual or other guidance, which sets out the purpose of the standards.	**Core**

1.5	**Criterion:** There is documented information on the assessment methods including who carries out assessments and the approaches used to determine compliance with the standards. **Guidance:** The information may include for example, whether assessments are, by on-site visit, virtual using online meeting tools, or desktop review of documentation, or a combination of these approaches. The information could include general information on the use of methodologies such as patient/service user tracers, audit trails and sampling. The criterion is asking for an outline of the methods to be used, not a detailed manual describing how each individual criterion is assessed. Information on who carries out the assessment could state, for example, surveyors who are peer professionals working in the type of organisation/service being assessed, or the external evaluation organisation's staff, or a combination. **Suggested evidence:** To complete the self-assessment tool, provide an extract from the information given to participating organisations, such as from the introduction to the standards manual or other guidance, which sets out how the organisation will be externally assessed for compliance against the standards.	
1.6	**Criterion:** The requirements in standards are evidence-informed, based on published research evidence, professional guidelines, national or regional law, regulations and policies. **Guidance:** The intention of the criterion is that standards are developed based on legislation, peer-reviewed literature, guidelines, such as those from WHO or other healthcare or social care professional bodies, with specific published sources used to inform the development of the standards/criteria statements referenced. **Suggested evidence:** To complete the self-assessment tool, describe how the information on relevant legislation, published evidence and professional guidance is sourced and reviewed by those developing the standards. This is supported by listing some of the key published sources on which the contents of the standards are based.	**Core**
1.7	**Criterion:** The organisation develops and revises standards with the support of relevant subject matter expert advisors. **Guidance:** Standards development organisations could seek advice on the content of standards from those experienced in the relevant field as practitioners, researchers, policymakers, or recipients of care. This could include healthcare clinicians, social care professionals, those with safety and quality improvement expertise and experts by experience who are patients/service users. These categories are provided as examples not as a required or exhaustive list. Organisations may consider who is best placed to provide relevant technical and lived experience advice to inform their standards development. **Suggested evidence:** To complete the self-assessment tool, describe which expert groups and individuals were involved in the standards development process, how they were invited and the method of involvement e.g. workshops, online meetings, e-mail consultation. This is supported by: • Copies of briefing papers for the experts • Meeting agendas • Meeting minutes/workshop write-ups	**Core**

1.8	**Criterion:** The organisation defines its stakeholders, and ensures that: a) they have opportunities to input into the standards development or revision process, through formal consultation on draft standards and providing ongoing feedback as standards are in use. b) improvements are made to the standards based on feedback received from stakeholders.	**Core**
	Guidance: The intent of this criterion is that organisations define and actively seek feedback from their stakeholders, both on draft standards, before they are finalised and have channels to receive feedback throughout the lifecycle of the standards. Stakeholders may include participating organisations, surveyors, patients/service users, healthcare and social care professional bodies and government bodies. Organisations may review their stakeholders each time they review their standards so that they are still relevant and may engage with additional stakeholders if the scope of the respective standards or their work as an organisation has changed since the previous revision. It is recognised that feedback may not be received from all the groups requested to provide it.	
	Suggested evidence: To complete the self-assessment tool, describe how the organisation has identified its stakeholders. Describe the ways in which stakeholders have opportunities for feedback and input to standards development and the level of response from stakeholders. Describe how the feedback received is collated and reviewed. This is supported by: • example e-mail circulated inviting consultation feedback on standards • examples of standards and criteria content which has been modified in response to stakeholder feedback.	
1.9	**Criterion:** New or revised standards are reviewed, prior to finalisation, by a sample of participating organisations, to ascertain if standard statements and criteria/measurable elements are relevant, understandable, measurable, beneficial and achievable, and feedback from the review is used to revise standards as necessary.	**Core**
	Guidance: The aim of the criterion is to check that what is proposed in the draft standards is practical for the organisations/services that will apply the standards in their field.	
	Suggested evidence: To complete the self-assessment tool, describe how participating organisations are invited to take part in this review, and how the feedback from the review exercise has been used to modify the requirements or wording of the standards. This is supported by examples from the standards where the content has been changed in response to feedback from the participating organisation review.	

1.10	**Criterion:** The organisation has a documented process for formal sign-off and for the standards to be released for participating organisations to use, which: a) names the body, committee, or post holders responsible and sets out the steps for finalisation and sign-off of the standards. b) is evidenced to have been followed, with the standards formally signed off by the organisation before they are released for use.	**Core**
	Guidance: The intention of the criterion is to ensure that before standards documents are made available to participating organisations for implementation that there is a formal process at senior management level to approve the standards for use.	
	Suggested evidence: To complete the self-assessment tool, describe the process for signing off standards. This is supported by: • the documented process • extracts from committee minutes, or other documented organisational communication to demonstrate how the standards which are submitted for accreditation were formally signed off prior to being released for use.	

1.11	**Criterion:** There is documented guidance on the methodology used to rate an organisation's performance including: a) guidance on how each standard, criterion or measurable element is rated. b) guidance on how the rating of all measurable elements is collated to generate an overall rating against the standards.	**Core**
	Guidance: The guidance may include, for example, how ratings such as 'fully met', 'partially met', 'not met' are applied, where these or similar terms are used. Or, where numerical scores or percentage scoring are used, guidance on the application of the scoring system. The aim of providing this guidance is to facilitate reliable and consistent application of the scoring system by different surveyors, to avoid bias by a personal preference for 'high' or 'low' scoring. The information on the rating/scoring methodology could provide guidance on how the rating of separate criteria is totalled or averaged (taking account of non-applicable criteria) to provide the rating for a standard and what the 'pass mark' is for each standard and to achieve accreditation against the set of standards.	
	Suggested evidence: To complete the self-assessment tool: • Describe how the methodology is used by surveyors and the award-making body. • Provide signposting to the sections of the document which set out how the rating for a standard is determined and how the overall achievement for accreditation is determined. This is supported by the documented guidance on the methodology.	

1.12	**Criterion:** The methodology for rating achievement against the standards includes decision rules on making an accreditation award, and- if different levels of accreditation can be awarded- which level is to be awarded in situations where some of the standards are not met, or only partially met. **Guidance:** The aim is for the decision rules to provide a system to review and assess how achievement against the standards is used to determine accreditation status, whether awarded or not awarded, or if different levels of accreditation can be awarded – how it is decided which level is to be awarded . This may include for example the role of 'core' or 'essential' criteria for safe services and whether these must be fully met, or how many of these per standard can be partially met for accreditation to be awarded. **Suggested evidence:** To complete the self-assessment tool: • Explain the methodology for how decisions are made when standards are not met or only partially met. This is supported by the documented guidance on the methodology.	
1.13	**Criterion:** The guidance on the rating methodology is provided to participating organisations, surveyors and those making the award decisions. **Guidance:** The rating methodology guidance may be included within the document which sets out the standards or it may be in a companion document which is a guide to the standards and their application in practice and assessment. **Suggested evidence:** To complete the self-assessment tool, describe how the rating methodology is made available to surveyors, participating organisations and award-making bodies.	
1.14	**Criterion:** The organisation plans for implementation of new or revised standards, with clear naming convention when it is a revised edition (such as 2nd edition) and including the timeframe from releasing an edition of the standards for use, to the first assessment against that edition of the standards, and the transitional arrangements between existing edition and revised edition of standards, where applicable. **Guidance:** The intention of the criterion is that planning for implementation demonstrates that the organisation has considered clear naming conventions such 1st edition/2nd edition and how long participating organisations are likely to need to be able to comply with the standards and prepare for assessment. When a revised set of standards is being implemented, the organisation needs to give notice to participating organisations and provide clarity on how long assessments will continue to be carried out against the previous edition of the standards and what the cut-off date is, when the previous edition of the standards will be withdrawn from use. Transitional arrangements from existing to new standards do not apply for the first edition of a set of standards. **Suggested evidence:** To complete the self-assessment tool, describe how the arrangements for implementation of standards (and, where applicable, transition to a new edition of the standards) are planned. This is supported by information about the standards implementation (and transition arrangements) circulated to participating organisations.	

1.15	**Criterion:** Information and ongoing education are provided on the new or revised standards, to enable consistent interpretation and effective implementation for participating organisations, surveyors, the standards organisation's staff and, where applicable, the staff of other external evaluation organisation(s) using the standards.	
	Guidance: The intention of the criterion is that information and education sessions are tailored to the standards to be used for assessment and may include guidance on how to apply them in the intended services and what is expected to be in place to achieve compliance. When revised editions are issued, this should include how the content differs from previous editions. The organisation may, for example, require surveyors to have undertaken training on the application and assessment of a new edition of standards before they assess using those standards.	
	Suggested evidence: To complete the self-assessment tool, describe the information and education provided and to whom it is provided. This is supported by: • Information briefing for surveyors, participating organisations, external evaluation staff on the content of new or revised standards • Agenda for education session on new or revised standards.	
1.16	**Criterion:** When standards are used by an external evaluation organisation, other than the organisation that developed the standards, there is a formal agreement between the different organisations in relation to use of the standards, which includes a system for feedback on the standards in practice.	
	Guidance: This criterion is not applicable when the standards are only used for external assessment by the organisation which has developed them. Where this does apply, the intention is that the organisation that is using the standards for external evaluation purposes provides feedback to the standards-developing organisation from their experience of assessing the standards and, where possible, may also collate feedback to pass on from participating organisations that are being assessed. Feedback may be about, for example, the interpretability of the standards (language and understanding), how easy or how difficult specific criteria are to apply in practice.	
	Suggested evidence: To complete the self-assessment tool, describe the formal arrangements for other external evaluation organisations to use the standards and how they provide feedback on the standards to the standards development organisation. This is supported by the formal documented agreement, or where this is commercially confidential, extracts from the formal agreement.	

Principle 2
Organisational Governance, Leadership and Management

Within the standards there are requirements through which the governance, leadership and management of healthcare and/or social care organisations can be assessed.

2.1	**Criterion:** The standards require organisations to describe to potential service users (and/or to professionals referring to the service) the scope of the healthcare and/or social care services which they provide.	
	Guidance: Within the standards there are requirements for organisations to explicitly describe the nature of the healthcare and/or social care services they provide and for which service users. It is recognised that in some cases, those directly using the service are not 'patients' but other care providers (for example, some laboratory services), in other cases the organisation may solely, or mainly, offer services based on referrals from other professionals. These statements are available for the community likely to use the services. This would typically be on an organisational website, health system service directory (online or hard copy) or notices put up at the premises where services are provided. Information states the service(s) provided, for example, diagnostic imaging services, and for whom, for example, whether services are provided for adults or children, or both, whether or not a healthcare organisation provides emergency care, or critical care services.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
2.2	**Criterion:** The standards require organisations to define and promote the mission, vision and values which underpin their work.	
	Guidance: • The organisational mission sets out what it wants to achieve at the highest level for its patients/service users. • The vision should describe a desired future in which the mission is actioned. • The values are the guiding principles as to how the healthcare or social care organisation provides its services. It is recognised that not all services will determine their own independent mission, vision and values, if they are part of a larger organisation. Services being assessed may apply those developed by the wider organisation.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

2.3	**Criterion:** The standards require organisations to have governance processes in place, setting out accountability for the quality and safety of the services provided. **Guidance:** The term 'governance' is intended to cover the accountability for the leadership and management of the organisation at the top level, including clinical governance, and responsibility for care to be delivered in line with: • professional requirements • taking account of good practice guidance and evidence • clinical and non-clinical safety guidance • respecting patients'/service users' rights • meeting laws and regulations which apply to the organisation • financial management • fair management of staff. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	**Core**
2.4	**Criterion:** The standards require that organisations: a) set strategic priorities which include defined goals. b) have processes to measure progress in achieving the goals. **Guidance:** 'Strategic priorities' would usually cover a period of two to five years and be written at a high level to describe priorities for the whole organisation in terms of service development, outcome goals, delivery of high quality and safe care. Requirements for these processes could include, for example, regular management reports against strategic goals and action plans in response to monitor results. Other approaches could include a high-level data dashboard to regularly report data related to strategic goals. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
2.5	**Criterion:** The standards require that organisations have: a) defined operational objectives for the delivery of their services. b) processes to measure progress in delivering the operational objectives. **Guidance:** 'Operational objectives' are usually planned over a timeframe of one to two years (although they may not change much from year to year, they may be regularly reviewed and refreshed). The objectives for service delivery usually include achievement of key performance indicators. Requirements for the processes to measure progress could include, for example, regular management reports against operational objectives and action plans in response to monitoring results. Other approaches could include management data dashboards to regularly report data related to operational objectives. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

2.6	**Criterion:** The standards require organisations to have a document control process for their policies, procedures and other operational documents, whether electronic, paper-based or a combination. **Guidance:** The document control process could include, for example, requirements for naming documents, dating of documents, approval and sign-off, review of documents at stated intervals and a process to ensure current documents are accessible to staff and obsolete documents are removed from circulation. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	**Core**
2.7	**Criterion:** The standards require organisations to have processes for information management, which include at least: a) ongoing data security, including defence against cyber-attack b) staff training on the use of information technology including internal data security measures c) a documented and tested disaster recovery plan d) back-up of critical data. **Guidance:** 'Information management' as a term covers the collection, management, use and safeguarding of information across the organisation, including paper-based records and cyber security for computer systems, with particular concerns for the integrity, confidentiality and security of personal data. Where standards are developed for use in one country, information management should align with the relevant national or regional data and information management laws and regulations in that country. The disaster recovery plan could take account of scenarios like a cyber-attack or information technology (IT) system failure, and how to enable continuity of services in such circumstances. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	**Core**
2.8	**Criterion:** The standards require that organisations have a data breach incident response plan to secure data and inform patients/service users of any instance where there has been a data breach affecting their personal information. **Guidance:** The criteria for a data breach incident response plan, in accordance with any national or regional legislation on data security and confidentiality, could include for example, steps to mitigate serious risk in the event of a data breach of patient information: • detection and analysis • containment and eradication by isolating the affected systems • recovery • communication to patients/service users • post-incident analysis. This criterion does apply in the context of an entirely paper-based system as there can also be data breaches when information is held on paper. The standards and criteria relating to confidentiality of information could include steps to mitigate confidentiality risks. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 3
Person-Centred Care

The standards are person-centred and encourage partnerships between patients/service users and healthcare and social care professionals, with involvement of family members (or other appointed substitute decision maker) as appropriate.

General guidance for Principle 3 Person-Centred Care:
Where standards are designed for organisations/services which do not have direct patient/service user contact, such as laboratory services which provide services to other healthcare or social care providers, there needs to be consideration of how the intent behind Principle 3 applies. It is not acceptable to state that Principle 3 in its entirety is not applicable.

3.1	**Criterion:** The standards require organisations to define and inform patients/service users of their rights and responsibilities.	**Core**
	Guidance: Patients'/service users' rights may be defined in national or regional legislation; in which case this will guide how these are expressed in the standards. Rights could include privacy, dignity, respect, confidentiality of information, personal safety and access to all information about their care. Responsibilities may include, for example, providing accurate information to care providers, facilitating the delivery of care and respecting the rights of staff.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.2	**Criterion:** The standards require organisations to provide staff providing care services with education that supports the delivery of compassionate, person-centred care which respects patients'/service users' rights.	
	Guidance: Education for staff might be provided by the care organisation or by external providers. The requirement is for staff to have undertaken training on these aspects of care provision, rather than that such education is 'available' or 'accessible' for staff. Education could cover for example, respecting patients'/service users' rights, ensuring patient privacy and dignity, communication skills, shared decision making, understanding what matters and is most important in their care for the individual patient/service user, understanding and respect for different beliefs, customs and traditions. The criterion would not be applicable in standards for services which have no direct patient/service user contact.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.3	**Criterion:** The standards require organisations to provide information for patients/service users about their care needs and options for care in a format which is accessible and understandable to the patient/service user. **Guidance:** The intention of the criterion is that information for patients/service users is produced with consideration of, the main languages spoken, use of simple language so that those unfamiliar with healthcare or social care can understand it, and the cognitive capabilities of patients/service users, this would include, for example, meeting the needs of people with learning difficulties and people with dementia, as appropriate to the service provided. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	**Core**
3.4	**Criterion:** The standards require organisations to involve patients/service users in decisions about their individual care, through discussion of the options for care and where appropriate, treatment, including explanation of the potential risks and benefits of the different options. **Guidance:** The intention of the criterion is that there is shared decision making between the patient/service user and the healthcare or social care professionals providing their care, considering what care is provided and how it is provided. The approach to person-centred care is sometimes described by the phrase 'Nothing about me – without me', meaning that no decisions should be made about the care or treatment of the person without them being involved in the decision making to the extent that they wish to be. Shared decision making may be used for decisions about care such as: • Who the patient/service user wants to be involved in discussions about their care, such as a spouse, other family member, appointed substitute decision makers, or no one. • How the person is addressed, by formal title (Mr. Lee), or given name (Joe). • The person's care and treatment options and the potential risks and benefits of the options. • Food, clothing and personal care routines. • Privacy and visitors. • End-of-life care wishes. The list above provides examples only and is not a list of requirements for the standards. The criterion would not be applicable in standards for services which have no direct patient/service user contact. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.5	**Criterion:** The standards require organisations to respect the autonomy of the patient/service user and to record their expressed preferences or choices for their care and treatment options, which reflect the health and care goals of the person and what is important to them.	
	Guidance: The preferences could be recorded in care notes, patient records or similar documentation, whether these are paper-based or electronic. While taking account of the patient's/ service user's preferences, it is recognised that care delivery will be in accordance with professional standards, taking account of the clinical advice received and aligned with the resources provided in the care system. The criterion would not be applicable in standards for services which have no direct patient/service user contact.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
3.6	**Criterion:** The standards require that organisations identify the appropriate family member(s)/appointed substitute decision maker(s) who can be involved in any discussions of care.	
	Guidance: Where there are national or regional legal requirements for patient representation, ensuring that individuals legally authorised to make decisions on behalf of the patient/service user are involved in discussions, the standards reflect these. In all settings, considerations may include: • maintaining patient confidentiality • the process for determining the appropriate family member or other appointed substitute decision maker • the patient's/ service user's right not to have family members or other representatives involved if that is their wish. Discussions on care include, for example, options for care or treatment, plans for care, progress in achieving care goals, discharge, transfer or onward referral from the service. The criterion would not be applicable in standards for services which have no direct patient/service user contact.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
3.7	**Criterion:** The standards require that organisations respect the privacy and dignity of patients/service users at all times.	**Core**
	Guidance: Privacy and dignity considerations include the physical layout of services, such as single sex wards, with curtains, screens, private changing areas, auditory privacy of information being discussed, toileting arrangements to preserve dignity, providing private secure space for personal effects. Consideration may include respectful communication with awareness of language barriers, use of interpreters and communication preferences. Respect for privacy also includes respecting and safeguarding the confidentiality of all personal information and identifiable data whether written up in the service area (for example on whiteboards) or in paper or electronic records.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.8	**Criterion:** The standards require that organisations respect and respond to different cultural requirements, spiritual preferences, diversity, values and religious beliefs of patients/service users and adapt their care processes to meet these while ensuring safety of all is not compromised.	
	Guidance: The standards may include, for example, how services for men and women are segregated when this is culturally appropriate, how the patient/service user has access to spiritual care that meets their needs, how dietary needs linked to faith and beliefs are catered for, how to ensure that specific treatment is not provided counter to religious beliefs (such as blood transfusion for some faiths). These examples are provided for illustration, not as a list of requirements. Those developing standards need to consider how the criterion can be met in the context where the standards will be applied. The criterion would not be applicable in standards for services which have no direct patient/service user contact.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.9	**Criterion:** The standards require that care facilities meet the needs of the patients/service users and enable universal accessibility, considering physical disability, sensory impairments and cognitive impairments.	
	Guidance: The standards could include requirements that care facilities are physically accessible to individuals with disabilities, including wayfinding and signage. This could include how any services offered by telephone, or virtual appointments are made accessible to patients/service users with sensory impairments or who do not have access to the internet for virtual appointments. When standards are specifically for a service provided for patients/service users with physical disabilities or sensory impairments they could include how accessibility is ensured for these patients/service users. The criterion would not be applicable in standards for services which have no direct patient/service user contact, or for home care services in which all care is provided in the patient's/ service user's own home.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.10	**Criterion:** The standards require that organisations have processes to ensure a holistic care approach, that considers the whole person, not just the stated reason for service admission or care provision.	
	Guidance: A holistic care approach considers the physical, mental, emotional, social and spiritual wellbeing of patients/service users, also considering that care may be provided by several providers, and that "holistic" applies to the totality of care provided. This may extend to consideration of the physical care needs of patients/service users in mental health services and the psychological wellbeing of people in physical healthcare services. For social care services, the standards may consider how services offering support around a specific issue are able to refer or signpost other services that may be relevant for the person. The criterion would not be applicable in standards for services which have no direct patient/service user contact	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

3.11	**Criterion:** The standards require that organisations have processes to a) consult with patients/service users, families and communities on how to improve its provision of care services b) review and consider all feedback received.	
	Guidance: The intent of this criterion is that healthcare and social care services constantly seek feedback from their patients/service users and the community they serve, and use this to consider how to improve. It is a separate issue from receiving and responding to complaints. The standards could include, for example, requirements for patient/service user satisfaction surveys to be undertaken, or consultation exercises, especially when there are plans to develop or change a service. Where a service has no direct contact with patients/service users there should be consideration of how they gain feedback on how to improve from the healthcare providers to whom they provide a service.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 4

Patient/Service User Safety and Organisational Risk Management

The standards include requirements for a planned approach to patient safety, with processes to protect the safety of patients/service users, staff, contractors and visitors, take action when there has been harm and manage risk to reduce the likelihood of harm.

4.1	**Criterion:** The standards require organisations to have a strategic approach to the safe provision of healthcare and/or social care.	
	Guidance: The strategic approach to safety could include for example: • responsibilities of senior staff for safety • defined goals for safety • workforce training requirements for safety • reporting mechanisms for safety incidents • safety performance indicators. These are provided as examples of the types of issues that might be covered, not as requirements for assessment. Organisations may consider the content of the WHO Global Patient Safety Action Plan 2021-2030 to inform their approach to patient/service user safety: **https://www.who.int/teams/integrated-health-services/patient-safety/policy/global-patient-safety-action-plan**	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.2	**Criterion:** The standards require organisations to have documented processes to identify risks and develop risk management and risk mitigation steps in response to identified risks.	**Core**
	Guidance: Proactive identification of risks is applicable to all healthcare and social care organisations and could include strategic, operational and financial risks as well as patient/service user and staff safety risks. Risk management and mitigation processes could include, for example: • risk management responsibilities and functions • processes for reporting risks • risk register to prioritise risks according to severity, probability and potential impact • risk management plans for major risks • mitigation action plans to reduce the risks. This list is provided as examples of risk management and mitigation processes and not as stated requirements.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.3	**Criterion:** The standards require organisations to routinely report on the results of risk identification, management and mitigation including lessons learnt, to their governing body	
	Guidance: The intention of the criterion is to ensure that the governing body is aware of potential risks and how these are being managed and mitigated. Risks should be reported as often as needed or required by the governing body. It is recognised that some types of health and/or social care organisations may not have a structure that includes a 'governing body', standards may reflect that risks are recorded, and the senior management are aware of risks and how they are being managed.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
4.4	**Criterion:** The standards require an approach to assess safety culture across the organisation.	
	Guidance: The United States Agency for Healthcare Research and Quality (AHRQ) defines safety culture as the extent to which an organisation's culture supports and promotes patient/service user safety. It refers to the values, beliefs, and norms that are shared by the organisation's staff (to include all those with practice privileges even if not classified as 'staff') that influence their actions and behaviours. Safety culture can be measured by determining the values, beliefs, norms, and behaviours related to patient safety that are rewarded, supported, expected, and accepted in an organisation. There are various well-researched and validated safety culture surveys for use in health and social care organisations. There are also other ways in which organisations can assess their safety culture, for example through focus groups, safety audits, or observation exercises.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
4.5	**Criterion:** The standards require organisations to undertake analysis of systems in response to patient/service user safety incidents, focused on the process and factors that contributed to the safety incident and learning what can be done to prevent recurrence in future.	**Core**
	Guidance: The term 'patient/service user safety incidents' includes near misses and errors in care processes which did not result in any harm to patients/service users, as well as incidents which do cause harm. It is deliberately a broader term than 'adverse events' which are those incidents which result in harm to patients/service users. The response to patient/service user safety incidents may emphasise sharing the learning from what happened to prevent similar events from happening again, versus error investigation.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.6	**Criterion:** The standards require organisations to provide open disclosure about an adverse event to the individual patients/service users affected by it, and/or their family members, as appropriate.	
	Guidance: This criterion relates to 'adverse events', which are those incidents which have caused harm to patients/service users. The elements of open disclosure can include an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient/service user to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.7	**Criterion:** The standards require organisations to support staff involved in patient/service user safety incidents.	**Core**
	Guidance: This approach considers wider systemic issues where things go wrong, enabling staff to speak out, without fear of blame or retribution and for the organisation to learn from incidents. The support for staff may be in line with the 'second victim' concept that staff involved in patient/service user safety incidents can suffer psychological harm. Organisations can support their staff, for example, through a fair process that does not single out individuals for blame, providing the opportunity to de-brief after the incident, involving staff in determining what actions may prevent recurrence.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.8	**Criterion:** The standards require organisations to have safety measures in place to protect patients/service users from the safety risks inherent to the type of services provided.	**Core**
	Guidance: The standards could include explicit requirements related to the likely risks for the type of care and/or treatment that the standards cover, such as: diagnosis, diagnostic tests and reporting results of tests, advice provided, care provided, care omissions, falls, safeguarding for vulnerable service users, absconding from the service, treatment, medication, surgical and invasive procedures, use of blood and blood products, biological sample identification and transfer, or any other interventions. The above is not an exclusive or exhaustive list of requirements, it is provided as examples to prompt organisations to consider a wide range of risks that may be relevant within their standards.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.9	**Criterion:** The standards require organisations to implement processes for infection prevention and control, suitable to the services provided.	Core
	Guidance: The focus on infection prevention and control will vary depending on the healthcare or social care services which the standards cover. Basic measures for low-risk settings may include: • hand hygiene • environmental cleaning • staff protection (for example, personal protective equipment) For healthcare services, the standards could include in addition to the above: • healthcare waste management • triage of infectious patients • staff immunization • antimicrobial stewardship For healthcare services providing laboratory services, acute care, surgery and/ or invasive procedures, standards may also cover: • sterilisation and decontamination procedures • outbreak prevention and management • standard and transmission-based precautions (for example, detailed, specific SOPs for the prevention of airborne pathogen transmission) • aseptic technique for invasive procedures, including surgery • monitoring, reporting and acting to reduce infection rates, including antimicrobial resistance. When developing standards for acute hospital services, organisations should consider how each of the WHO core components of infection prevention and control programmes (at the acute health care facility level) could be reflected: **https://www.who.int/publications/i/item/9789241549929**	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.10	**Criterion:** The standards require organisations to implement processes for medication management, covering the procurement, storage, prescribing, compounding, dispensing and administration of any medications to patients/service users, including medication reconciliation and safe disposal.	
	Guidance: Requirements relating to storage could include medication being kept in dry conditions at the correct temperature, cold chain management and how this is checked to ensure the integrity of the medication. Where services use dangerous drugs such as high alert medications, concentrated electrolytes, controlled substances (which includes but is not limited to opioids), the standards could include requirements for these to be stored in accordance with manufacturers' guidelines and national or regional regulations. The standards could require systems to ensure that 'look alike sound alike' medications are stored safely. Medication reconciliation is the process of listing all of the medications that a patient is taking. This reconciliation is done to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. 'Safe disposal' means that any unused medication is kept secure from improper use, before being disposed of in a way that ensures no contamination of water supplies or land. This criterion only applies to standards for healthcare or social care services which manage medication.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
4.11	**Criterion:** The standards require organisations to ensure sufficient space, with planned maintenance, cleaning and inspection of facilities to enable safe and effective delivery of services.	**Core**
	Guidance: The intent of the criterion is that standards include requirements for organisations to ensure an environment suitable for the service provided and which ensures that patient/service user safety is not compromised. It is recognised that where there are national or regional building regulations and/or facilities requirements the standards will be based on or in accordance with these. This may also include aspects such as planned and systematic building inspection and regular testing of utilities, including emergency power supply, and infrastructure such as fire safety systems, lifts, medical gases and ventilation systems, according to the type of service provided. Where organisations deliver care in the patient's/service user's home, the intent of the standards is that steps are taken to minimise environmental risk and maintain a safe environment for the staff to deliver care.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
4.12	**Criterion:** The standards require organisations to inspect, test, maintain and replace equipment, in a planned and systematic way, to support safe and effective delivery of care.	
	Guidance: The intent of the criterion is that standards require preventive maintenance of all patient care equipment and devices. This could include calibration of medical equipment and the steps to identify and segregate any equipment that fails inspection and testing.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

4.13	**Criterion:** For equipment used in the provision of care and/or treatment, the standards require organisations to: a) train staff on the safe operation of equipment, including medical devices b) ensure that only trained and competent people use specialised equipment.	
	Guidance: Equipment refers to any equipment which an organisation routinely uses in the course of delivering care and treatment and which could pose a risk to patients/service users or staff. Standards for specific services could explicitly cover the safe operation and training on the high-risk equipment required to deliver the service, such as diagnostic imaging, surgery, mechanical ventilation, radiotherapy, laboratory services and other technical areas of care. These are provided as examples only.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 5
Process of Care Delivery

The standards reflect the continuum of care and set out the expected steps for delivery of high-quality care.

General guidance for Principle 5 Process of Care Delivery:
Where standards are designed for organisations/services which do not have direct patient/service user contact, such as laboratory services, which provide services to other healthcare or social care providers, there needs to be consideration of how the intent behind Principle 5 applies. It is not acceptable to state that Principle 5 in its entirety is not applicable.

5.1	**Criterion:** The standards require organisations to have processes to obtain informed consent from patients/service users for care or treatment, these include the process to follow when a patient/service user declines care or treatment.	
	Guidance: The standards on informed consent will be based on any existing national or regional legislation. The standards may reference arrangements which are in place for minors or individuals who do not have the capacity to make informed decisions and the involvement of family member(s)/appointed substitute decision maker(s). The standards may specify how consent is obtained and recorded for activities such as: • operative and invasive procedures, anaesthesia and moderate/deep sedation • where there is a significant risk of adverse effects • participation in research or experimental procedures • 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 for services with no direct patient/service user contact. It is also recognised that explicit consent may not be required for certain services (for example, social care counselling, primary care consultations).	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
5.2	**Criterion:** The standards require organisations to have a process for the review, management and resolution of ethical dilemmas that may arise around the delivery of care or treatment, within a defined timeframe.	
	Guidance: This criterion relates to 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, or the disclosure of certain information about the patients/service users and their care. Ethical dilemmas could involve different professionals, the patient/service user and/or family member(s)/appointed substitute decision maker(s).	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

5.3	**Criterion:** The standards require organisations to have a process to verify the identity of the patient/service user before any test, care, treatment, or intervention is provided.	**Core**
	Guidance: Failure to correctly identify patients/service users can result in many types of errors such as inappropriate advice, medication errors, transfusion errors, wrong person procedures, and the discharge of infants to the wrong families. The intent of this criterion is that standards require organisations to have systems in place that: • Emphasise the primary responsibility of staff to check the identity of patients/service users and match the correct person with the correct care, test, medication or procedure before it is administered. • Promote good practice in terms of identification practices which could include: ▪ The use of at least two identifiers (for example; name, date of birth, patient/service user registration number or national identity number) to verify identity prior to the administration of care, tests, medication or any procedures. ▪ The use of patient wristbands being supported by additional verification. ▪ Ensuring that identification systems use identifiers which are specifically linked to the individual as opposed to generic identifiers such as the patient/service user's room number at the facility.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
5.4	**Criterion:** The standards require organisations to have processes for the review and adoption of evidence-based care guidelines, protocols or pathways for the delivery of care and treatment.	**Core**
	Guidance: Evidence-based care guidelines are systematically developed from the review of published evidence to assist practitioner decisions about appropriate care for specific circumstances. Guidelines can be used to reduce inappropriate variations in practice and to promote the delivery of high-quality, evidence-based care. Although most of the development and evaluation of clinical guidelines has occurred in the field of medicine, other areas of care provision are moving towards the use of guidelines as one means of facilitating evidence-based practice. It is recognised that there are many areas of healthcare and social care where there is insufficient high-quality evidence to develop evidence-based care guidelines, in which case these should be based on consensus for good practice.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

5.5	**Criterion:** The standards require processes for a documented individual assessment of the patient/service user at the commencement of care/treatment, carried out by appropriately qualified professionals.	**Core**
	Guidance: Assessments could relate to medical, physical, mental health and/or social care needs and may involve multiple professional disciplines. For laboratory standards, this could relate to the assessment of patient/service user test requests.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
5.6	**Criterion:** The standards require that individual care plans are developed with the patient/service user whenever possible and/or their family member(s)/appointed substitute decision maker as appropriate. Individual care plans are based on the assessment of needs, and that care is monitored in line with the documented care plans and expected outcomes.	
	Guidance: It is recognised that some care plans are based on national or regional pathways or guidelines so customisation may be limited. The standards may also set expectations for frequency of monitoring, reassessment and modification of care plans. This criterion would be not applicable for laboratory standards/standards for services 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.	
5.7	**Criterion:** The standards require organisations to have processes for safe transitions of care for planned and emergency situations, which include the provision of all relevant information to other services and to the patient/service user.	
	Guidance: As appropriate to the type of service to which standards apply, 'relevant information' may include: Patient's/service user's diagnosis, summary of treatment/care provided, information on medications given by the service and those being continued, advice on continuing care for the patient/service user, contact details of the service should any further information be required. Where appropriate, the standards may also cover how family member(s)/appointed substitute decision maker are included in the handover of relevant information. This criterion **does** apply to laboratory standards/standards for services with no direct patient/service user contact, as the information provided by these services is integral to the information required for safe transitions of care. This may include, for example, information on test(s) requested, all test results, any recommendations for further tests.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

5.8	**Criterion:** The standards require care providers to a) create and maintain current, complete and accurate records of the patient's/service user's care. b) ensure that patient/service user care records are only viewed and added to by people authorised to do so.	**Core**
	Guidance: The criterion applies to all healthcare and social care record systems, whether they are paper-based, electronic or a combination. The requirements for records take account of any relevant national or regional legal requirements and may include, as relevant to the service provided: • legible, dated, timely and signed entries • alert notations • progress notes, observations, consultation reports, diagnostic results. • all significant events such as alterations to patients'/service users' conditions and responses to treatment and care • any safety incidents including near misses and adverse events • use of only recognised abbreviations.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
5.9	**Criterion:** The standards require organisations to store patient/service user records, so that they are: a) kept confidential and secure b) retained for a period in accordance with relevant legislation c) destroyed in a way that maintains confidentiality during the process.	
	Guidance: The criterion applies to all care record systems whether they are paper-based, electronic or a combination of these. To ensure the safe retention of records, organisations may, for example, use digitisation of hard copy of records to keep as a back-up, and/or back-up of digital records on another device/at another location (for example cloud-based storage). The destruction of records when they have exceeded the required period for retention needs to be considered in the context of available storage space (whether physical or computer based). The process for destruction of records should be such to ensure that information is still kept confidential. For example, paper records are confidentially shredded or incinerated, never put out with general waste and electronic records are secured from unauthorised access through thorough 'wiping' of hard drives and other electronic storage media.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

5.10

Criterion: The standards require organisations to provide integrated care for patients/service users by:

a) coordinating care between departments in the same organisation

b) integrating their care with other care-providing organisations, including care homes and home care.

Guidance: Integrated care involves the provision of seamless, coordinated, effective and efficient care that reflects the whole of a person's health needs from prevention through to end of life and involves physical, psychosocial and mental health. In integrated care, individual professionals, services, departments and organisations work together to address a person's health, social and mental health needs.

Integrated care makes it easier for organisations to provide person-centred, high-quality care that working across organisational boundaries meets all the needs of the patient/service user. Services working together builds trust and relationships that facilitate transfer of information and joined-up working between organisations to enable better outcomes.

The content of standards might include, for example:

- requirements for timely communication between healthcare and social care providers
- criteria for joint assessments between organisations where appropriate, for example healthcare and social care for elderly people
- information sharing between social care organisations to provide joined up advice and counselling services (as appropriate).

The list above provides examples of the type of issues standards might address, rather than being points for assessment.

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

5.11

Criterion: The standards require organisations to provide information for patients/service users about preventive care and factors to improve health.

Guidance: Depending on the type of service to which the standards apply, this could include information on immunization, regular check-ups, dangers of over-prescribing antibiotics, healthy diet, benefits of exercise, stress management, mindfulness, benefits of undisturbed sleep, health disbenefits of alcohol, tobacco and other substances. Where different services provide care on the same pathway, avoiding duplication of information and effort is considered.

This criterion would be not applicable for laboratory standards/standards for services 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.

5.12	**Criterion:** The standards require organisations to have a documented complaints process with associated timeframes, which is made known to patients/service users, and uses a systems approach to investigate, resolve and identify opportunities for improvement and learning in the system from complaints received.	**Core**
	Guidance: Where there is national or regional legislation or regulations for service complaints the standards will align with these. The term 'systems approach' means that complaints received are collated and considered across the organisation, not looked at in isolation by separate departments, so that the organisation can gain understanding about aspects of the services that give rise to complaints. The standards could address: • How the complaints system is publicised to patients/service users (and family members/appointed substitute decision makers, as appropriate). • The requirements for recording, investigating and resolving complaints and timeframes for the processes. • How information from complaints is collated and acted upon for improvements to services to prevent the recurrence of issues which gave rise to complaints.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 6
Sustainable Care

The standards support environmentally sustainable healthcare and social care, including actions for providers to mitigate their environmental impact and increase their sustainability along with greater resilience in the face of environmental, climate and societal stressors.

General guidance for Principle 6 Sustainable Care:
It is recognised that Principle 6 is addressing a new area of content for standards for healthcare and social care delivery. However, ISQua EEA believes that all organisations providing healthcare and/or social care need to start taking action, at a level that is within their control, to consider the environmental impact of their activities, to mitigate this where possible so that their service becomes more sustainable in the way that it is delivered, and to take steps to build their resilience to the external factors that are likely to impact on their service.

'Sustainable care': The WHO defines an environmentally sustainable health care system as one 'that improves, maintains or restores health, while minimizing negative impacts on the environment and leveraging opportunities to restore and improve it, to the benefit of the health and wellbeing of current and future generations'

Sustainable care acknowledges the environmental, economic and social impact of delivering healthcare and social care and aims for the provision of services which do not damage the environment (either now or in the future), are economical and have a positive social impact.

6.1	**Criterion:** The standards require organisations to undertake a strategic level review of the impact of environmental issues, sustainability of service provision and how negative environmental impacts arising from activities can to some extent be mitigated.	
	Guidance: The aim of the criterion is for external evaluation standards to prompt health and/or social care organisations to formally consider the ways in which environmental issues such as climate change impact on their activities and the sustainability of delivering the services, the potential impact that the organisations has on the environment and what the organisation can themselves do to reduce any negative impacts.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

6.2	**Criterion:** The standards require organisations to provide information to their staff and patients/service users on the organisation's strategic approach to environmentally sustainable care and the organisation's goals in this area.	
	Guidance: Standards could aim to support organisations to work towards creating a culture of environmental awareness and engagement of staff in proactive efforts for 'sustainability' as a dimension of high-quality service provision.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

6.3	**Criterion:** The standards require organisations to monitor their progress against defined goals for environmentally sustainable care and to report on this progress to the governing body.	
	Guidance: The intention of the criterion is to ensure that the governing body is aware of the organisation's goals with regard to minimising environmental impact, thus taking these into consideration when making other decisions, as well as monitoring progress to achieve the goals. Reports on progress towards sustainable care goals should be made as often as needed or required by the governing body. It is recognised that some providers may not have a structure that includes a 'governing body'. The provider organisation's senior managers could, for example, record their organisation's environmental impact and monitor progress towards making care sustainable.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

6.4	**Criterion:** The standards require organisations to consider the responsible stewardship of resources in their use of supplies and management of procurement.	**Core**
	Guidance: Responsible stewardship of resources refers to the responsible use (including conservation) of natural resources in a way that takes a full and balanced account of the interests of society, future generations, and other species, as well as of private needs, and accepts significant answerability to society. The intention of the criterion is for standards to encourage healthcare and social care providers to reduce the wasteful use of supplies and resources, including issues such as: • reduction of packaging materials • recycling of waste materials • reducing unnecessary prescriptions • reducing tests requests where these are not clinically indicated • wasteful use of catering and other supplies • reducing the amount of paper printouts produced across the organisation • considering the materials goods are made from (for example, wood or bamboo for disposable cutlery instead of plastic) • reviewing the case for single use equipment (particularly single-use plastic items), while recognising that re-use and recycling of equipment should only occur in line with patient and staff safety considerations, manufacturers' instructions, and infection control principles. Consideration of good stewardship of resources could, for example, prioritise the purchase of environmentally friendly products and services and selecting suppliers with strong environmental and social responsibility commitments. Supply chains for procurement can be reviewed, to include how, and how far, supplies need to be transported and possible benefits of local production (especially for food items). These examples are provided as suggestions, not as requirements to be assessed.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

6.5	**Criterion:** The standards require organisations to manage their use of non-renewable energy by: a) monitoring their use of energy including electricity, gas, oil and other fuel sources b) taking steps to reduce the use of energy from fossil fuels.	
	Guidance: Renewable energy is any energy that is generated from natural resources, such as sunlight, wind or water. This is also referred to as 'green energy' or 'clean energy'. The intent of the criterion is to encourage healthcare and social care providers to transition to renewable sources of energy, where this is an option. Also to consider their use of energy and how it is practical to reduce this, for example, fitting LED lighting, which uses less electricity than other lighting systems, in areas where this lower intensity light would not compromise care. It is recognised that some providers will not have options to change their energy supply source and, that for some types of healthcare services, there are few options to reduce overall energy use.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

6.6	**Criterion:** The standards require organisations to carry out an assessment of their carbon footprint to monitor and help reduce greenhouse gases produced through the care processes provided.	
	Guidance: An organisation's carbon footprint is defined as a measure of the amount of greenhouse gases, including carbon dioxide, methane and other gases, released into the atmosphere as a result of the activities of the organisation. By reducing their emissions, healthcare and social care organisations can demonstrate their commitment to lowering the environmental impact of their activities. Developing a carbon footprint baseline is an important first step to achieve this goal. The carbon footprint can be based on a minimal dataset, such as energy use only, whilst a more sophisticated approach is to extend the carbon footprinting exercise to wider areas, such as anaesthetic gases, travel undertaken to deliver services and the carbon impact of all purchased products and services. It is recognised that some organisations will have less scope and fewer resources than others to be able to measure their carbon footprint, or to take practical steps to reduce it.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

6.7	**Criterion:** The standards require organisations to consider their resilience to major environmental, climate or health emergencies which could disrupt the provision of services and to plan for a range of actions in response.	**Core**
	Guidance: The intention of the criterion is for standards to prompt organisations to take a broad approach to planning for response to emergency situations, with awareness of factors such as the likelihood of pandemic outbreaks, extreme weather conditions causing heatwaves, droughts, violent storms and flooding, or wildfires. The requirements in standards may for example focus on organisations planning for situational assessment and response, to ensure safety and (where possible) continuing care for patients/service users, rather than specifics of the circumstances which might arise.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 7
Digital Care and Artificial Intelligence Systems for Care

The standards require systems for governance, security and monitoring of digital care (which includes telehealth and virtual consultations) and artificial intelligence (AI) systems to assess their effectiveness to support delivery of safe care.

General guidance for Principle 7 Digital Care and Artificial Intelligence Systems for Care
It is recognised that Principle 7 is addressing a new area of content for standards for healthcare and social care delivery. Through the standards, organisations should be prompted to consider the extent to which digital care and artificial intelligence systems are being used and governed within healthcare and social care providers.

The term **'digital care'** is used in the Principles to cover a range of care delivery approaches which include, but are not limited to, remote monitoring of patients/service users, smart-phone apps, wearable devices, virtual consultations which may be by telephone or online meeting platforms, remote reporting of test results, such as scans and X-rays. Other digital health approaches that are coming online should also be included.

Artificial Intelligence (AI) refers to dynamic systems which use approaches such as machine learning and rules-based algorithms, developed from large data sets, to support, for example, diagnosis or individualised medicine.

If the standards being assessed for ISQua EEA accreditation relate to a care context where there is no routine use of digital care or AI systems in the delivery of services, Principle 7 in its entirety may be 'Not Applicable'.

However, in most contexts, there will be some providers who are using digital care and/or AI systems to contribute to care delivery, even though this may not be commonplace across that sector. It is for organisations to decide to what extent their standards for this area apply for their individual clients.

External evaluation organisations need to keep the designation of 'Not Applicable' for large numbers of criteria in Principle 7 under review. For example, while some types of organisations or contexts for care may not currently be using AI systems, they are likely to be working with other care providers who do use AI systems, so there should still be strategic consideration around AI systems and how these impinge on their delivery of care.

<table>
<tr><td rowspan="3">7.1</td><td>Criterion: The standards require organisations to have a documented process for the assessment, costing, implementation and ongoing management of digital care systems.</td><td rowspan="3"></td></tr>
<tr><td>Guidance: The intention of the criterion is that standards encourage organisations to systematically carry out:
• a cost/benefit analysis before implementing digital care
• risk management of the degree of inter-operability between digital care systems and mitigation of risks where systems do not 'talk to each other' (that is, they are not inter-operable)
• consideration of any potential unintended consequences from the introduction of digital care systems.</td></tr>
<tr><td>Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.</td></tr>
</table>

7.2	**Criterion:** The standards require that organisations have a process to ensure that the use of digital care does not disadvantage patients/service users who are not able to use digital devices or do not have access to the internet to facilitate the use of digital approaches.	Core
	Guidance: The intent of the criterion is that services are fully accessible to those patients/service users who cannot use the digital route for whatever reason. Therefore, the introduction of digital care services such as, for example, online virtual appointments could be pre-tested with representatives of the intended group of patients/service users before implementation.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
7.3	**Criterion:** The standards require organisations to have access to technical expertise to support the effective use of digital care systems.	
	Guidance: The term 'access to technical expertise' includes, for example, from the vendors of the systems, an in-house technical team, or other contractual arrangements for technical support. The technical expertise provided could include the necessary testing and quality checks before any system is fully implemented.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
7.4	**Criterion:** The standards require organisations to introduce and manage AI systems in accordance with any national or regional legislation or regulations on the use of AI, where these exist, or in their absence, based on available guidance for best practice.	
	Guidance: To support the implementation and use of AI in health and care services, several organisations have developed guidance and best practice advice, these include: The World Health Organization (WHO) which has produced guidance on ethics and governance for the use of different types of AI systems: **https://www.who.int/publications/i/item/9789240084759** The US Food and Drug Administration (FDA) has produced guidance on Artificial Intelligence and Machine Learning Software as a Medical Device: **https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device** The English National Health Service (NHS) has produced guidance on adopting AI systems in healthcare: **https://www.digitalregulations.innovation.nhs.uk/regulations-and-guidance-for-adopters/**	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

7.5	**Criterion:** The standards require organisations to monitor and evaluate the use of AI systems to deliver safe, high-quality care, with mitigation of any unintended consequences.	
	Guidance: Monitoring the use of AI systems could include, for example: • Feedback from staff on how the system is working • Auditing reported test results, where these are generated using AI systems, to check for over-diagnosis and missed diagnosis and strategies to mitigate these • Monitoring if there are patient/service user complaints/suggestions for improvement related to the use of AI systems • Monitoring how much support is required for technical assistance with AI systems • Collating statistics on the proportion of patients/service users whose care is delivered with the use of AI systems as compared to person-to-person care delivery. Unintended consequences could include, for example, higher than expected diagnosis rates if the AI system is better at detecting symptoms than the traditional approach, or for example, missed symptoms if the AI system has been trained on a different population to the population where it is being used. The above text is to provide examples for guidance only, it does not constitute a list of points for assessment.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
7.6	**Criterion:** The standards require organisations to consult with staff delivering care, prior to the introduction of AI systems, to gain understanding of the practical implications and staff training needs.	
	Guidance: Many AI systems are intended to be ‘disruptive innovations’ in that they bring about change beyond the initial context for deployment. Organisations need to involve the staff working in the service in discussions about what the impact of the new system is likely to be and considering what training staff need, to be able to fully realise the intended benefits of the technology.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

7.7	**Criterion:** The standards require that organisations consider accountability arrangements for all care and treatment delivered with support from AI systems. **Guidance:** The intention of the criterion is to prompt consideration of how standards can support health and social care systems to consider what the implementation of AI systems means with regard to accountability for care decisions and assuring safety, as care providers may be held accountable if use of the AI system results in patient/service user harm. This may include, for example, consideration of: • potential biases in AI systems, linked to the data on which the system is trained • concerns over data privacy and how individual patient data is used by AI systems • the lack of transparency in how the AI algorithms work to support clinical decision-making. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
7.8	**Criterion:** The standards require organisations to inform patients/service users when aspects of care are delivered with the use of AI systems. **Guidance:** This is in accordance with any national or regional legislation on informing patients/service users of the use of AI in care provision. The intention of the criterion is that patients/service users are informed about how aspects of care and treatment are being delivered, such as the role of artificial intelligence systems in diagnosis, developing personalised medicine treatment for individuals, the ways in which the system is tested for bias and the security of the information. **Suggested evidence:** The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 8
Supporting the Care Workforce

The standards require healthcare and social care organisations to support the mental and physical wellbeing and professional development of their workforce and keep people safe at work.

General Guidance for Principle 8: The term 'workforce' is intended to cover all those who:

- are employed as staff by the organisation
- are independent practitioners granted practice privileges
- deliver services on behalf of the organisation but through a contracted entity (patients and service users would perceive them as care/service providers for the organisation)
- work as volunteers within the organisation.

8.1	**Criterion:** The standards require organisations to have processes for assurance that all appointed members of the workforce have the required qualifications, licences or professional scope of practice, training and competence for the roles they undertake and do not practice outside their scope.	**Core**
	Guidance: The intention of the criterion is that organisations demonstrate processes to ensure that people have the appropriate qualifications, training and competency to safely carry out the work they are appointed to undertake. 'Scope of practice' relates to the range and type of procedures that a healthcare or social care practitioner is permitted to perform within the organisation. Qualifications are likely to be awarded by national or regional bodies and the standards should reflect the organisation's role to check the validity of qualifications.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
8.2	**Criterion:** The standards require organisations to have processes to regularly evaluate the continued competency and ongoing performance of all members of the workforce, in line with their job descriptions and scope of practice.	**Core**
	Guidance: The processes by which ongoing competency is assured could include, for example, reviews of scope of practice, competency assessments, performance evaluations, completion of required training to maintain skills. These examples are provided as guidance to the type of activities, not individual points for assessment. It is recognised that the type of activities and frequency of assessment will vary between different types of service provider.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.3	**Criterion:** The standards require organisations to ensure all members of the workforce undertake on-going education (courses and training sessions) to maintain the required level of performance and have opportunities to develop and extend their skills.	
	Guidance: Education opportunities may be attendance at formalised training sessions, held internally or externally to the organisation, or may be integrated into the work environment.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	
8.4	**Criterion:** The standards require organisations to protect the health and safety of the workforce while carrying out their duties.	**Core**
	Guidance: The type of issues covered will vary depending on the healthcare or social care services where the standards are applied. In social care this could include, for example: • Lone worker safety procedures • Confidentiality of staff personal contact details • Ensuring professional boundaries are maintained For healthcare services this could include, for example: • Required vaccinations for staff • Provision of personal protective equipment (PPE) • Prevention of manual handling injuries • Prevention of needlestick injuries For laboratory services, examples could include: • Protection from dangerous pathogens and chemicals • Provision of safety equipment, including PPE.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.5	**Criterion:** The standards require organisations to have processes for the investigation and resolution of workplace issues raised by members of the workforce.	
	Guidance: The type of workplace issues will vary between different types of services and in different cultural contexts. For example, they may include grievances about management practices, perceived lack of fairness in applying organisational policies, concerns about issues such as safety, confidentiality or organisational corruption. Members of the workforce raising concerns about wrongdoing in the organisation is referred to as 'whistleblowing'. It is important that those who raise concerns are protected from adverse treatment by the organisation's management. Where there is national or regional legislation on whistleblowing the standards should be in line with this.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.6	**Criterion:** The standards require organisations to take steps to protect staff from violence and aggression from individuals including patients/service users.	
	Guidance: Violence and abuse towards members of the workforce can have a serious impact on health and wellbeing, as well as retention of staff. Violence at work refers to acts or threats of violence directed against staff, either by other staff or by patients/service users or their family members, it can range from verbal abuse, bullying, harassment, and physical assaults to homicide. It is recognised that the type of steps taken to protect staff from violence and aggression from individuals including patients/service users will vary and will reflect the type of service provided or the setting in which the health or social care service is provided. When developing standards consider how the WHO Health Worker Safety Charter could be reflected: **https://www.who.int/docs/default-source/world-patient-safety-day/health-worker-safety-charter-wpsd-17-september-2020-3-1.pdf**	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.7	**Criterion:** The standards require organisations to have a systematic approach to gaining feedback from the workforce on their experience of working for the organisation and to implement improvement based on the feedback.	
	Guidance: Ways to gain feedback could include for example workforce satisfaction surveys, exit interviews with people leaving the organisation's workforce, consultations with the workforce on issues relating to the experience of working there. The standards should be explicit that the feedback information gathered is collated, analysed for trends and that there is an action plan implemented in response.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.8	**Criterion:** The standards require organisations to monitor and analyse data on staff sick leave and the reasons for staff leaving and these are used to inform organisational learning and changes in practice to support staff wellbeing and retention.	
	Guidance: The intention of the criterion is that quality standards should be encouraging organisations to collect and collate workforce data to be aware of the relevant issues in their sector which can impact on their staffing, especially in a context where many health and social care systems are facing acute staff shortages and struggling to retain experienced staff to work in the care system. The data could include, for example, rates of sickness absence, the rates of staff leaving or retiring due to ill health, the rates of staff resigning for reasons other than health, with data analysed for trends over time and benchmark comparisons between departments. The guidance points are provided as suggestions for the type of data that will help organisations respond to workforce requirements, rather than specific points to be assessed. Different data will be appropriate in different contexts.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.9	**Criterion:** The standards require organisations to have processes to monitor, review and respond to issues of equality, diversity, inclusion and equity, in relation to recruitment, work allocation, scheduling and promotions across the workforce.	
	Guidance: Equality means offering the same rights and opportunities to all members of the workforce, irrespective of factors such as their age, gender, ethnicity/race, religious beliefs among others. Diversity is understanding people's differences, including their beliefs, abilities, preferences, backgrounds, values, and identities. Inclusion is an extension of equality and diversity. It means including respecting and appreciating all individuals as valuable members of the workforce. Organisations can promote these values in relation to the workforce through, for example: • Equal opportunities policies • Staff training on equal opportunities, diversity, inclusion and equity • Monitoring the implementation of the policy/policies and making changes to be more effective • Reviewing data on recruitment and promotions to see how employment and progression reflect the local population demographics • Encouraging workforce networks and mutual support groups These examples are provided as illustrations not as points for assessment. Different types of organisations and contexts will develop different approaches.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

8.10	**Criterion:** The standards require organisations to support workforce wellbeing and psychological safety.	
	Guidance: Wellbeing in the workplace refers to the overall state of an individual's physical, mental, and emotional health in relation to their work environment. It encompasses factors such as job satisfaction, work-life balance, stress management, and a supportive and inclusive workplace culture. The term psychological safety refers to an environment where people feel able to express themselves without fear that others will think less of them. In the workplace, that translates to employees feeling comfortable speaking up, whether they're sharing ideas, asking questions, expressing concerns or acknowledging mistakes. Ways in which organisations can support staff wellbeing and psychological safety could include, for example: • access to occupational health services • health-promoting environment including healthy food • flexible working • stress management support • staff engagement programmes for planning and strategy • opportunities for personal development and growth These examples are provided as illustrations, different types of organisations and contexts will develop different approaches.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Principle 9

Quality Performance

The standards require organisations to use a range of data sources to monitor, analyse and improve the quality of the service provision.

9.1	**Criterion:** The standards require organisations to set performance indicators to monitor the quality of the service provision.	Core
	Guidance: The performance indicators should relate to dimensions of quality. For healthcare these are often defined as, effectiveness, safety, timeliness, person-centred care, efficiency and equity. For social care other dimensions may be more appropriate, such as, for example, access, or peer support. Performance indicators will vary depending on the most pertinent aspects of quality for the services where the standards are to be applied. The ways in which organisations review performance could, for example, include looking at trend data over time, or benchmarking with similar organisations.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

9.2	**Criterion:** The standards require organisations to audit and review outcomes data.	
	Guidance: Outcomes data is data that provides an indication of how the care, treatment or other services provided are improving the health status and wellbeing of the patients/service users accessing and using the services. The type of outcomes data used by an organisation will vary depending on the nature and type of services provided. Outcomes data can also include patient-reported outcome measures also known as PROMs. According to the Australian Agency for Clinical Innovation PROMs assess the patient's perspectives about how illness or care impacts on their health and wellbeing. Reference: **About patient-reported measures | Agency for Clinical Innovation (nsw.gov.au)** The ways in which organisations review outcomes data could, for example, include looking at trend data over time, or benchmarking with similar organisations.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

9.3	**Criterion:** The standards require organisations to develop quality improvement activities based on issues identified through performance and outcomes data (where the latter are available).	Core
	Guidance: Quality improvement activities could include objectives, allocated responsibilities, identified resources and a timescale for implementation.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

9.4	**Criterion:** The standards require organisations to report to the governing body on: a) performance data for the organisation b) outcomes data c) quality improvement activities and the results of these.	
	Guidance: The intention of the criterion is to ensure that the governing body is aware of performance and outcomes data and how quality improvement activities are being implemented in response to the issues arising. The information should be reported as often as needed or required by the governing body. It is recognised that some small providers may not have a structure that includes a 'governing body'. The standards should reflect that performance and outcomes data and improvement in response are recorded and known to the senior managers of the organisation.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

9.5	**Criterion:** The standards require organisations to make their performance results and outcome data publicly available.	
	Guidance: The intention of the criterion is to encourage healthcare and social care providers to be open with service users about their results, thus helping people make informed choices about services. Performance reports and outcome data could, for example, be published on the organisation's website, be displayed on public notice boards in the organisation's premises, be published by professional bodies on their websites or in published documents. It is recognised that there may be reasons why performance results and/or outcomes data cannot be published in certain sectors or in certain countries/jurisdictions, and this should be discussed with ISQua EEA.	
	Suggested evidence: The self-assessment should include examples from the standards that demonstrate how this criterion is met.	

Appendix A - Comparative Table

5th Edition to 6th Edition

The table below shows where criteria on various topics from the 5th Edition are now to be found in the 6th Edition. As the Principles have been completely revised from the 5th to the 6th Edition, the exact wording of the criteria may have changed, with slightly different requirements, even though the criterion is on the same topic. In all cases, please carefully read the full wording in the 6th Edition to decide what evidence is needed. What was sufficient for the 5th Edition may no longer be the case.

5th Edition Principle/Criterion/Topic	5th Edition Reference	6th 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	-
Standards development plan	1.3	1.2
Public availability of standards development process	1.4	-
Standards based on research, guidelines, national/international recommendations and technical input	1.5	1.6
Stakeholder engagement	1.6	1.8
Scope of standards	1.7	1.3
Purpose of standards	1.8	1.4
Standards framework	1.9	-
Wording of standards	1.10	-
Testing/piloting of standards	1.11	1.9
Approval of standards	1.12	1.10
Use of standards by an independent assessment organisation	1.13	1.16
Plan for implementation	1.14	1.14
Information and education provided to clients and surveyors	1.15	1.15

5th Edition Principle/Criterion/Topic	5th Edition Reference	6th Edition Reference
Ongoing collection and analysis of feedback	1.16	1.8
Principle 2- Standards Measurement		
System for rating performance on each standard, criterion or element	2.1	1.11
Documented methodology for measuring overall achievement	2.2	1.12
Guidance on using the measurement / rating system	1.3	1.13
Collection and analysis of feedback on the measurement / rating system	2.4	-
Principle 3 – Organisational Role, Planning and Performance		
Defined mission, values, ethics, strategic objectives	3.1	2.2 & 2.4
Operational plan, measurement in achieving objectives	3.2	2.5
Plans, policies and procedures, document control	3.3	2.6
Corporate and clinical governance responsibilities	3.4	2.3
Operational and financial management responsibilities	3.5	-
Integration of legal and health and/or social care policy requirements	3.6	-
Staff planning, staffing levels, skill mix	3.7	-
Education, skills, experience, orientation, training	3.8	8.2
Credentialing, defined scope of practice	3.9	8.1
Performance/competency evaluation	3.10	8.2
On-going education	3.11	8.3
Staff well-being, workplace issue resolution	3.12	8.5
Use of evidence-based standards, protocols and guidelines	3.13	5.4
Involvement of patients/service users and staff in planning	3.14	3.11

5th Edition Principle/Criterion/Topic	5th Edition Reference	6th Edition Reference
Coordination within and between departments and external services	3.15	5.10
Principle 4 – Safety & Risk		
Risk management framework	4.1	4.2
Risk management plan, risk management policy, risk register	4.2	4.2
Risks to patients/service users, mitigation of these risks	4.3	-
High risk procedures and treatments, mitigation of these risks	4.4	4.8
Safety incident investigation, reporting and communicating	4.5	4.5 & 4.6
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	8.4
Staff training on equipment	4.9	4.13
Safety law, building and equipment safety	4.10	4.11 & 4.12
Disaster recovery planning	4.11	6.7
Patient/service user records	4.12	5.8 & 5.9
Principle 5 – Person-Centred Approach		
Patient/service user rights and responsibilities	5.1	3.1
Performance/competency evaluation	3.10	8.2
On-going education	3.11	8.3
Processes to receive and resolve ethical dilemmas	5.2	5.2
Discussing options for care, respecting choices	5.3	3.4
Informed consent	5.4	5.1

5th Edition Principle/Criterion/Topic	5th Edition Reference	6th Edition Reference
Support for patients/service users in improving and maintaining health	5.5	5.11
Cultural and spiritual sensitivity	5.6	3.8
Staff education on person-centred care	5.7	3.2
Information on admission processes and range of services	5.8	2.1
Access to care or services	5.9	3.9
Patient/service user assessment	5.10	5.5
Patient/service user treatment or care plans	5.11	5.6
Following, monitoring progress, revising treatment or care plans	5.12	5.6
Discharge, referral	5.13	5.7
Patient/service user feedback, complaint management	5.14	5.12
Principle 6 – Quality Performance		
Collection of information relating to service performance	6.1	9.1
Evaluation and use of performance data	6.2	9.3
Quality improvement plans	6.3	9.3
Reporting of quality information to governing body	6.4	9.4
Publication of performance data	6.5	9.5

Change in Scale

	5th Edition	6th Edition
Principles	**6**	**9**
Criteria	**66**	**90**

Appendix B - Acknowledgements

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