

Laboratory Standards

The complete ASF accreditation standard for medical laboratories — standalone, hospital, or clinic laboratories alike. Every criterion is published in full — statement, classification, and the verification questions used by Monitors and supervisors. Free. No account required.

13 standards · 81 criteria · 33 non-negotiable · 33 core · 15 standard-level · Version 4.0 · Complete, with full guidance for every criterion

STANDARD 1 · MANDATORY

Governance & Document Control

1.1 Named Accountable Person

NON-NEGOTIABLE

A named individual — the Laboratory Director or an equivalent role — holds documented, final accountability for the quality management system. The name is current, not a vacant title inherited from a predecessor. Financial accountability is named separately, even where the same person holds both roles, and a brief, genuine statement of mission and values exists for the laboratory.

1. Is there a named, current Laboratory Director or equivalent, not a title left over from someone who has since left? — Verified against actual employment records, not an organizational chart that hasn't been updated.
2. Does that person hold documented authority to stop unsafe testing or release of results? — Authority on paper only is not authority.
3. Can staff correctly name this person if asked directly? — If frontline staff don't know who it is, the accountability is not functioning in practice.
4. Is financial accountability named separately from quality-system accountability, even if held by the same person? — A distinct, named responsibility, not assumed to be covered by the Director role alone.
5. Does a brief, genuine statement of mission and values exist, specific to this laboratory? — A real, specific statement, not an absence of one on the assumption a lab doesn't need it.

1.2 Document Control: One Current Version

NON-NEGOTIABLE

Every controlled policy, procedure, and SOP exists in exactly one current, identifiable version at the bench. Superseded versions are removed from use, not merely marked obsolete while remaining accessible.

1. Pick any SOP at random at the bench — is it the current version, verifiable against the master document register? — Spot-checked, not taken on the laboratory's word.
2. Are superseded versions physically or digitally removed from the work area, not just labeled "obsolete"? — A marked-obsolete copy still on the shelf gets used under pressure.
3. Is there a single master document register that lists every controlled document and its current version? — Not several partial lists kept by different section heads.

1.3 Document Approval Before Use

NON-NEGOTIABLE

No policy, procedure, or SOP is used at the bench before it has been formally reviewed and approved by the accountable person or their documented delegate.

1. Does every controlled document show a named approver and approval date before its effective date? — Not a document in active use with no visible sign-off.
2. Where approval is delegated, is the delegation itself documented and current? — An informal "they usually handle it" is not a documented delegation.
3. Can the laboratory produce the approval record for any document the Monitor selects at random? — On request, not after a delay to "find it."

1.4 Risk Register, Reviewed on a Schedule

CORE

A risk register identifies specific risks to result accuracy and patient safety across the specimen pathway, with a named owner and review date for each entry, reviewed on a fixed schedule rather than only after an incident.

1. Does the risk register name specific risks — not generic entries like "human error" with no detail? — Vague entries that could apply to any laboratory anywhere are not genuine risk identification.
2. Does each entry have a named owner responsible for it? — A risk with no owner does not get managed.
3. Is the register reviewed on a fixed schedule, verifiable by actual review dates, not only reactively after something goes wrong? — A register untouched for over a year despite a stated quarterly cycle fails this.

1.5 Retention Schedule Matches Legal Minimum

CORE

A documented retention schedule states how long each record type — patient results, quality control data, equipment maintenance logs, competence records — is kept, and meets or exceeds the applicable national legal minimum.

1. Does a written retention schedule exist covering every major record type, not just patient results? — Equipment and competence records are frequently the gap.
2. Does each retention period meet or exceed the national legal minimum for that record type? — Checked against the actual current law, not an assumption carried over from years ago.
3. Can the laboratory retrieve a record from several years back within the stated retention period, not just recent ones? — A retention policy that exists on paper but fails in practice when records are actually needed.

STANDARD 2

Management Requirements

2.1 Internal Audit, On a Fixed Schedule

NON-NEGOTIABLE

The full quality management system is internally audited at least once per year against a documented audit schedule, covering every section of the laboratory over a defined cycle, not only the sections most convenient to review.

1. Does a documented audit schedule exist covering every laboratory section within a defined cycle? — Not just the sections an auditor finds easiest to reach.
2. Did the most recent audit actually happen on or near its scheduled date? — A schedule that is routinely missed is not functioning.
3. Are audit findings recorded in enough detail that someone outside the audit could understand what was actually checked? — A checklist with ticks and no detail is not a usable audit record.

2.2 Corrective Action Closes the Root Cause

NON-NEGOTIABLE

Every nonconformance with potential impact on patient results triggers a documented corrective action that identifies the root cause, not only the immediate symptom, and the action is verified as effective after implementation.

1. Pick a recent corrective action at random — does it name a root cause, or only restate the symptom? — "Staff error" is a symptom; what allowed the error to happen is the root cause.
2. Was the corrective action's effectiveness checked after a defined interval, not just implemented and assumed to have worked? — A documented follow-up check, not an assumption.
3. Where the same type of nonconformance has recurred, was that recurrence itself investigated as a sign the original action failed? — A repeat failure without a fresh investigation suggests the corrective action process is not functioning.

2.3 Preventive Action, Not Only Reactive

CORE

The laboratory identifies potential nonconformances before they occur — from trend data, near-misses, risk register entries, or external quality assessment patterns — and acts on them, not only responding after an actual failure.

1. Can the laboratory show at least one preventive action taken from trend data or a near-miss, not triggered by an actual failure? — If every action on file follows an actual incident, prevention is not genuinely functioning.
2. Is external quality assessment performance trended over time, not just checked pass/fail each round? — A single-round pass can mask a worsening trend across several rounds.
3. Is there a named person responsible for reviewing trends on a schedule? — Trend data nobody is assigned to review does not drive prevention.

2.4 Management Review, With Minutes and Actions

CORE

Senior management formally reviews the quality management system at least annually, with documented minutes, inputs covering audits/complaints/nonconformances/external quality assessment, and tracked output actions with owners and dates.

1. Do management review minutes exist for the most recent cycle, with named attendees? — Not a verbal assurance that "we discussed it."
2. Do the minutes cover the required inputs — audit results, complaints, nonconformances, external quality assessment performance? — A review that only covers budget is not a quality management review.
3. Are output actions from the previous review traceable to completion, with a named owner for each? — Actions agreed and never followed up are a common, specific failure.

2.5 Complaints Logged, Investigated, Closed

CORE

Every complaint, from any source — patient, clinician, referring facility — is logged in a single register, investigated, and closed with a documented outcome communicated back to the complainant where contact information exists.

1. Does a single complaints register exist, or are complaints handled informally by whoever receives them? — Complaints handled verbally and never logged are effectively invisible to the quality system.
2. Is there a documented outcome for each logged complaint, not just a record that it was received? — Receipt without resolution is not complaint handling.
3. Where contact information exists, was the complainant actually informed of the outcome? — Closing a complaint internally without telling the person who raised it undermines trust.

2.6 Impartiality: No Commercial Pressure on Results

NON-NEGOTIABLE

No staff member's remuneration, performance evaluation, or continued employment is tied, directly or indirectly, to the volume or outcome of specific test results. Laboratory personnel are protected from undue commercial or financial pressure that could influence technical judgment.

1. Is any part of technical staff compensation linked to test volume, result patterns, or referral relationships? — A volume-linked bonus for technical staff creates exactly the pressure this criterion prohibits.
2. Is there a documented policy explicitly protecting staff who report a quality concern from retaliation? — Protection that exists informally but isn't written down fails under pressure.
3. Would a technician who identified a result requiring re-testing feel safe raising it, even if it delays turnaround? — Tested through confidential staff conversation, not management's own assurance.

2.7 Conflict of Interest Declared and Reviewed

CORE

Staff and management with influence over testing, purchasing, or reporting decisions declare financial or personal interests that could reasonably affect impartiality, and these declarations are reviewed on a fixed schedule, not only collected once at hiring.

1. Do current declarations exist for everyone in a position of influence, not just a one-time declaration from years ago? — Circumstances change; a declaration never refreshed becomes stale.
2. Is there a named person or body responsible for reviewing declarations and deciding what action, if any, is needed? — A declaration filed and never reviewed by anyone accomplishes nothing.
3. Where a genuine conflict was identified, is there a record of what mitigation was actually applied? — Identification without documented mitigation is incomplete.

2.8 External Service and Supply Evaluation

CORE

Reference laboratories, equipment service providers, and critical reagent suppliers are formally evaluated before use and periodically thereafter, against documented criteria relevant to the service each provides.

1. Is there a documented evaluation on file for the laboratory's current reference laboratory and key equipment service providers? — Not a relationship that began informally and was never formally assessed.
2. Are these evaluations repeated on a periodic schedule, not only at the start of the relationship? — A provider's performance can decline over years without a fresh check.
3. Where a provider's performance has been unsatisfactory, is there a record of how the laboratory responded? — Continuing with an underperforming provider with no documented response is a gap.

STANDARD 3

Personnel & Competence

3.1 Documented Qualification Before Independent Work

NON-NEGOTIABLE

No staff member performs a laboratory procedure unsupervised until their competence in that specific procedure has been formally assessed and documented, not merely inferred from a general qualification or job title.

1. Pick a staff member at random — does a documented competence record exist for every procedure they perform unsupervised? — A nursing or laboratory degree is not, by itself, documented competence in a specific procedure.
2. Was the competence assessment performed by someone else, not self-certified by the staff member? — Self-assessment of one's own competence is not independent verification.
3. Is there a record of the actual date competence was confirmed, not just a start date of employment? — The two dates are often different and the distinction matters.

3.2 Competence Reassessed on a Schedule

NON-NEGOTIABLE

Staff competence is formally reassessed at defined intervals — not only at hiring — and immediately following any extended absence, procedural change, or identified performance concern.

1. Is there a fixed reassessment interval, and does the most recent reassessment date for staff fall within it? — A policy stating annual reassessment that hasn't actually happened in two years fails this.
2. Following a staff member's return from extended leave, was competence reconfirmed before they resumed unsupervised work? — Skills can lapse; resuming without reconfirmation is a real risk.
3. Where a performance concern was identified, was a targeted reassessment triggered specifically because of it? — Not just folded into the next routine cycle months later.

3.3 Orientation Before First Independent Shift

CORE

Every new staff member completes a documented orientation covering the laboratory's quality management system, safety procedures, and their specific role's SOPs before working an unsupervised shift.

1. Does a signed orientation record exist for current staff, dated before their first unsupervised shift? — Dated after the fact does not satisfy this criterion.
2. Does orientation cover safety procedures specifically, not only administrative onboarding? — HR paperwork alone is not safety orientation.
3. Can a recently hired staff member describe what their orientation actually covered? — Verified by asking the person directly, not only checking the signed form.

3.4 Training Records Tied to Specific SOPs

CORE

Training records name the specific SOP or procedure version a staff member was trained on, and are updated whenever that SOP is revised, so the laboratory can show at any time exactly which version of a procedure each staff member is currently qualified to perform.

1. Do training records name the specific SOP and version, not just a general subject area? — "Trained on specimen handling" is too vague; which SOP, which version?
2. When an SOP was last revised, were affected staff retrained and the record updated before the new version took effect? — A revised SOP with no corresponding retraining record is a gap.
3. Can the laboratory produce, for any current staff member, the exact list of SOP versions they are currently qualified on? — On request, without needing to reconstruct it from scattered files.

3.5 Adequate Staffing for Safe Operation

CORE

Staffing levels at all operating hours are sufficient for safe specimen handling, timely result reporting, and compliance with the laboratory's own written procedures, with a documented plan for covering absence.

1. Does the laboratory have a documented minimum staffing level for each operating shift? — Not an informal assumption of "we manage."
2. Is there a documented plan for covering unplanned absence that doesn't rely on an already-fatigued remaining staff member working alone? — Relevant especially for small or single-staffed sections.
3. Have critical procedures ever been delayed or skipped due to understaffing, and if so, was this logged as a quality event? — Understaffing-driven shortcuts that go unrecorded are a hidden risk.

STANDARD 4

Equipment, Reagents & Traceability

4.1 Calibration Current on Every Reportable Instrument

NON-NEGOTIABLE

Every instrument used to generate a reportable patient result has a current, traceable calibration record, and no instrument is used past its calibration due date without being formally removed from service first.

1. Pick any analyzer in current use — is its calibration record current, with a traceable certificate or reference standard? — Not a certificate from a prior calibration cycle still displayed.
2. Is there any instrument past its calibration due date still generating reportable results? — A single instance of this is a direct patient-safety failure.
3. Where an instrument is taken out of service, is it physically or digitally flagged so staff cannot use it by mistake? — An unflagged out-of-service instrument gets used under time pressure.

4.2 Preventive Maintenance on a Fixed Schedule

NON-NEGOTIABLE

Every piece of critical equipment is maintained according to the manufacturer's recommended schedule or a validated equivalent, with maintenance records retained and reviewed before each instrument returns to reportable use after service.

1. Does a maintenance log exist for critical equipment showing the manufacturer's recommended interval was actually met? — Not a schedule that exists on paper but is routinely missed.
2. After servicing, is there a documented verification step before the instrument returns to reporting patient results? — Returning equipment to use immediately after service, with no verification, is a gap.
3. Are maintenance records retained for the full retention period set in Standard 1.5? — Equipment history is frequently the specific record type that gets discarded early.

4.3 Reagent Lot Verification Before Use

NON-NEGOTIABLE

Each new reagent lot is verified against the laboratory's own quality control material before being used for reportable patient results, and expired reagents are physically segregated from, and never used in, active testing.

1. Can the laboratory show lot-verification records for its currently open reagent lots? — A new lot opened and put directly into use without verification is a direct failure.
2. Are expired reagents physically separated from current stock, not just marked and left in the same storage area? — Separation prevents accidental use under time pressure far more reliably than a label alone.
3. Is reagent storage temperature monitored and logged, with a documented response procedure for excursions? — Temperature-sensitive reagents used after an unlogged excursion risk invalid results.

4.4 Metrological Traceability to a Recognized Reference

CORE

Calibration of measuring equipment is traceable through an unbroken chain to an internationally recognized reference material or method, documented at each link, not simply asserted by the equipment manufacturer.

1. Can the laboratory produce documentation showing the traceability chain for a selected instrument back to a recognized reference? — A manufacturer's general claim of traceability, with no laboratory-specific documentation, is insufficient.
2. Where a reference material is used, is its own certificate of traceability on file and current? — An expired reference material certificate breaks the chain.
3. Is the traceability chain reviewed whenever equipment or reference materials change? — A chain established once and never revisited can silently break.

4.5 Equipment Malfunction: Documented Response

CORE

A written procedure governs the laboratory's response to equipment malfunction, including immediate removal from reportable use, assessment of results produced since the last verified-good check, and notification of affected clinicians where results may be unreliable.

1. Does the malfunction procedure require assessing results produced since the last known-good check, not only results produced after the malfunction was noticed? — A malfunction is often identified after it began, not at its onset.
2. Is there a documented instance of a clinician being notified after a malfunction affected previously reported results? — If this has never happened, ask whether it's because it's never been needed, or because the step is skipped.
3. Is the malfunction procedure accessible to staff during an actual event, not only during planned audits? — A procedure staff can't locate under pressure is not functioning.

STANDARD 5

Facilities, Environment & Suppliers

5.1 Environmental Conditions Monitored and Logged

NON-NEGOTIABLE

Temperature, humidity, and other environmental conditions affecting test validity are continuously monitored in each relevant area, logged, with a documented, time-bound response procedure for excursions outside defined limits.

1. Is environmental monitoring actually logged, not just equipped with a sensor nobody checks? — A thermometer on the wall with no log is not monitoring.
2. Where an excursion occurred, is there a documented record of what action was taken and when? — An excursion logged with no follow-up action recorded is incomplete.
3. Are defined limits specific to each area's actual requirements, not one generic range applied everywhere? — Reagent storage and specimen processing areas often have different real requirements.

5.2 Physical Separation of Incompatible Activities

NON-NEGOTIABLE

Activities that could cross-contaminate or interfere with each other — specimen reception and clean processing, molecular amplification stages, biohazardous waste handling and clean workspace — are physically separated according to recognized practice for each discipline operated.

1. Is specimen reception physically separated from areas where processed samples are handled? — Shared space for both creates genuine cross-contamination risk.
2. Where molecular testing is performed, are pre- and post-amplification areas separated per recognized practice? — This is a well-established, specific requirement where applicable, not a general suggestion.
3. Is biohazardous waste handling physically separated from clean workspace and specimen processing? — Shared pathways between waste and clean work areas are a recurring, identifiable risk.

5.3 Access Control to the Testing Area

CORE

Access to the active testing area is restricted to authorized personnel, with visitor and non-laboratory staff access logged and escorted, protecting both specimen integrity and staff safety.

1. Is the testing area physically restricted, not an open space any staff member can enter? — A locked door or controlled entry point, not an honor-system expectation.
2. Is non-laboratory visitor access logged, with a record of who entered and when? — Unlogged access makes any later investigation of a contamination or security concern impossible.

3. Are visitors actually escorted, or left to move through the space unaccompanied? — A stated escort policy that isn't followed in practice fails this.

5.4 Utility Failure: Documented Contingency

CORE

A written contingency plan covers loss of power, water, or network connectivity, including protection of in-process specimens and stored reagents, and is tested at a defined interval rather than existing only as an untested document.

1. Does the plan specifically address protection of specimens and reagents already in process at the moment of failure? — Generic continuity language without this detail misses the point most relevant to patient safety.
2. Has the plan been tested within a defined interval, with a record of what the test found? — An untested plan frequently fails in ways nobody anticipated.
3. Do staff on shift know where to find the plan and what their specific role in it is? — A plan known only to management does not function during an actual event at 2am.

5.5 Waste Segregated by Hazard Class

NON-NEGOTIABLE

Biohazardous, chemical, and sharps waste are segregated at the point of generation into clearly marked, appropriate containers, with documented disposal through a licensed contractor or equivalent regulated pathway.

1. Are the correct waste containers actually present and in use at each bench, not centralized in a way that encourages mixing? — Segregation only works if the right container is within reach at the point of generation.
2. Is there documentation of licensed, regulated disposal, not an informal arrangement? — A disposal manifest or equivalent record, verifiable on request.
3. Are sharps containers replaced before reaching unsafe fill levels, verified by spot check? — An overfilled sharps container is an immediate, specific injury risk.

5.6 Critical Supplier Agreements, Documented

STANDARD

Agreements with critical suppliers — reagent manufacturers, waste contractors, reference laboratories — are documented in writing, specifying the service or product, quality expectations, and renewal terms.

1. Does a written agreement exist for each critical supplier, not an informal, undocumented working relationship? — Especially relevant for long-standing suppliers where formal paperwork is sometimes allowed to lapse.
2. Do agreements specify quality expectations relevant to patient safety, not only commercial terms? — A contract covering price and delivery but silent on quality standards is incomplete for this purpose.
3. Is there a process for renewing or re-evaluating agreements before they lapse? — An expired agreement still being operated under is a gap worth noting even if the relationship itself continues smoothly.

STANDARD 6

Pre-Examination: Specimen Pathway

6.1 Two-Identifier Patient Verification

NON-NEGOTIABLE

Before specimen collection, the patient's identity is verified using at least two independent identifiers — never room number or visual recognition alone — and the verification is actively performed, not merely asked as a rhetorical formality.

1. Observe a live collection — are two genuine identifiers actually checked, not just a name spoken while the patient is expected to confirm passively? — "You're Mrs. Johnson, right?" to a half-asleep patient is not active verification.
2. Is room number or bed number ever used as one of the two identifiers? — Room numbers change; using one as an identifier is a specific, recurring failure mode.
3. For a patient unable to confirm identity verbally, is there a documented alternative verification procedure? — Unconscious, pediatric, or language-barrier patients need a real, written alternative, not an exception that defaults to no verification.
4. Is the patient's right to decline specimen collection genuinely honoured, with staff able to describe what happens when a patient exercises it? — A real right, not an assumption that arriving for the test obligates the patient to complete it.

6.2 Specimen Labeled at the Point of Collection

NON-NEGOTIABLE

Every specimen is labeled in the presence of the patient, immediately following collection, before moving to the next patient or task — never batch-labeled afterward from memory or a separate list.

1. Is labeling observed to happen at bedside/chairside, before the collector moves on? — Pre-printed labels applied later, away from the patient, is a well-documented cause of mix-ups.
2. Are there any workflows where multiple specimens are collected before any labeling occurs? — Even a short delay across several patients creates real mix-up risk.
3. Does the label include enough information to re-verify identity independently of the collector's memory? — At minimum, two identifiers plus date/time of collection.

6.3 Rejection Criteria, Applied Consistently

NON-NEGOTIABLE

Written specimen rejection criteria — hemolysis, clotting, insufficient volume, unlabeled or mislabeled specimens, wrong container — are applied consistently regardless of how difficult the specimen was to obtain or who is requesting results urgently.

1. Can staff describe the rejection criteria without looking them up? — If criteria exist only on paper and staff don't actually know them, they aren't functioning.
2. Is there a documented instance of a specimen being rejected despite clinical pressure to proceed anyway? — Evidence the criteria hold even under pressure, not just when convenient.
3. Is rejection logged with reason and communicated back to the requesting clinician, not just silently discarded? — Silent rejection can delay care without anyone realizing why results never arrived.

6.4 Transport Conditions Preserve Specimen Integrity

NON-NEGOTIABLE

Specimens requiring specific transport conditions — temperature, time limits, light protection — are transported accordingly, with the conditions actually monitored, not assumed to be met because a general policy exists.

1. For temperature-sensitive specimens, is the actual transport temperature verified, not just assumed from the container type used? — An insulated bag without verification is an assumption, not a control.
2. Is time from collection to receipt tracked for time-sensitive analytes? — Without a timestamp at both ends, a transport delay goes undetected.
3. Where a specimen arrives outside acceptable transport conditions, is this documented and does it affect result interpretation or trigger rejection? — A condition breach that's noted but has no consequence for the result is not a real control.

6.5 Chain of Custody for Forensic or Legal Specimens

CORE

Where the laboratory processes specimens with forensic, legal, or chain-of-custody requirements, a documented, unbroken custody record accompanies the specimen from collection through final disposition, with every handler's signature and timestamp.

1. Does a chain-of-custody form exist, with every transfer point requiring a signature, not just collection and final testing? — A gap anywhere in the chain undermines the specimen's legal validity.
2. Are chain-of-custody specimens physically secured differently from routine specimens? — Locked storage or restricted access, not sitting in the same open rack as routine work.
3. Is staff specifically trained on chain-of-custody requirements, distinct from routine specimen handling training? — Routine training alone does not cover the additional legal requirements.

6.6 Specimen Accessioning Logged in Real Time

CORE

Specimen receipt is logged in the laboratory information system at the time of actual receipt, creating a verifiable, time-stamped record of when the specimen entered the laboratory's custody, not backdated to match the collection time.

1. Does the accessioning timestamp reflect actual receipt time, verifiable against another independent record such as a courier log? — A timestamp that always exactly matches the requested collection time, with no variation, suggests backdating rather than real-time logging.
2. Is there a backlog where specimens sit unaccessioned for a meaningful period before entry? — A delay here distorts turnaround-time reporting and can delay result release.
3. Can the laboratory produce the accessioning record for any specimen the Monitor selects, on request? — Immediately retrievable, not reconstructed after the fact.

6.7 Urgent/STAT Specimens Prioritized and Tracked

CORE

A written procedure defines how urgent or STAT specimens are flagged, prioritized through processing, and tracked against a defined turnaround-time target, distinct from routine specimen handling.

1. Is there a visible, physical or digital flagging system that actually changes how a STAT specimen is handled, not just a label with no operational effect? — A "STAT" sticker that doesn't change queue position accomplishes nothing.
2. Is STAT turnaround time actually tracked and reviewed, with a defined target? — Without tracking, there's no way to know whether the prioritization is actually working.
3. Where STAT turnaround targets are missed, is this logged and reviewed as a quality event? — Missed STAT targets with no follow-up suggest the system tolerates the failure.

6.8 Specimen Retention Before Discard

STANDARD

Tested specimens are retained for a defined minimum period appropriate to the test type before discard, allowing repeat testing or additional analysis to be requested without recollection.

1. Does a written retention schedule exist by specimen and test type, not one blanket period applied regardless of test? — Different analytes have genuinely different stability and retention needs.
2. Is retained specimen storage condition-appropriate, matching what the specimen actually requires? — Retained specimens stored incorrectly are effectively unusable if a repeat test is later needed.
3. Can the laboratory locate and retrieve a specific retained specimen within its stated retention window? — A retention policy that exists but fails in practice when a specimen is actually needed again.

STANDARD 7

Examination: Process & Safety

7.1 Method Validation Before Clinical Use

NON-NEGOTIABLE

Every examination method used for reportable patient results has documented validation or verification data — accuracy, precision, reportable range, reference intervals — completed before the method was first used clinically, not retrospectively assembled.

1. Pick a currently used method — does validation data exist with a completion date before the method's first clinical use date? — Validation dated after clinical use began indicates retrospective paperwork, not real verification.
2. Where a manufacturer's validation data is relied upon instead of in-house validation, has the laboratory verified it performs equivalently in its own hands? — Manufacturer data alone, without local verification, is insufficient for most method categories.
3. Are reference intervals appropriate to the actual patient population served, not simply copied from a manufacturer insert? — A population mismatch between the reference source and the laboratory's actual patients is a real, specific risk.

7.2 Internal Quality Control Run Before Patient Results Released

NON-NEGOTIABLE

Internal quality control is run and reviewed as acceptable before any patient result from that run is released, with a written, followed procedure for what happens when quality control fails.

1. Is there any instance of patient results being released before quality control for that run was reviewed? — A single such instance is a direct patient-safety failure, not a minor process gap.
2. When quality control fails, is there a documented instance of the correct response being followed — investigation, correction, re-run — before results were released? — Not just a written procedure that's never actually been tested in practice.
3. Is quality control frequency appropriate to test volume and stability, not merely the minimum the laboratory can get away with? — A written justification for the chosen frequency, not an arbitrary number.

7.3 External Quality Assessment Participation

NON-NEGOTIABLE

The laboratory participates in an external quality assessment or proficiency testing scheme for every discipline it operates where a scheme is available, with results reviewed by the accountable person and unsatisfactory performance investigated.

1. Does current enrollment and recent participation exist for every operated discipline with an available scheme? — A discipline quietly excluded from participation is a specific, checkable gap.
2. Is there documented review of each round's results by the accountable person, not just filing the certificate? — Participation without genuine review of the results defeats the purpose.
3. Where performance was unsatisfactory, was a documented investigation and corrective action completed? — An unsatisfactory result with no follow-up record is a significant gap.

7.4 Critical Value Communication, Verified Received

NON-NEGOTIABLE

Critical or panic values are communicated directly to a responsible clinician without delay, with verification that the message was actually received and understood — not left on voicemail or sent by a method with no confirmation of receipt — and the communication is logged.

1. Is there a written list of what constitutes a critical value for each relevant analyte? — Without a defined list, "critical" becomes a matter of individual judgment rather than a consistent system.
2. Does the communication log show read-back verification or equivalent confirmation of understanding, not just that a call was placed? — A call attempted is not the same as a value successfully communicated and understood.

3. Is there a documented escalation path when the first contact attempt fails to reach a responsible clinician? — A single failed call attempt with no escalation leaves a critical value effectively unreported.

7.5 Personal Protective Equipment, Available and Used

NON-NEGOTIABLE

Appropriate personal protective equipment is available at the point of use for every task requiring it, in adequate supply, and observed to be actually worn, not merely available but unused under time pressure.

1. Observe actual bench work — is PPE being worn correctly for the task being performed? — Observed directly, not asked about, since self-report on safety compliance is unreliable.
2. Is PPE actually available at the point of use, not stored somewhere requiring staff to leave the bench to retrieve it? — Inconvenient access is a well-documented cause of PPE non-compliance.
3. Has PPE ever run out during a shift, and if so, was this logged as a safety event? — Stockouts that go unrecorded suggest supply monitoring is inadequate.

7.6 Exposure Incident: Documented Response Protocol

NON-NEGOTIABLE

A written protocol governs response to a biological exposure incident — needlestick, splash, spill — including immediate first aid, reporting, and post-exposure medical follow-up, known to staff and accessible at the point of need.

1. Can staff describe the first steps of the exposure protocol without consulting a document? — In an actual exposure, staff will not have time to look up a procedure from scratch.
2. Is there a documented recent exposure incident, and did the actual response match the written protocol? — Where no incident has occurred, confirm the protocol has at least been drilled or walked through.
3. Is post-exposure medical follow-up actually accessible, not just named in the policy with no real arrangement in place? — A referenced occupational health service that doesn't actually respond when called is not a functioning arrangement.

7.7 Information System Access Controlled and Logged

CORE

Access to the laboratory information system is controlled through individual, non-shared user credentials, with access levels matched to role, and a log of who accessed or modified patient data.

1. Are login credentials individual, or does staff share a single generic login? — Shared logins make it impossible to know who actually performed a given action.
2. Do access levels differ by role, with results-amendment permission restricted to appropriate staff? — Every staff member having full edit access to released results is a specific, checkable risk.
3. Is the access log actually reviewed periodically, not just generated and left unexamined? — A log nobody reviews provides no real oversight.

7.8 Result Amendment Traceable to Original

CORE

Where a released result is amended, the original value, the amended value, the reason, the person making the change, and the date are all retained and visible together — the original is never simply overwritten or deleted.

1. Pick an amended result at random — is the original value still visible alongside the amendment, not replaced? — An overwritten original with no trace is a significant traceability failure.
2. Does the amendment record show who made the change and why? — An amendment with no attributed reason undermines confidence in the correction itself.
3. Was the ordering clinician notified when a previously released result was amended? — An amendment the requesting clinician never learns about can lead to clinical decisions based on the wrong value.

STANDARD 8

Post-Examination: Reporting & Critical Values

8.1 Result Authorization Before Release

NON-NEGOTIABLE

Every result is reviewed and authorized by qualified staff before release to the requesting clinician, with the authorization step distinct from the generation of the raw instrument value and traceable to a named individual.

1. Is there a documented authorization step separate from instrument output, attributable to a specific named person? — Auto-verification rules, where used, still need a documented, validated basis — not simply every result passing through untouched.
2. Where auto-verification rules release results without manual review, are the rules themselves validated and periodically reviewed? — An auto-verification rule set that was configured once and never revisited is a specific, checkable gap.
3. Can the laboratory show, for any result selected at random, who authorized it and when? — Retrievable on request, not reconstructed from memory.

8.2 Report Content Meets a Defined Minimum

NON-NEGOTIABLE

Every report includes, at minimum, patient identification, specimen type and collection date/time, test name, result with units, reference interval, and any flag or interpretive comment needed for safe clinical use.

1. Pick a report at random — are all required elements present, not just the result value itself? — A result with no reference interval or units attached is not safely interpretable by the receiving clinician.
2. Where a result falls outside the reportable range of the method, is this clearly flagged rather than reported as an exact number? — Reporting a value beyond the validated range as if it were precise is misleading.
3. Is specimen quality that may affect interpretation — hemolysis, lipemia — noted on the report when relevant? — A clinician interpreting a result without this context may draw the wrong conclusion.

8.3 Report Delivered to the Correct Recipient

NON-NEGOTIABLE

A written procedure confirms the result report reaches the correct requesting clinician or facility, with a check in place to catch and correct misdirected reports before they reach the wrong recipient.

1. Is there a documented instance of a misdirected report being caught and corrected, demonstrating the check actually functions? — A theoretical safeguard that has never actually been tested in practice is less reassuring than one with a real catch on record.
2. For electronic delivery, is there confirmation the receiving system actually accepted the transmission, not just that it was sent? — A sent message with no delivery confirmation can silently fail.
3. Where a patient has been transferred between facilities, is there a defined process for ensuring pending results follow them? — Results pending at the time of a transfer are a well-documented point where results get lost.

8.4 Turnaround Time Monitored Against a Target

CORE

Turnaround time from specimen receipt to result release is tracked against a defined target for each major test category, reviewed periodically, with documented action when targets are consistently missed.

1. Are turnaround targets defined per test category, not one blanket figure applied regardless of complexity? — A single target applied to both a basic chemistry panel and a complex send-out test obscures real performance.

2. Is turnaround time data actually reviewed on a schedule, not just collected and left unexamined? — Data collection without review provides no operational value.
3. Where targets are consistently missed for a category, is there a documented response, not just repeated observation? — Noting the same shortfall month after month without action is not functioning monitoring.

8.5 Supplementary and Referred Test Results Tracked to Closure

CORE

Tests referred to another laboratory are tracked from referral through to receipt and reporting of the result, with a defined escalation point if the result does not return within an expected timeframe.

1. Does a log exist of all currently outstanding referred tests, with expected return dates? — Without a tracked log, a referred test can be forgotten entirely.
2. Is there a documented instance of an overdue referred result being actively followed up, not just passively awaited? — Evidence the escalation actually happens, not just exists as policy.
3. When a referred result finally arrives, does it go through the same authorization and critical-value process as an in-house result? — Referred results sometimes bypass normal review simply because they arrive through a different channel.

8.6 Cumulative/Historical Results Available at Review

CORE

Prior results for the same patient and analyte are available alongside a new result at the point of review, allowing delta-check comparison, so a clinically significant change from a patient's own baseline is not missed.

1. Is prior-result history actually visible to the person authorizing a new result, not requiring a separate manual lookup they may skip? — If accessing history takes extra deliberate effort, it will often be skipped under time pressure.
2. Does the system flag a significant delta from the patient's own prior value, not just an absolute reference-range flag? — A result that stays within the general reference range can still represent a dangerous change for a specific patient.
3. Is there a documented instance where a delta check caught a potential specimen mix-up or clinically significant change? — Evidence the check functions as a real safety mechanism, not just a theoretical feature.

8.7 Interpretive Comments Added Where Clinically Needed

STANDARD

Where a result pattern requires clinical interpretation beyond the raw numbers — an unusual combination, a known interference, a testing limitation — qualified staff add an interpretive comment to the report rather than releasing the number alone.

1. Can the laboratory show examples of interpretive comments added to reports where genuinely needed? — Not every result needs commentary, but a laboratory with zero examples ever may be under-using this practice.
2. Is there a defined list of result patterns or situations that trigger a required interpretive comment? — Without defined triggers, whether a comment gets added depends entirely on individual initiative.
3. Are interpretive comments written by staff qualified to make that clinical judgment, not added by whoever happens to be reviewing the result? — Interpretation requires a level of expertise beyond routine result authorization.

STANDARD 9

Refugee & Migrant Health

9.1 Specimen Collection Adapted to Migration and Displacement Experience

NON-NEGOTIABLE

Specimen collection is genuinely adapted to a patient's migration and displacement experience — including trauma-informed phlebotomy practice and awareness that prior experiences of detention or coercive medical procedures may affect how collection is approached — not delivered identically regardless of that history.

1. Are collection staff trained in trauma-informed practice specific to blood draw and specimen collection, not just a general cultural-awareness session? — Genuine adaptation to the collection act itself, which can be a specific trigger point.
2. Is consent for collection genuinely explained and confirmed, not assumed from the patient's presence at the appointment? — Presence at a scheduled visit is not the same as informed, freely given consent for the specific procedure.
3. Can staff recognize and appropriately respond to visible distress during collection linked to past medical trauma? — A documented, practiced response, not an assumption that staff will improvise appropriately.

9.2 Trained Interpreters, Not Family Members, for Test Explanation

NON-NEGOTIABLE

Trained interpreters or cultural mediators are engaged for language-discordant explanation of tests, collection procedures, and results — never minor children, and only family members when genuinely no other option exists and the situation is not high-risk or sensitive.

1. Is a trained interpreter actually engaged for language-discordant patients, verifiable through a usage log, not just available in policy? — Verified against actual recent use, not only the existence of an interpreter contract.
2. Is there any documented instance of a minor child being used to interpret a sensitive result? — A single such instance is a direct, serious failure of this criterion.
3. For sensitive results — infectious disease, reproductive health — is a qualified interpreter used rather than a family member, even when a family member is readily available and willing? — Availability and willingness of a family member does not substitute for a qualified, impartial interpreter on sensitive results.

9.3 No Documentation Status Barrier to Urgent Testing

NON-NEGOTIABLE

Lack of national identification, insurance documentation, or immigration status documentation never delays or blocks urgent or clinically necessary testing, and front-line staff are explicitly trained that this is the rule, not left to infer it.

1. Can front-line staff state clearly, without hesitation, that undocumented status does not block urgent testing? — Hesitation or uncertainty in the answer suggests the policy isn't genuinely embedded in practice.
2. Is there a documented instance of testing proceeding for a patient without standard documentation? — Evidence the policy functions in practice, not only on paper.
3. Is patient identity still verified through an alternative, documented method even without standard documents? — Removing the documentation barrier does not mean removing identity verification; an alternative method must still exist.

9.4 Results Explained in Plain Language, Understanding Verified

CORE

Where the laboratory communicates results directly to a patient, this is done in plain language, with understanding actively verified through methods like teach-back, not assumed from silence or a nod.

1. Is understanding actively checked using teach-back, not just "do you have any questions"? — Asking the patient to explain back what the result means, not a closed question inviting silence.
2. Are results explained without unexplained medical jargon or reference-range numbers presented with no context? — A number and a reference range alone, with no explanation, is not meaningful communication for most patients.
3. Is written material, where provided, available in the patient's own language or in plain, translated form? — Written material only in the facility's operating language is not genuinely accessible.

9.5 Records Transferable When a Patient Relocates

CORE

A patient who relocates, including across borders, can obtain a copy or transfer of their laboratory history in a usable format, without unreasonable cost or delay acting as a practical barrier.

1. Is there a documented, straightforward process for a patient to request their own laboratory history? — A process that exists but is so burdensome in practice that it functions as a barrier fails this criterion's intent.
2. Is any fee charged for this proportionate and not a practical barrier to a patient with limited means? — A fee that most displaced or low-income patients genuinely cannot afford defeats the purpose of the right to transfer.
3. Is the record provided in a format usable by a receiving facility elsewhere, not only in a proprietary format the laboratory's own system produces? — A record unusable outside the originating laboratory's own system does not genuinely support continuity.

9.6 Staff Trained on Migration-Competent Practice

CORE

Staff with direct patient contact receive specific training on migration- and displacement-competent practice — not general cultural-sensitivity training alone — covering trauma-informed collection, working with interpreters, and recognizing documentation-status barriers.

1. Does training specifically address migration and displacement contexts, distinct from generic customer-service or cultural-sensitivity content? — General cultural-awareness training alone does not cover the specific issues this standard addresses.
2. Is this training completed by all staff with direct patient contact, not only a subset? — Any staff member who collects specimens or communicates results needs this training.
3. Is the training refreshed on a schedule, not delivered once at hiring and never revisited? — A single onboarding session years ago does not keep practice current.

STANDARD 10

Radiology

10.1 Radiation Dose Optimization and Justification

NON-NEGOTIABLE

Every imaging study involving ionizing radiation is clinically justified before performing, with dose optimized to the lowest level consistent with diagnostic quality, not a default protocol applied regardless of patient size, age, or clinical indication.

1. Is clinical justification actually documented before the study is performed, not assumed from the referral order alone? — A referral placed is not the same as a documented clinical justification for that specific radiation exposure.
2. Are dose protocols adjusted for patient size and age, particularly for pediatric patients, not a single adult default applied to everyone? — A pediatric patient given an adult-dose protocol receives meaningfully excess radiation exposure.
3. Is actual delivered dose tracked and reviewable, not just the protocol setting assumed to reflect what was delivered? — Verified against actual dose records, not only the intended protocol.

10.2 Equipment Quality Assurance and Calibration

NON-NEGOTIABLE

All imaging equipment undergoes documented quality assurance testing and calibration on a defined schedule by qualified personnel, with any equipment failing to meet standards immediately removed from clinical use until corrected.

1. Is quality assurance testing actually performed on schedule, verified against real completion records, not just a schedule that exists on paper? — A testing schedule that's routinely missed is not functioning.
2. Is equipment failing quality standards immediately removed from clinical use, not kept in service while awaiting repair? — Continued use of equipment known to be out of calibration is a specific, direct patient safety risk.
3. Is testing performed by genuinely qualified personnel, verifiable through credentials, not informally by whoever is available? — Quality assurance testing requires specific technical qualification, not general staff availability.

10.3 Timely, Accurate Reporting with Critical Finding Escalation

NON-NEGOTIABLE

Imaging studies are reported within a defined time frame appropriate to clinical urgency, with a documented, genuinely functioning critical finding communication protocol ensuring an urgent result reaches the referring clinician directly, not left in a queue for routine review.

1. Is reporting turnaround time actually tracked and meeting defined targets, not assumed to be adequate? — Verified against real turnaround data, not a general sense that reports "go out quickly enough."
2. Does a critical finding trigger genuine, direct, documented communication to the referring clinician, not just entered into the standard reporting queue? — A critical finding left in a routine queue can go unnoticed for a dangerously long period.
3. Is there a documented instance of the critical finding protocol actually being used? — Evidence the protocol genuinely functions, not just exists on paper.

10.4 Contrast Media Safety Protocol

CORE

A written protocol governs contrast media use, including pre-screening for allergy and renal function, informed consent, and a documented, immediately accessible emergency response plan for a contrast reaction — not a generic allergy question treated as sufficient screening.

1. Does pre-screening genuinely cover both allergy history and renal function, not a generic "any allergies?" question alone? — Renal function specifically matters for contrast safety and is easy to overlook without a specific check.
2. Is emergency response equipment and medication for a contrast reaction immediately accessible at the point of care, not stored elsewhere requiring retrieval time? — A contrast reaction can develop rapidly; retrieval delay for emergency response equipment is a specific, direct risk, particularly relevant in a standalone diagnostic setting without on-site emergency department backup.
3. Are staff drilled on the emergency response protocol, not only given it as a reference document? — A drilled response functions differently under real stress than one only read about.

10.5 MRI Safety Screening and Zone Control

CORE

Every patient and accompanying individual is screened for MRI contraindications before entering the magnetic field, with physical zone control preventing unscreened access — not a screening form completed but not actually verified before entry.

1. Is screening genuinely verified before entry into the magnet room, not just a form completed somewhere earlier in the process? — A completed form that isn't actually checked at the point of entry

provides no real protection.

2. Does physical zone control genuinely prevent unscreened individuals from entering, not relying solely on a sign or verbal instruction? — A physical barrier or access control, not just a posted warning, is the genuine safeguard.
3. Are accompanying individuals — not just the patient — also genuinely screened? — A family member or support person entering unscreened carries the same risk as an unscreened patient.

10.6 Integration with Laboratory Results for Combined Reporting

STANDARD

Where imaging and laboratory services operate within the same facility, there is a genuine, working process for correlating relevant findings — such as a lab result that should prompt review of a related imaging report — not two services operating in complete isolation under one roof.

1. Is there a real, defined process for flagging when a laboratory result should prompt correlation with imaging, or vice versa, not left to chance? — A specific, working trigger, not an assumption that staff will happen to notice a connection.
2. Can staff describe a specific instance where this correlation process actually functioned? — Evidence the process genuinely operates, not just exists as a stated intention.
3. Are imaging and laboratory reports for the same patient genuinely accessible to each other's reporting staff, not siloed in separate systems with no cross-visibility? — Separate, non-communicating systems undermine the value of operating under one roof.

STANDARD 11

Sustainable Care

11.1 Reagent and Chemical Waste Is Genuinely Minimised, Not Accepted as Fixed

CORE

The laboratory genuinely reviews reagent and chemical consumption for opportunities to reduce waste — expired stock, over-ordering, unnecessary repeat testing — not treating reagent waste as a fixed, unexamined cost of laboratory operations.

1. Is reagent consumption genuinely reviewed for waste reduction opportunities? — A real, documented review.
2. Is expired reagent stock genuinely tracked and its cause genuinely investigated, not simply discarded and reordered? — A real, investigated pattern, not an accepted recurring cost.
3. Is there a real, documented instance of ordering practice genuinely adjusted to reduce waste? — A concrete, real example.

11.2 Energy-Intensive Equipment Use Is Genuinely Reviewed for Efficiency

STANDARD

The laboratory genuinely reviews the energy use of freezers, incubators, autoclaves, and other continuously-running equipment for efficiency opportunities — not an unexamined assumption that this equipment's real energy cost is simply unavoidable and therefore not worth genuine attention.

1. Has equipment energy use been genuinely reviewed for efficiency opportunities? — A real, documented review.
2. Where equipment consolidation or scheduling could genuinely reduce energy use without compromising sample integrity, has this been genuinely considered? — A real, considered option, with sample integrity genuinely protected throughout.
3. Is there a real, documented instance of an efficiency measure genuinely implemented? — A concrete, real example.

11.3 Cold-Chain Continuity Genuinely Balances Sample Integrity and Energy Use

STANDARD

Cold-chain and refrigeration practice genuinely balances the real, non-negotiable requirement of sample and reagent integrity with genuine attention to energy efficiency — sample integrity is never compromised, but energy use within that safe requirement is genuinely reviewed, not left unexamined on the assumption that any efficiency measure is automatically a safety risk.

1. Is cold-chain energy use genuinely reviewed within the bounds of safe sample integrity? — A real, documented review, with integrity never compromised.
2. Is refrigeration equipment genuinely maintained for efficiency, not just for function? — A real, proactive maintenance practice.
3. Is there a real, documented instance of an efficiency measure genuinely implemented without compromising integrity? — A concrete, real example.

11.4 Staff Are Genuinely Engaged in Sustainability Practice

STANDARD

Laboratory staff genuinely understand and participate in the facility's sustainability practices — not a policy known only to management with no real staff awareness or input into practical, bench-level improvements.

1. Can staff asked directly describe at least one genuine sustainability practice? — Real, demonstrated staff awareness, not a policy known only to management.
2. Is staff input genuinely sought on practical, bench-level sustainability measures? — Real, two-way engagement, drawing on staff who genuinely know the day-to-day workflow best.
3. Is there a real, documented instance of a staff suggestion genuinely implemented? — A concrete, real example.

11.5 Sustainability Commitments Are Genuinely Reviewed, Not Static

STANDARD

The laboratory's sustainability goals and practices are genuinely reviewed and updated as circumstances change — not a document written once and never genuinely examined for whether it still reflects actual practice.

1. Are sustainability goals genuinely reviewed on a real, defined schedule? — A real, periodic review.
2. Is there a real, documented instance of a goal genuinely being revised based on actual experience? — A concrete, real example.
3. Is responsibility for this review genuinely assigned to a specific person or role? — A real, named accountability.

STANDARD 12

Digital Care and Artificial Intelligence

12.1 AI-Assisted Diagnostic Tools Are Genuinely Validated Before Clinical Use

CORE

Any AI-assisted tool used in result interpretation — automated image analysis, pattern recognition in laboratory data — is genuinely validated against the laboratory's own real patient population and testing conditions before clinical use, not deployed on the strength of a vendor's general performance claims alone.

1. Is an AI-assisted diagnostic tool genuinely validated against the laboratory's own patient population before clinical use? — A real, local validation, not a vendor's general claim alone.

2. Is this validation genuinely documented, with real performance figures recorded? — A real, documented validation record.
3. Is re-validation genuinely triggered by a meaningful change in equipment, reagents, or patient population? — A real, triggered re-validation, not a one-time check assumed to remain valid indefinitely.

12.2 A Qualified Professional Genuinely Reviews Every AI-Assisted Result

CORE

Every result genuinely involving AI-assisted interpretation is genuinely reviewed by a qualified laboratory professional before release — not an automated interpretation released directly to the clinician with no real human verification step.

1. Is every AI-assisted result genuinely reviewed by a qualified professional before release? — Real, genuine human verification, not a rubber-stamp step.
2. Can the reviewing professional genuinely override or amend the AI-generated interpretation? — A real, functioning override capability.
3. Is there a real, documented instance of a professional genuinely overriding an AI-generated interpretation? — A concrete, real example demonstrating this isn't a formality.

12.3 AI-Assisted Tool Performance Is Genuinely Monitored on an Ongoing Basis

STANDARD

The accuracy of an AI-assisted diagnostic tool is genuinely monitored on an ongoing basis after deployment, with real tracking of discrepancies between AI-assisted and professional interpretation — not initial validation treated as sufficient for the tool's entire operational lifetime.

1. Is AI-assisted tool accuracy genuinely monitored on an ongoing basis after deployment? — Real, continuous monitoring, not initial validation alone.
2. Are discrepancies between AI-assisted and professional interpretation genuinely tracked? — A real, documented discrepancy log.
3. Does a genuine pattern of discrepancy trigger a real, defined response? — A real, usable escalation process.

12.4 Laboratory Staff Are Genuinely Consulted and Trained Before an AI Tool Is Introduced

STANDARD

Laboratory staff who will actually use or review AI-assisted tools are genuinely consulted before introduction, with real training on the tool's genuine limitations — not a tool deployed with staff expected to trust its output without real understanding of where and how it can genuinely be wrong.

1. Are staff genuinely consulted before a new AI tool's introduction? — Real, prior consultation.
2. Does training genuinely cover the tool's specific, known limitations, not just how to operate it? — Real, substantive training on genuine failure modes.
3. Can staff asked directly describe a genuine limitation of the AI tool they use? — Tests whether training actually conveyed real understanding, not just procedural steps.

12.5 Accountability for AI-Assisted Diagnostic Decisions Is Explicitly Defined

CORE

The laboratory has genuinely considered and documented accountability for a diagnostic decision informed by an AI-assisted tool — who is responsible when the tool is wrong — not leaving this as an unexamined question until an actual misdiagnosis forces an answer.

1. Is accountability for an AI-assisted diagnostic decision explicitly documented? — A real, clear answer.

2. Do reviewing professionals genuinely understand their own accountability when relying on AI-assisted output? — Real, demonstrated understanding.
3. Is there a defined process for reviewing accountability when an AI-assisted result contributes to a diagnostic error? — A real, usable process, not a question left entirely open until an actual error forces it.

12.6 The Ordering Clinician Is Genuinely Informed When a Result Involved AI-Assisted Interpretation

STANDARD

Where AI genuinely assisted in interpreting a diagnostic result, the ordering clinician is genuinely informed of this on or alongside the report — not left to assume every result was generated by human interpretation alone — so that the clinician can, in turn, inform the patient as part of normal clinical practice.

1. Does the report or an accompanying note genuinely indicate when AI assisted in interpreting a result? — A real, standard disclosure on or alongside the report, not an assumption the clinician will simply know.
2. Is this disclosure genuinely clear enough for the ordering clinician to pass on to the patient in plain terms? — A real, usable note, not technical language only a specialist would understand.
3. Can an ordering clinician asked directly confirm they genuinely noticed and understood this disclosure on a recent report? — A real, concrete confirmation.

STANDARD 13

Supporting the Care Workforce

13.1 A Quality or Safety Concern Can Genuinely Be Raised Without Fear of Reprisal

CORE

A genuine, protected process exists for staff to raise a quality or safety concern — including about a colleague's work, a systemic process failure, or pressure to cut corners under turnaround-time demands — with real protection from adverse treatment, not a reporting line that exists on paper with no real, demonstrated protection.

1. Is there a genuine, accessible process for staff to raise a quality or safety concern? — A real, known process.
2. Are staff genuinely protected from adverse treatment when raising a concern, including about a colleague? — Real, demonstrated protection.
3. Is there a real, documented instance of a raised concern genuinely leading to a real investigation and resolution? — Genuine follow-through, not a process untested in practice.

13.2 Occupational Health Monitoring Is Genuinely Specific to Real Laboratory Exposure Risks

CORE

Occupational health monitoring genuinely addresses the real exposure risks specific to laboratory work — biological, chemical, and radiation exposure where applicable — not a generic workplace health policy applied unchanged with no genuine attention to these real, setting-specific risks.

1. Does occupational health monitoring genuinely address real laboratory-specific exposure risks? — A real, setting-specific monitoring programme.
2. Is exposure monitoring genuinely conducted on a real, defined schedule for at-risk staff? — Real, periodic monitoring, not a one-time baseline assumed to remain valid.
3. Is there a real, defined response when monitoring genuinely identifies an exposure concern? — A genuine corrective process.

13.3 Turnaround-Time Pressure Is Genuinely Monitored for Its Real Effect on Staff Wellbeing

STANDARD

The laboratory genuinely monitors the real wellbeing effect of sustained turnaround-time pressure on staff — not treating this pressure as an unexamined, fixed cost of laboratory operations with no genuine attention to its real toll on the people managing it.

1. Does the laboratory genuinely consider the wellbeing effect of sustained turnaround-time pressure? — A real, considered attention to this specific pressure.
2. Are genuine, regular check-ins conducted that go beyond throughput metrics? — Real, human contact, not performance review alone.
3. Can staff describe a real instance where this genuinely made a difference? — A real, concrete example.

13.4 Staff Have Genuine Access to Ongoing Education Beyond Mandatory Competence Reassessment

STANDARD

Every staff member has genuine access to ongoing professional education beyond the mandatory competence reassessment covered under Standard 3 — not education treated as complete once minimum regulatory requirements are met, with no real opportunity for broader professional development.

1. Does every staff member have genuine, ongoing access to education beyond mandatory reassessment? — Real, continuing access.
2. Can staff asked directly describe a genuine education opportunity taken in the past year? — A real, specific example.
3. Is this access genuinely equitable across shifts, including night and weekend staff? — Real, equitable access, not education opportunities that genuinely only reach day-shift staff.

13.5 Staff Feedback Is Genuinely Gathered and Acted On

STANDARD

The laboratory has a genuine, systematic approach to gathering feedback from its staff, with real analysis and a genuine, implemented response — not feedback collected occasionally with no real pattern of actual improvement.

1. Is staff feedback genuinely gathered on a systematic, recurring basis? — Real, ongoing collection.
2. Is collected feedback genuinely analysed for trends? — A real, documented analysis process.
3. Is there a documented instance where feedback genuinely led to an implemented change? — A real, concrete example.

13.6 Equality, Diversity and Inclusion Across the Workforce Are Genuinely Monitored

STANDARD

The organisation genuinely monitors and responds to real patterns of equity across recruitment, work allocation, scheduling, and promotion — not an assumption that fair treatment exists simply because no formal complaint has been raised.

1. Is workforce data on recruitment, work allocation, scheduling, and promotion genuinely monitored for patterns of inequity? — A real, documented monitoring process, not an assumption that fairness exists by default.
2. Where a genuine pattern is identified, is there a real, defined response? — A genuine corrective process, not data collected with no real follow-through.
3. Is there a real, documented instance of this monitoring genuinely informing a change in practice? — A concrete, real example.