



approximately 1,200 workforce members, comprising physicians, nurses, allied health professionals, pharmacists, laboratory and imaging staff, and non-clinical support workers.

Care is delivered from a main hospital campus and two satellite outpatient clinics. The main campus provides a 24-hour emergency department, inpatient medical and surgical wards, four operating theatres, an intensive care and high-dependency unit, obstetric and neonatal services, a pharmacy, a clinical laboratory, diagnostic imaging, a blood bank and transfusion service, sterile services, and a range of outpatient specialty clinics. The two satellite clinics provide primary and specialty outpatient consultations, minor procedures, diagnostics and follow-up care, extending access closer to the communities served.

The organization's key clinical processes include emergency care, inpatient care, surgical services, maternity care, critical care, pharmacy and medication management, laboratory and diagnostic services, and blood transfusion. These are supported by facilities management, procurement, human resources, information management, infection prevention and control, and quality and patient safety functions. The organization is licensed and registered with [relevant authority], licence or registration number [Registration Number], and is legally responsible for its activities.

The organization is directed and controlled by a Board of Directors, which delegates executive authority to the Chief Executive. Clinical governance is led by the Medical Director and the Director of Nursing, and quality governance is coordinated by the Quality Director through the Quality and Patient Safety Committee and its sub-committees for medication safety, infection prevention and control, risk, and ethics. An outline organisational chart is provided in Annex F.

[Company Name] has pursued a structured quality journey over recent years, moving from isolated departmental initiatives to an integrated, organization-wide management system for quality. This journey has been characterised by a growing emphasis on measurement, on learning from incidents through a just culture, and on the active involvement of service users in the design and evaluation of care. The adoption of ISO 7101:2023 formalises this direction and provides an internationally recognised framework within which the organization's quality and patient-safety activities are coordinated, evidenced and continually improved.

The workforce is the organization's most important resource. [Company Name] invests in the competence, credentialing and wellbeing of its people, recognising that safe, compassionate and effective care depends on a workforce that is properly resourced, supported and engaged. The organization's culture is built on respect, transparency and accountability, and on the principle that every worker, whatever their role, contributes to the quality of care and is empowered to raise concerns and propose improvements without fear of blame.



The organization has determined that climate change is a relevant issue, in view of its effect on the burden of disease, on the continuity of services during extreme weather, and on the organization's environmental responsibilities, and it addresses climate-related risks through its risk-management and emergency-preparedness processes. [Company Name] is an entity that can be held legally responsible for its activities.

Description of approach in practice. In practice, the Quality Director coordinates an annual context review, drawing on epidemiological data for the catchment population, regulatory updates, workforce and financial data, and the outputs of risk assessment. The review is an input to strategic planning and to management review, and material changes in context trigger reassessment of risks, objectives and, where necessary, the scope of the system.

Inputs, outputs and interfaces. The key inputs to this requirement are the strategic plan, regulatory and epidemiological data, workforce and financial reports, and prior risk assessments. The key outputs are a documented statement of internal and external issues and a determination on climate change. It interfaces principally with clause 4.2 stakeholders, clause 6.1 risk, and clause 9.3 management review, and the records listed below provide the evidence of conformity retained by the organization.

Supporting documents: QP-01 Context, Stakeholders and Scope; POL-01 Healthcare Quality Policy.

Records and evidence: Context and issues analysis (QF-01-01), reviewed at management review.

4.2 Understanding the needs and expectations of stakeholders

Statement of conformity. The organization determines the stakeholders relevant to the QMS, their relevant requirements, and which of those requirements are addressed through the QMS, and monitors this information, in conformity with clause 4.2.

Stakeholders include service users, families and caregivers; the workforce; the Ministry or Department of Health and other regulators; funders and health-insurance bodies; external providers; and, where they apply, global financing partners and the governmental, intergovernmental and non-governmental bodies the organization holds agreements with. Their requirements are captured in a stakeholder and requirements register and reviewed at defined intervals.

The organization monitors stakeholder information and requirements, maintains documented information, and demonstrates accountability towards agreed expectations, including requirements that may relate to climate change.

Description of approach in practice. Stakeholders are mapped by the Quality Department with input from clinical and non-clinical leads, and their requirements are recorded, prioritised and assigned to owning processes. The register is reviewed at least annually and when new agreements are entered



Document Control

Document title	Patient Safety Policy	Document number	POL-03
Revision	[Revision]	Effective date	[Date]
Standard	ISO 7101:2023	Clause(s) addressed	8.12.1 (framework: 6.1, 8.12.2-8.12.9)
Prepared by	ISO Consultant Panel	Owner	[Designation Here]
Reviewed by	[Name] / [Designation Here]	Approved by	[Name] / [Designation Here]

Revision History

Version	Date	Description of change	Author	Approval
1	[Date]	Initial issue.	ISO Consultant Panel	[Name]

POLICY

Patient Safety

[Company Name] is committed to a systematic, organization-wide patient safety programme that creates the cultures, processes, behaviours, technologies and environments that make error less likely and reduce its impact when it occurs.

1 Purpose and context

Patient safety is a framework of organized activities that consistently and sustainably lowers risk and reduces the occurrence of avoidable harm (ISO 7101:2023, 3.41). This policy sets out top management's commitment to patient safety across all settings in which [Company Name] provides services, including inpatient wards, operating theatres, the emergency department, outpatient clinics and satellite sites.

Avoidable harm in healthcare arises from a combination of system weaknesses and human factors rather than from individual carelessness alone. [Company Name] therefore treats safety as a property



Role	Responsibilities and authority
Top management	Accountable for service user focus and for ensuring access to care within the organization's mandate and applicable law.
Quality Director	Coordinates experience assessment and the service user voice mechanisms and reports results.
Clinical and department leads	Ensure service user rights are known and act on experience findings in their areas.
Front-line staff	Inform service users of their rights, capture feedback, and support participation in care.

5 Definitions and scales

The terms and definitions of ISO 7101:2023, clause 3, apply. Any specialised terms, scales or thresholds used in this procedure are defined at the point of use so that the procedure is self-contained.

6 Process

The process is carried out in the numbered steps below. Each step states who performs the activity, when it is triggered, where it applies, how it is done, the criteria or decision rule that applies, and the record it produces. The steps are followed in sequence, and every decision point has a defined criterion so that the process is performed consistently by every person who carries it out.

The intent of describing the process at this level of detail is to give real, followable instructions rather than a summary that a process exists. A new member of the workforce, or an external assessor, should be able to read a step and understand exactly what is done, by whom, against what criterion, and what evidence results. Where a step needs finer, task-level detail, for example an exact clinical technique or a system configuration, that detail is placed in the associated work instruction named at the step, which forms part of the same controlled system.

6.1 Define and communicate service user rights

Who: Top management with clinical leads **When:** On establishment and reviewed periodically
Where: All service areas

The organization ensures the rights of service users are clearly known, for example through a patient bill of rights and responsibilities (QF-03-01) displayed and provided at points of care, and it meets the requirements of service users in the delivery of care.

Acceptance criteria / decision rule: A patient bill of rights and responsibilities exists, is communicated, and is available to service users.



ISO 7101:2023 clauses 8.12.1 to 8.12.3; POL-03 Patient Safety Policy; QP-04 Risk Management; QP-32 Improvement, Nonconformity and Corrective Action; WI-22-01 Patient Identification; WI-22-02 Patient Safety Incident Reporting. Nationally and internationally recognized patient-safety objectives and guidelines are also drawn upon.

This procedure is self-contained: the definitions, scales, criteria and decision rules needed to perform it are embedded in the sections below or in its appendices, which are part of this controlled document. References to other documents are for supplementary information only, and any critical criterion needed to perform an activity is stated here rather than only referenced. Where this procedure interfaces with another, the interface and the document that owns the adjacent activity are named at the relevant step.

4 Responsibilities

The following roles carry the responsibilities and authorities set out below for this procedure. Responsibilities, authorities and accountabilities are assigned, communicated and understood, and are consistent with the roles and authorities assignment (QF-02-02). Where a role is consolidated in a smaller organization, the segregation-of-duties principle is preserved by ensuring that no single person both performs and independently verifies the same critical activity, and the consolidation and its safeguards are recorded.

Role	Responsibilities and authority
Top management / Patient Safety Committee	Governs the safety programme and reviews safety data.
Risk lead	Coordinates incident capture, analysis and lessons learned.
Clinical staff	Identify patients correctly, report incidents and apply safety practices.
Quality Director	Ensures the programme is documented, monitored and improved.

5 Definitions and scales

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ISO 7101:2023 clause 8.12.6; WI-25-01 Hand Hygiene; WI-25-02 Transmission-Based (Isolation) Precautions; QP-11 Facilities Management; QP-13 Waste Management.

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Role	Responsibilities and authority
IPC lead / team	Owns and runs the IPC programme, surveillance and audit.
IPC committee	Governs IPC, updates technical guidance and addresses emerging challenges.
Clinical and support staff	Apply IPC measures and report infections and breaches.
Quality Director	Ensures IPC is monitored and improved.

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This instruction applies to all surgical and procedural teams, surgeons, anaesthetists and theatre nurses, in the operating theatres and other areas where invasive procedures are performed at the main campus.

3 Safety and environmental considerations

Follow theatre infection-control and safety precautions (QP-25). The checklist is a safety barrier; the risk being controlled is catastrophic surgical error, so it is performed as a genuine shared pause, not a formality.

4 Tools, equipment and materials

Item	Specification / note
Surgical safety checklist	Current version (QF-24-01)
Site-marking materials	Approved skin marker
Count board / record	For instrument, swab and sharps counts

5 Definitions and acceptance criteria

The surgical safety checklist has three phases: sign-in before induction of anaesthesia, time-out before skin incision, and sign-out before the patient leaves theatre. The time-out is a deliberate pause by the whole team to confirm patient, procedure and site.

Acceptance criteria: the checklist is completed correctly only when all three phases are performed with the relevant team members present and engaged, patient identity (two identifiers), procedure and marked site are verified at the time-out, and counts reconcile at sign-out. A phase completed by one person while others continue working does not meet the criteria.

6 Instructions

Perform the following steps in sequence. Each step gives the action, the detail needed to do it correctly, the acceptance criterion where one applies, and the record to complete.

6.1 Sign-in (before induction of anaesthesia)

Before induction, confirm the patient's identity with two identifiers, the procedure and the marked site, that consent is in place, allergies, anaesthetic safety and any specific risks such as aspiration or blood loss. Resolve any discrepancy before proceeding.

Acceptance criteria: Identity, procedure, site, consent, allergies and anaesthetic safety are confirmed before induction.



This instruction applies to all workforce who have contact with service users, their surroundings or care equipment at the main campus and satellite clinics, including clinical, support and visiting staff.

3 Safety and environmental considerations

Use products safe for skin and follow any contraindications, for example soap and water rather than alcohol-based rub when hands are visibly soiled or after caring for a patient with certain infections. Report skin problems from frequent hand hygiene to occupational health.

4 Tools, equipment and materials

Item	Specification / note
Alcohol-based hand rub	At the point of care
Soap and running water	Where hands are visibly soiled
Single-use towels	For drying after washing

5 Definitions and acceptance criteria

Hand hygiene means decontaminating the hands using alcohol-based hand rub or soap and water. The recognized moments are summarised as five: before touching a service user, before a clean or aseptic procedure, after body-fluid exposure risk, after touching a service user, and after touching the service user's surroundings.

Acceptance criteria: hand hygiene is correct only when it is performed at each recognized moment, with the correct product for the situation, covering all surfaces of the hands for the required time (typically 20 to 30 seconds for rub and 40 to 60 seconds for wash), and hands are fully dried after washing. Being bare below the elbows, with no wristwatch, rings other than a plain band, or long or artificial nails, is required for effective hand hygiene.

6 Instructions

Perform the following steps in sequence. Each step gives the action, the detail needed to do it correctly, the acceptance criterion where one applies, and the record to complete.

6.1 Prepare

Be bare below the elbows, remove wristwatches and rings other than a plain band, keep nails short and unvarnished with no artificial nails, and cover any cuts with a waterproof dressing, so that hand hygiene can be effective.

Acceptance criteria: Bare below the elbows with short natural nails and covered cuts before care.

	FORM Surgical Safety Checklist Associated procedure: QP-24 Surgical Safety [Company Name]	QF-24-01 Rev [Revision] Issue [Date]
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1 IDENTIFICATION

SERVICE USER	PROCEDURE
THEATRE / DATE	TEAM LEAD

2 SIGN-IN (BEFORE INDUCTION)

Check	Confirmed
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3 TIME-OUT (BEFORE INCISION)

Check	Confirmed
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4 SIGN-OUT (BEFORE LEAVING THEATRE)

Check	Confirmed
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AUTHORIZATION

Surgeon	Anaesthetist	Nurse
Name: [Name] Signature: [Signature] Date: [Date]	Name: [Name] Signature: [Signature] Date: [Date]	Name: [Name] Signature: [Signature] Date: [Date]

ISOFOLDER



FORM

Informed Consent Form

Associated procedure: QP-19

Provision of Services | [Company
Name]

QF-19-02

Rev [Revision]

Issue [Date]

1 IDENTIFICATION

SERVICE USER

.....

PROCEDURE

.....

CLINICIAN

.....

DATE

.....

2 CONSENT DISCUSSION

NATURE AND BENEFITS EXPLAINED

.....

MATERIAL RISKS EXPLAINED

.....

ALTERNATIVES EXPLAINED

.....

UNDERSTANDING CONFIRMED

.....

3 CONSENT

Consent given:

☐ Yes ☐ No

4 SPECIAL CIRCUMSTANCES

CAPACITY

.....

INTERPRETER USED

.....

REPRESENTATIVE (IF APPLICABLE)

LIMITATIONS PLACED