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NON-GOVERNMENTAL, NON-PROFIT

ASF Health Standards Version 11

Standard 2: Governance and Accountability

Core standard · applies to all nine facility types

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APPROVAL



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Date: 1 November 2026

Complete on its own, without internet access. References are listed in section 11. The current version is at france-asf.fr.

Contents

1 Introduction

2 About ASF and this standard

3 How to use this standard

4 Scope

5 Ratings and colours

6 Abbreviations

7 Terms and definitions

8 Standard 2 at a glance: criteria, responsibilities, training

9 Criteria 2.1 to 2.10 (each on its own page)

10 Questions and answers

11 References

12 Document register

Criterion pages: 2.1 The Board Is Accountable · 2.2 There Is a Written Strategic Plan · 2.3 Policy Gets Followed · 2.4 Patient Data Is Kept Secure · 2.5 Records Are Kept Exactly as Long as Required · 2.6 Serious Incidents Get Properly Investigated · 2.7 Safety Culture Is Measured · 2.8 Patient Experience Is Measured Continuously, Not Only After Discharge · 2.9 An Ethics Consultation Process Exists · 2.10 Patients and Families Have a Voice in Governance.

1 Introduction

This document is Standard 2 of ASF Health Standards. It sets out how a facility is governed and how it is held accountable: who the governing body is and what it answers for, how the strategic plan and the code of conduct give direction, how policies are kept in practice, how patient information and records are protected and kept, how serious incidents are learned from, how safety culture and patient experience are measured, how ethical dilemmas are supported, and how patients and families have a voice in governance.

A standard is a set of numbered criteria. Each criterion says what must be in place (the criterion statement), how it is rated for each setting, what the assessor will check and what evidence the facility must show. The guidance in this document explains what each criterion means in practice, so that a reader who has only this paper can understand and meet it.

Purpose of this document. Standard 2 defines the minimum accountability structure a facility needs. Clinical and operational standards can be trusted only where someone is answerable for them, and this standard makes that answerability real.

Who should read it. Members of the governing body, the chief executive, managers, quality and risk staff, the secretary and records staff, and the assessors who verify the facility. Each criterion names the positions responsible for it (section 8.2).

The standard is a tool to improve care, not a list of paperwork. Templates and forms named in this document are reference drafts. You may adapt them, replace them with your own, or upload your own documents, provided they meet the same criterion.

2 About ASF and this standard

Accréditation Sans Frontières (ASF) is a non-governmental, non-profit accreditation body. It was legally established in Paris in 2020. ASF develops health standards that are practical, affordable and open to all facilities, including those working with limited resources, in crisis, or in transition.

ASF believes accreditation should be accessible in every sense: geographically, so that facilities in remote areas can take part; financially, so that cost is not a barrier; and in language and format, so that staff can read and use the standard in their own working environment.

Each standard is an independent document. Standard 2 has been written so that it can be read and used on its own. It repeats the definitions, abbreviations and references it needs. A reader who has only this document can understand every criterion in it. Where a criterion depends on another standard, the reference is stated in full.

3 How to use this standard

If you are a member of the governing body or a facility manager, read section 4 to confirm the standard applies, then section 5 to find the rating for your setting. Read each criterion from 2.1 to 2.10, paying attention to the rating, the guidance and the evidence. Prepare the evidence named in each criterion, covering the period stated.

If you are an assessor, use the sample and the checks in each criterion. The pass rule and the immediate-fail rule decide each criterion. A criterion is met only when all its checks are passed and no immediate-fail event is found.

Reading a criterion. Each criterion has: the criterion statement; the three ratings (humanitarian, transition and fragile, standard); the rating rule; the guidance; what good looks like; common mistakes; why it matters; the sample; the checks, with method, evidence and pass condition; the immediate-fail event; the documents with who writes, approves and checks them; the positions responsible; and the references.

How to prepare. Start with the rating for your setting, then gather the evidence named in each criterion for the period it covers. For each criterion, check your own records against the checks, and fix any gap before the assessor arrives.

Document codes. Each document has a code made of a topic prefix, a type and a number, for example GOV-POL-001 (governance, policy, 001). The type is one of FRM (form, a record kept as evidence), REG (register), PLN (plan), POL (policy), SOP (standard operating procedure) or GDL (guide). The codes identify documents only. The full list is in section 12.

4 Scope

Standard 2 is a core standard, so it applies to all nine facility types. It covers the governing body, the strategic plan and code of conduct, adherence to policy, the protection and retention of patient records, the investigation of serious incidents, the measurement of safety culture and patient experience, access to ethics consultation, and the voice of patients and families in governance.

The standard applies in three settings. The rating for each criterion is given for each setting, and the facility uses the rating for its own setting: **humanitarian settings** (emergency or crisis, very limited resources), **transition and fragile settings** (a health system in change or under strain), and **standard settings** (full resources).

WHERE STANDARD 2 APPLIES

Standard 2 is a core standard, so every facility type is assessed against all ten of its criteria. No criterion is marked N/A for any facility type. The applicability of all 70 standards is in **Annex 1: Applicability of ASF Health Standards by facility type** (ASF-HS11-ANX01), published on france-asf.fr.

Criterion	Applies to
2.1 The Board Is Accountable	all nine facility types
2.2 There Is a Written Strategic Plan	all nine facility types
2.3 Policy Gets Followed	all nine facility types
2.4 Patient Data Is Kept Secure	all nine facility types
2.5 Records Are Kept Exactly as Long as Required	all nine facility types
2.6 Serious Incidents Get Properly Investigated	all nine facility types
2.7 Safety Culture Is Measured	all nine facility types
2.8 Patient Experience Is Measured Continuously, Not Only After Discharge	all nine facility types
2.9 An Ethics Consultation Process Exists	all nine facility types
2.10 Patients and Families Have a Voice in Governance	all nine facility types

5 Ratings and colours

Rating	Colour	Meaning
Must		Required in every setting. Criteria that can directly affect a patient's life are always Must, and no setting lowers them.
Medium		Required, adapted to what a transition setting can realistically do.
Minimum		The lowest acceptable level in a humanitarian setting, where resources are very limited.

In standard settings every criterion is Must.

TRAINING LEVELS

Level	Colour	Meaning
Essential		Must be completed by the people named in the role table.
Recommended		Good practice. Not checked as a requirement.
Optional		May be used for development.

6 Abbreviations

Abbreviation	Meaning
ASF	Accréditation Sans Frontières (Accreditation Without Borders), a non-governmental, non-profit accreditation body
FRM	Form. A record that is filled in and kept as evidence
GDL	Guide. Reference guidance for staff
ISCO-08	International Standard Classification of Occupations, 2008 edition (International Labour Organization)
PAHO	Pan American Health Organization
PLN	Plan. A written plan with aims, owners and dates
POL	Policy. A written statement of what the facility will do and why
REG	Register. A running record of entries, such as members, actions or consultations
SOP	Standard operating procedure. A step-by-step description of how a task is done
WHO	World Health Organization

DOCUMENT CODE PREFIXES

Prefix	Topic
CON	Consent, patient rights and patient experience documents
DIG	Digital care and information security documents
GOV	Governance and accountability documents
INC	Incident management documents
QUA	Quality and safety culture documents
REC	Records management documents

7 Terms and definitions

Term	Definition
Assessor	The ASF-trained person who verifies, against the evidence, whether a facility meets each criterion. Also called the surveyor.
Criterion	One numbered requirement in a standard, for example 2.1. Each criterion has its own rating, pass rule and immediate-fail rule.
Evidence	The records, documents and observations that show a criterion is met.
Ethics consultation	A process through which staff can ask for advice on an ethical dilemma in patient care, from a committee, a named resource or an external arrangement.
Governing body	The group with final authority over the facility, with named members and documented terms of reference.
Humanitarian setting	A facility working in emergency or crisis conditions with very limited resources.
Immediate fail	One event that means a criterion is not met, whatever else is in place.
Must, Medium, Minimum	The three ratings of a criterion. Must is required in every setting; Medium is required, adapted to what a transition setting can realistically do; Minimum is the lowest acceptable level in a humanitarian setting. See section 5.
Pass rule	The condition that shows a criterion is met, given as a number, a percentage or a yes/no test.
Quality improvement plan	A plan that sets improvement aims, owners and indicators across the facility, approved by the governing body and reviewed on dated cycles.
Retention period	The minimum time a record must be kept, set by the legal requirement of the country and the facility's retention policy.
Root cause analysis	A structured method for finding the underlying causes of an incident, such as system, process or equipment factors, rather than only the immediate event.
Safety culture	The shared beliefs and behaviours that decide whether staff feel able to report errors and near misses, and whether reports lead to action.
Sample	The set of records, meetings or patients that the assessor checks for a criterion. The sample is stated for each criterion.
Serious incident	An incident that caused, or could have caused, serious harm to a patient, as the facility defines it in its incident procedure (INC-SOP-001).

Term	Definition
Setting	The context in which a facility works: humanitarian, transition and fragile, or standard. Each criterion is rated for each setting.
Standard setting	A facility with full resources. Every criterion is Must in standard settings.
Transition and fragile setting	A facility in a health system that is changing or under strain, able to meet part of the standard at Medium level.
Verified micro-credential	A training credential that can be checked against the issuer's record, such as one held in the GMJ Academy micro-credential portfolio.

8 Standard 2 at a glance

Standard 2: Governance and Accountability is a core standard of ASF Health Standards. Every facility type meets it. It covers who governs the facility and what the governing body answers for, the strategic plan and code of conduct, whether policies are followed in practice, how patient information and records are protected and retained, how serious incidents are investigated, how safety culture and patient experience are measured, how ethics consultation is available, and how patients and families take part in governance.

The standard has ten criteria. Each is shown below and explained on its own page in section 9. Each criterion states its own rating for each setting, its evidence and its pass rule.

8.1 CRITERIA AND RATINGS

No.	Criterion	Humanitarian	Transition	Standard
2.1	The Board Is Accountable	Medium	Must	Must
2.2	There Is a Written Strategic Plan	Medium	Must	Must
2.3	Policy Gets Followed	Medium	Must	Must
2.4	Patient Data Is Kept Secure	Medium	Must	Must
2.5	Records Are Kept Exactly as Long as Required	Medium	Must	Must
2.6	Serious Incidents Get Properly Investigated	Medium	Must	Must
2.7	Safety Culture Is Measured	Medium	Must	Must
2.8	Patient Experience Is Measured Continuously, Not Only After Discharge	Minimum	Medium	Must
2.9	An Ethics Consultation Process Exists	Minimum	Medium	Must
2.10	Patients and Families Have a Voice in Governance	Minimum	Medium	Must

8.2 RESPONSIBILITIES

Each criterion names the positions responsible for it. Each position should have written terms of reference. ISCO-08 codes are shown for each role and are recorded in the staff register.

No.	Criterion	Positions responsible or involved
2.1	The Board Is Accountable	Chief executive (ISCO 1120) · Governing body members · Secretary (ISCO 3344)
2.2	There Is a Written Strategic Plan	Chief executive (ISCO 1120) · Governing body members
2.3	Policy Gets Followed	Chief executive (ISCO 1120) · Manager (ISCO 1342)
2.4	Patient Data Is Kept Secure	Chief executive (ISCO 1120) · Manager (ISCO 1342)
2.5	Records Are Kept Exactly as Long as Required	Manager (ISCO 1342) · Secretary (ISCO 3344)

No.	Criterion	Positions responsible or involved
2.6	Serious Incidents Get Properly Investigated	Chief executive (ISCO 1120) · Manager (ISCO 1342)
2.7	Safety Culture Is Measured	Chief executive (ISCO 1120) · Manager (ISCO 1342)
2.8	Patient Experience Is Measured Continuously, Not Only After Discharge	Manager (ISCO 1342)
2.9	An Ethics Consultation Process Exists	Governing body members · Chief executive (ISCO 1120)
2.10	Patients and Families Have a Voice in Governance	Governing body members · Secretary (ISCO 3344)

Reporting lines. The reporting line and supervision of each role are taken from the ASF terms of reference for that role, published on france-asf.fr. A facility with a different structure records its own reporting lines in its organogram.

Role	Reports to	Supervises
Chief executive (ISCO 1120)	The board of directors.	The executive team (COO, CMO, CNO, CFO, CQO, CHRO, CIO, CSO), and the legal, data protection, compliance and communications leads.
Governing body members	Shareholders or owners of the organisation.	The chief executive officer. The board chair leads the board.
Manager (ISCO 1342)	The chief quality and safety officer (CQO).	Quality assurance, patient safety, accreditation, clinical audit, infection prevention and complaints teams.
Secretary (ISCO 3344)	The head of department (per specialty).	No direct reports.

8.3 TRAINING FOR STANDARD 2

Training is shown by course. Essential training must be completed by the people named. Recommended training is good practice. The colours follow section 5.

Course	Essential for	Recommended for	Criteria	GMJ Academy course page
Governance & Management (H-07)	Chief executive, Governing body members	None	2.1	English · Georgian
Safety Management System & Leadership (MGMT-01)	Chief executive	Governing body members, Manager	2.1, 2.2, 2.7	Georgian Georgian version only
Quality Management in Healthcare (A-02)	Chief executive	Governing body members	2.2	Georgian Georgian version only

Course	Essential for	Recommended for	Criteria	GMJ Academy course page
Documentation Fundamentals (A-03)	Manager	Chief executive	2.3	Georgian Georgian version only
Document Control and the Records System (T-02)	Manager, Secretary	None	2.3, 2.5	Georgian Georgian version only
Document Control Fundamentals (A-06)	Manager	None	2.3	English · Georgian
Records, Confidentiality and Data Protection (T-11)	Manager, Secretary	Chief executive, Manager	2.4, 2.5	English · Georgian
Security Protocols & Incident Response (SEC-01)	Manager	None	2.4	Georgian Georgian version only
Incident Reporting, Just Culture and Open Disclosure (T-09)	Manager	Chief executive	2.6, 2.7	English · Georgian
Nonconformity, Corrective Action and Risk (T-04)	Manager	Chief executive	2.6	English · Georgian
Complaints Handling and Patient Feedback (T-12)	None	Manager, Governing body members	2.8, 2.10	English · Georgian
Healthcare Ethics for ASF Accreditation (A-07)	None	Governing body members, Chief executive	2.9	Georgian Georgian version only

Each course is published in the GMJ Academy (academy.gmj.ge). Where a course has an English and a Georgian version, both are linked. Six courses are published in Georgian only.

8.4 RELATED COURSES IN THE GMJ ACADEMY

These courses cover the same subjects in more depth or for a specific type of facility. They are optional. They are not required by the criteria.

Course	Subject	Criteria	GMJ Academy course page
Governance & Management for Ambulatory Clinics (AMB-07)	Governance course for your facility type	2.1	English · Georgian
Governance & Staffing for Small Primary Care Practices (PHC-07)	Governance course for your facility type	2.1	English · Georgian
Governance & Staffing for Long-Term Care Accreditation (LTC-07)	Governance course for your facility type	2.1	English · Georgian

Course	Subject	Criteria	GMJ Academy course page
Governance & Staffing for Home-Based Care (HC-07)	Governance course for your facility type	2.1	English · Georgian
Governance & Provider Credentialing for Telemedicine (TM-07)	Governance course for your facility type	2.1	English · Georgian
Governance & Document Control for Laboratory Accreditation (LAB-01)	Governance course for your facility type	2.1	English · Georgian
Governance & Management for ASF Accreditation (MT-07)	Governance course for your facility type	2.1	English · Georgian
Leadership, policy, objectives and management review (T-02)	Leadership, policy and management review	2.2, 2.3	English
Management Review: Inputs, Outputs, and Real Decisions (T-05)	Leadership, policy and management review	2.2, 2.3	English · Georgian
Understanding ISO 9001 in a Clinic (T-01)	Leadership, policy and management review	2.2, 2.3	English · Georgian
Document Control and Record Management (ISO-04)	Document and record control	2.3, 2.5	English
Data Privacy & Patient Confidentiality (TM-06)	Data privacy and system security	2.4	English · Georgian
Technology Platform Reliability & Security (TM-01)	Data privacy and system security	2.4	English · Georgian
Nonconformity, Corrective Action and CAPA (ISO-10)	Corrective action, risk and audit	2.6	English
Risk-Based Thinking and the Risk Register (ISO-05)	Corrective action, risk and audit	2.6	English
Internal Audit — Planning, Performing, Reporting (T-03)	Corrective action, risk and audit	2.6	English · Georgian
Raising and Resolving Workplace Concerns	Staff voice and workplace concerns	2.7	English
Workforce Feedback and Action (BAS-13)	Staff voice and workplace concerns	2.7	English
Customer Satisfaction and Complaints (ISO-11)	Patient feedback and patient representatives	2.8, 2.10	English
PC-01: Patient Council Chair Training (PC-01)	Patient feedback and patient representatives	2.8, 2.10	English · Georgian
Patient Identification, Informed Consent and Patient Rights (T-07)	Consent, rights and difficult care decisions	2.9	English · Georgian

Course	Subject	Criteria	GMJ Academy course page
Withdrawal of Care and End-of-Life Decisions (WD-01)	Consent, rights and difficult care decisions	2.9	English

Evidence of training may be a verified micro-credential in the GMJ Academy micro-credential portfolio, or a training certificate kept in the staff file.

2.1 The Board Is Accountable

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A governing body exists, with named members and clear, documented authority over safety and quality, clinical governance, and financial stewardship — not an informal ownership arrangement functioning without oversight structure.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: a governing body with named members, and minutes kept for each meeting.

GUIDANCE

The governing body is the group answerable for the facility. It has named members, each with a defined term of office, and written terms of reference that set out its authority over safety and quality, clinical governance and financial stewardship. An arrangement in which one owner or manager makes every decision, with no body to oversee it, does not meet this criterion.

The body meets on the schedule set in its procedure (GOV-SOP-001). The secretary keeps the minutes on the minutes template (GOV-FRM-003) for each meeting, and keeps the register of members (GOV-REG-001) up to date. At each meeting the body reviews quality and safety, and the minutes show what was decided and who will act.

> **Good practice.** The governing body has named members, written terms of reference and a fixed meeting schedule. Its minutes record decisions on safety, quality and finance, and each member knows what they are accountable for.

> **Partial because.** A governing body exists, but membership, authority or meeting records are incomplete, or the body does not clearly hold authority over safety and quality.

WHAT GOOD LOOKS LIKE

- Terms of reference (GOV-POL-001) that name the body's authority over safety, quality, clinical governance and finance.
- A register of members (GOV-REG-001) showing each person's name, role and term of office.
- Minutes (GOV-FRM-003) for every scheduled meeting in the last 12 months, each with a quality and safety review.
- Decisions in the minutes that are followed up at the next meeting.

COMMON MISTAKES

- Meetings held only when there is a crisis, with no minutes.
- A register that still lists members whose terms have ended.
- Minutes that record attendance but no discussion of quality or safety.
- Treating the owner's signature as governance, with no body involved.

> **Why it matters.** A facility with no clearly accountable governing body has no one answerable for safety and quality when things go wrong. Named members with documented authority make that accountability real.

WHAT THE ASSESSOR CHECKS

Sample. Review the governing body's records for the last 12 months, and its terms of reference.

1 **A governing body with named members and defined terms exists.**

Method. Check the terms of reference and the membership register for named members and their terms of office.

Evidence to show. GOV-POL-001 Governing Body Terms of Reference; GOV-REG-001 Register of Governing Body Members.

Pass when. Every member is named and has a defined term.

2 **The body meets on a fixed schedule, with minutes kept.**

Method. Compare the meeting dates in the minutes with the schedule set in the procedure.

Evidence to show. GOV-FRM-003 Governing Body Minutes Template, completed for each meeting.

Pass when. Meetings take place on the scheduled dates, and minutes exist for each one.

3 **Quality, safety and financial oversight are assigned to the board.**

Method. Read the minutes for a quality and safety review at each meeting, and check that clinical governance and financial stewardship are named board responsibilities.

Evidence to show. GOV-SOP-001 Governing Body Meetings and Decisions on Safety and Quality; minutes.

Pass when. Each meeting records a quality and safety review, and both responsibilities are named in the procedure.

Pass. The criterion is met when every check above is passed.

Immediate fail. The governing body does not exist, or has no minutes for the last 12 months. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
GOV-SOP-001	Governing Body Meetings and Decisions on Safety and Quality	Chief executive	Governing body members	Chief executive
GOV-FRM-003	Governing Body Minutes Template	Manager	Chief executive	Manager
GOV-REG-001	Register of Governing Body Members	Secretary	Chief executive	Manager
GOV-POL-001	Governing Body Terms of Reference	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries operational accountability to the board	Governance & Management; Safety Management System & Leadership Essential in all settings
Governing body members	Holds the authority this criterion requires	Governance & Management; Safety Management System & Leadership Essential in all settings
Secretary (ISCO 3344)	Keeps the register and the minutes	— Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Hospital Safety Index: Guide for Evaluators, 2nd ed. https://news.gmj.ge/guideline/hospital-safety-index-guide-for-evaluators-2nd-ed/

2.2 There Is a Written Strategic Plan

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A documented plan states the facility's mission, values, and a code of conduct for staff behaviour, and guides resourcing decisions — not a one-page mission poster disconnected from how money and staff time get allocated, and not a mission statement with no accompanying statement of values or expected conduct.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: a written plan with a mission, values and a code of conduct for staff.

GUIDANCE

A written strategic plan gives the facility its direction over several years. It states the mission and values and is approved by the governing body. A mission statement on the wall is not a plan unless budget and staffing decisions follow it.

The code of conduct for staff (GOV-POL-002) is a separate document from the mission. It sets out expected behaviour, including respect for patients, honesty about errors and how conflicts of interest are declared. Staff should be able to describe its main points in their own words. Resourcing decisions refer back to an objective in the plan, so the link between plan and money can be traced.

> **Good practice.** The strategic plan states the mission, values and a code of conduct, and the budget and staffing decisions visibly follow from it. Staff can state the mission and the main priorities in their own words.

> **Partial because.** A plan exists and states a mission, but values or the code of conduct are missing, or resourcing decisions do not follow from the plan.

WHAT GOOD LOOKS LIKE

- A strategic plan (GOV-PLN-001) covering several years, with a mission and approval by the governing body.
- A code of conduct (GOV-POL-002), approved and dated, separate from the mission statement.
- A budget or staffing decision from the last year that refers to an objective in the plan.
- Staff who can describe the code of conduct when asked.

COMMON MISTAKES

- A mission statement with no values or code of conduct beside it.
- A plan written once and never reviewed or approved.
- Budget decisions that do not refer to the plan.
- A code of conduct copied from another organisation without adaptation.

> **Why it matters.** A facility without a written plan drifts, and its resources follow whichever problem is loudest that week. A written plan with a mission, values and code of conduct sets the direction that staff and the board can be held to.

WHAT THE ASSESSOR CHECKS

Sample. Review the plan and the code of conduct currently in force, and the decisions made in the last year.

1 **A written strategic plan covers at least several years.**

Method. Check the plan's period, its approval record and its mission statement.

Evidence to show. GOV-PLN-001 Strategic Plan (template and approval).

Pass when. The plan is approved, covers a multi-year period and states a mission.

2 **A resourcing decision can be traced to the plan.**

Method. Select one budget or staffing decision from the last year and trace its link to a plan objective.

Evidence to show. The budget or staffing decision record, and the plan.

Pass when. The decision refers to a plan objective.

3 **Values and a code of conduct guide staff behaviour.**

Method. Ask staff to describe the code of conduct, and check that it is separate from the mission statement.

Evidence to show. GOV-POL-002 Code of Conduct for Staff.

Pass when. The code of conduct is approved, separate from the mission, and staff can describe its main points.

Pass. The criterion is met when every check above is passed.

Immediate fail. The facility has no written strategic plan, or no code of conduct for staff. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
GOV-PLN-001	Strategic Plan (template and approval)	Chief executive	Governing body members	Chief executive
GOV-POL-002	Code of Conduct for Staff	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries operational accountability to the board	Quality Management in Healthcare; Safety Management System & Leadership Essential in all settings
Governing body members	Holds the authority this criterion requires	Quality Management in Healthcare; Safety Management System & Leadership Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Hospital Safety Index: Guide for Evaluators, 2nd ed. https://news.gmj.ge/guideline/hospital-safety-index-guide-for-evaluators-2nd-ed/

2.3 Policy Gets Followed

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A policy framework exists and staff can describe how it is applied in practice, not merely confirm that policies are filed and technically available. The framework includes a formal, comprehensive quality improvement plan covering every part of the facility, with allocated responsibilities and defined performance indicators.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: policies are checked against practice, and every gap has a recorded action.

GUIDANCE

A policy protects patients only if people follow it. The facility checks adherence on a set schedule: the manager selects policies, asks staff in two areas how each one is applied in their daily work, and records the result on the policy application audit form (GOV-FRM-002). The results are entered in the policy register (GOV-REG-002).

Each gap found has a recorded action, an owner and a date. The quality improvement plan (GOV-PLN-002) covers every area of the facility, names an owner and an indicator for each area, and is approved and reviewed on dated cycles. Policy development, approval, review and application follow GOV-POL-003.

> **Good practice.** Staff can describe how each key policy is applied in their daily work. Policy application is audited, and the quality improvement plan covers every service with named owners and deadlines.

> **Partial because.** Policies are written and filed, but staff cannot explain how they are applied, or the quality improvement plan covers only some services or has no owners.

WHAT GOOD LOOKS LIKE

- A policy register (GOV-REG-002) listing each policy, its version, owner and review date.
- Completed audit forms (GOV-FRM-002) showing that staff describe the policy as it is written.
- A quality improvement plan (GOV-PLN-002) with an owner and an indicator for every area.
- A recorded action for every gap, with the date it was closed.

COMMON MISTAKES

- A complete set of policies that staff have never read.
- Audit forms completed from the document, not from talking to staff.
- A quality improvement plan that covers only clinical areas.
- Gaps found, but no action recorded.

> **Why it matters.** Many facilities have a complete set of policies that nobody follows. A policy that staff cannot explain in practice is a document, not a control.

WHAT THE ASSESSOR CHECKS

Sample. Select three policies at random and check them against practice in the last 12 months.

1 Staff can describe how a named policy is applied.

Method. Ask staff in two areas to describe how one selected policy is applied in their daily work.

Evidence to show. GOV-FRM-002 Policy Application Audit Form, completed for each selected policy.

Pass when. Staff describe the policy as it is written.

2 Adherence is checked and gaps have a defined response.

Method. Read the audit records and check that each gap has an action recorded.

Evidence to show. GOV-REG-002 Policy Register; GOV-FRM-002 audit records.

Pass when. Every gap found has a recorded action.

3 The quality improvement plan is complete, authorised and reviewed.

Method. Check the plan covers every area of the facility, that each area has a named owner and an indicator, and that its approval and review are dated.

Evidence to show. GOV-PLN-002 Quality Improvement Plan; GOV-POL-003 Policy Development, Approval, Review and Application.

Pass when. The plan covers all areas, each has a named owner and an indicator, and approval and review are dated.

Pass. The criterion is met when every check above is passed.

Immediate fail. A policy is in use with no adherence check, and no response when a policy-practice gap is found. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
GOV-FRM-002	Policy Application Audit Form	Manager	Chief executive	Manager
GOV-REG-002	Policy Register	Secretary	Chief executive	Manager
GOV-PLN-002	Quality Improvement Plan	Chief executive	Governing body members	Chief executive
GOV-POL-003	Policy Development, Approval, Review and Application	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries operational accountability to the board	Documentation Fundamentals Essential in all settings
Manager (ISCO 1342)	Runs the process this criterion measures	Documentation Fundamentals; Document Control and the Records System; Document Control Fundamentals Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Hospital Safety Index: Guide for Evaluators, 2nd ed. https://news.gmj.ge/guideline/hospital-safety-index-guide-for-evaluators-2nd-ed/

2.4 Patient Data Is Kept Secure

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Health information is protected with defined access controls and a breach response plan, using practical, achievable security measures appropriate to the facility's resources.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: access to patient data is restricted by role, and the breach plan is tested.

GUIDANCE

Patient health information is protected by the information security and access control policy (DIG-POL-001). Everyone who can see patient records, whether electronic or on paper, has a role that needs that access. Access is reviewed when staff join, change role or leave.

The breach response procedure (DIG-SOP-001) names the steps to take if information is lost or seen by someone who should not see it, who acts at each step, and how the breach is reported. The plan is tested or reviewed, and the test record (DIG-FRM-001) shows the date, the result and the action taken. The measures should be realistic for the facility's resources: in a small facility, a locked cabinet with a named key holder and a password policy for shared systems can meet the criterion.

> **Good practice.** Access to health information is limited by role and recorded, and a breach response plan has been tested. Measures are proportionate to the facility's resources and are checked at regular intervals.

> **Partial because.** Access controls exist for the main records system, but some records are shared informally, or the breach response plan has not been tested.

WHAT GOOD LOOKS LIKE

- An access control policy (DIG-POL-001) that matches access to staff roles.
- A breach response procedure (DIG-SOP-001) with named steps, responsible people and a reporting route.
- A breach response test record (DIG-FRM-001) dated within the last 12 months, with actions closed.
- Access lists checked against current staff when people join, move or leave.

COMMON MISTAKES

- Shared log-in details for clinical systems.
- Access granted to the whole team 'to be safe'.
- A breach plan that has never been tested.
- Paper records left unlocked in corridors or open rooms.

> **Why it matters.** Patient health information is sensitive, and a breach can harm patients and families. Defined access controls and a breach response plan keep it protected, even in a temporary setting.

WHAT THE ASSESSOR CHECKS

Sample. Review the access controls and the breach response plan currently in force.

1 Access to patient data is restricted by role.

Method. Check the access list against staff roles for a sample of systems and paper records.

Evidence to show. DIG-POL-001 Information Security and Access Control Policy.

Pass when. Every person with access has a role that needs it.

2 A breach response plan exists and is actionable.

Method. Read the procedure and check that it names the steps, the responsible person and the reporting route.

Evidence to show. DIG-SOP-001 Patient Data Breach Response Procedure.

Pass when. The procedure names who acts, what they do and how it is reported.

3 Access controls and the breach plan have been tested.

Method. Check the date and result of the most recent test or review.

Evidence to show. DIG-FRM-001 Breach Response Test Record.

Pass when. A test or review is recorded within the last 12 months, with actions closed.

Pass. The criterion is met when every check above is passed.

Immediate fail. Patient records can be accessed by staff with no role-based need, and no breach response plan exists. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-SOP-001	Patient Data Breach Response Procedure	Manager	Chief executive	Chief executive
DIG-FRM-001	Breach Response Test Record	Manager	Chief executive	Manager
DIG-POL-001	Information Security and Access Control Policy	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries operational accountability to the board	Records, Confidentiality and Data Protection Essential in all settings
Manager (ISCO 1342)	Runs the process this criterion measures	Records, Confidentiality and Data Protection; Security Protocols & Incident Response Essential in all settings

REFERENCES FOR THIS CRITERION

- WHO SMART Trust. Ethical Considerations and Data Protection Principles. https://smart.who.int/trust/ethical_principles.html
- ISO 27799:2016. Health informatics: Information security management in health using ISO/IEC 27002. https://www.iso.org/standard/62777.html
- International Agency for Research on Cancer (WHO). Confidentiality of medical records, section 3: Access to and storage of data. https://gicr.iarc.who.int/static/public/docs/Confidentiality%20IACR-IARC%20(Tech%20Rep%202004-3).pdf

2.5 Records Are Kept Exactly as Long as Required

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A retention policy governs how long records are kept and how they are disposed of, aligned with a stated requirement for the country where the facility operates, not a generic assumption.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: a stated retention period for each record type, and recorded disposal.

GUIDANCE

The retention policy sets how long each type of record is kept, and it cites the legal requirement for the country where the facility operates. Each period must be at least as long as that requirement. The policy sits with the record register, so staff can see what records exist and how long they are kept.

Disposal is secure and recorded on the records disposal record (REC-FRM-003), with the date, the method and the person who authorised it. A record is not destroyed before its retention period ends, and a record needed for an open investigation or claim is kept until the matter is closed.

> **Good practice.** A retention policy sets a period for each record type, aligned with the national requirement. Disposal is recorded with the date, method and authorising person.

> **Partial because.** A retention policy exists but does not set periods for each record type, or disposal is not recorded.

WHAT GOOD LOOKS LIKE

- A retention policy listing each record type and its period.
- A citation of the national legal requirement, checked against the current law.
- Disposal records (REC-FRM-003) with date, method and authoriser.
- Secure disposal for paper and for electronic media, with the destruction recorded.

COMMON MISTAKES

- One retention period applied to every type of record.
- Disposing of records still needed for an open investigation.
- Disposal with no record of what was destroyed.
- Keeping everything indefinitely because nobody has checked the requirement.

> **Why it matters.** Keeping records forever is costly and risky, and destroying them too early can break the law and remove evidence a patient needs. A retention policy sets the period for each record type, and the disposal is recorded.

WHAT THE ASSESSOR CHECKS

Sample. Review the retention policy and the disposal records for the last 12 months.

1 **A written retention policy sets periods for each record type.**

Method. Check that the policy lists each record type with its retention period.

Evidence to show. The retention policy and the record register.

Pass when. Each record type has a stated period.

2 **The periods match the national requirement.**

Method. Compare the periods with the legal requirement for the country where the facility operates.

Evidence to show. The national requirement cited in the policy.

Pass when. Each period is at least the national requirement.

3 **Disposal is secure and documented.**

Method. Select disposal records and check the date, method and authoriser.

Evidence to show. REC-FRM-003 Records Disposal Record.

Pass when. Each disposal is recorded with its date, method and authoriser.

Pass. The criterion is met when every check above is passed.

Immediate fail. Records are disposed of with no retention policy, or are destroyed before the retention period ends. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
REC-FRM-003	Records Disposal Record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the process this criterion measures	Records, Confidentiality and Data Protection Essential in all settings
Secretary (ISCO 3344)	Keeps the register and the minutes	Records, Confidentiality and Data Protection; Document Control and the Records System Essential in all settings

REFERENCES FOR THIS CRITERION

- International Agency for Research on Cancer (WHO). Confidentiality of medical records, section 3: Access to and storage of data. https://gicr.iarc.who.int/static/public/docs/Confidentiality%20IACR-IARC%20(Tech%20Rep%202004-3).pdf

2.6 Serious Incidents Get Properly Investigated

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Root cause analysis is used for serious incidents, with a resulting, tracked action plan — not a brief note explaining what happened without examining why it happened.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: a root cause analysis and a tracked action plan for each serious incident.

GUIDANCE

Every serious incident is investigated with a structured root cause analysis (INC-SOP-001), recorded on the root cause analysis record (INC-FRM-001). The analysis asks why the event happened, through the systems and processes involved, and does not stop at who was involved. It identifies root causes, not only the immediate event.

The analysis produces an action plan. Each action has an owner, a date and a status on the incident action tracker (INC-REG-001). An incident is not closed while an action is open with no owner. Where an action cannot be completed on time, the reason for the delay is recorded and the action is reviewed.

> **Good practice.** Each serious incident has a root cause analysis that looks at system causes, and the action plan has owners, deadlines and follow-up. Staff who were involved take part in the review.

> **Partial because.** Incidents are investigated and described, but the analysis stops at individual actions, or the action plan is not tracked to completion.

WHAT GOOD LOOKS LIKE

- A root cause analysis procedure (INC-SOP-001) and a record for each serious incident (INC-FRM-001).
- Analyses that identify system causes, such as workload, equipment, communication or process.
- An incident action tracker (INC-REG-001) with an owner, a date and a status for every action.
- Evidence that lessons are shared with the teams involved.

COMMON MISTAKES

- Closing an incident with a note of what happened but no analysis.
- Stopping at the individual who made the error.
- Actions with no owner or no date.
- Open actions that are never reviewed.

> **Why it matters.** Root cause analysis finds why an incident happened, not who was involved. A tracked action plan that is followed through is what makes the investigation worth doing.

WHAT THE ASSESSOR CHECKS

Sample. Select every serious incident from the last 12 months.

1 A structured root cause analysis is used.

Method. Read the analysis for each serious incident and check that it follows the procedure.

Evidence to show. INC-SOP-001 Root Cause Analysis of Serious Incidents; INC-FRM-001 Root Cause Analysis Record.

Pass when. Each analysis follows the procedure and identifies root causes, not only the immediate event.

2 The analysis produces a tracked action plan.

Method. Check each action in the tracker for an owner, a date and a status.

Evidence to show. INC-REG-001 Incident Action Tracker.

Pass when. Every action has an owner and a date.

3 Actions are followed through to completion.

Method. Check the status of each action against its due date.

Evidence to show. INC-REG-001 Incident Action Tracker.

Pass when. Every action is closed or has a recorded reason for the delay.

Pass. The criterion is met when every check above is passed.

Immediate fail. A serious incident is closed with no root cause analysis, or its action plan is left open with no owner. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
INC-SOP-001	Root Cause Analysis of Serious Incidents	Manager	Chief executive	Chief executive
INC-FRM-001	Root Cause Analysis Record	Manager	Chief executive	Manager
INC-REG-001	Incident Action Tracker	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries operational accountability to the board	Incident Reporting, Just Culture and Open Disclosure; Nonconformity, Corrective Action and Risk Essential in all settings
Manager (ISCO 1342)	Runs the process this criterion measures	Incident Reporting, Just Culture and Open Disclosure; Nonconformity, Corrective Action and Risk Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Hospital Safety Index: Guide for Evaluators, 2nd ed. https://news.gmj.ge/guideline/hospital-safety-index-guide-for-evaluators-2nd-ed/
- World Health Organization (2020). Patient Engagement: Technical Series on Safer Primary Care. https://news.gmj.ge/guideline/patient-engagement-technical-series-on-safer-primary-care/

2.7 Safety Culture Is Measured

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Medium	Must	Must

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A validated survey measures whether staff feel safe raising concerns, conducted regularly and acted on, not assumed from the absence of complaints.

Rating rule. Medium in humanitarian settings. Must in transition and standard settings: a validated safety culture survey, run on schedule and acted on.

GUIDANCE

The facility uses a recognised, validated safety culture survey, so that results can be compared over time. The survey asks whether staff feel safe to report errors and near misses, and whether concerns lead to action. A home-made questionnaire is not enough unless it has been checked against a recognised tool.

The survey runs on the schedule in its procedure (QUA-SOP-001). The quality team and the governing body review the results. Each result that needs follow-up has an action in the safety culture action plan register (QUA-REG-001), and staff are told what has changed. A survey whose results are never shared does not meet the criterion.

> **Good practice.** A validated safety culture survey is run at a fixed interval. Results are shared with staff, and the action plan that follows is tracked and reported to the governing body.

> **Partial because.** A survey is run, but it is not validated, is not repeated at a fixed interval, or its results are not acted on.

WHAT GOOD LOOKS LIKE

- A validated safety culture survey (QUA-FRM-001), with the source of the tool named.
- A survey procedure (QUA-SOP-001) with a schedule.
- Survey records with dates and response numbers.
- A safety culture action plan register (QUA-REG-001) showing each action and its follow-up.

COMMON MISTAKES

- Assuming the culture is good because no one has complained.
- Using a questionnaire that has not been validated.
- Running the survey once and never repeating it.
- Publishing no results and taking no action.

> **Why it matters.** Staff who are afraid to raise a concern will stay silent about the mistake that harms a patient. A validated survey, repeated and acted on, shows whether they feel able to speak up.

WHAT THE ASSESSOR CHECKS

Sample. Review the survey records and action plans for the last 12 months.

1 A validated safety culture survey is used.

Method. Check the survey instrument and the procedure for its use.

Evidence to show. QUA-FRM-001 Safety Culture Survey (template); QUA-SOP-001 Safety Culture Survey Procedure.

Pass when. The instrument is a recognised, validated tool and the procedure is approved.

2 The survey runs on a defined schedule.

Method. Compare the survey dates with the schedule in the procedure.

Evidence to show. Survey records held under QUA-SOP-001.

Pass when. Surveys run on the scheduled dates.

3 Results are reviewed and acted on.

Method. Check the action register for each result that needed follow-up.

Evidence to show. QUA-REG-001 Safety Culture Action Plan Register.

Pass when. Each result has a reviewed action, and follow-up is visible to staff.

Pass. The criterion is met when every check above is passed.

Immediate fail. No safety culture survey has been conducted in the last 12 months. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
QUA-SOP-001	Safety Culture Survey Procedure	Manager	Chief executive	Chief executive
QUA-FRM-001	Safety Culture Survey (template)	Manager	Chief executive	Manager
QUA-REG-001	Safety Culture Action Plan Register	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries operational accountability to the board	Incident Reporting, Just Culture and Open Disclosure; Safety Management System & Leadership Essential in all settings
Manager (ISCO 1342)	Runs the process this criterion measures	Incident Reporting, Just Culture and Open Disclosure; Safety Management System & Leadership Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Hospital Safety Index: Guide for Evaluators, 2nd ed. https://news.gmj.ge/guideline/hospital-safety-index-guide-for-evaluators-2nd-ed/

2.8 Patient Experience Is Measured Continuously, Not Only After Discharge

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Patient experience is measured through structured, ongoing feedback during the course of care, not only through a complaint channel that captures concerns after discharge, which by its nature only picks up concerns raised after the event.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: feedback is collected during the stay, not only after discharge.

GUIDANCE

Patient experience is measured during the stay, not only after discharge. A structured in-stay feedback form (CON-FRM-004), used under the in-stay feedback procedure (CON-SOP-002), gives the facility a chance to act while the patient is still in its care. Patients who did not volunteer feedback are asked too, so that the results are not limited to people who were already comfortable speaking up.

The quarterly patient feedback summary (QUA-REG-002) records what patients said and at least one improvement made as a result. The manager and the governing body review it. In a humanitarian setting the method may be simpler, such as a short structured conversation at a fixed point in the stay, provided it is recorded in the same way.

> **Good practice.** Patients are asked about their experience during their stay, through a structured method. Responses are reviewed regularly and change care while the patient is still in it.

> **Partial because.** Feedback is collected, but only after discharge or only through complaints, so concerns raised during care are not captured.

WHAT GOOD LOOKS LIKE

- An in-stay feedback form (CON-FRM-004) completed during the stay.
- A procedure (CON-SOP-002) that asks patients who do not volunteer feedback.
- A quarterly summary (QUA-REG-002) with at least one improvement recorded.
- Feedback results shared with the ward and clinic teams.

COMMON MISTAKES

- Handing out forms only at discharge.
- Counting only the forms returned, without asking the other patients.
- Collecting feedback but never summarising it.
- Improvements listed as intentions, with no evidence that they happened.

> **Why it matters.** Patients who ask only after they leave may not say what went wrong during their stay. Feedback gathered during care, while there is still time to act, improves the care the patient is actually getting.

WHAT THE ASSESSOR CHECKS

Sample. Review the feedback collected in the last quarter.

1 **Feedback is collected during the stay.**

Method. Check that the structured feedback form is used during the stay, not only after discharge.

Evidence to show. CON-FRM-004 Structured In-Stay Feedback Form; CON-SOP-002 In-Stay Patient Experience Feedback Procedure.

Pass when. Forms are completed during the stay.

2 **Feedback is collected broadly.**

Method. Compare the number of forms with the number of patients in the period, and check that patients who did not volunteer feedback were asked.

Evidence to show. CON-FRM-004 forms.

Pass when. Feedback is sought from patients who did not volunteer it.

3 **Feedback is used to improve care.**

Method. Read the quarterly summary and check for at least one improvement made from it.

Evidence to show. QUA-REG-002 Patient Feedback Summary (quarterly).

Pass when. The quarterly summary records a resulting improvement.

Pass. The criterion is met when every check above is passed.

Immediate fail. Patient experience is measured only after discharge, with no feedback during the stay. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
CON-SOP-002	In-Stay Patient Experience Feedback Procedure	Manager	Chief executive	Chief executive
CON-FRM-004	Structured In-Stay Feedback Form	Manager	Chief executive	Manager
QUA-REG-002	Patient Feedback Summary (quarterly)	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the process this criterion measures	Complaints Handling and Patient Feedback Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2020). Patient Engagement: Technical Series on Safer Primary Care. https://news.gmj.ge/guideline/patient-engagement-technical-series-on-safer-primary-care/

2.9 An Ethics Consultation Process Exists

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Staff facing an ethical dilemma in patient care have access to a usable ethics consultation process — a committee, a named resource, or an external arrangement — not left to resolve difficult cases alone or through informal corridor conversations.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: a route to ethics consultation that staff can use and have used.

GUIDANCE

Staff sometimes face decisions that are hard to make alone, such as whether treatment should continue or stop, or how to weigh the wishes of a patient and family against clinical advice. The facility provides a route to ethics consultation: a committee, a named resource or an external arrangement. The clinical ethics consultation policy (GOV-POL-004) names the route, its terms of reference and who may use it.

Staff know how to request a consultation (GOV-SOP-002). Each consultation is recorded in the ethics consultation log (GOV-REG-003), with the question, the advice given and the outcome. If no consultation has been needed in the last 12 months, the log records that, and the route is still explained to staff.

> **Good practice.** Staff know how to request an ethics consultation, and the route is written and has been used. Consultations are logged, and the outcomes are reviewed.

> **Partial because.** An ethics route exists on paper, but staff do not know how to use it or it has never been used.

WHAT GOOD LOOKS LIKE

- An ethics consultation policy and terms of reference (GOV-POL-004).
- A consultation procedure (GOV-SOP-002) that staff can describe.
- A log of consultations (GOV-REG-003), or a recorded reason why none was needed.
- Contact details for the route, shown to staff.

COMMON MISTAKES

- A committee that exists on paper and has never met.
- Staff who do not know whom to contact.
- Consultations held informally, with no record.
- Asking for advice only after a decision has been made.

> **Why it matters.** Clinical staff sometimes face decisions about care that are hard to make alone, such as when treatment should stop. A usable ethics consultation route gives them somewhere to go before a poor decision is made.

WHAT THE ASSESSOR CHECKS

Sample. Review the consultation log for the last 12 months.

1 An ethics consultation process is in place.

Method. Check the policy and the terms of reference for the committee, named resource or external arrangement.

Evidence to show. GOV-POL-004 Clinical Ethics Consultation Policy and Terms of Reference.

Pass when. The policy names a route that staff can use.

2 Staff know how to access it.

Method. Ask staff how they would request an ethics consultation.

Evidence to show. GOV-SOP-002 Ethics Consultation Procedure.

Pass when. Staff describe the route correctly.

3 The process has been used.

Method. Check the log for any consultation in the last 12 months.

Evidence to show. GOV-REG-003 Ethics Consultation Log.

Pass when. At least one consultation is recorded, or the reason none was needed is recorded.

Pass. The criterion is met when every check above is passed.

Immediate fail. No ethics consultation route exists, or it has never been used. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
GOV-SOP-002	Ethics Consultation Procedure	Chief executive	Governing body members	Chief executive
GOV-REG-003	Ethics Consultation Log	Secretary	Chief executive	Manager
GOV-POL-004	Clinical Ethics Consultation Policy and Terms of Reference	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Governing body members	Holds the authority this criterion requires	Healthcare Ethics for ASF Accreditation Humanitarian: Recommended; Transition: Recommended; Standard: Recommended
Chief executive (ISCO 1120)	Carries operational accountability to the board	Healthcare Ethics for ASF Accreditation Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- Pan American Health Organization (2020). Ethics guidance for the use of scarce resources in the delivery of critical health care during the COVID-19 pandemic. https://news.gmj.ge/guideline/ethics-guidance-for-the-use-of-scarce-resources-in-the-delivery-of-critical-health-care-during-the-covid-19-pandemic/
- Pan American Health Organization (2020). Template and operational guidance for the ethics review and oversight of COVID-19-related research. https://news.gmj.ge/guideline/template-and-operational-guidance-for-the-ethics-review-and-oversight-of-covid-19-related-research/

2.10 Patients and Families Have a Voice in Governance

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** At least one patient or family representative has a structured role in quality review or governance discussions — not a governance and quality structure that is entirely staff and board-facing, with patient input arriving only indirectly through complaints or surveys.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: a patient or family representative with a defined role.

GUIDANCE

At least one patient or family representative has a defined role in quality review or governance discussion. The role is written in the policy (GOV-POL-005), with duties in governance or quality review. The representative takes part in discussions. The attendance register (GOV-REG-004) and the minutes show their contributions.

The representative's input should be able to change a decision. Where it did, the minutes record the decision and what the representative said. Where no suitable representative is available, the facility records its search and the role is still written down. In a humanitarian setting a smaller role may be agreed, such as the representative being consulted before each quarterly review, if it is written in the policy and used.

> **Good practice.** At least one patient or family representative sits on a quality or governance committee with a written role, and their input is recorded in the minutes.

> **Partial because.** Patient or family views reach governance only through complaints or surveys, or a representative is named but has no written role.

WHAT GOOD LOOKS LIKE

- A written role for the patient or family representative (GOV-POL-005).
- An attendance register (GOV-REG-004) showing the representative at governance meetings.
- Minutes that record the representative's contributions.
- A recorded decision that changed because of patient or family input.

COMMON MISTAKES

- Naming a representative who never attends.
- Inviting a representative to a meeting but not asking for their view.
- Using a staff member as the 'patient voice'.
- Recording input that was heard, with no explanation of why nothing changed.

> **Why it matters.** A service designed without the people who use it misses what matters to them. A patient or family representative in governance brings the view from outside the staff room.

WHAT THE ASSESSOR CHECKS

Sample. Review the attendance register and minutes for the last 12 months.

1 **A patient or family representative has a defined role.**

Method. Check the role description in the policy.

Evidence to show. GOV-POL-005 Patient and Family Representative Role in Governance.

Pass when. The role is written, with duties in governance or quality review.

2 **The representative takes part in discussion.**

Method. Check the attendance register and the minutes for their contributions.

Evidence to show. GOV-REG-004 Attendance Register (governance meetings); minutes.

Pass when. The representative attends and contributes, not only observes.

3 **Input has changed a decision.**

Method. Ask for one recorded decision where patient or family input shaped the outcome.

Evidence to show. Minutes showing the decision.

Pass when. At least one decision is traceable to patient or family input.

Pass. The criterion is met when every check above is passed.

Immediate fail. No patient or family representative takes part in quality review or governance discussion. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
GOV-REG-004	Attendance Register (governance meetings)	Secretary	Chief executive	Manager
GOV-POL-005	Patient and Family Representative Role in Governance	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Governing body members	Holds the authority this criterion requires	Complaints Handling and Patient Feedback Humanitarian: Recommended; Transition: Recommended; Standard: Recommended
Secretary (ISCO 3344)	Keeps the register and the minutes	— Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2020). Patient Engagement: Technical Series on Safer Primary Care. https://news.gmj.ge/guideline/patient-engagement-technical-series-on-safer-primary-care/

10 Questions and answers

Do I need to meet every criterion in Standard 2?
Yes. Standard 2 is the base governance standard, so every facility meets all ten criteria, in every setting. Each criterion has its own pass rule and its own immediate-fail rule. Meeting nine out of ten does not pass the standard: a failure on any one criterion means that criterion is not met. Because the criteria are separate, the facility should check each one against its own evidence rather than assuming that good practice in one area covers another. The rating shown on each criterion tells you how strict the requirement is in humanitarian, transition and fragile, and standard settings.

What is an immediate fail?
An immediate fail is one event or finding that means a criterion is not met, even if everything else in that criterion is in place. For example, if the governing body has no minutes for the last 12 months, criterion 2.1 fails outright, whatever the quality of the terms of reference. Each criterion in this document lists its own immediate fail under "Immediate fail". Facilities should read these before the survey, because they are the points on which the outcome is decided most quickly.

Which documents do I submit?
The documents are the forms, policies and procedures listed under each criterion in the "Evidence and documents" table. Registers and records, such as the Register of Governing Body Members (GOV-REG-001) or the Incident Action Tracker (INC-REG-001), are kept as working files with one row for each entry. Policies and procedures are signed documents that show the version, date, owner and approver. Upload or have them ready before the survey, and check that each one covers the period stated in its criterion, usually the last 12 months. You may use your own document if it meets the same check, as long as it is clearly the same record.

What must the governing body record?
The governing body must have named members with written terms of office, a set of terms of reference that gives it authority over safety, quality, clinical governance and finance, and minutes for every scheduled meeting. The terms of reference are GOV-POL-001, the register of members is GOV-REG-001, and the minutes use the template GOV-FRM-003. The minutes must show that quality, safety and financial oversight were on the agenda and that decisions were followed up at the next meeting, because a body that meets without recording what it decided cannot show that it governs.

What must the strategic plan include?
The written strategic plan (template GOV-PLN-001) must set out the facility's mission and values, and it must cover several years rather than a single year. It should be possible to trace resourcing decisions back to the plan: when the budget or a staffing decision is made, the minutes or decision record should show how it follows from the plan. The plan is supported by a code of conduct for staff behaviour (GOV-POL-002), which sets out the values in practice. A mission statement with no values, no code of conduct and no link to budget decisions does not meet the criterion.

How is policy application checked?
The criterion has three checks. First, staff can describe how a named policy is applied in their daily work, not only confirm that it exists. Second, adherence is checked, using the Policy Application Audit Form (GOV-FRM-002), and any gap has a defined response. Third, the quality improvement plan is complete, authorised and reviewed, covering every service in the facility, with named owners and dates (GOV-PLN-002). The policy framework itself is in GOV-POL-003 and the register of policies in GOV-REG-002. A policy that is filed but not followed fails this criterion.

How is patient data protected?
Access to patient health information must be restricted by role, so that only staff with a current need can open a record, and the access must be recorded. The breach response procedure (DIG-SOP-001) sets out what happens if information is lost, shared in error or accessed without need, and it must be tested. The test is recorded on the Breach Response Test Record (DIG-FRM-001), and the rules themselves are in the Information Security and Access Control Policy (DIG-POL-001). A facility with a breach plan on paper that has never been tested cannot show that the plan works.

How long do we keep records?
Each record type should have a stated retention period, set by the national requirement for the country where the facility operates. A written retention policy must give a period for each type of record, not a single general period. When records are disposed of, the disposal must be secure and documented on the Records Disposal Record (REC-FRM-003), showing the date, method and the person who authorised it. Records destroyed before their retention period ends, or disposed of with no policy at all, fail the criterion.

How are serious incidents investigated?
Every serious incident must go through a structured root cause analysis (INC-SOP-001), recorded on the Root Cause Analysis Record (INC-FRM-001). The analysis looks at why the incident happened, not who was involved, and it produces an action plan. Each action is tracked on the Incident Action Tracker (INC-REG-001) until it is completed. A serious incident that is closed with no analysis, or whose action plan is left open with no owner, is an immediate fail, so the surveyor will usually select incidents from the last 12 months and check the full trail for each one.

How is safety culture measured?
A safety culture survey must use a validated tool, run on a defined schedule (QUA-SOP-001), and recorded on the survey template (QUA-FRM-001). Results must be reviewed and acted on, and each action is tracked on the Safety Culture Action Plan Register (QUA-REG-001). A survey that is not validated, is not repeated on schedule, or has no action after the results is not enough. If no survey has been run in the last 12 months, the criterion fails immediately.

How is patient experience measured during care?
The criterion expects feedback from patients while they are still in the facility, so that problems can be fixed during the stay. Feedback is collected with the structured in-stay form (CON-FRM-004), following the in-stay procedure (CON-SOP-002). It should be gathered from a broad range of patients, not only the most satisfied ones, and the results are summarised each quarter (QUA-REG-002). The post-discharge complaint route is still needed, but it does not replace feedback during care. A facility that measures only after discharge fails this criterion.

How can staff get an ethics consultation?
Staff facing a difficult decision in patient care, such as when treatment should stop, must have a usable route to an ethics consultation. The route is set out in the Ethics Consultation Procedure (GOV-SOP-002) and the Clinical Ethics Consultation Policy (GOV-POL-004). Each consultation is logged on the Ethics Consultation Log (GOV-REG-003). The surveyor will check that staff know how to use the route, not only that a policy exists, and that the route has actually been used. A route that exists on paper but has never been used does not meet the criterion.

How do patients and families take part in governance?
At least one patient or family representative must have a defined role in quality review or governance discussion. The role is set out in the Patient and Family Representative Role policy (GOV-POL-005), and attendance is recorded on the governance attendance register (GOV-REG-004). The representative should take part in the discussion, and the minutes should show that their input was considered and, where relevant, changed a decision. A representative who is named but does not take part, or no representative at all, fails the criterion.

What do the colours mean?
Red means Must: the criterion is required in every setting, and criteria that protect life are always red. Yellow means Medium: the criterion is required, but adapted to what a transition setting can realistically do. Green means Minimum: the lowest acceptable level in a humanitarian setting, where resources are very limited. In standard settings every criterion is Must. Each criterion shows its rating for each of the three settings, so a facility can see exactly what applies to it. Section 5 shows the colours.

Do we have to use your forms and policies?
No. Every policy, procedure, form and course in this document is a reference draft to help you meet the criterion. You can adapt it to your facility, write your own, or upload your own documents. What the assessor checks is that the standard is met and that you can show how. If you use your own document, make sure it covers the same content as the reference and that it is current, signed and dated, so that the assessor can match it to the criterion without difficulty.

What does essential or recommended training mean for my staff?
In the training tables, red means essential: the course is required for that role in that setting. Green means recommended: the course is advised for that role. Yellow means optional. Each course shows its level for humanitarian, transition and fragile, and standard settings, because the requirement can differ between them. Staff evidence is a verified micro-credential in the GMJ Academy micro-credential portfolio, or a training certificate kept in the staff file.

Do we have to use ISCO-08 codes?
The staff tables give each occupation its ISCO-08 code, so that roles can be compared between facilities and countries. You are not required to change your job titles. What matters is that each role named in the standard can be matched to the person who does that job and to the training they have had. If your titles differ, record the match in your staff file so that the assessor can follow it.

Which training do staff need?
The e-learning table under each criterion shows who must take each course and who is recommended. The table is read together with the staff table, which shows the level for each setting. Staff can show evidence through a verified micro-credential in the GMJ Academy micro-credential portfolio, or through a training certificate kept in the staff file.

What will the surveyor see on the day?
The surveyor works through the criteria, following the "Sample" and "Checks" given for each one. For example, for the governance criteria the surveyor reviews the last 12 months of minutes, the terms of reference and the policy register, and checks how they match practice. The surveyor may also speak with staff to test whether they understand the policies and their own roles, and may look at records and practice directly. The surveyor records whether each check is passed and whether any immediate-fail rule applies. Accreditation surveys commonly follow the patient or a process through the facility (a "tracer") to see how the standards work in practice.

How does the surveyor choose which records to check?
Each criterion states its own sample, such as "Select every serious incident from the last 12 months" or "Select three policies at random". The surveyor uses the sample given on the criterion page rather than choosing records to suit the facility. Preparing for the survey means keeping the records for the whole period stated, organised so that any item in the sample can be produced quickly. A facility that cannot produce the sampled records loses the criterion, whatever else it has in place.

What if we do not have the written protocol yet?
A criterion cannot be met on the basis of an unwritten or informal arrangement, because the assessor needs something to check against. If a protocol does not yet exist, write one before the survey, using the reference draft or your own version, and make sure it is signed, dated and in use. Staff must be able to explain it in practice.

Where can I get the full text?
The full text of each criterion, with its rating, why it matters, the assessor checks, the immediate-fail rule and the documents, is in section 9 of this document. The same criteria are published on france-asf.fr, which holds the controlling copy. The questions and answers in this section summarise the criteria, and if they ever differ, the criterion text is the authority.

Who can I ask about this standard?
For questions about this standard, contact Accréditation Sans Frontières through the contact page of france-asf.fr. Please give the standard number and the criterion (for example 2.4) so that your question can be answered against the right text.

The criterion text is the authority. These answers summarise it.

11 References

CITED FOR CRITERIA

1. World Health Organization (2021). Hospital Safety Index: Guide for Evaluators, 2nd ed. https://news.gmj.ge/guideline/hospital-safety-index-guide-for-evaluators-2nd-ed/ (criterion 2.1, 2.2, 2.3, 2.6, 2.7)
2. WHO SMART Trust. Ethical Considerations and Data Protection Principles. https://smart.who.int/trust/ethical_principles.html (criterion 2.4)
3. ISO 27799:2016. Health informatics: Information security management in health using ISO/IEC 27002. https://www.iso.org/standard/62777.html (criterion 2.4)
4. International Agency for Research on Cancer (WHO). Confidentiality of medical records, section 3: Access to and storage of data. https://gicr.iarc.who.int/static/public/docs/Confidentiality%20IACR-IARC%20(Tech%20Rep%202004-3).pdf (criterion 2.4, 2.5)
5. World Health Organization (2020). Patient Engagement: Technical Series on Safer Primary Care. https://news.gmj.ge/guideline/patient-engagement-technical-series-on-safer-primary-care/ (criterion 2.6, 2.8, 2.10)
6. Pan American Health Organization (2020). Ethics guidance for the use of scarce resources in the delivery of critical health care during the COVID-19 pandemic. https://news.gmj.ge/guideline/ethics-guidance-for-the-use-of-scarce-resources-in-the-delivery-of-critical-health-care-during-the-covid-19-pandemic/ (criterion 2.9)
7. Pan American Health Organization (2020). Template and operational guidance for the ethics review and oversight of COVID-19-related research. https://news.gmj.ge/guideline/template-and-operational-guidance-for-the-ethics-review-and-oversight-of-covid-19-related-research/ (criterion 2.9)

INTERNATIONAL STANDARDS CITED

1. International Labour Organization (2008). International Standard Classification of Occupations, ISCO-08. Geneva: ILO.

12 Document register

Every document code used in Standard 2, with its type and the criteria that use it. The codes identify the documents; a facility may use its own document if it meets the same criterion. Each document has its own page at france-asf.fr/documents/, under its code.

Code	Document	Type	What it is for	Criteria
CON-FRM-004	Structured In-Stay Feedback Form	Form (record)	To record a patient's answers to fixed questions during their stay or day-care visit. The patient may decline any question.	2.8
CON-SOP-002	In-Stay Patient Experience Feedback Procedure	Procedure (SOP)	To learn about the patient's experience while they are receiving care, so problems can be fixed before the patient leaves, not only through complaints after discharge.	2.8
DIG-FRM-001	Breach Response Test Record	Form (record)	To record the yearly test of the breach response plan: a simulated breach, the steps taken and the time to complete each step.	2.4
DIG-POL-001	Information Security and Access Control Policy	Policy	To protect patient health information from unauthorised access, loss, change or disclosure, using practical security measures.	2.4
DIG-SOP-001	Patient Data Breach Response Procedure	Procedure (SOP)	To make sure any breach of patient information is contained, assessed, reported where required, and used to strengthen controls.	2.4
GOV-FRM-002	Policy Application Audit Form	Form (record)	To check, in practice, how staff apply a sampled policy. Complete one form per policy.	2.3
GOV-FRM-003	Governing Body Minutes Template	Form (record)	Record every governing body meeting: attendance, quorum, declarations, decisions on safety and quality, actions and owners.	2.1
GOV-PLN-001	Strategic Plan (template and approval)	Plan	To set out what the facility is for, what it values, how staff are expected to behave, and where resources will go over the coming years.	2.2
GOV-PLN-002	Quality Improvement Plan	Plan	To set out how the facility measures and improves quality in every part of the service, with responsibilities and indicators.	2.3
GOV-POL-001	Governing Body Terms of Reference	Policy	To set out who governs the facility, what authority they hold, and how they hold the service to account for safety, quality and money.	2.1
GOV-POL-002	Code of Conduct for Staff	Policy	To state the standards of personal and professional conduct expected of everyone who acts for the facility.	2.2

Code	Document	Type	What it is for	Criteria
GOV-POL-003	Policy Development, Approval, Review and Application	Policy	To make sure policies are written, approved, kept current and applied in practice, not only filed.	2.3
GOV-POL-004	Clinical Ethics Consultation Policy and Terms of Reference	Policy	To give staff a usable route to ethical advice on difficult patient care decisions, so that they are not left to resolve these alone.	2.9
GOV-POL-005	Patient and Family Representative Role in Governance	Policy	To make sure patients and families have a structured role in improving governance and quality, not only indirect input through complaints and surveys.	2.10
GOV-REG-001	Register of Governing Body Members	Register	The current list of named members of the governing body, their roles, terms and declared interests.	2.1
GOV-REG-002	Policy Register	Register	The list of every policy, its owner, version, approval, review date and status.	2.3
GOV-REG-003	Ethics Consultation Log	Register	Records each ethics consultation, without patient identifiers, so the route can be shown to work and reviewed.	2.9
GOV-REG-004	Attendance Register (governance meetings)	Register	Records who attended each governance and quality meeting, including the patient or family representative.	2.10
GOV-SOP-001	Governing Body Meetings and Decisions on Safety and Quality	Procedure (SOP)	To make sure the governing body meets regularly, takes decisions on safety and quality in the open, and records them so that actions can be followed up.	2.1
GOV-SOP-002	Ethics Consultation Procedure	Procedure (SOP)	To describe step by step how a staff member or family asks for ethics advice and what happens next.	2.9
INC-FRM-001	Root Cause Analysis Record	Form (record)	To record a serious incident review: facts, timeline, root causes, actions and the sign-off.	2.6
INC-REG-001	Incident Action Tracker	Register	The log of every action from a serious incident review, showing owner, due date and status until closed.	2.6
INC-SOP-001	Root Cause Analysis of Serious Incidents	Procedure (SOP)	To find out why a serious incident happened, change the system so it does not happen again, and track the change until it is complete.	2.6
QUA-FRM-001	Safety Culture Survey (template)	Form (record)	Template for the staff safety culture survey. The committee replaces the sample items below with the items of the validated tool selected, without changing its wording.	2.7
QUA-REG-001	Safety Culture Action Plan Register	Register	Tracks each action from the safety culture survey to completion.	2.7

Code	Document	Type	What it is for	Criteria
QUA-REG-002	Patient Feedback Summary (quarterly)	Register	Quarterly summary of in-stay patient feedback for each service, for the governing body.	2.8
QUA-SOP-001	Safety Culture Survey Procedure	Procedure (SOP)	To measure whether staff feel safe to report errors and concerns, and to act on what the survey shows.	2.7
REC-FRM-003	Records Disposal Record	Form (record)	The record of every disposal of patient or governance records, showing that the retention period had been met and how the record was destroyed.	2.5