

AI Performance and Safety Monitoring

Standard operating procedure (SOP) | AI-SOP-001

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Title	AI Performance and Safety Monitoring
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Replaces	None (new document)
Standards and criteria supported	Standard 2D, criterion 2D.5
Evidence basis	E-011, E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

At a glance: what to do

1. Audit a sample of AI-assisted decisions each quarter for over-diagnosis and missed diagnosis.
2. Track every complaint or concern about AI-assisted care.
3. Act on any finding: retrain, restrict use, or stop.
4. Record each audit on AI-REG-001.

Stop and get help straight away if: an audit shows harm or a pattern of error, and use continues without review.

1. Purpose

To monitor AI systems after introduction for over-diagnosis, missed diagnosis, complaints and other unintended effects, and to act on findings [E-011, EC].

2. Scope

Applies to	Clinical leads, quality lead, IT lead
Locations	All clinical areas using AI systems at {{facility.legal_name}}
When	Quarterly audit; continuous complaint tracking
Does not apply to	General clinical audit, covered by SOP-N26

3. Definitions and abbreviations

Term	Meaning in this SOP
Over-diagnosis	A condition recorded or treated that would not otherwise have needed it
Missed diagnosis	A condition the AI system or its use failed to detect
Audit sample	A set of AI-assisted decisions selected for checking against the clinical outcome

4. Background and rationale

An AI tool can perform well in testing and poorly in use. Criterion 2D.5 requires ongoing checks for over-diagnosis, missed diagnosis and other unintended effects, not an assumption that the tool works as intended.

5. Responsibilities

Role	Duties in this SOP	Competence needed
Clinical lead for each system	Runs the quarterly audit	Clinical
Quality lead	Reviews findings and trends	Quality (SOP-N26)
IT lead	Checks performance data and system changes	Health informatics (EC)

6. Equipment, materials and resources

Item	Specification or standard	Check before use
Audit sample list (random, 10 per quarter, EC)	Current	Generated each quarter
AI-REG-001 Monitoring Register	Current	Quality file

7. Safety and infection prevention

- Patients affected by a suspected error are reviewed clinically at once, not left until the next audit.

8. Before you start

- Confirm the system version and the audit period.

9. Procedure

Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.

Step	Action	How to do it	Key point
1	Select a sample.	- Select a random sample of AI-assisted decisions each quarter (EC size). - Include decisions where the clinician agreed and where they overrode the AI output.	Cases where clinicians overrode the AI are a useful source of error.
2	Check against outcome.	- For each case, compare the AI output with the clinical outcome or expert review. - Record over-diagnosis, missed diagnosis, and other effects.	The outcome, not the agreement of the clinician, is the check.
3	Track complaints.	- Record every complaint or concern about AI-assisted care on INC-POL-002, flagged as AI-related. - Review each one with the clinical lead.	Patients often notice errors first.
4	Act on findings.	- For each finding, decide: no action, retrain, add a check, restrict use, or stop use. - Record the decision and its owner on AI-REG-001.	A finding with no action is a finding that repeats.
5	Report.	Report results each quarter to the quality committee, and to the governing body yearly.	Reporting keeps the monitoring visible.

Decision points

- If the audit shows a pattern of missed diagnosis, use is restricted at once while the cause is found.

10. Special situations

Situation	What to do
Vendor update	Re-run the audit sample after the update before full use.

11. Problems and escalation

- Patient harm linked to an AI system is reported as an incident at once (INC-POL-001).

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
Quarterly audit completed	100%	Quarterly	Clinical lead	Escalate to quality lead
AI complaints tracked and reviewed	100%	Quarterly	Quality lead	Escalate
Findings with decision recorded	100%	Quarterly	Quality lead	Escalate to chief executive

13. Records

Record	Where it is kept	Kept for
AI-REG-001 AI Monitoring Register	Quality file	{{facility.records_retention_years}} years

14. Training and competence

- Clinical auditors are trained in the method at appointment (EC).

15. Related documents

ID	Title	Relationship
AI-REG-001	AI Monitoring Register	Used in steps 2 to 4
SOP-N26	Internal Audit, Quality Oversight and Learning Policy (generic)	General audit
AI-POL-001	Responsible Use of AI in Care Policy	Parent policy

16. Evidence

ID	Source and status
E-011	WHO (2021), Ethics and governance of artificial intelligence for health. Used as the basis for AI governance. Link and wording to verify before publication.
E-009	ASF Expert Committee consensus. Sample size and thresholds to be agreed.

EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.

17. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	First version	Approved by the ASF Expert Committee
1.1	{{document.effective_date}}	Internal quality review: corrected cross-references, status wording and document control	Approved by the ASF Expert Committee