ACCRÉDITATION SANS FRONTIÈRES (ASF)
NON-GOVERNMENTAL, NON-PROFIT

ASF Health Standards Version 11

Standard 5: Digital Care and AI

Core standard · applicability by facility type shown for each criterion

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APPROVAL



Prof. Giorgi Pkhakadze, MD, MPH, PhD
Chair, Public Health Institute of Georgia

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.

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1 Introduction

This document is Standard 5 of ASF Health Standards. It sets out how a facility introduces and manages digital care and artificial intelligence safely and fairly: how digital care systems are assessed before use, how patients who cannot use digital care are still cared for well, how technical expertise supports the systems, and how AI systems are governed, monitored and explained to staff and patients, with clear accountability for the care they support.

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 5 makes sure that new technology improves care for every patient, and does not leave anyone behind or make decisions that no one is accountable for.

Who should read it. Members of the governing body, the chief executive, clinical leads, the information and digital lead, staff who use digital or AI systems, patient information 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 5 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.

3 How to use this standard

If you are a facility manager or a member of the facilities team, read section 4 to confirm which criteria apply to your facility type, then section 5 to find the rating for your setting. Read each criterion from 5.1 to 5.8, 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.

Document codes. Each document has a code made of a topic prefix, a type and a number, for example ENV-SOP-001 (environment, procedure, 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 5 covers the assessment and management of digital care systems, the alternative route for patients who cannot use digital care, the technical expertise that supports these systems, and the introduction, monitoring, staff consultation, accountability and patient information for AI systems used in care.

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 5 APPLIES

Standard 5 applies to every facility type. Every criterion applies to all nine facility types, so no criterion is marked N/A. 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
5.1 Digital Care Systems Follow an Assessment and Management Process	all nine facility types
5.2 Digital Care Never Disadvantages a Patient Who Cannot Use It	all nine facility types
5.3 Technical Expertise Supports Digital Care Systems	all nine facility types
5.4 AI Systems Are Introduced in Line With WHO AI Governance Guidance	all nine facility types
5.5 AI Systems Are Monitored for Unintended Consequences	all nine facility types
5.6 Staff Are Consulted Before an AI System Is Introduced	all nine facility types
5.7 Accountability for AI-Assisted Care Is Explicitly Defined	all nine facility types
5.8 Patients Are Informed When Their Care Involves AI	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.

Rating	Colour	Meaning
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
AI	Artificial intelligence
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)
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 monitoring results or complaints
SOP	Standard operating procedure. A step-by-step description of how a task is done
WHO	World Health Organization

DOCUMENT CODE PREFIXES

Prefix	Topic
AI	Artificial intelligence documents
DIG	Digital care and information documents

7 Terms and definitions

Term	Definition
Artificial intelligence system	Software that performs a task that normally needs human judgement, such as reading an image, sorting patients by urgency or suggesting a diagnosis.
Criterion	One numbered requirement in a standard, for example 5.1. Each criterion has its own rating, pass rule and immediate-fail rule.
Digital care system	Any electronic system used to deliver or support care, such as a telehealth platform, a remote monitoring tool or a patient-facing app.
Evidence	The records, documents and observations that show a criterion is met.
Immediate fail	One event that means a criterion is not met, whatever else is in place.
Interoperability	The ability of two systems to exchange and use information without manual re-entry.
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.
Over-diagnosis and under-diagnosis	Over-diagnosis is a finding of a condition that is not present. Under-diagnosis is a failure to detect a condition that is present.
Pass rule	The condition that shows a criterion is met, given as a number, a percentage or a yes/no test.
Sample	The set of records, systems or patients that the assessor checks for a criterion. The sample is stated for each criterion.
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 5 at a glance

Standard 5: Digital Care and AI is a core standard of ASF Health Standards. It applies to every facility type. It covers how digital care systems and artificial intelligence are assessed, introduced, monitored and explained, and who is accountable for the care they support.

The standard has eight criteria. Each is shown below and explained on its own page in section 9.

8.1 CRITERIA AND RATINGS

No.	Criterion	Humanitarian	Transition	Standard
5.1	Digital Care Systems Follow an Assessment and Management Process	Minimum	Medium	Must
5.2	Digital Care Never Disadvantages a Patient Who Cannot Use It	Minimum	Medium	Must
5.3	Technical Expertise Supports Digital Care Systems	Minimum	Medium	Must
5.4	AI Systems Are Introduced in Line With WHO AI Governance Guidance	Minimum	Medium	Must
5.5	AI Systems Are Monitored for Unintended Consequences	Minimum	Medium	Must
5.6	Staff Are Consulted Before an AI System Is Introduced	Minimum	Medium	Must
5.7	Accountability for AI-Assisted Care Is Explicitly Defined	Minimum	Medium	Must
5.8	Patients Are Informed When Their Care Involves AI	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
5.1	Digital Care Systems Follow an Assessment and Management Process	Manager (ISCO 1342) · Secretary (ISCO 3344)
5.2	Digital Care Never Disadvantages a Patient Who Cannot Use It	Manager (ISCO 1342) · Secretary (ISCO 3344)
5.3	Technical Expertise Supports Digital Care Systems	Manager (ISCO 1342)
5.4	AI Systems Are Introduced in Line With WHO AI Governance Guidance	Chief executive (ISCO 1120) · Manager (ISCO 1342) · Nurse (ISCO 2221)
5.5	AI Systems Are Monitored for Unintended Consequences	Manager (ISCO 1342) · Nurse (ISCO 2221)

No.	Criterion	Positions responsible or involved
5.6	Staff Are Consulted Before an AI System Is Introduced	Manager (ISCO 1342) · Nurse (ISCO 2221)
5.7	Accountability for AI-Assisted Care Is Explicitly Defined	Chief executive (ISCO 1120) · Manager (ISCO 1342) · Nurse (ISCO 2221)
5.8	Patients Are Informed When Their Care Involves AI	Manager (ISCO 1342) · Nurse (ISCO 2221)

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. For this standard the manager is the IT manager. 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.
Manager (ISCO 1342)	The chief information officer (CIO).	Systems, database, network and help desk teams.
Nurse (ISCO 2221)	The head nurse.	Nursing associates and health care assistants.
Secretary (ISCO 3344)	The head of department (per specialty).	No direct reports.

8.3 TRAINING FOR STANDARD 5

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
Technology Platform Reliability & Security (TM-01)	Manager	Secretary	5.1	English · Georgian
Artificial Intelligence in Healthcare Safety (AI-001)	Chief executive, Manager, Nurse	None	5.4, 5.5, 5.6, 5.7, 5.8	English · Georgian
Artificial Intelligence Systems for Care (TELE-10)	Manager	Nurse	5.4	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. One course is published in Georgian only. 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.

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
Digital Care Assessment and Management Process (BAS-06)	Assessing and managing a digital care system	5.1	English
Data Privacy & Patient Confidentiality (TM-06)	Data privacy in digital care	5.1	English · Georgian
Digital Inclusion for Patients Who Cannot Use Digital Tools (BAS-07)	Patients who cannot use digital tools	5.2	English · Georgian
Technical Support for Digital Care Systems	Technical support for digital systems	5.3	English
Digital Care and Artificial Intelligence in the Lab (LAB-12)	Digital care and AI for your type of service	5.4 to 5.8	English · Georgian
Digital Care and Artificial Intelligence (MT-10)	Digital care and AI for your type of service	5.4 to 5.8	English · Georgian
Digital Care and AI Systems for Care (FIT-12)	Digital care and AI for your type of service	5.4 to 5.8	English · Georgian

5.1 Digital Care Systems Follow an Assessment and Management Process

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

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

> **Criterion.** Before any digital care system — telehealth platform, remote monitoring tool, patient-facing app — is introduced, the facility assesses its costs and benefits, manages its implementation, and continues to manage it afterwards — not adopted because a vendor made a compelling pitch, with no internal evaluation.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: every digital care system assessed for cost, benefit, interoperability and unintended consequences before it is introduced.

GUIDANCE

Before a digital care system is introduced, the facility assesses it. This covers telehealth platforms, remote monitoring tools and patient-facing apps. The assessment (DIG-SOP-002) weighs the costs against the expected benefits, checks that the system can exchange information with the facility's other records, and considers in advance what could go wrong, such as errors in data, loss of records or delays in care. The assessment is recorded on the assessment form (DIG-FRM-002).

A system that has been bought or installed without this assessment does not meet the criterion, even if it works well. The assessment is repeated when the system changes in a way that affects patients.

> **Good practice.** Each digital care system has a written assessment dated before go-live. It covers costs, benefits and interoperability, and lists the risks with a mitigation for each. The system continues to be managed after it is introduced.

> **Partial because.** An assessment exists, but it was completed after go-live, or interoperability is not recorded, or some risks have no mitigation.

WHAT GOOD LOOKS LIKE

- A written assessment (DIG-SOP-002) covering cost, benefit, interoperability and unintended consequences.
- A completed assessment form (DIG-FRM-002) before implementation.
- A check that the system exchanges information with the facility's records.
- A repeat assessment when the system changes.

COMMON MISTAKES

- Buying a system and assessing it only afterwards.
- Assuming a system works with existing records without checking.
- Considering only the benefits, not the risks.
- Introducing a patient-facing app with no alternative for patients without a phone.

> **Why it matters.** A digital tool introduced into care without a check can slow care down, expose data, or fail when most needed. Assessing a tool before it is used, and managing it afterwards, protects the patient and the service.

WHAT THE ASSESSOR CHECKS

Sample. Review the assessment for each digital care system in use.

1 A cost/benefit analysis is done before implementation.

Method. Check the assessment record dated before the go-live date.

Evidence to show. DIG-FRM-002 Digital Tool Assessment Template; DIG-SOP-002 Digital Care System Assessment and Management.

Pass when. The analysis is dated before go-live.

2 Interoperability is assessed.

Method. Check that the assessment covers integration with existing clinical systems.

Evidence to show. DIG-FRM-002 Digital Tool Assessment Template.

Pass when. Interoperability and its risks are recorded.

3 Unintended consequences are considered in advance.

Method. Check the record for an identified risk list and its mitigations.

Evidence to show. DIG-FRM-002 Digital Tool Assessment Template.

Pass when. The risk list is complete and each risk has a mitigation.

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

Immediate fail. A digital care system is introduced with no cost/benefit analysis and no interoperability check. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-SOP-002	Digital Care System Assessment and Management	Manager	Chief executive	Chief executive
DIG-FRM-002	Digital Tool Assessment Template	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Technology Platform Reliability & Security Essential in all settings
Secretary (ISCO 3344)	Front desk and records support	Technology Platform Reliability & Security Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Recommendations on digital interventions for health system strengthening. https://news.gmj.ge/guideline/recommendations-on-digital-interventions-for-health-system-strengthening/

5.2 Digital Care Never Disadvantages a Patient Who Cannot Use It

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

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

> **Criterion.** A process ensures that patients who cannot use digital devices, lack internet access, or are otherwise unable to engage with digital approaches are never disadvantaged by the facility's use of digital care — not digital convenience for most patients purchased at the cost of access for the patients least able to adapt.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: a defined alternative route for patients who cannot use digital care, with equivalent care.

GUIDANCE

Digital care must never be the only way a patient can receive care. A patient who cannot use a device, has no internet access, or is otherwise unable to take part in a digital approach has a defined alternative route, set out in the procedure (DIG-SOP-003). The alternative provides equivalent care, not a reduced service.

Before the service goes live, it is pre-tested with people who might struggle with it, such as older patients, people with limited literacy and people without a phone or internet access. The test and its results are recorded on DIG-FRM-003.

> **Good practice.** Every digital service has a defined alternative route that gives equivalent care. The service was tested beforehand with people who might struggle to use it, and each use of the alternative is recorded.

> **Partial because.** An alternative route exists, but the service was not pre-tested with the people who might struggle, or the records do not show that care through the alternative is equivalent.

WHAT GOOD LOOKS LIKE

- A written alternative route (DIG-SOP-003) for patients who cannot use digital care.
- Equivalent care delivered through the alternative, recorded in the same way.
- Pre-testing with people who might struggle (DIG-FRM-003).
- Staff who know how to offer the alternative without judgement.

COMMON MISTAKES

- Digital care as the only option.
- An alternative that gives a shorter visit or less information.
- No test with patients who are less confident with technology.
- Patients who are turned away because they cannot use the app.

> **Why it matters.** Some patients cannot use a phone app, do not have internet, or find video calls hard. A service that moves everything online without an alternative leaves those patients without care.

WHAT THE ASSESSOR CHECKS

Sample. Select the digital care services in use and the records of patients who used the alternative route.

1 A defined alternative exists.

Method. Check the procedure for the alternative route.

Evidence to show. DIG-SOP-003 Digital Care Access and Alternatives.

Pass when. The alternative is defined and available.

2 The service was pre-tested with people who might struggle.

Method. Check the test record for a group of potential users.

Evidence to show. DIG-FRM-003 Digital Alternative Record.

Pass when. A pre-test with those users is recorded.

3 Patients using the alternative receive equivalent care.

Method. Select records of patients who used the alternative and compare the service they received.

Evidence to show. DIG-FRM-003 Digital Alternative Record.

Pass when. The service received is equivalent.

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

Immediate fail. A patient who cannot use digital care has no alternative route, and receives reduced service. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-SOP-003	Digital Care Access and Alternatives	Manager	Chief executive	Chief executive
DIG-FRM-003	Digital Alternative Record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	— Essential in all settings
Secretary (ISCO 3344)	Front desk and records support	— Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2024). Implementation toolkit for accessible telehealth services. https://news.gmj.ge/guideline/implementation-toolkit-for-accessible-telehealth-services/

5.3 Technical Expertise Supports Digital Care Systems

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

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

> **Criterion.** The facility has access to technical expertise — in-house, vendor-provided, or contracted — to support the effective use of its digital care systems, including testing and quality checks before full implementation, not digital systems left running with no technical support behind them.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: technical expertise available for digital care systems, and testing before full use.

GUIDANCE

Digital care systems need people who understand them. The facility has access to technical expertise, in-house, from the vendor or under contract, to support the effective use of each system. The support route is written in the implementation plan (DIG-PLN-001), and staff know how to reach it.

Testing takes place before full use. The test is recorded on the implementation form (DIG-FRM-004). A system that was switched on for all patients without a test does not meet the criterion.

> **Good practice.** Each digital care system has a named route to technical expertise and was tested before full use. Staff can say how to get support when the system fails.

> **Partial because.** A support route exists, but testing before full use is not recorded, or staff cannot describe the route.

WHAT GOOD LOOKS LIKE

- A named route for technical support, in-house, vendor or contracted (DIG-PLN-001).
- A test recorded on the implementation form (DIG-FRM-004) before full use.
- Staff who know how to contact support.
- A support record showing problems raised and resolved.

COMMON MISTAKES

- A system with no one to call when it fails.
- Switching on for all patients on the first day with no test.
- Support that exists only in the vendor's contract, unknown to staff.
- Problems fixed by staff with no record.

> **Why it matters.** A digital system that no one can support when it fails leaves staff stuck and patients unseen. Access to technical expertise, in-house or from a vendor, keeps the system working when it matters.

WHAT THE ASSESSOR CHECKS

Sample. Review the testing records and the support log for each digital care system.

1 Technical expertise is available.

Method. Check the support arrangement, in-house or contracted.

Evidence to show. DIG-PLN-001 Technical Support and Testing Arrangement.

Pass when. A named route to expertise exists.

2 Testing is done before full implementation.

Method. Check the test record dated before full use.

Evidence to show. DIG-FRM-004 Digital System Test and Support Record.

Pass when. Testing is recorded before full use.

3 Staff know the support route.

Method. Ask staff how they would get technical help for a digital system.

Evidence to show. DIG-PLN-001.

Pass when. Staff describe the route correctly.

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

Immediate fail. A digital care system has no technical support route and was not tested before full use. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-FRM-004	Digital System Test and Support Record	Manager	Chief executive	Manager
DIG-PLN-001	Technical Support and Testing Arrangement	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	— Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2022). Consolidated telemedicine implementation guide. https://news.gmj.ge/guideline/consolidated-telemedicine-implementation-guide/

5.4 AI Systems Are Introduced in Line With WHO AI Governance Guidance

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

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

> **Criterion.** Any artificial intelligence system used to support diagnosis, triage, or care decisions is introduced and managed in accordance with WHO's Ethics and governance of artificial intelligence for health (2021). No such system is adopted without reference to this standard of responsible use.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: AI systems introduced in line with WHO guidance on the ethics and governance of AI for health.

GUIDANCE

Any AI system used to support diagnosis, triage or care decisions must be introduced and managed in line with WHO's guidance on the ethics and governance of artificial intelligence for health. The facility assesses the system before introduction (AI-FRM-001) and sets out a responsible-use policy (AI-POL-001) that says what the system is for, what it must not be used for, and who may use it.

The facility can name the governance basis it used. Where local law or national guidance applies, that is named too. An AI system in clinical use with no assessment and no governance basis does not meet this criterion.

> **Good practice.** Each AI system has an assessment made before introduction that cites the WHO guidance. An approved responsible-use policy covers every system, and the facility can name its governance basis.

> **Partial because.** A policy exists, but it does not cover every AI system in use, or an assessment does not cite the guidance.

WHAT GOOD LOOKS LIKE

- An AI assessment (AI-FRM-001) completed before introduction.
- A responsible-use policy (AI-POL-001) stating the purpose and the limits of use.
- A named governance basis, drawn from WHO guidance and any local rules.
- A list of the staff who are allowed to use the system.

COMMON MISTAKES

- A tool bought for clinical use with no assessment.
- Use of a general-purpose AI tool for patient decisions with no policy.
- A policy copied from elsewhere without adapting it to the facility.
- No record of who approved introduction.

> **Why it matters.** Artificial intelligence can help with diagnosis and triage, but it can also make errors that look confident. WHO's guidance on AI in health asks for safety, transparency and human oversight, and a facility that introduces AI must follow it.

WHAT THE ASSESSOR CHECKS

Sample. Review the assessment and policy for each AI system in clinical use.

1 An assessment is made before introduction.

Method. Check the assessment against WHO guidance on the ethics and governance of AI for health.

Evidence to show. AI-FRM-001 AI System Assessment.

Pass when. Each system has an assessment that cites the guidance.

2 A responsible-use policy is in force.

Method. Check that the policy is approved and covers each system in use.

Evidence to show. AI-POL-001 Responsible Use of AI in Care Policy.

Pass when. The policy is approved and covers each system.

3 The facility can name its governance basis.

Method. Ask the responsible person for the governance basis of one named system.

Evidence to show. AI-FRM-001 AI System Assessment.

Pass when. The basis is named and recorded.

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

Immediate fail. An AI system is in clinical use with no assessment and no governance basis. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-FRM-001	AI System Assessment	Manager	Chief executive	Manager
AI-POL-001	Responsible Use of AI in Care Policy	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries accountability to the governing body	Artificial Intelligence in Healthcare Safety Essential in all settings
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety; Artificial Intelligence Systems for Care Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence Systems for Care Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

5.5 AI Systems Are Monitored for Unintended Consequences

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

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

> **Criterion.** The facility monitors and evaluates its AI systems — auditing results for over-diagnosis or missed diagnosis, tracking patient complaints related to AI-assisted care, and checking for other unintended consequences — not deploying an AI tool and assuming it works as intended with no ongoing scrutiny.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: AI output audited for over- and under-diagnosis, with a recorded response to any finding.

GUIDANCE

AI systems are monitored after introduction. The facility audits the output (AI-SOP-001) for over-diagnosis, where the system flags a condition that is not present, and under-diagnosis, where it misses one. The audit results are recorded in the AI monitoring register (AI-REG-001).

Complaints that relate to AI-assisted care are tracked, and each monitoring finding leads to a recorded response, such as retraining the staff, changing the threshold or stopping use. A known performance problem with no response does not meet this criterion.

> **Good practice.** Each AI system is audited for over-diagnosis and missed diagnosis. Complaints related to AI are logged and reviewed, and at least one recorded finding shows the response that followed.

> **Partial because.** Audits are recorded for some AI systems only, or AI-related complaints are not logged, or findings have no recorded response.

WHAT GOOD LOOKS LIKE

- An audit procedure (AI-SOP-001) that checks for over- and under-diagnosis.
- A monitoring register (AI-REG-001) with the results and the date.
- A complaints log that shows AI-related complaints separately.
- A recorded response to each monitoring finding.

COMMON MISTAKES

- Checking the system only when someone complains.
- Results recorded but never reviewed.
- A known error with no change made.
- Monitoring that stops after the first month.

> **Why it matters.** An AI system can work well at first and then drift, missing diagnoses or over-diagnosing as the patients change. Auditing its results regularly is the only way to notice.

WHAT THE ASSESSOR CHECKS

Sample. Review the monitoring register for each AI system in use over the last 12 months.

1 AI output is audited for over- and under-diagnosis.

Method. Check the audit record for a sample of AI-assisted decisions.

Evidence to show. AI-SOP-001 AI Performance and Safety Monitoring.

Pass when. Audits are recorded for each system.

2 AI-related complaints are tracked.

Method. Check the complaints log for AI-related entries and their review.

Evidence to show. AI-REG-001 AI Monitoring Register.

Pass when. AI-related complaints are logged and reviewed.

3 A monitoring finding led to a response.

Method. Ask for one recorded case where monitoring found a problem and check the response.

Evidence to show. AI-REG-001 AI Monitoring Register.

Pass when. A recorded case shows a finding and a response.

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

Immediate fail. An AI system's output is not checked, and a known performance problem has no recorded response. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-SOP-001	AI Performance and Safety Monitoring	Manager	Chief executive	Chief executive
AI-REG-001	AI Monitoring Register	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

5.6 Staff Are Consulted Before an AI System Is Introduced

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 who will deliver care using a new AI system are consulted before it is introduced, to understand the practical implications and identify training needs — not an AI tool rolled out to clinical staff with no engagement beyond a brief notification that it now exists.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: staff consulted before an AI system is introduced, with training needs met before go-live.

GUIDANCE

The staff who will deliver care with a new AI system are consulted before the decision to introduce it is final. The consultation (AI-SOP-002) covers the practical effect on their work, the risks they see and the training they will need. Its outcome is recorded on the consultation form (AI-FRM-002).

Training needs identified in the consultation are met before go-live. A system that goes live before staff have been consulted does not meet the criterion, even if it is later accepted by the team.

> **Good practice.** Staff who will use the AI system are consulted before the decision is final. The training needs they raise are met before go-live, and staff confirm that the consultation took place.

> **Partial because.** Staff were consulted before the decision, but the training identified was not completed before go-live, or the consultation is not recorded.

WHAT GOOD LOOKS LIKE

- A recorded consultation (AI-SOP-002) with the staff who will use the system.
- A consultation form (AI-FRM-002) showing the views and the training needs.
- Training completed before go-live.
- Staff able to describe what was discussed.

COMMON MISTAKES

- A decision made by managers and then announced.
- A consultation held after the system is live.
- No record of the staff who were consulted.
- Training planned but not delivered before go-live.

> **Why it matters.** Staff who will use an AI system every day know the practical problems that a manager may not. Consulting them before it is introduced finds those problems early.

WHAT THE ASSESSOR CHECKS

Sample. Review the consultation record for each AI system introduced in the last 12 months.

1 Staff are consulted before introduction.

Method. Check the consultation record dated before the decision was final.

Evidence to show. AI-FRM-002 Staff Consultation Record.

Pass when. Consultation is recorded before the decision.

2 Training needs are identified and met before go-live.

Method. Check that the consultation identified training needs and that training was recorded before go-live.

Evidence to show. AI-SOP-002 Staff Consultation Before AI Introduction.

Pass when. Identified training was completed before go-live.

3 Staff can describe the consultation.

Method. Ask staff who use a recent AI system whether they were consulted.

Evidence to show. AI-FRM-002 Staff Consultation Record.

Pass when. Staff confirm the consultation took place.

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

Immediate fail. An AI system goes live with no staff consultation before the decision was final. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-SOP-002	Staff Consultation Before AI Introduction	Manager	Chief executive	Chief executive
AI-FRM-002	Staff Consultation Record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

5.7 Accountability for AI-Assisted Care Is Explicitly Defined

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

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

> **Criterion.** The facility has considered and documented accountability arrangements for care and treatment delivered with AI support — who is responsible when an AI-assisted decision is wrong — not leaving this as an unexamined question until the first time it matters.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: accountability for AI-assisted care documented, understood by clinicians and reviewed after incidents.

GUIDANCE

When care is delivered with AI support, someone must be accountable for each decision. The accountability arrangements are documented in the AI accountability policy (AI-POL-002). The policy says who is responsible when an AI-assisted decision is wrong, and it is not left between the clinician and the system.

Clinicians understand their own accountability and can describe it. Accountability is reviewed after any AI-related safety incident, and the review is recorded.

> **Good practice.** A written policy states who is accountable for an AI-assisted decision, and the care records reflect it. Clinicians can describe their accountability, and it is reviewed after any AI-related incident.

> **Partial because.** Accountability is written in the policy, but clinicians cannot describe it, or it is not reflected in the records of AI-assisted decisions.

WHAT GOOD LOOKS LIKE

- An AI accountability policy (AI-POL-002) that names who is responsible for each type of decision.
- Clinicians who can describe their own accountability.
- A review recorded after any AI-related incident.
- A clear route for escalation when the AI output is doubted.

COMMON MISTAKES

- Accountability left unclear between the clinician and the vendor.
- A clinician who is asked to sign off decisions they cannot check.
- No review after an incident.
- A policy that no clinician has read.

> **Why it matters.** When an AI system contributes to a wrong decision, it is not clear who is responsible: the clinician, the vendor or the facility. A documented accountability arrangement answers that question before there is an incident.

WHAT THE ASSESSOR CHECKS

Sample. Review the accountability policy and the records of AI-assisted decisions in the last 12 months.

1 Accountability is explicitly documented.

Method. Check the policy and a sample of AI-assisted decision records.

Evidence to show. AI-POL-002 Accountability for AI-Assisted Care.

Pass when. Clinical accountability is stated in the policy and the records.

2 Clinicians understand their accountability.

Method. Ask clinicians who use AI-supported tools to describe their accountability for the final decision.

Evidence to show. AI-POL-002 Accountability for AI-Assisted Care.

Pass when. Clinicians describe it correctly.

3 Accountability is reviewed after an incident.

Method. Check the process for any AI-related safety incident.

Evidence to show. AI-POL-002 Accountability for AI-Assisted Care; INC-SOP-001 Root Cause Analysis of Serious Incidents.

Pass when. A review of accountability follows any such incident.

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

Immediate fail. Accountability for an AI-assisted decision is not documented, and no review follows an AI-related safety incident. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-POL-002	Accountability for AI-Assisted Care	Chief executive	Governing body members	Chief executive

Other records in the criterion: INC-SOP-001 Root Cause Analysis of Serious Incidents

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries accountability to the governing body	Artificial Intelligence in Healthcare Safety Essential in all settings
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

5.8 Patients Are Informed When Their Care Involves AI

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

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

> **Criterion.** A patient whose care involves an aspect delivered with AI system support is informed of this — not left to assume every decision was made by a human clinician alone, with disclosure treated as optional rather than a standard part of informed care.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: patients told in understandable language when their care involves an AI system.

GUIDANCE

A patient whose care involves an AI system is told so, in language they can understand. The information is given under the patient information procedure (AI-SOP-003), and it is not buried in a general consent form. It says what the AI does in their care and that a clinician remains involved.

The information is recorded on the patient information form (AI-FRM-003), and the record shows that the patient was told. Staff check that patients understood, and confirm it on the record.

> **Good practice.** Patients are told when AI supports their care, in plain language and as separate information. The disclosure is recorded, and patients confirm that they were told.

> **Partial because.** Patient information exists, but disclosure is not recorded for every case of AI-supported care, or the information is not written in plain language.

WHAT GOOD LOOKS LIKE

- Patient information (AI-SOP-003) in understandable language, given before the care.
- An information form (AI-FRM-003) recorded in the patient file.
- A statement that a clinician remains involved in the decision.
- A check that the patient understood the information.

COMMON MISTAKES

- Mentioning AI only in a long general consent form.
- Using technical words the patient cannot follow.
- Not telling patients when AI has supported their care.
- Recording the information but never checking understanding.

> **Why it matters.** A patient who is treated with the help of AI has a right to know. Telling them, rather than leaving them to assume, is part of informed consent and trust.

WHAT THE ASSESSOR CHECKS

Sample. Review the patient information and the records of AI-supported care for the last 12 months.

1 **Patients are informed when AI supports their care.**

Method. Check the information given and the record of disclosure.

Evidence to show. AI-SOP-003 Informing Patients About AI-Supported Care.

Pass when. Disclosure is recorded for AI-supported care.

2 **The information is understandable.**

Method. Read the patient information for plain language and check it is not buried in a general consent form.

Evidence to show. AI-FRM-003 Patient Information on AI-Supported Care (template).

Pass when. The information is written in plain language and given separately.

3 **Patients confirm they were told.**

Method. Ask a sample of patients whether they were told AI was involved.

Evidence to show. AI-FRM-003 Patient Information on AI-Supported Care (template).

Pass when. Patients confirm they were informed.

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

Immediate fail. A patient is not informed that AI supported their care, and no information is available. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-SOP-003	Informing Patients About AI-Supported Care	Manager	Chief executive	Chief executive
AI-FRM-003	Patient Information on AI-Supported Care (template)	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

10 Questions and answers

Do I need to meet every criterion in Standard 5?
Yes. Standard 5 is a core standard, and all eight criteria apply to all nine facility types. Each criterion has its own pass rule and its own immediate-fail rule, so each one must be met on its own. Criteria 5.1 to 5.3 are about digital care systems, and criteria 5.4 to 5.8 are about artificial intelligence. The samples for 5.4 to 5.8 are the AI systems in clinical use. If your facility uses no AI system at all, tell ASF before the survey so that the scope can be confirmed.

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 an AI system is in clinical use with no assessment and no governance basis, criterion 5.4 fails outright. 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 procedures, policies, forms and registers listed under each criterion in the "Evidence and documents" table. Records, such as the Digital Tool Assessment Template (DIG-FRM-002) completed for each system, or the AI Monitoring Register (AI-REG-001), are kept as working files. 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 counts as a digital care system?
Any digital system used to deliver or support care: a telehealth platform, a remote monitoring tool, a patient-facing app, or clinical software. The criterion is about how the system came into use. Each one needs an assessment made by the facility itself before it is introduced, and it must be managed afterwards. A system adopted because a vendor presented it well, with no internal evaluation, does not meet criterion 5.1.

What must the assessment of a digital system cover?
Three things, all recorded on the Digital Tool Assessment Template (DIG-FRM-002) under the assessment procedure (DIG-SOP-002). First, a cost and benefit analysis dated before go-live. Second, interoperability, meaning how the system works with the systems you already use, and the risks of that. Third, the unintended consequences considered in advance, as a list of risks with a mitigation for each one. The surveyor reviews the assessment for each digital care system in use. A system introduced with no cost and benefit analysis and no interoperability check is an immediate fail.

What do we owe patients who cannot use digital care?
An alternative route that gives equivalent care. Some patients cannot use an app, have no internet access, or find video calls hard, and they must not receive a reduced service. The procedure is DIG-SOP-003, and the Digital Alternative Record (DIG-FRM-003) records the route each patient prefers and any alternative used. The surveyor also checks that the digital service was tested beforehand with people who might struggle to use it. A patient with no alternative route who receives reduced service is an immediate fail.

What technical support is expected?
Each digital care system needs a named route to technical expertise, which may be in-house, provided by the vendor or contracted. The arrangement is written in the Technical Support and Testing Arrangement (DIG-PLN-001), and tests are recorded on the Digital System Test and Support Record (DIG-FRM-004). Testing must be done before full implementation. The surveyor reviews the testing records and the support log, and asks staff how they get support, so staff should be able to describe the route.

Which AI systems does the standard cover, and what does it ask?
It covers any artificial intelligence system used to support diagnosis, triage or care decisions. Such a system must be introduced and managed in line with the World Health Organization guidance, Ethics and governance of artificial

intelligence for health (2021), which asks for safety, transparency and human oversight. Each system needs an assessment made before introduction that cites the guidance (AI-FRM-001), and an approved Responsible Use of AI in Care Policy (AI-POL-001) that covers it. The surveyor reviews the assessment and the policy for each AI system in clinical use.

How do we monitor an AI system after it is introduced?
An AI system can work well at first and then change as the patients change, so its results must be checked regularly. Under the monitoring procedure (AI-SOP-001), the output of each system is audited for over-diagnosis and missed diagnosis, and complaints related to AI-assisted care are logged and reviewed. Audits, complaints, findings and actions are recorded on the AI Monitoring Register (AI-REG-001). The surveyor reviews the register for the last 12 months and looks for at least one case where a finding led to a response. An AI system whose output is not checked, with a known problem left unanswered, is an immediate fail.

Why must staff be consulted before an AI system is introduced?
Staff who will use the system every day know practical problems that a manager may not see. They must be consulted before the decision is final, not informed afterwards. The procedure is AI-SOP-002, and the consultation, with the concerns raised and the responses, is recorded on the Staff Consultation Record (AI-FRM-002). Training needs found in the consultation must be met before go-live. The surveyor reviews the record for each AI system introduced in the last 12 months and asks staff whether the consultation took place.

Who is accountable when an AI-assisted decision is wrong?
The standard does not give one answer for every facility. It requires the facility to decide and to write the answer down in advance, in the Accountability for AI-Assisted Care policy (AI-POL-002), so that the question is settled before an incident and not after it. Clinical accountability must be stated in the policy and reflected in the records of AI-assisted decisions, and clinicians must be able to describe it. After any AI-related safety incident, accountability is reviewed, using the root cause analysis procedure (INC-SOP-001).

Do we have to tell patients that AI was used?
Yes. A patient whose care involves AI support must be told, as a normal part of informed care. The procedure is AI-SOP-003, and the patient information template (AI-FRM-003) gives a plain-language notice that is handed over as separate information, not hidden in other paperwork. The disclosure is recorded. The surveyor reviews the patient information and the records of AI-supported care for the last 12 months, and asks patients to confirm that they were told.

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. Two criteria, 5.2 and 5.3, name no required course; an optional academy course is shown there instead. 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 the checks given for each one. For each digital care system, the surveyor reviews the assessment, the testing records and the support log. For each AI system, the surveyor reviews the assessment, the policy, the monitoring register, the staff consultation record and the patient information. The surveyor also talks to people: staff are asked how they get technical support and whether they were consulted, clinicians are asked to describe their accountability, and patients are asked whether they were told that AI supported their care.

How does the surveyor choose which records to check?
Each criterion states its own sample, such as "Review the assessment for each digital care system in use" or "Review the monitoring register for each AI system in use over the last 12 months". The surveyor uses the sample given on the criterion rather than choosing records to suit the facility. Preparing for the survey means keeping a list of every digital care system and every AI system in use, with its records organised so that any item 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 5.4) 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). Recommendations on digital interventions for health system strengthening. https://news.gmj.ge/guideline/recommendations-on-digital-interventions-for-health-system-strengthening/ (criterion 5.1)
2. World Health Organization (2024). Implementation toolkit for accessible telehealth services. https://news.gmj.ge/guideline/implementation-toolkit-for-accessible-telehealth-services/ (criterion 5.2)
3. World Health Organization (2022). Consolidated telemedicine implementation guide. https://news.gmj.ge/guideline/consolidated-telemedicine-implementation-guide/ (criterion 5.3)
4. World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/ (criterion 5.4, 5.5, 5.6, 5.7, 5.8)

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 5, 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.

Code	Document	Type	What it is for	Criteria
AI-FRM-001	AI System Assessment	Form (record)	Assessment of each AI system against WHO principles, with the human oversight rule.	5.4
AI-FRM-002	Staff Consultation Record	Form (record)	Records the consultation with staff before an AI system is introduced, with concerns and responses.	5.6
AI-FRM-003	Patient Information on AI-Supported Care (template)	Form (record)	Plain-language notice telling patients when an AI system supported their care, and what that means.	5.8
AI-POL-001	Responsible Use of AI in Care Policy	Policy	To make sure AI systems used in diagnosis, triage or care decisions are introduced and governed in line with WHO guidance on the ethics and governance of AI for health.	5.4
AI-POL-002	Accountability for AI-Assisted Care	Policy	To define, in writing and in advance, who is accountable when an AI-assisted care decision is wrong, so that the question is answered before it matters.	5.7
AI-REG-001	AI Monitoring Register	Register	Records each AI audit, complaint, finding and action, for the last four quarters and onward.	5.5
AI-SOP-001	AI Performance and Safety Monitoring	Procedure (SOP)	To monitor AI systems after introduction for over-diagnosis, missed diagnosis, complaints and other unintended effects, and to act on findings.	5.5
AI-SOP-002	Staff Consultation Before AI Introduction	Procedure (SOP)	To make sure staff who will deliver care with an AI system understand its practical effect, raise their concerns, and are trained before go-live.	5.6
AI-SOP-003	Informing Patients About AI-Supported Care	Procedure (SOP)	To make sure patients know when AI is part of their care, in words they understand, and can ask questions about it.	5.8
DIG-FRM-002	Digital Tool Assessment Template	Form (record)	Assessment of a digital care system before introduction: costs, benefits, interoperability and unintended consequences.	5.1
DIG-FRM-003	Digital Alternative Record	Form (record)	Records the patient’s preferred route and any alternative route used for a digital service.	5.2
DIG-FRM-004	Digital System Test and Support Record	Form (record)	Records the test before full use, after each change, and the support contact for each digital system.	5.3
DIG-PLN-001	Technical Support and Testing Arrangement	Plan	To make sure each digital care system has accessible technical expertise and is tested before and after full use.	5.3
DIG-SOP-002	Digital Care System Assessment and Management	Procedure (SOP)	To make sure every digital care system (telehealth, remote monitoring, patient-facing app, clinical software) is assessed, implemented and managed through a defined process, not adopted on a vendor pitch.	5.1
DIG-SOP-003	Digital Care Access and Alternatives	Procedure (SOP)	To make sure patients who cannot or prefer not to use digital care are never disadvantaged by it, and receive the same service through another route.	5.2
INC-SOP-001	Root Cause Analysis of Serious Incidents	Procedure (SOP)		5.7