

Laboratory Standards — Full Guidance

Complete criterion-by-criterion guidance: worked examples, first steps, common mistakes, implementation plans, and Monitor verification methods for all 64 criteria.

10 standards · 64 criteria · Version 2.0

Standard 6 — Pre-Examination: Specimen Pathway

8 criteria · 4 non-negotiable · 3 core · 1 standard-level · Version 1.0

CRITERIA IN THIS STANDARD

- 6.1 — Two-Identifier Patient Verification
- 6.2 — Specimen Labeled at the Point of Collection
- 6.3 — Rejection Criteria, Applied Consistently
- 6.4 — Transport Conditions Preserve Specimen Integrity
- 6.5 — Chain of Custody for Forensic or Legal Specimens
- 6.6 — Specimen Accessioning Logged in Real Time
- 6.7 — Urgent/STAT Specimens Prioritized and Tracked
- 6.8 — Specimen Retention Before Discard

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.

In plain terms: The collector genuinely confirms who the patient is, using two real identifiers, every single time — not a quick glance or a question nobody actually waits to hear answered properly.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Patient misidentification at collection is one of the most consequential, entirely preventable errors a laboratory can make — a specimen correctly processed but drawn from the wrong patient produces a result that is perfectly accurate for someone else’s blood and dangerously wrong for the patient it’s reported against. The failure is rarely dramatic; it is usually a rushed, routine moment where a name is spoken as a statement rather than genuinely confirmed.

WHAT GOOD LOOKS LIKE

- Two genuine identifiers are actively checked, every time.
- Room or bed number is never used as one of the identifiers.
- A real, documented alternative exists for patients who cannot verbally confirm identity.

COMMON FAILURE MODES

- A name is stated and the patient’s silence or nod is treated as confirmation.
- Room number is used as a de facto second identifier.
- No defined process exists for unconscious or language-barrier patients.

WORKED EXAMPLE

IN PRACTICE	
<i>A busy outpatient phlebotomy station during a morning rush.</i>	
BEFORE	A phlebotomist called out “Maria Chikviladze?” to the waiting room, a patient stood up, and collection proceeded without any further confirmation — the call-out itself was treated as sufficient identification.
ACTION	The laboratory retrained all collection staff on active two-identifier verification — asking the

patient to state their own full name and date of birth, rather than confirming a name spoken by staff — and built this specifically into the collection SOP with a required verbal script.

AFTER

The Monitor observed three live collections and confirmed each phlebotomist asked the patient to state their own name and date of birth rather than confirming a name spoken aloud by staff.
Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Observe actual collections today — is verification active or passive?
2. Build a required verbal script asking patients to state their own identifiers.
3. Define a specific alternative process for patients who cannot verbally respond.

The most common mistake: Calling out a patient's name and treating their response to being called as identity confirmation, rather than actively asking the patient to state their own identifiers.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Direct observation during survey

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.*

Evidence: Collection SOP, direct observation

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.*

Evidence: Written alternative identification procedure

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.*

Evidence: Staff interview

COMMON REASONS FOR A PARTIAL ANSWER

- **Verification happens but is passive — confirming a stated name rather than asking the patient to state it.**
- **No written alternative exists for patients who can't verbally respond.**

IMPLEMENTATION PLAN

When	What
Week 1	Observe current collection practice for active versus passive verification.
Week 2	Build a required verbal script and retrain collection staff.
Week 3	Write the alternative procedure for non-verbal patients.
Ongoing	Spot-check live collections periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Live collection observation	Directly observes collections to confirm active, two-identifier verification is genuinely performed.

EVIDENCE BASE

World Health Organization. Patient Identification. Patient Safety Solutions, Volume 1, Solution 2. Geneva: WHO; 2007.

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.2.6. Geneva: ISO; 2022.

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.

In plain terms: The label goes on the tube right there, with the patient still present — never later, from memory, after moving on to someone else.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Delayed or batch labeling is one of the most well-documented, preventable causes of specimen mix-up in laboratory medicine. Even a short delay across two or three patients collected in quick succession creates a real window for confusion — tubes look alike, memory is fallible under time pressure, and the consequence of a mix-up is a result reported under the wrong patient's name.

WHAT GOOD LOOKS LIKE

- Labeling is observed happening at bedside or chairside, before moving on.
- No workflow exists where multiple specimens are collected before any labeling.
- Labels carry enough information for independent re-verification.

COMMON FAILURE MODES

- Pre-printed labels are applied later, away from the patient.
- Several specimens are collected in sequence before any are labeled.
- Labels carry only a name, with no date/time or second identifier.

WORKED EXAMPLE

IN PRACTICE

A home-visit phlebotomy service collecting from several patients in one morning route.

BEFORE	The phlebotomist collected specimens from three patients in a row during a home visit route, planning to label all three once back in the vehicle using a pre-written list — a workflow that had developed informally for efficiency.
ACTION	The laboratory introduced a hard rule, specifically addressing the home-visit workflow: no specimen moves to the next patient's door until the current specimen is fully labeled, in the current patient's presence.
AFTER	The Monitor accompanied a home-visit collection route and confirmed each specimen was labeled before the phlebotomist left each patient's home. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether any current workflow allows multiple collections before labeling.
2. Build an explicit rule: label before moving on, no exceptions, including off-site collection.
3. Check label content includes enough information for independent verification.

The most common mistake: Off-site or multi-patient collection routes developing an informal batch-labeling workflow for efficiency, specifically because the point-of-collection labeling rule wasn't explicitly extended to those situations.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Direct observation

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.*

Evidence: Workflow review, including off-site collection

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.*
Evidence: Label content review

COMMON REASONS FOR A PARTIAL ANSWER

- In-facility labeling is correct, but off-site or home-visit collection has a separate, uncontrolled workflow.
- Labels carry a name but lack a second identifier or timestamp.

IMPLEMENTATION PLAN

When	What
Week 1	Review all collection workflows, including off-site, for labeling timing.
Week 2	Build an explicit point-of-collection labeling rule covering every workflow.
Week 3	Retrain all collection staff, including off-site teams.
Ongoing	Spot-check labeling practice periodically, including off-site visits.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Live collection observation	Observes the actual timing of specimen labeling relative to collection and patient departure.

EVIDENCE BASE

Clinical and Laboratory Standards Institute. GP33-A: Accuracy in Patient and Sample Identification. Wayne (PA): CLSI; 2010.

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.

In plain terms: A bad specimen gets rejected every time, by the same rules — even when it was hard to get, and even when someone’s pushing for a fast result.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Rejection criteria exist precisely because certain specimen conditions make a result unreliable regardless of how urgently it’s needed or how difficult the specimen was to collect. The moment exceptions begin — “just this once, the patient was a hard draw” — the criteria stop functioning as genuine safeguards and become guidelines applied only when convenient, which defeats their purpose entirely.

WHAT GOOD LOOKS LIKE

- Staff can describe rejection criteria without needing to look them up.
- A documented instance exists of rejection holding despite clinical pressure.
- Rejections are logged with reason and communicated to the requesting clinician.

COMMON FAILURE MODES

- Criteria exist on paper but staff don’t actually know them.
- Difficult-to-obtain specimens are quietly accepted despite not meeting criteria.
- Rejected specimens are silently discarded with no clinician notification.

WORKED EXAMPLE

IN PRACTICE

A pediatric blood draw that was genuinely difficult to obtain.

BEFORE

A hemolyzed specimen from a difficult pediatric draw was processed anyway, because the collecting nurse explained how hard it had been to get and the requesting physician wanted results urgently, with no formal exception process — just an informal decision to proceed.

ACTION	The laboratory reinforced with all staff that rejection criteria apply regardless of collection difficulty, with a clear process for the requesting clinician to be notified immediately so a recollection could be arranged without delay, rather than compromising the result.
AFTER	The Monitor found a documented instance of a similarly difficult specimen being correctly rejected, with prompt clinician notification and recollection arranged. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Confirm written rejection criteria exist and staff can describe them unprompted.
2. Check recent records for any instance of criteria being bypassed under pressure.
3. Build a fast notification process so rejection doesn't feel like it's only causing delay.

The most common mistake: Making a quiet, informal exception specifically for specimens that were difficult to obtain, treating the collection effort as a reason to lower the quality bar.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Staff interview

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.*

Evidence: Rejection log

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.*

Evidence: Rejection log with clinician notification record

COMMON REASONS FOR A PARTIAL ANSWER

- Criteria are applied inconsistently for difficult-to-obtain specimens.
- Rejections happen but aren’t consistently communicated back to clinicians.

IMPLEMENTATION PLAN

When	What
Week 1	Confirm written rejection criteria are current and complete.
Week 2	Brief all staff and reinforce no-exception application.
Week 3	Build a fast clinician notification process for rejections.
Ongoing	Review rejection log periodically for consistency.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
ASK	Staff knowledge check	Asks staff to describe rejection criteria without reference material.
DOCUMENT	Rejection log review	Reviews rejection log entries for consistency and clinician notification.

EVIDENCE BASE

Clinical and Laboratory Standards Institute. GP44-A4: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture. Wayne (PA): CLSI; 2017.

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.

In plain terms: Specimens that need special handling during transport actually get it, verified — not just assumed because a cooler bag was used.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

An insulated transport container is a tool, not a guarantee — without actual verification, a cooler bag left in a hot vehicle for an extended period can still fail to maintain required temperature, and nobody would know unless conditions are genuinely checked rather than assumed from the equipment used. Time-sensitive analytes are particularly vulnerable to this gap, since degradation can occur without any visible sign in the specimen itself.

WHAT GOOD LOOKS LIKE

- Transport temperature is actually verified, not assumed from container type.
- Time from collection to receipt is tracked for time-sensitive analytes.
- Out-of-condition specimens have a documented effect on interpretation or rejection.

COMMON FAILURE MODES

- An insulated bag is used with no actual temperature verification.
- No timestamp exists at both collection and receipt for time-sensitive tests.
- A noted condition breach has no consequence for how the result is used.

WORKED EXAMPLE

IN PRACTICE

A referred specimen requiring cold-chain transport from a satellite clinic.

BEFORE

Specimens were transported in a standard insulated cooler bag with no actual temperature verification — the bag itself was assumed sufficient regardless of ambient conditions or transport duration, which varied considerably by season.

ACTION	The laboratory introduced a temperature logger inside the transport container, checked on arrival against the required range, with any out-of-range arrival triggering a documented impact assessment before the specimen was processed.
AFTER	The Monitor reviewed recent transport logger records and found consistent within-range results, with one documented summer excursion that triggered the correct impact assessment and specimen rejection. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Identify every specimen type with specific transport requirements.
2. Introduce actual temperature verification, not just an insulated container.
3. Add collection and receipt timestamps for time-sensitive analytes.

The most common mistake: Treating the use of an insulated transport container as equivalent to verified temperature control, without ever actually checking the temperature achieved.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Transport temperature log

2. Is time from collection to receipt tracked for time-sensitive analytes? — *Without a timestamp at both ends, a transport delay goes undetected.*

Evidence: Collection and receipt timestamps

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.*

Evidence: Impact assessment record

COMMON REASONS FOR A PARTIAL ANSWER

- A cooler or insulated bag is used but temperature is never actually checked.
- Timestamps exist at collection but not at receipt, or vice versa.

IMPLEMENTATION PLAN

When	What
Week 1	Identify transport-sensitive specimen types and their requirements.
Week 2	Introduce temperature logging in transport containers.
Week 3	Add collection/receipt timestamping where missing.
Ongoing	Review transport condition logs periodically for trends.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Transport log review	Reviews temperature logging and timestamp records for transported specimens.

EVIDENCE BASE

Clinical and Laboratory Standards Institute. GP44-A4: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture. Wayne (PA): CLSI; 2017.

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.

In plain terms: For legally sensitive specimens, there’s a complete paper trail showing exactly who had the specimen and when, with no gaps, from start to finish.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Where applicable	Where applicable	Where applicable

WHY THIS MATTERS

A single gap anywhere in a chain-of-custody record — a handoff with no signature, a storage period with no logged access control — can undermine the legal validity of the specimen and its result entirely, regardless of how carefully every other step was handled. This is a case where a process that is otherwise rigorous but incomplete in just one link fails the whole purpose of the requirement.

WHAT GOOD LOOKS LIKE

- Every transfer point requires a signature, with no gaps.
- Chain-of-custody specimens are physically secured differently from routine ones.
- Staff receive training specific to chain-of-custody requirements.

COMMON FAILURE MODES

- Some transfer points are signed, others informally skipped.
- Specimens sit in the same open rack as routine specimens.
- Staff apply routine handling training to chain-of-custody specimens by default.

WORKED EXAMPLE

IN PRACTICE

A laboratory processing an occasional forensic toxicology specimen.

BEFORE

A chain-of-custody form existed and was generally used, but internal transfers between the receiving desk and the testing bench were handled informally without a signature, since staff considered it “all within the same building.”

ACTION

The laboratory required signature at every single handoff point, including internal transfers, and introduced locked, separate storage specifically for chain-of-custody specimens with access logged.

AFTER

The Monitor reviewed the most recent chain-of-custody record and found an unbroken signature chain including internal transfers, with no gap anywhere from collection to final disposition. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Map every handoff point a chain-of-custody specimen passes through, including internal ones.
2. Check for any point currently missing a signature requirement.
3. Set up separate, secured storage for these specimens.

The most common mistake: Treating internal transfers within the same building as not needing formal chain-of-custody signature, when any gap — internal or external — breaks the chain.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Chain-of-custody form

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.*

Evidence: Secure storage inspection

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.*

Evidence: Chain-of-custody-specific training record

COMMON REASONS FOR A PARTIAL ANSWER

- External transfers are signed but internal transfers are skipped.
- No separate secure storage exists for these specimens.

IMPLEMENTATION PLAN

When	What
Week 1	Map all handoff points including internal transfers.

When	What
Week 2	Close any signature gaps found.
Week 3	Establish separate secure storage and specific staff training.
Ongoing	Audit chain-of-custody records for completeness on every case.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Chain-of-custody record review	Reviews a recent custody record for an unbroken chain of signatures at every transfer point.

EVIDENCE BASE

Clinical and Laboratory Standards Institute. GP19-A2: Laboratory Instruments and Data Management Systems. Wayne (PA): CLSI; 2009.



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.

In plain terms: When a specimen actually arrives, that moment gets logged right then — the timestamp isn’t quietly adjusted to look tidier later.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

An accessioning timestamp that mysteriously always matches the expected collection time, with no natural variation, is a signal of backdating rather than genuine real-time logging — and it distorts

every downstream turnaround-time metric built on that timestamp, hiding exactly the delays the laboratory most needs visibility into to improve its own process.

WHAT GOOD LOOKS LIKE • Accessioning timestamp reflects genuine receipt time, with natural variation. • No meaningful backlog of unaccessioned specimens exists. • Any record can be retrieved immediately for a selected specimen.	COMMON FAILURE MODES • Timestamps are manually entered to match the requested collection time. • A backlog of specimens sits unaccessioned during busy periods. • Records require reconstruction rather than immediate retrieval.
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WORKED EXAMPLE

IN PRACTICE <i>A laboratory reviewing its accessioning practice during peak morning volume.</i>	
BEFORE	During the morning rush, specimens were physically received and set aside to be logged later once volume slowed, with staff manually entering a receipt time that approximated when they believed the specimen had actually arrived.
ACTION	The laboratory introduced barcode scanning at the point of physical receipt, automatically timestamping the moment a specimen entered the building, removing manual entry from the process entirely.
AFTER	The Monitor cross-checked accessioning timestamps against an independent courier log for several specimens and found consistent, genuine correlation rather than suspiciously exact matches to collection time. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether current accessioning timestamps show natural variation or suspiciously always match collection time.
2. Consider automated scanning at the point of physical receipt if currently manual.
3. Check for any backlog of unaccessioned specimens right now.

The most common mistake: Manually backdating accessioning timestamps during busy periods to make turnaround-time metrics look better than the actual process achieved.

SELF-ASSESSMENT QUESTIONS

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.*
Evidence: Timestamp cross-check against courier or transport log
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.*
Evidence: Accessioning backlog check
3. Can the laboratory produce the accessioning record for any specimen the Monitor selects, on request? — *Immediately retrievable, not reconstructed after the fact.*
Evidence: Live record retrieval

COMMON REASONS FOR A PARTIAL ANSWER

- **Manual entry during busy periods introduces inaccurate timestamps.**
- **A regular backlog exists during predictable peak volume times.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current accessioning timestamp accuracy.
Week 2	Consider automated scanning if accuracy is a genuine issue.
Week 3	Address any identified backlog pattern during peak periods.

When	What
Ongoing	Periodically cross-check timestamps against an independent record.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Timestamp cross-check	Compares accessioning timestamps against an independent record for genuine correlation.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.2.7. Geneva: ISO; 2022.

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.

In plain terms: STAT specimens genuinely jump the queue, in a way that actually changes how fast they get processed — not just a sticker that doesn’t change anything.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A STAT flag that doesn’t genuinely change a specimen’s position in the processing queue is worse than no flag at all — it creates false confidence among requesting clinicians that urgency is being honored, when in practice nothing operational has changed. Real STAT

prioritization requires both a physical or digital mechanism that actually alters processing order and ongoing tracking to confirm it's working as intended.

WHAT GOOD LOOKS LIKE • A visible flagging system genuinely changes processing priority. • STAT turnaround time is actually tracked against a defined target. • Missed STAT targets are logged and reviewed as quality events.	COMMON FAILURE MODES • A “STAT” label exists but doesn’t change actual queue position. • Turnaround time is tracked for routine specimens but not specifically for STAT. • Missed STAT targets go unreviewed with no follow-up.
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WORKED EXAMPLE

IN PRACTICE <i>A chemistry section receiving a mix of routine and urgent specimens throughout the day.</i>	
BEFORE	STAT specimens were marked with a colored sticker, but were placed in the same processing queue as routine specimens in the order received, with the sticker serving only as a visual note rather than actually changing processing sequence.
ACTION	The laboratory introduced a dedicated STAT processing lane with its own tracking, a defined turnaround target of thirty minutes, and monthly review of actual performance against that target.
AFTER	The Monitor reviewed recent STAT turnaround data showing consistent performance against the thirty-minute target, with one documented miss that had triggered a logged review. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your current STAT flag actually changes processing order in practice.
2. Set a specific, defined STAT turnaround-time target.
3. Build a tracking and review mechanism for STAT performance.

The most common mistake: Using a visual flag for urgent specimens that signals urgency to staff but doesn't actually change the specimen's position in the processing sequence.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Observed prioritization in practice

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.*

Evidence: STAT turnaround data

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.*

Evidence: Quality event log

COMMON REASONS FOR A PARTIAL ANSWER

- A flagging system exists but doesn't genuinely alter processing order.
- Turnaround is tracked but missed targets aren't reviewed.

IMPLEMENTATION PLAN

When	What
Week 1	Observe whether current STAT flagging actually changes processing order.
Week 2	Set a specific turnaround target and build genuine prioritization.
Week 3	Build tracking and a review process for missed targets.
Ongoing	Review STAT performance monthly.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Processing flow observation	Observes whether a flagged STAT specimen genuinely moves ahead in actual processing order.

EVIDENCE BASE

Clinical and Laboratory Standards Institute. GP27-A2: Using Proficiency Testing to Improve the Clinical Laboratory. Wayne (PA): CLSI; 2007.

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.

In plain terms: Tested specimens are kept around for a sensible amount of time afterward, so a repeat test can happen without making the patient come back.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Different analytes genuinely have different stability profiles, which means a single blanket retention period applied regardless of test type will be either unnecessarily long for some specimens or too short for others. Retention that's genuinely matched to each test's real needs, with storage conditions that preserve the specimen appropriately, is what actually makes repeat testing possible rather than only theoretically available.

WHAT GOOD LOOKS LIKE

- A written schedule varies retention period genuinely by test type.
- Storage conditions actually match what each

COMMON FAILURE MODES

- One blanket retention period is applied regardless of analyte stability.

retained specimen requires.

- A specific retained specimen can genuinely be located and retrieved.

- Retained specimens are stored in conditions that don't match their requirements.
- Retention exists in policy but retrieval in practice proves difficult.

WORKED EXAMPLE

IN PRACTICE

A chemistry section with a single generic retention policy.

BEFORE

All specimens were retained for a flat seven days regardless of test type, with no distinction between genuinely stable analytes and those that degrade much faster, and retained specimens were stored in a general refrigerator without specific condition matching.

ACTION

The laboratory built a test-type-specific retention schedule based on actual analyte stability data, with appropriately matched storage conditions for each category.

AFTER

The Monitor requested retrieval of a specimen from several days prior and the laboratory located and retrieved it within its stated retention window, stored under the correct condition for its test type. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your current retention period is genuinely analyte-appropriate, not one blanket figure.
2. Confirm storage conditions actually match what each retained specimen type needs.
3. Test retrieval of a specific older retained specimen.

The most common mistake: Applying one convenient, blanket retention period to all specimen types regardless of how differently they actually degrade over time.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Test-specific retention schedule

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.*

Evidence: Storage condition inspection

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.*

Evidence: Retrieval test

COMMON REASONS FOR A PARTIAL ANSWER

- **A single retention period is applied regardless of analyte-specific stability.**
- **Retrieval in practice is slower or less reliable than the policy implies.**

IMPLEMENTATION PLAN

When	What
Week 1	Review analyte-specific stability data for major test types.
Week 2	Build a test-type-specific retention schedule.
Week 3	Match storage conditions to each retention category.
Ongoing	Test retrieval periodically to confirm practical reliability.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
ASK	Retrieval test	Requests retrieval of a specific retained specimen and times the result.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.2.10. Geneva: ISO; 2022.

← **Laboratory Standards —**
all standards

Standard 7 — Examination:
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ASF STANDARDS · LABORATORY · STANDARD 7

Standard 7 — Examination: Process & Safety

8 criteria · 6 non-negotiable · 2 core · Version 1.0

CRITERIA IN THIS STANDARD

- 7.1 — Method Validation Before Clinical Use
- 7.2 — Internal Quality Control Run Before Patient Results Released
- 7.3 — External Quality Assessment Participation
- 7.4 — Critical Value Communication, Verified Received
- 7.5 — Personal Protective Equipment, Available and Used
- 7.6 — Exposure Incident: Documented Response Protocol
- 7.7 — Information System Access Controlled and Logged
- 7.8 — Result Amendment Traceable to Original

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.

In plain terms: Every test method was properly checked and proven to work correctly before it was ever used on a real patient — not after, as paperwork catching up.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Validation completed after a method is already in clinical use defeats its entire purpose — the point is to confirm a method works correctly before any patient result depends on it, not to retroactively document that it probably worked. A validation date that falls after the method's first recorded clinical use is a clear, specific signal that paperwork was assembled to satisfy a review rather than to genuinely protect patients.

WHAT GOOD LOOKS LIKE

- Validation completion predates first clinical use, verifiably.
- Manufacturer data is locally verified, not relied on alone.
- Reference intervals match the laboratory's actual patient population.

COMMON FAILURE MODES

- Validation paperwork is dated after clinical use already began.
- Manufacturer insert data is used without any local verification.
- Reference intervals are copied wholesale without population relevance review.

WORKED EXAMPLE

IN PRACTICE

A laboratory introducing a new point-of-care glucose method.

BEFORE

A new point-of-care device was deployed to a clinic site and used clinically for several weeks before the central laboratory got around to completing formal validation documentation, which was assembled retrospectively using data gathered after clinical use had already begun.

ACTION	The laboratory instituted a hard rule: no new method or device goes into clinical use anywhere, including satellite sites, until validation is complete and formally signed off by the quality manager.
AFTER	The Monitor reviewed the most recently introduced method and found validation completion dated eleven days before its first recorded clinical use. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull validation records for your most recently introduced method and check the dates.
2. Confirm manufacturer data has been locally verified, not simply adopted.
3. Check reference intervals against your own patient population's characteristics.

The most common mistake: Deploying a new method to a satellite or point-of-care site quickly, with formal validation documentation only catching up afterward because the central laboratory's usual process didn't extend to that location in practice.

SELF-ASSESSMENT QUESTIONS

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.

Evidence: Validation record with completion date

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.*

Evidence: Local verification record

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.

Evidence: Reference interval verification record

COMMON REASONS FOR A PARTIAL ANSWER

- **Satellite or point-of-care deployments bypass the central validation process.**
- **Reference intervals are adopted wholesale without population review.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit recent method introductions for validation-before-use dating.
Week 2	Build a hard rule extending to every site, including satellite locations.
Week 3	Review reference intervals for population appropriateness.
Ongoing	Require validation sign-off before any new method deployment, anywhere.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Validation date cross-check	Compares validation completion date against first recorded clinical use date.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.3.2. Geneva: ISO; 2022.

Clinical and Laboratory Standards Institute. EP15-A3: User Verification of Precision and Estimation of Bias. Wayne (PA): CLSI; 2014.

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.

In plain terms: Quality control gets checked and approved first, before any real patient results from that same run go out — every single time, no exceptions.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Releasing patient results before confirming quality control is acceptable inverts the entire purpose of quality control — the check exists specifically to catch a problem before it reaches a patient, and releasing first removes that protection entirely. This failure mode often emerges not from carelessness but from workflow pressure, where results are queued for release automatically while quality control review happens “in parallel” rather than strictly first.

WHAT GOOD LOOKS LIKE

- No instance exists of results released before quality control review.
- A real, tested response procedure exists for quality control failure.
- Quality control frequency is justified, not just minimized.

COMMON FAILURE MODES

- Automated systems release results before a human confirms quality control passed.
- A written failure-response procedure exists but has never actually been followed in practice.
- Quality control frequency is set at the bare minimum with no documented justification.

WORKED EXAMPLE

IN PRACTICE

A chemistry analyzer with automated result release configured by default.

BEFORE	The laboratory information system's default configuration released patient results automatically as they were generated, with quality control results reviewed separately afterward by a technologist, rather than release being gated on prior quality control confirmation.
ACTION	The quality manager reconfigured the system so result release is explicitly held pending confirmed quality control acceptance for that specific run, closing the gap between generation and gated release.
AFTER	The Monitor reviewed system configuration and recent run logs and found no instance of results released ahead of quality control confirmation. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check your actual system configuration — is release truly gated on quality control, or just reviewed in parallel?
2. Test your quality control failure response procedure for real, don't just read it.
3. Document the justification for your current quality control frequency.

The most common mistake: Assuming that reviewing quality control “shortly after” result release is equivalent to reviewing it before release, when the sequence itself is what protects the patient.

SELF-ASSESSMENT QUESTIONS

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.*
Evidence: System configuration and release logs
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.
Evidence: Quality control failure response record

- 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.*
Evidence: Frequency justification document

COMMON REASONS FOR A PARTIAL ANSWER

- **Automated release isn't genuinely gated on prior quality control confirmation.**
- **The failure-response procedure exists but has never actually been exercised.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit system configuration for true release-gating on quality control.
Week 2	Reconfigure if a gap is found.
Week 3	Document quality control frequency justification.
Ongoing	Periodically audit for any release-before-review instance.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Configuration and log audit	Checks system configuration and historical logs for any release-before-review instance.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.3.5. Geneva: ISO; 2022.

Westgard JO. Basic QC Practices, 4th ed. Madison (WI): Westgard QC; 2016.

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.

In plain terms: The lab proves to an outside party, regularly, that it’s actually getting results right — not just trusting its own internal checks.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Internal quality control confirms consistency within a laboratory’s own system, but it cannot reveal a systematic bias shared across that entire system — external quality assessment is specifically designed to catch exactly that blind spot by comparing results against an independent, external benchmark. A discipline quietly excluded from participation, often simply because it’s smaller or newer than the laboratory’s main services, loses this safeguard entirely without anyone necessarily deciding that deliberately.

WHAT GOOD LOOKS LIKE

- Every operated discipline with an available scheme is currently enrolled.
- Results are genuinely reviewed by the accountable person, not just filed.
- Unsatisfactory performance triggers a real, documented investigation.

COMMON FAILURE MODES

- A newer or smaller discipline was never enrolled in a scheme at all.
- Certificates are filed without genuine review of the underlying performance.
- An unsatisfactory result has no documented follow-up.

WORKED EXAMPLE

IN PRACTICE

A laboratory that recently added a small coagulation testing service.

BEFORE	The laboratory's established chemistry and hematology sections were enrolled in external quality assessment, but the recently added coagulation service, run by just one technologist, had never been enrolled — nobody had specifically added it when the service launched.
ACTION	The quality manager built a checklist requiring external quality assessment enrollment as a mandatory step before any new testing discipline launches, and immediately enrolled the coagulation service.
AFTER	The Monitor confirmed current, active enrollment across every operated discipline, including the recently added coagulation service, with documented review of the most recent round's results. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every testing discipline currently operated, including smaller or newer ones.
2. Check enrollment status for each against available schemes.
3. Enroll any gaps found immediately.

The most common mistake: A newer or smaller testing service launches without external quality assessment enrollment being explicitly built into the launch checklist, simply falling through the cracks of an otherwise solid program.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Enrollment records

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.*

Evidence: Review sign-off record

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.*

Evidence: Investigation record

COMMON REASONS FOR A PARTIAL ANSWER

- **A newer discipline was never formally enrolled.**
- **Certificates are filed but genuine review isn't documented.**

IMPLEMENTATION PLAN

When	What
Week 1	List all operated disciplines and check enrollment status.
Week 2	Enroll any gaps found.
Week 3	Build a mandatory enrollment step into new-service launch checklists.
Ongoing	Review every round's results with the accountable person.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Enrollment and review check	Verifies current enrollment for every operated discipline and checks for documented result review.

EVIDENCE BASE

International Organization for Standardization. ISO/IEC 17043:2023, Conformity assessment — General requirements for the competence of proficiency testing providers. Geneva: ISO; 2023.

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.3.6. Geneva: ISO; 2022.

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.

In plain terms: A genuinely dangerous result reaches a real clinician, directly, fast — and the lab actually confirms it landed, not just that a call was attempted.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A critical value left on voicemail or sent through a channel with no delivery confirmation can sit unseen for hours, during which exactly the urgent clinical response the alert was meant to trigger never happens. The read-back verification step — having the receiving clinician repeat the value back — exists specifically because verbal communication under time pressure is genuinely error-prone, and this is the step most often skipped when staff are busy.

WHAT GOOD LOOKS LIKE

- A written list defines exactly what counts as a critical value, per analyte.
- Communication logs show genuine read-back verification, not just a call attempt.
- A defined escalation path exists for a failed first contact attempt.

COMMON FAILURE MODES

- “Critical” is left to individual judgment with no written definition.
- A voicemail is left and treated as communication complete.
- No escalation path exists if the first call attempt isn’t answered.

WORKED EXAMPLE

IN PRACTICE

A critical potassium result identified late in the evening shift.

BEFORE	The technologist called the ordering physician's listed number, reached voicemail, left a message describing the result, and logged the call as "critical value communicated" with no further action, since the call itself had been attempted.
ACTION	The laboratory built a formal escalation procedure requiring a second and third contact attempt through alternative channels, including the covering physician or charge nurse, if the first attempt isn't answered within a defined window, with read-back verification required at whatever point contact is made.
AFTER	The Monitor reviewed the communication log for a recent critical value and found a documented read-back verification with the responding clinician, completed within the required window. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Confirm a written critical value list exists for your major analytes.
2. Check whether your communication log shows read-back verification or just call attempts.
3. Build a defined escalation path for failed first contact.

The most common mistake: Treating a voicemail message as completed critical value communication, when the entire point of the requirement is confirmed, verified receipt by a responsible clinician.

SELF-ASSESSMENT QUESTIONS

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.

Evidence: Written critical value list

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.*

Evidence: Communication log with read-back record

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.*

Evidence: Escalation procedure

COMMON REASONS FOR A PARTIAL ANSWER

- **Voicemail is treated as sufficient communication.**
- **No escalation path exists for a failed first attempt.**

IMPLEMENTATION PLAN

When	What
Week 1	Confirm or build a written critical value list.
Week 2	Build a required read-back verification step into the communication log.
Week 3	Build and brief staff on an escalation path for failed contact.
Ongoing	Audit critical value logs for genuine read-back completion.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Communication log review	Reviews recent critical value communications for read-back verification and timely resolution.

EVIDENCE BASE

World Health Organization. Communication During Patient Hand-Over. Patient Safety Solutions, Volume 1, Solution 3. Geneva: WHO; 2007.

College of American Pathologists. Critical Values/Critical Results Reporting. Northfield (IL): CAP; 2021.

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.

In plain terms: The right protective gear isn't just sitting somewhere in the lab — it's right there where it's needed, and staff actually wear it, genuinely, even when busy.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

PPE compliance is one of the most well-documented gaps between written policy and actual practice — availability alone says nothing about use, and self-reported compliance is notoriously unreliable since staff know the expected answer. Direct observation during an actual, unannounced moment of bench work is the only way to genuinely assess whether PPE use is a real habit or a policy that exists mainly on paper.

WHAT GOOD LOOKS LIKE

- PPE is actually observed worn correctly during real bench work.
- PPE is physically located at the point of use, not requiring a trip to retrieve.
- Any stockout is logged as a safety event, not quietly absorbed.

COMMON FAILURE MODES

- PPE is available but not consistently worn under time pressure.
- PPE is stored somewhere inconvenient, discouraging use.
- Stockouts happen occasionally and go unrecorded.

WORKED EXAMPLE

IN PRACTICE

A busy microbiology bench during a high-volume morning.

BEFORE	Gloves and eye protection were stored in a supply cabinet at the far end of the room. During a high-volume morning, several staff members worked without eye protection because retrieving it from across the room felt disruptive to workflow.
ACTION	The laboratory relocated PPE supplies directly to each bench station, eliminating the retrieval friction, and the supervisor began conducting brief, unannounced compliance spot-checks during actual peak periods.
AFTER	The Monitor observed bench work during a genuinely busy period and found consistent, correct PPE use across all observed staff. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Observe actual bench work during a busy period, not a calm one.
2. Check PPE's physical location relative to each workstation.
3. Relocate supplies if retrieval friction is discouraging use.

The most common mistake: Storing PPE in a central supply location rather than directly at each point of use, creating just enough friction that compliance quietly drops during busy periods.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Direct observation, ideally unannounced

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.

Evidence: Bench inspection

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.*
Evidence: Safety event log

COMMON REASONS FOR A PARTIAL ANSWER

- **PPE is available but located too far from actual point of use.**
- **Compliance drops specifically during high-volume periods.**

IMPLEMENTATION PLAN

When	What
Week 1	Observe actual PPE use during a genuinely busy period.
Week 2	Relocate PPE supplies to each point of use if friction is found.
Week 3	Build a stockout logging mechanism.
Ongoing	Conduct periodic unannounced compliance spot-checks.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Bench work observation	Directly observes actual bench work, ideally during a busy period, for genuine PPE compliance.

EVIDENCE BASE

World Health Organization. Laboratory biosafety manual, 4th ed. Geneva: WHO; 2020.

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.

In plain terms: If someone has an actual exposure incident, there's a real, known plan everyone can follow immediately — not a document to go find and read for the first time in that moment.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

The first minutes after a biological exposure incident genuinely matter for post-exposure outcomes, and this is precisely the moment staff have the least capacity to calmly look up and read an unfamiliar procedure from scratch. A protocol that exists only as a document, without having been actively taught or drilled, functions very differently in theory than it does during the stress of a real event.

WHAT GOOD LOOKS LIKE

- Staff can describe the first steps without needing to consult a document.
- A recent actual incident's response genuinely matched the written protocol.
- Post-exposure medical follow-up is a real, responsive arrangement.

COMMON FAILURE MODES

- Staff know a protocol exists but can't describe its actual first steps.
- The referenced occupational health service doesn't respond promptly when called.
- The protocol has never been drilled, only distributed as a document.

WORKED EXAMPLE

IN PRACTICE

A laboratory reviewing readiness after a near-miss sharps incident.

BEFORE

A written exposure protocol existed in the laboratory's policy manual, but when asked, several staff members could not describe its first steps and had never actually practiced it, having

	only read it once during initial onboarding years earlier.
ACTION	The laboratory conducted a tabletop drill walking through an actual exposure scenario step by step, confirmed the referenced occupational health service's actual response time by testing it directly, and posted a simplified quick-reference card at each bench.
AFTER	The Monitor asked two staff members to describe the first steps of the exposure protocol without reference material, and both answered correctly and confidently. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Ask two or three staff members right now to describe the exposure protocol's first steps.
2. Test your referenced occupational health service's actual response time.
3. Consider a quick-reference card at each bench, not just a policy manual entry.

The most common mistake: Treating onboarding-stage reading of the exposure protocol as sufficient preparation, with no refresher or drill ever repeated afterward.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Staff interview

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.*

Evidence: Incident record or drill record

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.

Evidence: Occupational health service responsiveness check

COMMON REASONS FOR A PARTIAL ANSWER

- **Staff read the protocol once at onboarding and never again.**
- **The occupational health referral exists on paper but hasn't been tested for real responsiveness.**

IMPLEMENTATION PLAN

When	What
Week 1	Ask current staff to describe the protocol's first steps.
Week 2	Conduct a tabletop drill and test occupational health responsiveness.
Week 3	Post a quick-reference card at each bench.
Ongoing	Refresh training periodically, not only at onboarding.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
ASK	Staff knowledge check	Asks staff to describe the protocol's first steps without reference material.

EVIDENCE BASE

World Health Organization. Laboratory biosafety manual, 4th ed. Geneva: WHO; 2020.

Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures. MMWR Recomm Rep. 2013;62(RR-10):1-19.

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.

In plain terms: Every person has their own login, not a shared one — and what each person can see or change in the system actually matches what their role genuinely needs.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A shared generic login makes it fundamentally impossible to answer “who actually did this” when a question arises about a specific data access or change — the accountability that individual credentials provide isn’t a bureaucratic nicety, it’s the only mechanism that makes any later investigation of an error or concern possible at all. Over-broad access permissions compound this risk by giving more staff than necessary the ability to alter released results.

WHAT GOOD LOOKS LIKE

- Every staff member has individual, non-shared credentials.
- Access levels genuinely differ by role, restricting amendment permission appropriately.
- The access log is actually reviewed periodically, not just generated.

COMMON FAILURE MODES

- A shared generic login is used for convenience, especially on shared terminals.
- Every staff member has full edit access regardless of actual role need.
- The access log exists technically but nobody ever reviews it.

WORKED EXAMPLE

IN PRACTICE

A shared terminal used by multiple rotating phlebotomists.

BEFORE

A single generic “phlebotomy” login was used on the shared terminal for convenience, since rotating staff found individual logins slower during busy periods, making it impossible to determine

	which specific staff member performed any given accessioning action.
ACTION	The laboratory implemented individual badge-swipe login specifically designed to be fast enough not to disrupt workflow, eliminating the convenience justification for shared credentials.
AFTER	The Monitor reviewed system access logs and confirmed every action traced to an individual, identifiable staff member with no shared login in use. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether any shared or generic logins are currently in use.
2. Review access levels against actual role requirements.
3. Schedule a periodic access log review if none currently happens.

The most common mistake: A shared login persisting specifically on a busy, multi-user terminal because individual login felt too slow, without exploring a faster individual-login method like badge swipe.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: System credential audit

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.*

Evidence: Access level configuration

3. Is the access log actually reviewed periodically, not just generated and left unexamined? — *A log nobody reviews provides no real oversight.*

Evidence: Log review record

COMMON REASONS FOR A PARTIAL ANSWER

- Shared logins persist on busy, multi-user terminals.
- Access logs exist but are never actually reviewed.

IMPLEMENTATION PLAN

When	What
Week 1	Audit current login practice for any shared credentials.
Week 2	Implement individual credentials, including fast methods like badge swipe where needed.
Week 3	Review and correct access levels by role.
Ongoing	Review access logs on a fixed schedule.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Credential and access audit	Checks for individual, non-shared credentials and reviews access level assignments.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.3.9. Geneva: ISO; 2022.

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.

In plain terms: If a result gets corrected after release, you can still see what it originally said, what it was changed to, why, and by whom — nothing just quietly disappears.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

An overwritten original value removes the ability to understand what actually happened — whether the original was a transcription error, an instrument malfunction, or something more concerning, and whether a clinician may have already acted on the incorrect original value. Full traceability, including notification to the ordering clinician, is what allows both internal quality review and appropriate downstream clinical correction.

WHAT GOOD LOOKS LIKE • The original value remains visible alongside any amendment, never deleted. • Every amendment shows a documented reason and who made it. • The ordering clinician is notified when a previously released result is amended.	COMMON FAILURE MODES • The original value is overwritten with no trace remaining. • An amendment exists but with no documented reason attached. • The ordering clinician never learns the result they already saw was amended.
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WORKED EXAMPLE

IN PRACTICE	
<i>A transcription error discovered after result release.</i>	
BEFORE	A manually entered result was found to contain a transcription error the day after release. The value was corrected directly in the system, overwriting the original, with no notification sent to the ordering physician who had already seen and potentially acted on the incorrect value.
ACTION	The laboratory configured the system to preserve amended values as an addition rather than an overwrite, visible alongside the original with reason and amender name, and built a mandatory clinician notification step for any amendment to a previously released result.
AFTER	The Monitor selected a recent amendment and found the original value still visible, a documented

reason, and a recorded clinician notification.
Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check your system configuration — does amendment overwrite or preserve the original?
2. Build a mandatory reason field for any amendment.
3. Build a required clinician notification step for amendments to released results.

The most common mistake: Correcting an error directly by overwriting the original value, treating the correction itself as the priority while overlooking that the ordering clinician already saw and may have acted on the wrong value.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Amendment record

2. Does the amendment record show who made the change and why? — *An amendment with no attributed reason undermines confidence in the correction itself.*

Evidence: Amendment reason and attribution

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.*

Evidence: Clinician notification record

COMMON REASONS FOR A PARTIAL ANSWER

- **System configuration overwrites rather than preserves the original.**
- **Clinician notification isn't consistently completed for amendments.**

IMPLEMENTATION PLAN

When	What
Week 1	Check system configuration for amendment preservation versus overwrite.
Week 2	Reconfigure if the original is currently overwritten.
Week 3	Build a mandatory clinician notification step.
Ongoing	Audit amendment records periodically for completeness.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Amendment record review	Selects an amended result and verifies original preservation, documented reason, and clinician notification.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.4.4. Geneva: ISO; 2022.

← Laboratory Standards — all standards

Standard 8 — Post-Examination: Reporting & Critical Values →

ASF STANDARDS · LABORATORY · STANDARD 8

Standard 8 — Post-Examination: Reporting & Critical Values

7 criteria · 3 non-negotiable · 3 core · 1 standard-level · Version 1.0

CRITERIA IN THIS STANDARD

- 8.1 — Result Authorization Before Release
- 8.2 — Report Content Meets a Defined Minimum
- 8.3 — Report Delivered to the Correct Recipient
- 8.4 — Turnaround Time Monitored Against a Target
- 8.5 — Supplementary and Referred Test Results Tracked to Closure
- 8.6 — Cumulative/Historical Results Available at Review
- 8.7 — Interpretive Comments Added Where Clinically Needed

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.

In plain terms: A real, qualified person actually reviews and approves every result before it goes out — that approval is a genuine, separate step, not just the instrument spitting out a number.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

An instrument generating a numeric output is not the same as a qualified authorization decision — the review step is what catches an unflagged specimen quality issue, an implausible value given the patient’s clinical context, or a pattern suggesting instrument malfunction that the raw number alone wouldn’t reveal. Auto-verification rules can legitimately handle routine, predictable results, but only when the rules themselves were deliberately validated and are periodically revisited, not simply left running indefinitely since initial configuration.

WHAT GOOD LOOKS LIKE

- Authorization is a distinct, attributable step separate from instrument output.
- Auto-verification rules, where used, are validated and periodically reviewed.
- Any result’s authorizer and timing is retrievable on request.

COMMON FAILURE MODES

- Results pass through with no real human review step.
- Auto-verification rules were configured once and never revisited.
- No clear record exists of who authorized a specific result.

WORKED EXAMPLE

IN PRACTICE

A chemistry section with auto-verification enabled for routine panels.

BEFORE

Auto-verification rules had been configured three years earlier when the analyzer was first installed and had never been reviewed since, despite the laboratory’s patient population and test menu having changed meaningfully over that period.

ACTION	The quality manager scheduled an annual review of auto-verification rule performance, comparing auto-released results against a manual review sample to confirm the rules were still appropriately calibrated.
AFTER	The Monitor reviewed the auto-verification rule set and found a documented annual review history with the most recent review completed within the past year. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check when your auto-verification rules, if used, were last reviewed.
2. Confirm you can trace any specific result to its named authorizer.
3. Schedule a periodic review if none currently exists.

The most common mistake: Configuring auto-verification rules once at system setup and treating them as permanently correct, without revisiting them as the laboratory's actual patient population or test menu evolves.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Authorization record

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.*

Evidence: Auto-verification rule review history

3. Can the laboratory show, for any result selected at random, who authorized it and when? — *Retrievable on request, not reconstructed from memory.*

Evidence: Live record retrieval

COMMON REASONS FOR A PARTIAL ANSWER

- Auto-verification rules exist but haven’t been reviewed since initial setup.
- Manual authorization happens but isn’t clearly attributed to a named individual.

IMPLEMENTATION PLAN

When	What
Week 1	Audit current authorization practice and any auto-verification rules.
Week 2	Schedule a review of auto-verification rules if overdue.
Week 3	Confirm clear attribution exists for every authorization.
Ongoing	Review auto-verification rules annually or whenever test menu changes.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Authorization record check	Selects a result at random and verifies authorizer attribution and timing.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.4.1. Geneva: ISO; 2022.

Clinical and Laboratory Standards Institute. AUTO10-A: Autoverification of Clinical Laboratory Test Results. Wayne (PA): CLSI; 2006.

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.

In plain terms: Every report has everything a clinician actually needs to correctly understand a result — not just the number by itself.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A number without units, a reference interval, or context about specimen quality is not genuinely interpretable, regardless of how accurate the underlying measurement was — report completeness is what converts a correct analytical result into something a clinician can safely act on. Gaps here are often subtle, a reference interval occasionally missing from certain report templates, rather than a complete absence of structure.

WHAT GOOD LOOKS LIKE

- Every required element is present, not just the result value.
- Out-of-range values are clearly flagged, not reported as falsely precise.
- Specimen quality issues affecting interpretation are noted when relevant.

COMMON FAILURE MODES

- A reference interval is missing from a specific report template.
- A value beyond reportable range is shown as an exact number with no flag.
- Specimen quality issues go unnoted even when they could affect interpretation.

WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory auditing its various report templates across test categories.</i>	
BEFORE	Most report templates included all required elements, but a recently added point-of-care test's report template, built quickly during service launch, omitted the reference interval entirely.
ACTION	The quality manager built a standard report-template checklist covering all required elements, applied it retroactively to every existing template,

	and made the checklist a mandatory step for any future new test launch.
AFTER	The Monitor selected reports at random across several test categories and found every required element present consistently. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull sample reports from every test category you offer.
2. Check each against the full required element list.
3. Fix any template gaps found, especially newer or less-used templates.

The most common mistake: A newer test category's report template, built quickly during service launch, misses an element that older, more established templates include by default.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Sample report review

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.*

Evidence: Out-of-range result example

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.*

Evidence: Specimen quality flag example

COMMON REASONS FOR A PARTIAL ANSWER

- A newer or less common test category's template is missing an element.
- Out-of-range flagging isn't consistently applied.

IMPLEMENTATION PLAN

When	What
Week 1	Audit all report templates against the required element checklist.
Week 2	Fix any templates found missing elements.
Week 3	Build the checklist into any future new-test launch process.
Ongoing	Re-audit templates periodically, especially after system updates.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Report content review	Reviews sample reports across test categories for required element completeness.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.4.1. Geneva: ISO; 2022.
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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.
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In plain terms: There’s a real safety net catching reports that might go to the wrong place, not just hope that the system always routes correctly.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A correct result delivered to the wrong clinician is, from the patient's perspective, functionally equivalent to no result at all — the clinician who actually needs to act on it never sees it, while the recipient who received it by mistake has no reason to act on information that isn't theirs to interpret. A misdirection-catching safeguard that has never actually caught anything is less reassuring than one with a genuine, documented catch demonstrating it functions in practice.

WHAT GOOD LOOKS LIKE

- A real, documented instance exists of a misdirected report being caught and fixed.
- Electronic delivery includes actual confirmation of receipt, not just transmission.
- A defined process exists for pending results following a transferred patient.

COMMON FAILURE MODES

- A theoretical safeguard exists but has never actually been tested.
- Electronic delivery is treated as successful once sent, with no receipt confirmation.
- Results pending at patient transfer silently fail to follow the patient.

WORKED EXAMPLE

IN PRACTICE

A referring clinic network with multiple similarly named practitioners.

BEFORE

Two physicians with similar surnames occasionally had results confused in the electronic routing system. The laboratory was unaware this had ever happened until a physician called asking why she'd received a result for a patient she didn't recognize.

ACTION

The laboratory built a secondary verification step specifically for similarly named recipients, cross-checking against the ordering clinician's unique provider identifier rather than name alone, and logged the earlier catch as a formal nonconformance with corrective action.

AFTER

The Monitor reviewed the nonconformance record and the resulting corrective action, confirming the verification step had since prevented any further similar incidents. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your delivery process confirms actual receipt, not just transmission.
2. Identify any recipient name-collision risks in your routing system.
3. Build a specific process for pending results following a patient transfer.

The most common mistake: Assuming electronic transmission success is equivalent to delivery confirmation, when a sent message can fail silently without the sender ever knowing.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Nonconformance 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.*

Evidence: Delivery confirmation log

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.*

Evidence: Transfer process documentation

COMMON REASONS FOR A PARTIAL ANSWER

- **No verification process exists for similarly named recipients.**
- **Pending results at patient transfer have no defined follow-through process.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit delivery confirmation practice for electronic routing.
Week 2	Identify and address any recipient name-collision risks.
Week 3	Build a pending-results-at-transfer process.
Ongoing	Log any misdirection catch as a formal nonconformance.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Delivery and nonconformance review	Checks for delivery confirmation records and any documented misdirection catch.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.4.3. Geneva: ISO; 2022.
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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.

In plain terms: The lab actually tracks how long each type of test takes and reviews whether it’s meeting real targets — and does something about it when it isn’t.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A single blanket turnaround target applied across wildly different test complexities obscures genuine performance — a basic chemistry panel and a complex send-out test have fundamentally different realistic timelines, and measuring both against one figure makes neither number meaningful. Data collected but never actually reviewed provides no operational value at all; the review step is where turnaround problems actually get identified and addressed.

WHAT GOOD LOOKS LIKE • Targets are defined per test category, reflecting genuine complexity differences. • Turnaround data is actually reviewed on a schedule. • Consistent target misses trigger a documented response, not just observation.	COMMON FAILURE MODES • One blanket target is applied regardless of test complexity. • Data is collected but sits unreviewed. • The same shortfall is noted repeatedly with no action taken.
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WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory tracking turnaround across a mixed test menu.</i>	
BEFORE	A single sixty-minute turnaround target was applied to all tests, from simple basic chemistry to complex send-out panels, making the metric essentially meaningless since complex tests routinely and unavoidably exceeded it while simple tests had no real stretch target at all.
ACTION	The quality manager built category-specific targets reflecting genuine achievable timelines, with monthly review meetings specifically examining any category consistently missing its target.
AFTER	The Monitor reviewed the past six months of category-specific turnaround data and found one category with a documented, implemented

response to a consistent shortfall. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your current targets are category-specific or one blanket figure.
2. Build realistic, test-specific targets if needed.
3. Schedule a genuine periodic review, not just data collection.

The most common mistake: Applying one convenient, round-number turnaround target across the entire test menu, which makes the metric meaningless for both the fastest and slowest test categories.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Category-specific target documentation

2. Is turnaround time data actually reviewed on a schedule, not just collected and left unexamined? — *Data collection without review provides no operational value.*

Evidence: Review meeting records

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.*

Evidence: Response action record

COMMON REASONS FOR A PARTIAL ANSWER

- **Targets exist but aren't genuinely category-specific.**
- **Reviews happen but produce no documented action.**

IMPLEMENTATION PLAN

When	What
Week 1	Build category-specific turnaround targets.
Week 2	Set up tracking by category if not already in place.

When	What
Week 3	Schedule the first formal review meeting.
Ongoing	Document action whenever a category consistently misses target.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Turnaround data and review record check	Reviews category-specific turnaround targets and any response to consistent misses.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.4.1. Geneva: ISO; 2022.

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.

In plain terms: A test sent out to another lab doesn’t just disappear from view — it’s actively tracked until the result actually comes back and gets reported.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A referred test exists in a genuine accountability gap — it has physically left the laboratory’s own systems, but the requesting clinician still expects the result to come from this laboratory. Without an active tracking log, a referred test can be forgotten entirely, with

nobody specifically responsible for noticing it never came back, since it isn't visible in the laboratory's own routine workflow the way in-house tests are.

WHAT GOOD LOOKS LIKE • A log of all currently outstanding referred tests exists with expected return dates. • Overdue referred results are actively followed up, not passively awaited. • Referred results go through the same authorization and critical-value process on arrival.	COMMON FAILURE MODES • No tracked log exists; referred tests are simply awaited informally. • An overdue result is noticed only when the clinician calls asking about it. • Referred results bypass normal authorization because they arrive differently.
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WORKED EXAMPLE

IN PRACTICE <i>A referred specialized hormone panel sent to an external reference laboratory.</i>	
BEFORE	Referred tests were tracked informally by whichever staff member had sent the specimen, with no central log. A referred test was forgotten for three weeks until the requesting physician called asking why no result had come back.
ACTION	The laboratory built a central referred-test log with expected return dates based on the reference laboratory's stated turnaround, with a weekly review flagging anything overdue for active follow-up.
AFTER	The Monitor reviewed the central log and found a recent instance of an overdue result being actively followed up within two days of its expected return date, before any clinician inquiry prompted it. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Build a single central log of all currently outstanding referred tests.
2. Set expected return dates based on reference laboratory turnaround data.
3. Schedule a regular review to flag anything overdue.

The most common mistake: Relying on individual staff memory to track referred tests informally, rather than a central log that doesn't depend on any one person remembering.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Referred test log

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.*

Evidence: Follow-up record

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.*

Evidence: Referred result authorization record

COMMON REASONS FOR A PARTIAL ANSWER

- Tracking relies on informal staff memory rather than a central log.
- Referred results bypass the normal authorization workflow.

IMPLEMENTATION PLAN

When	What
Week 1	Build a central log of all currently outstanding referred tests.
Week 2	Set expected return dates and a review schedule.
Week 3	Confirm referred results route through standard authorization.
Ongoing	Review the log weekly for overdue items.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Referred test log review	Reviews the central log for completeness and checks for proactive overdue follow-up.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.6.3. Geneva: ISO; 2022.

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.

In plain terms: Whoever reviews a result can easily see the patient’s own past results right alongside it — so a meaningful change from their personal baseline doesn’t get missed.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A result that falls entirely within the general population reference range can still represent a dangerous change for a specific patient — a significant drop in hemoglobin, for instance, might still land within the broad normal range while representing genuine, active bleeding for that particular person. Delta checking against the patient’s own history catches exactly this category of risk, but only if prior results are genuinely visible without requiring extra deliberate effort that gets skipped under time pressure.

WHAT GOOD LOOKS LIKE

COMMON FAILURE MODES

- Prior history is visible automatically at review, no separate lookup required.
 - The system flags a significant delta from the patient's own baseline.
 - A documented instance exists where a delta check caught a genuine issue.
- History requires a separate manual lookup, easily skipped under pressure.
 - Only absolute reference-range flags exist, with no patient-specific delta check.
 - No example exists of the delta check ever actually catching something.

WORKED EXAMPLE

IN PRACTICE

A hematology result reviewed during a routine authorization workflow.

BEFORE	Prior patient results were accessible but required navigating to a separate screen, a step reviewing technologists frequently skipped during busy periods since the current result fell within the general reference range and appeared unremarkable on its own.
ACTION	The laboratory reconfigured the system to display the three most recent prior results automatically alongside any new result at the review screen, with an automatic flag for any analyte showing a significant percentage change from the immediately prior value.
AFTER	The Monitor reviewed a recent case where the delta flag had caught a significant hemoglobin drop that remained within the general reference range, triggering a clinician call that led to timely identification of active bleeding. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether prior results require a separate lookup or display automatically.
2. If display requires extra effort, work with your system to make it automatic.

3. Build a delta-flag mechanism if one doesn't currently exist.

The most common mistake: Having prior-result history technically accessible but requiring an extra deliberate step to view it, which busy staff predictably skip for results that otherwise appear unremarkable.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Review screen configuration

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.*

Evidence: Delta-flag configuration

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.*

Evidence: Delta-check catch record

COMMON REASONS FOR A PARTIAL ANSWER

- **History is technically available but requires an extra, skippable lookup step.**
- **No real delta-flag mechanism exists beyond absolute reference ranges.**

IMPLEMENTATION PLAN

When	What
Week 1	Check current review-screen history visibility.
Week 2	Work with your system provider to automate history display if needed.
Week 3	Build or confirm a delta-flag mechanism.
Ongoing	Document any instance where the delta check catches a genuine issue.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Review workflow observation	Observes the actual review screen to confirm prior-result visibility without extra steps.

EVIDENCE BASE

Clinical and Laboratory Standards Institute. EP33: Use of Delta Checks in the Medical Laboratory. Wayne (PA): CLSI; 2016.

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.

In plain terms: When a result genuinely needs extra context to be understood correctly, a qualified person adds that context to the report — not just leaving the clinician with a bare number.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Certain result patterns carry meaning that isn’t obvious from the number alone — a known assay interference, an unusual combination suggesting a specific condition, a testing limitation relevant to the specific clinical question. A laboratory that never adds interpretive comments, treating every result as self-explanatory, may be under-using a genuinely valuable tool for improving the clinical usefulness of its reports, particularly for less common or more complex findings.

WHAT GOOD LOOKS LIKE

- Examples exist of interpretive comments

COMMON FAILURE MODES

- No interpretive comments are ever added, even

genuinely added where needed.

- A defined list identifies which situations trigger a required comment.
- Comments are written by staff qualified to make the specific clinical judgment.

where clearly warranted.

- Whether a comment gets added depends entirely on individual staff initiative.
- Comments are added by staff without the relevant clinical qualification.

WORKED EXAMPLE

IN PRACTICE

A laboratory reviewing its use of interpretive commenting over the past year.

BEFORE

Interpretive comments were occasionally added by individual technologists when they personally noticed something warranting explanation, with no defined list of triggering situations and significant variation in practice between staff members.

ACTION

The laboratory built a defined list of specific result patterns requiring a mandatory interpretive comment, with comments restricted to staff holding the appropriate qualification to make that specific clinical judgment.

AFTER

The Monitor reviewed recent reports matching the defined trigger list and found consistent, appropriately qualified interpretive commenting applied. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check your recent reports for any history of interpretive comments at all.
2. Build a defined list of situations that should trigger a comment.
3. Confirm who is actually qualified to write them.

The most common mistake: Leaving interpretive commenting entirely to individual staff initiative with no defined trigger list,

resulting in significant inconsistency in when and whether comments actually get added.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Sample report with interpretive comment

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.*

Evidence: Defined trigger list

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.*

Evidence: Comment authorization record

COMMON REASONS FOR A PARTIAL ANSWER

- **No defined trigger list exists; practice depends on individual initiative.**
- **Comments are occasionally added by staff without the relevant qualification.**

IMPLEMENTATION PLAN

When	What
Week 1	Review recent reports for interpretive comment practice.
Week 2	Build a defined trigger list for required comments.
Week 3	Confirm and restrict comment-writing to appropriately qualified staff.
Ongoing	Review comment consistency periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Interpretive comment review	Reviews sample reports against the trigger list for consistent, appropriately qualified commenting.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.4.1. Geneva: ISO; 2022.

← Laboratory Standards — all standards

Standard 9 — Refugee & Migrant Health →

Standard 9 — Refugee & Migrant Health

6 criteria · 3 non-negotiable · 3 core · Version 1.0

CRITERIA IN THIS STANDARD

- 9.1 — Specimen Collection Adapted to Migration and Displacement Experience
- 9.2 — Trained Interpreters, Not Family Members, for Test Explanation
- 9.3 — No Documentation Status Barrier to Urgent Testing
- 9.4 — Results Explained in Plain Language, Understanding Verified
- 9.5 — Records Transferable When a Patient Relocates
- 9.6 — Staff Trained on Migration-Competent Practice

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.

In plain terms: Collection staff genuinely understand that for some patients, a blood draw can trigger real trauma from past experiences — and they adjust how they approach it, not just proceed as usual.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

For a patient with a history of detention or coercive medical procedures, a routine blood draw can trigger genuine, significant distress that generic phlebotomy training doesn't prepare staff to recognize or respond to appropriately. Treating every patient identically, rather than being attentive to signals that someone may need a different, more carefully explained approach, can turn a routine procedure into a re-traumatizing experience that also undermines future willingness to seek care.

WHAT GOOD LOOKS LIKE

- Collection staff receive training specific to trauma-informed phlebotomy.
- Consent for collection is genuinely explained and confirmed, not assumed.
- Staff can recognize and appropriately respond to visible distress during collection.

COMMON FAILURE MODES

- Training covers only general cultural awareness, not collection-specific trauma response.
- Consent is assumed from the patient's presence at the scheduled appointment.
- Staff proceed with collection despite visible patient distress, unsure how to respond.

WORKED EXAMPLE

IN PRACTICE

A community clinic laboratory serving a significant refugee population.

BEFORE

A phlebotomist proceeded with a routine blood draw on a patient who became visibly distressed and withdrew his arm partway through, and the phlebotomist, uncertain how to respond, simply

	tried to continue more quickly rather than pausing.
ACTION	The laboratory introduced specific trauma-informed collection training covering recognition of distress signals, the importance of pausing and explaining each step before proceeding, and the patient's right to stop the procedure at any point.
AFTER	The Monitor reviewed the training curriculum and confirmed it specifically addressed collection-related trauma response, distinct from general cultural awareness content, and confirmed completion records for current collection staff. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether current staff training addresses collection-specific trauma response, not just general cultural awareness.
2. Build or source specific trauma-informed phlebotomy training.
3. Establish a clear, known process for pausing collection if distress is observed.

The most common mistake: Treating general cultural-sensitivity training as sufficient, when it typically doesn't address the specific, practical response needed when a patient shows distress during an actual blood draw.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Training curriculum and completion records

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.

Evidence: Direct observation

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.

Evidence: Staff interview, training record

COMMON REASONS FOR A PARTIAL ANSWER

- Training exists but is general cultural awareness, not collection-specific.
- Consent is implicitly assumed rather than actively confirmed each time.

IMPLEMENTATION PLAN

When	What
Week 1	Review current training content for collection-specific trauma coverage.
Week 2	Source or build specific trauma-informed collection training.
Week 3	Train all current collection staff and establish a pause process.
Ongoing	Include this training in onboarding for all new collection staff.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Training content review	Reviews training curriculum for collection-specific trauma-informed content, distinct from general awareness training.

EVIDENCE BASE

World Health Organization. Health of refugees and migrants: regional situation analysis, practices, experiences, lessons learned and ways forward. Geneva: WHO; 2018.

World Health Organization Regional Office for Europe. Global Competency Standards for Refugee and Migrant Health. Copenhagen: WHO/Europe; 2024.

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.

In plain terms: When a patient doesn't share a language with staff, a real trained interpreter explains things — never a child, and a family member only as a genuine last resort for low-risk situations.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Using a minor child to interpret sensitive medical information places an inappropriate burden on that child and can produce inaccurate or incomplete interpretation at exactly the moment accuracy matters most. Family member interpretation, even from willing adults, introduces real risks for sensitive results — a patient may not disclose or fully understand a reproductive health or infectious disease finding honestly through a relative, and the family member's own emotional involvement can distort what gets communicated.

WHAT GOOD LOOKS LIKE

- A trained interpreter is actually used, verifiable through a usage log.
- No instance exists of a minor child interpreting a sensitive result.
- Sensitive results specifically use a qualified

COMMON FAILURE MODES

- An interpreter contract exists but is rarely actually used in practice.
- A child accompanying a parent is used informally to interpret.
- A willing, available family member is used even for sensitive results.

interpreter, not a willing family member.

WORKED EXAMPLE

IN PRACTICE

A laboratory explaining a sensitive infectious disease result to a language-discordant patient.

BEFORE

The patient had arrived with her teenage son, who spoke the local language fluently from school. Staff, under time pressure and without easy access to the contracted interpreter service, asked the son to interpret the sensitive result directly.

ACTION

The laboratory invested in a faster-access phone interpreter line specifically to remove the time-pressure justification for informal interpretation, and explicitly trained staff that minors are never used to interpret, regardless of apparent fluency or convenience.

AFTER

The Monitor reviewed the interpreter usage log and found consistent use of the professional phone interpreter service for sensitive results, with no documented instance of minor interpretation since the change. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check your interpreter usage log — is it actually being used, or bypassed under time pressure?
2. If access is slow, consider a faster-access phone or video interpreter line.
3. Explicitly brief all staff that minors are never used to interpret, regardless of convenience.

The most common mistake: Using an available child or family member specifically when the contracted interpreter service feels too slow or inconvenient to access in the moment, rather than treating interpreter access as non-negotiable.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Interpreter usage log

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.*

Evidence: Incident review, staff interview

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.*

Evidence: Sensitive result interpreter usage record

COMMON REASONS FOR A PARTIAL ANSWER

- **An interpreter service exists but is slow to access, encouraging informal workarounds.**
- **Family members are used for sensitive results when “readily available.”**

IMPLEMENTATION PLAN

When	What
Week 1	Review current interpreter access speed and usage patterns.
Week 2	Improve access speed if delays are driving informal workarounds.
Week 3	Brief all staff explicitly on the no-minors, sensitive-results-require-professional-interpreter rules.
Ongoing	Review interpreter usage logs periodically for consistency.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Interpreter usage log review	Reviews the usage log for actual, consistent interpreter engagement, particularly for sensitive results.

EVIDENCE BASE

World Health Organization Regional Office for Europe. Global Competency Standards for Refugee and Migrant Health. Copenhagen: WHO/Europe; 2024.

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.

In plain terms: Not having the “right” papers never stops someone from getting an urgent test — and staff know this rule clearly, not just as something they’re left to guess at.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

An undocumented or underdocumented patient facing urgent clinical need cannot afford administrative delay, yet front-line staff who are never explicitly told this policy may default to the cautious, delay-causing choice of insisting on standard documentation first, simply because nobody told them clearly that urgent testing takes priority. The gap between a written policy existing somewhere and front-line staff genuinely, confidently knowing and applying it in the moment is exactly where this criterion is most often only partially met.

WHAT GOOD LOOKS LIKE

- Front-line staff state the rule clearly, without hesitation, when asked.
- A documented instance exists of testing proceeding without standard documentation.
- An alternative identity verification method is actually used, not simply skipped.

COMMON FAILURE MODES

- Staff hesitate or seem unsure when asked about the policy directly.
- No real example exists of the policy being applied in an actual situation.
- Removing documentation requirements also inadvertently removes any identity verification at all.

WORKED EXAMPLE

IN PRACTICE

A clinic laboratory receiving an urgent test request for an undocumented patient.

BEFORE

A written policy existed stating documentation status should never delay urgent testing, but front-line reception staff had never been specifically briefed on it and, when an undocumented patient arrived needing urgent testing, hesitated and asked a supervisor before proceeding, causing a meaningful delay.

ACTION

The laboratory explicitly briefed all front-line staff on the policy, built a simple alternative identity verification method using a name, date of birth, and photograph taken at the point of care, and ran a tabletop scenario to confirm staff understood the process.

AFTER

The Monitor asked front-line staff directly about the policy and received clear, confident, correct answers, and reviewed a recent documented instance of urgent testing proceeding without standard documentation. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Ask front-line staff directly, right now, what happens if an undocumented patient needs urgent testing.
2. If the answer is hesitant or unclear, brief staff explicitly on the policy.
3. Build a simple alternative identity verification method.

The most common mistake: A correct, well-intentioned policy exists in writing but was never explicitly communicated to the front-line staff who actually encounter the situation, leaving them to default to caution and delay when the policy actually requires the opposite.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Staff interview

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.*

Evidence: Case record

3. Is patient identity still verified through an alternative, documented method even without standard documentation? — *Removing the documentation barrier does not mean removing identity verification; an alternative method must still exist.*

Evidence: Alternative identification procedure

COMMON REASONS FOR A PARTIAL ANSWER

- The policy exists in writing but front-line staff were never explicitly briefed.
- No alternative identity verification method exists once standard documentation is waived.

IMPLEMENTATION PLAN

When	What
Week 1	Ask front-line staff directly about the current policy understanding.
Week 2	Brief staff explicitly if any hesitation or gap is found.

When	What
Week 3	Build an alternative identity verification method.
Ongoing	Include this explicitly in onboarding for all front-line staff.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
ASK	Front-line staff interview	Asks front-line staff directly, without prompting, what happens when an undocumented patient needs urgent testing.

EVIDENCE BASE

World Health Organization. Health of refugees and migrants: regional situation analysis, practices, experiences, lessons learned and ways forward. Geneva: WHO; 2018.

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.

In plain terms: When a patient gets their results explained directly, it's in genuinely plain language — and staff actually check the patient understood, rather than assuming from a nod.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Where applicable	Where applicable	Where applicable

WHY THIS MATTERS

A patient's silence or nod during a results explanation is frequently a signal of politeness, deference, or simple confusion rather than genuine comprehension, particularly across language and cultural

differences where a patient may feel it's inappropriate to admit not understanding. Teach-back — asking the patient to explain the result back in their own words — is a specific, evidence-based technique precisely because it tests comprehension directly rather than relying on an ambiguous social cue.

WHAT GOOD LOOKS LIKE • Teach-back is actively used, for both the result and its clinical meaning. • Results are explained without unexplained medical jargon. • Written material, where provided, is in the patient's own language or plain translated form.	COMMON FAILURE MODES • “Do you have any questions?” is used instead of genuine teach-back. • Explanations include unexplained technical terms assumed to be understood. • Written material exists only in the facility's operating language.
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WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory explaining a diabetes screening result directly to a patient.</i>	
BEFORE	A technologist explained an elevated glucose result using the term “hyperglycemia” and reference range numbers, then asked “does that make sense?” The patient nodded, and the technologist moved on, with no actual confirmation of genuine understanding.
ACTION	The laboratory retrained staff on teach-back specifically, requiring the patient to explain the result and its meaning back in their own words before the conversation concluded, and built simplified, plain-language explanation scripts for common result categories.

AFTER

The Monitor observed a results explanation and confirmed genuine teach-back was used, with the patient accurately restating the result's meaning in her own words. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Observe a current results explanation — is it teach-back, or “any questions?”
2. Build plain-language explanation scripts for common result categories.
3. Train staff specifically on genuine teach-back technique.

The most common mistake: Treating “does that make sense?” or a patient’s nod as equivalent to teach-back, when genuine comprehension verification requires the patient to actively explain the information back, not simply confirm understanding passively.

SELF-ASSESSMENT QUESTIONS

1. Is understanding actively checked using teach-back, for both the result and its clinical meaning? — *Asking the patient to explain back in their own words, not just “do you understand?”*

Evidence: Direct observation

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.*

Evidence: Direct observation of explanation content

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.*

Evidence: Written material review

COMMON REASONS FOR A PARTIAL ANSWER

- “Any questions?” is used in place of genuine teach-back.
- Written material exists only in the operating language.

IMPLEMENTATION PLAN

When	What
Week 1	Observe current results-explanation practice.
Week 2	Train staff on genuine teach-back technique.
Week 3	Build plain-language scripts and translated written materials for common languages served.
Ongoing	Spot-check results explanations periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Results explanation observation	Observes an actual results explanation for genuine teach-back and plain-language use.

EVIDENCE BASE

World Health Organization Regional Office for Europe. Global Competency Standards for Refugee and Migrant Health. Copenhagen: WHO/Europe; 2024.

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.

In plain terms: If a patient moves away, including to another country, they can actually get their lab history in a form a new doctor can use — without it costing too much or taking too long to be realistic.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Displaced and migrant patients relocate far more frequently than settled populations, which makes continuity of their own medical history disproportionately important to their ongoing care — yet they are also the patients most likely to face practical barriers like cost or bureaucratic delay when records systems weren't designed with this need in mind. A record technically available but practically unaffordable or impractically slow to obtain fails this requirement just as surely as a policy that outright denies the request.

WHAT GOOD LOOKS LIKE

- A straightforward, documented process exists for requesting one's own history.
- Any fee charged is genuinely proportionate, not a practical barrier.
- The record is provided in a format usable by a receiving facility elsewhere.

COMMON FAILURE MODES

- A process exists on paper but is burdensome enough to function as a barrier.
- A fee is set without consideration of affordability for low-income patients.
- Records are provided only in a proprietary format unusable elsewhere.

WORKED EXAMPLE

IN PRACTICE

A patient relocating internationally and requesting her laboratory history.

BEFORE

The laboratory's standard record request process required a written application, a processing fee set at a level reasonable for most local patients but genuinely difficult for someone with very limited means, and a two-week processing time — workable for routine requests but a real barrier for someone relocating urgently.

ACTION	The laboratory introduced a fee waiver option for patients demonstrating financial hardship, an expedited request path for relocation-driven requests, and began providing records in a standard, portable format alongside any internal system export.
AFTER	The Monitor reviewed a recent relocation-driven record request and found it processed within three days at no cost, in a portable format. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Review your current record request process for cost and realistic processing time.
2. Build a fee waiver option for patients facing financial hardship.
3. Check whether records are exported in a format usable elsewhere, not just internally.

The most common mistake: Setting a standard fee and processing timeline that's reasonable for the general patient population without considering that displaced or low-income patients relocating urgently may find even a modest fee or short delay a genuine, practical barrier.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Record request process documentation

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.*

Evidence: Fee schedule, waiver policy

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.
Evidence: Sample exported record format

COMMON REASONS FOR A PARTIAL ANSWER

- No fee waiver exists for patients facing genuine financial hardship.
- Records export only in a proprietary, internally-usable format.

IMPLEMENTATION PLAN

When	What
Week 1	Review current record request process for cost and timing barriers.
Week 2	Build a fee waiver and expedited path for relocation-driven requests.
Week 3	Confirm records export in a portable, externally usable format.
Ongoing	Review request processing time and fee impact periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Record request process review	Reviews the record request process for genuine accessibility, including cost and format.

EVIDENCE BASE

World Health Organization. Health of refugees and migrants: regional situation analysis, practices, experiences, lessons learned and ways forward. Geneva: WHO; 2018.

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.

In plain terms: Patient-facing staff get real, specific training on working with migrant and displaced patients — not just a generic “be culturally sensitive” session.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

This criterion functions as the training backbone supporting every other criterion in this standard — trauma-informed collection, proper interpreter use, and documentation-status awareness all depend on staff actually having received specific training in these areas, not general cultural-sensitivity content that often doesn’t translate into concrete behavioral change. Training delivered once at onboarding and never refreshed also fails to keep practice current as staff turn over and as the laboratory’s own understanding of good practice develops.

WHAT GOOD LOOKS LIKE

- Training specifically addresses migration and displacement contexts, not generic content.
- All staff with direct patient contact complete it, not a subset.
- Training is refreshed on a schedule, not delivered once and forgotten.

COMMON FAILURE MODES

- Only general cultural-sensitivity or customer-service training is provided.
- Some patient-facing staff, especially newer or part-time hires, are missed.
- Training was delivered once, years ago, with no refresher since.

WORKED EXAMPLE

IN PRACTICE

A laboratory auditing its training coverage across all patient-facing roles.

BEFORE

Full-time collection staff had received migration-competent training during a one-time session two years earlier, but part-time and newer staff hired

	since then had never received it, and no refresher had been scheduled for anyone.
ACTION	The laboratory built migration-competent training into mandatory onboarding for every patient-facing role, including part-time staff, with a biennial refresher requirement for all current staff going forward.
AFTER	The Monitor reviewed training completion records across all patient-facing roles, including part-time staff, and found full, current coverage with no gaps. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every role with direct patient contact, including part-time and newer staff.
2. Check training completion against this full list, not just full-time staff.
3. Build a refresher schedule, not a one-time-only requirement.

The most common mistake: Training full-time, longer-tenured staff thoroughly while part-time or more recently hired patient-facing staff are quietly missed from the same requirement.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Training curriculum

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.*

Evidence: Training completion records for all patient-facing roles

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.*

Evidence: Refresher training schedule and records

COMMON REASONS FOR A PARTIAL ANSWER

- Part-time or newer staff are missed from the training requirement.
- No refresher schedule exists beyond the original onboarding session.

IMPLEMENTATION PLAN

When	What
Week 1	List all patient-facing roles and current training completion status.
Week 2	Close any gaps found, including part-time staff.
Week 3	Build a refresher schedule and add the training to standard onboarding.
Ongoing	Track completion for every new hire and scheduled refresher.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Training completion audit	Reviews training completion records across all patient-facing roles, including part-time staff, for current coverage.

EVIDENCE BASE

World Health Organization Regional Office for Europe. Global Competency Standards for Refugee and Migrant Health. Copenhagen: WHO/Europe; 2024.

← Laboratory Standards — all standards

Standard 10 — Radiology →

ASF STANDARDS · LABORATORY · STANDARD 10

Standard 10 — Radiology

6 criteria · 3 non-negotiable · 2 core · 1 standard-level · Version 1.0

CRITERIA IN THIS STANDARD

**10.1 — Radiation Dose
Optimization and Justification**

**10.2 — Equipment Quality
Assurance and Calibration**

**10.3 — Timely, Accurate
Reporting with Critical Finding
Escalation**

**10.4 — Contrast Media Safety
Protocol**

**10.5 — MRI Safety Screening
and Zone Control**

**10.6 — Integration with
Laboratory Results for
Combined Reporting**

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.

In plain terms: Every scan involving radiation has a real clinical reason behind it, and the dose is genuinely tailored to the patient — not a one-size-fits-all setting applied regardless of who's actually being scanned.

Lab type	Standalone lab	Hospital lab	Clinic lab
Applicability	Where imaging offered	Where imaging offered	Where imaging offered

WHY THIS MATTERS

A placed referral is not the same thing as documented clinical justification — the distinction matters because justification is the step that genuinely weighs the diagnostic benefit against the radiation risk for this specific patient and situation. A pediatric patient given an adult-dose protocol receives meaningfully excess radiation exposure relative to their smaller body size, which is why age- and size-adjusted protocols are a specific, checkable safeguard rather than a general good practice statement, and this applies in a standalone diagnostic center exactly as it does in a hospital.

WHAT GOOD LOOKS LIKE

- Clinical justification is actually documented before the study, not assumed from the referral.
- Dose protocols are genuinely adjusted for patient size and age.
- Actual delivered dose is tracked and reviewable.

COMMON FAILURE MODES

- A referral is treated as equivalent to documented clinical justification.
- A single adult-dose protocol is applied regardless of patient size or age.
- Dose tracking relies on the intended protocol setting, not verified actual delivery.

WORKED EXAMPLE

IN PRACTICE

A standalone diagnostic center reviewing its pediatric imaging practice.

BEFORE

CT studies were performed using a single standard adult protocol regardless of patient age, meaning the occasional pediatric referral received meaningfully higher radiation exposure relative to body size than clinically necessary.

ACTION	The center built age- and weight-adjusted dose protocols specifically for pediatric patients, with a required clinical justification field completed before any study is performed, and a dose tracking system logging actual delivered dose per study.
AFTER	The Monitor reviewed recent pediatric studies and found age-adjusted protocols applied with documented justification and tracked actual dose for each. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether current protocols are adjusted for patient age and size.
2. Build age- and weight-adjusted protocols, particularly for pediatric patients.
3. Build a required clinical justification field and an actual dose tracking system.

The most common mistake: Applying a single standard adult imaging protocol regardless of the patient's actual age or size, which results in meaningfully excess radiation exposure for smaller or pediatric patients relative to what's clinically necessary.

SELF-ASSESSMENT QUESTIONS

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.*
Evidence: Justification record
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.*
Evidence: Age/weight-adjusted protocol documentation
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.

Evidence: Dose tracking log

COMMON REASONS FOR A PARTIAL ANSWER

- **Justification is documented inconsistently, not for every study.**
- **Pediatric protocols exist but aren't consistently applied.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit current dose protocol practice for age/size adjustment.
Week 2	Build age- and weight-adjusted protocols.
Week 3	Build a required justification field and dose tracking system.
Ongoing	Review dose tracking data periodically for outliers.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Dose protocol and justification review	Checks recent pediatric and adult studies for appropriately adjusted protocols and documented justification.

EVIDENCE BASE

International Atomic Energy Agency. Radiation Protection and Safety in Medical Uses of Ionizing Radiation. Vienna: IAEA; 2018.

World Health Organization. Communicating Radiation Risks in Paediatric Imaging. Geneva: WHO; 2016.

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.

In plain terms: Every imaging machine is genuinely tested and calibrated on a real schedule by someone actually qualified to do it — and if it fails, it stops being used immediately, not kept running while a fix is arranged.

Lab type	Standalone lab	Hospital lab	Clinic lab
Applicability	Where imaging offered	Where imaging offered	Where imaging offered

WHY THIS MATTERS

A testing schedule that exists on paper but is routinely missed in practice offers no real protection — the genuine safeguard is a schedule that actually functions, verified against real completion records. In a standalone diagnostic center without the backup resources of a larger hospital system, the temptation to keep a single imaging machine running while awaiting repair, rather than losing capacity entirely, can be particularly strong, which is exactly why this hard rule matters here.

WHAT GOOD LOOKS LIKE

- Quality assurance testing is actually performed on schedule, verified against records.
- Equipment failing standards is immediately removed from clinical use.
- Testing is performed by genuinely qualified, verifiable personnel.

COMMON FAILURE MODES

- A testing schedule exists but is routinely missed or delayed.
- Equipment known to be out of calibration stays in service while awaiting repair.
- Testing is done informally by whoever is available, not specifically qualified staff.

WORKED EXAMPLE

IN PRACTICE

A standalone diagnostic center with a single X-ray unit discovering a calibration failure.

BEFORE

Routine testing revealed the center’s sole X-ray unit was outside acceptable calibration tolerance, but with no backup unit and significant daily

	patient volume, the unit remained in use for a week while awaiting a service technician.
ACTION	The center built a hard rule immediately removing any failing equipment from clinical use, with a formal referral arrangement to a nearby partner facility for exactly this situation, accepting the short-term capacity loss as necessary.
AFTER	The Monitor reviewed a subsequent calibration failure and found the equipment immediately taken out of service, with patients redirected to the partner facility until repair was completed. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check current testing completion records against the required schedule.
2. Build a hard rule for immediate removal of failing equipment.
3. Arrange a formal referral partnership for backup capacity.

The most common mistake: In a standalone center with limited equipment redundancy, keeping a failing unit in service rather than accepting the capacity loss, because no backup arrangement was ever established in advance.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Testing completion log

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.*

Evidence: Equipment removal record

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.
Evidence: Tester credential verification

COMMON REASONS FOR A PARTIAL ANSWER

- Testing happens but is occasionally delayed past the scheduled date.
- No formal backup referral arrangement exists for equipment downtime.

IMPLEMENTATION PLAN

When	What
Week 1	Audit current testing completion against the schedule.
Week 2	Build a hard removal rule for failing equipment.
Week 3	Arrange a formal backup referral partnership.
Ongoing	Track testing schedule adherence and any removal events.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Testing record review	Checks quality assurance completion records against the required schedule and any equipment removal events.

EVIDENCE BASE

International Atomic Energy Agency. Radiation Protection and Safety in Medical Uses of Ionizing Radiation. Vienna: IAEA; 2018.

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.

In plain terms: Reports go out within a real, tracked timeframe, and a critical finding genuinely reaches the referring clinician directly — not sitting in a routine queue where it could go unnoticed.

Lab type	Standalone lab	Hospital lab	Clinic lab
Applicability	Where imaging offered	Where imaging offered	Where imaging offered

WHY THIS MATTERS

A general sense that reports “go out quickly enough” is considerably less reliable than actual tracked turnaround data against a defined target — perception and reality can diverge meaningfully without active measurement. In a standalone diagnostic setting, the referring clinician is often entirely external to the facility, which makes a direct, documented critical finding communication process specifically important, since there’s no shared internal system or hallway conversation to fall back on if formal notification doesn’t happen.

WHAT GOOD LOOKS LIKE

- Reporting turnaround time is actually tracked and meeting defined targets.
- A critical finding triggers genuine, direct, documented communication, not a routine queue entry.
- A documented instance exists of the critical finding protocol actually being used.

COMMON FAILURE MODES

- Turnaround time is assumed adequate without actual tracking.
- A critical finding is entered into the standard queue rather than directly communicated.
- No example exists of the critical finding protocol ever actually being used.

WORKED EXAMPLE

IN PRACTICE

A standalone diagnostic center identifying an unexpected critical

finding.

BEFORE

An unexpected critical finding was entered into the standard reporting system and faxed to the referring external clinic, with no direct phone confirmation, risking a significant delay before someone at the clinic actually saw the fax.

ACTION

The center built a mandatory direct-call protocol for any critical finding, requiring the radiologist to personally reach the referring clinician by phone, documented with the time of notification, with fax or electronic transmission as a supplementary record only.

AFTER

The Monitor reviewed a recent critical finding record showing a direct call made and documented within minutes of the finding being identified. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Build a mandatory direct-communication protocol for critical findings.
2. Build a turnaround time tracking system against defined targets.
3. Check whether a real instance of the critical finding protocol exists.

The most common mistake: Relying on fax or electronic transmission alone for a critical finding to an external referring clinician, without a direct phone confirmation, which risks a significant delay before the finding is actually seen by someone able to act on it.

SELF-ASSESSMENT QUESTIONS

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.”*

Evidence: Turnaround time tracking data

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.*

Evidence: Critical finding protocol

3. Is there a documented instance of the critical finding protocol actually being used? — *Evidence the protocol genuinely functions, not just exists on paper.*

Evidence: Critical finding notification record

COMMON REASONS FOR A PARTIAL ANSWER

- Turnaround tracking exists but isn't actively reviewed against targets.
- A critical finding protocol relies on fax/electronic transmission without direct confirmation.

IMPLEMENTATION PLAN

When	What
Week 1	Build a turnaround time tracking system.
Week 2	Build a mandatory direct-communication protocol for critical findings.
Week 3	Brief all radiology staff on the critical finding protocol.
Ongoing	Review turnaround data and any critical finding events periodically.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Critical finding record review	Reviews turnaround time data and a specific critical finding notification record for direct, documented communication.

EVIDENCE BASE

World Health Organization. Patient Safety: Make Health Care Safer. Geneva: WHO; 2021.

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.

In plain terms: Contrast safety screening genuinely covers both allergy and kidney function, and emergency response equipment for a reaction is right there, ready to go — especially important in a standalone setting without an on-site emergency department to call on.

Lab type	Standalone lab	Hospital lab	Clinic lab
Applicability	Where imaging offered	Where imaging offered	Where imaging offered

WHY THIS MATTERS

A generic “any allergies?” question, while useful, doesn’t specifically address renal function, which matters distinctly for contrast safety and is easy to overlook without a dedicated check. A contrast reaction can develop rapidly, and this matters with particular weight in a standalone diagnostic setting without an on-site emergency department to call on — the center’s own emergency response capability, genuinely accessible and genuinely drilled, is what stands between a reaction and effective treatment in those crucial early minutes.

WHAT GOOD LOOKS LIKE

- Pre-screening genuinely covers both allergy history and renal function.
- Emergency response equipment is immediately accessible at the point of care.
- Staff are drilled on the emergency response

COMMON FAILURE MODES

- Screening covers allergy but not renal function specifically.
- Emergency response equipment is stored elsewhere, requiring retrieval time.
- Staff have read the protocol but have never actually drilled it.

protocol, not just given a reference document.

WORKED EXAMPLE

IN PRACTICE

A standalone diagnostic center reviewing its contrast emergency readiness.

BEFORE	Emergency response medication for a contrast reaction was stored in a locked cabinet with the facility manager holding the only key, and staff had never actually drilled the response protocol beyond reading it during onboarding.
ACTION	The center relocated emergency response medication to an unlocked, immediately accessible cart within the imaging suite itself, and built a quarterly drill schedule specifically because no on-site emergency department exists to call on.
AFTER	The Monitor confirmed emergency equipment was immediately accessible without needing a key or manager presence, and reviewed a recent drill record. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Build a specific renal function screening step, not just a general allergy question.
2. Relocate emergency response equipment to be immediately accessible, with no access barrier.
3. Build a regular drill schedule for the emergency response protocol.

The most common mistake: Storing emergency response medication behind a lock requiring a specific staff member's key, which introduces exactly the kind of retrieval delay this criterion is designed to prevent, particularly critical in a setting with no on-site emergency department to call on.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Pre-screening record

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.*

Evidence: Equipment location inspection

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.*

Evidence: Drill record

COMMON REASONS FOR A PARTIAL ANSWER

- **Screening covers allergy but renal function checking is inconsistent.**
- **Emergency equipment is nearby but requires a key or specific person’s presence.**

IMPLEMENTATION PLAN

When	What
Week 1	Build a specific renal function screening step.
Week 2	Relocate emergency response equipment to barrier-free, immediate access.
Week 3	Run an initial emergency response drill.
Ongoing	Repeat drills on a regular schedule.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Point-of-care inspection	Confirms emergency response equipment accessibility and checks recent pre-screening records.

EVIDENCE BASE

World Health Organization. Patient Safety: Make Health Care Safer. Geneva: WHO; 2021.

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.

In plain terms: Everyone, patient or accompanying person, is genuinely screened before entering the magnet room, with a real physical barrier preventing unscreened access — not just a form filled out somewhere earlier and a posted warning sign.

Lab type	Standalone lab	Hospital lab	Clinic lab
Applicability	Where MRI offered	Where MRI offered	Where MRI offered

WHY THIS MATTERS

A screening form completed earlier in the process, but not actually verified at the point of entry into the magnet room, provides no genuine protection — the verification step itself is what actually prevents an unscreened person or metallic object from entering the field. A posted warning sign relies on an individual’s own judgment and attention; a genuine physical barrier or access control is the real safeguard, and this distinction matters because MRI contraindication incidents, though rare, can be serious.

WHAT GOOD LOOKS LIKE

- Screening is genuinely verified at the point of entry, not just completed earlier.
- Physical zone control genuinely prevents

COMMON FAILURE MODES

- A screening form is completed but not re-verified at the magnet room entry.
- Access relies on a posted sign rather than a genuine

unscreened access, not just a posted sign.

- Accompanying individuals are also genuinely screened, not only the patient.

physical barrier.

- Accompanying family members or support persons aren't screened.

WORKED EXAMPLE

IN PRACTICE

A family member accompanying a pediatric patient for an MRI at a diagnostic center.

BEFORE	The patient's screening form was completed at intake, but when a parent accompanied the child into the scan room for comfort, the parent themselves had not been screened, relying only on a posted warning sign at the door.
ACTION	The center built a mandatory screening verification step at the magnet room door itself, covering any accompanying individual, with a physical access-controlled entry preventing anyone unscreened from proceeding.
AFTER	The Monitor observed the screening verification process at the magnet room entry and confirmed an accompanying parent was screened before entry. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Build a mandatory screening verification step at the magnet room entry itself.
2. Extend screening explicitly to any accompanying individual.
3. Build a genuine physical access control, not just a posted sign.

The most common mistake: Relying on a screening form completed earlier in the process, without a genuine re-verification step at the actual point of entry into the magnet room, and relying on a posted warning sign rather than a real physical access barrier.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Entry verification process

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.*

Evidence: Zone control inspection

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.*

Evidence: Accompanying-individual screening record

COMMON REASONS FOR A PARTIAL ANSWER

- **Patients are screened but accompanying individuals sometimes aren't.**
- **Zone control relies more on signage than a genuine physical barrier.**

IMPLEMENTATION PLAN

When	What
Week 1	Review current screening verification practice at point of entry.
Week 2	Build a mandatory entry-point verification step covering accompanying individuals.
Week 3	Build or confirm a genuine physical access control.
Ongoing	Observe entry practice periodically for consistency.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Entry point observation	Observes the screening verification process and physical access control at the magnet room entry.

EVIDENCE BASE

World Health Organization. Patient Safety: Make Health Care Safer. Geneva: WHO; 2021.

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.

In plain terms: When a lab and imaging service share a building, they genuinely talk to each other about relevant findings — not just two separate operations that happen to be under the same roof with no real connection.

Lab type	Standalone lab	Hospital lab	Clinic lab
Applicability	Where co-located with imaging	Where co-located with imaging	Where co-located with imaging

WHY THIS MATTERS

Operating imaging and laboratory services within the same facility creates a real opportunity for clinically valuable correlation — a significant lab finding that would naturally prompt a radiologist to re-examine a recent image, or vice versa — but this value is lost entirely if the two services function as effectively separate operations that happen to share a building. Leaving correlation to chance, hoping staff will happen to notice a connection between a lab result and an imaging report for the same patient, is a specific, checkable gap this criterion exists to close.

WHAT GOOD LOOKS LIKE

- A real, defined process flags when correlation between lab and imaging is warranted.

COMMON FAILURE MODES

- No defined trigger exists for flagging a potential correlation; it's left to chance.

- Staff can describe a specific instance where this correlation actually functioned.
- Imaging and lab reports for the same patient are genuinely cross-visible.
- No example exists of the correlation process ever actually functioning.
- Lab and imaging systems are siloed, with no cross-visibility for reporting staff.

WORKED EXAMPLE

IN PRACTICE

A diagnostic center with both lab and imaging services under one roof.

BEFORE	A significantly abnormal lab result was reported through the lab system, with no mechanism to flag that the same patient had a recent imaging study that, in light of the new result, might warrant re-review, since the two systems operated with no cross-visibility.
ACTION	The center built a specific flagging rule for defined significant lab-finding categories, triggering a notification to radiology for potential correlation, alongside shared system access allowing each department's reporting staff to view the other's results for a shared patient.
AFTER	The Monitor reviewed a recent instance where a significant lab finding triggered the flagging rule, prompting the radiologist to re-review a recent imaging study with the new context in mind. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Define specific categories of findings that should trigger cross-correlation.
2. Build a flagging or notification mechanism between the two departments.
3. Build shared system access for cross-visibility of results.

The most common mistake: Operating laboratory and imaging services within the same building with no actual working connection between them, leaving a clinically valuable correlation opportunity entirely to chance rather than a defined, functioning process.

SELF-ASSESSMENT QUESTIONS

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.*

Evidence: Flagging rule documentation

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.*

Evidence: Staff interview

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.*

Evidence: Cross-system access confirmation

COMMON REASONS FOR A PARTIAL ANSWER

- **A policy intention exists but no concrete flagging mechanism has been built.**
- **Systems are technically connected but staff don't actually use the cross-visibility.**

IMPLEMENTATION PLAN

When	What
Week 1	Define specific finding categories warranting cross-correlation.
Week 2	Build a flagging or notification mechanism between departments.
Week 3	Build shared system access for cross-visibility.
Ongoing	Review correlation instances periodically for genuine use.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
ASK	Staff interview	Asks staff to describe a specific instance of the lab-imaging correlation process functioning.

EVIDENCE BASE

World Health Organization. People-Centred and Integrated Health Services: An Overview of the Evidence. Geneva: WHO; 2015.

- ← Laboratory Standards — all standards
- ← Standard 9 — Refugee & Migrant Health