WORK SAMPLE

Requirements Traceability Matrix and Gap Register

A generic, illustrative version of the tracker structure I build when a set of external requirements has to be proven satisfied, item by item, to somebody who will audit the answer. The worked rows use a neutral electronic-records control set. No client or employer content appears in this document.

1. What a tracker is actually for

A tracker earns its keep at one moment: when somebody who did not build it starts pulling threads. Everything in the structure below exists to survive that moment. A tracker that only serves the team maintaining it is a status report wearing a matrix costume.

Three properties decide whether it holds. Traceability runs in both directions, so every requirement reaches evidence and every piece of evidence answers a requirement. Gaps are first-class records with owners and dates, rather than adjectives in a status column. And closure requires verification evidence produced by someone other than the person who did the remediation.

2. Traceability matrix, field definitions

Field	Definition, and the reason it exists
Req ID	Stable identifier, issued once. Never reused, never renumbered, because external correspondence will cite it.
Source	The clause or citation the requirement comes from, specific enough that the reader can go check it themselves.
Requirement	The obligation in the source's own words. Paraphrasing into house language is where scope quietly changes.
Interpretation and scope	How the requirement is being read for this system, and the boundary of what it covers. Recorded before verification, because an interpretation written afterward is worth very little.
Owner	The named person accountable. A function name is not an owner and cannot be asked a question.
Verification method	How satisfaction is demonstrated: executed test case, document review, configuration inspection, or vendor evidence assessed on its merits rather than accepted on assertion.
Evidence ref	The specific artifact and version. A pointer to a folder is not evidence, it is a place evidence might be.
Status	Satisfied, partially satisfied, gap, or not applicable with written justification. Four values, defined below, no free text.
Gap ref	Link to the gap register entry, mandatory for any status other than satisfied.

3. Status taxonomy, and why it has only four values

Ambiguous status language is how trackers become decorative. Each value has an entry rule and an exit rule, and 'in progress' is deliberately not among them, because it describes the team's activity rather than the requirement's condition.

Value	Entry rule	Exit rule
Satisfied	Verification executed, evidence attached and referenced, reviewed by someone other than the person who performed it.	Reopens on any change to the system, the requirement, or the interpretation.
Partially satisfied	The control exists but does not cover the full scope recorded in the interpretation column. Never rounded up.	Exits to satisfied only when the uncovered scope is closed and verified, not when the covered part is re-demonstrated.
Gap	No control, or a control that verification showed does not work. Vendor assertions with no assessment sit here, not in satisfied.	Exits when remediation is verified independently.
Not applicable	Requires a written justification naming why the requirement does not reach this system. Silence is treated as unanswered.	Reviewed at every periodic re-baseline, because scope changes and yesterday's exclusion becomes today's gap.

4. Worked extract

Illustrative rows against a generic electronic-records control set. Note the partially satisfied row that is not rounded up, and the vendor claim recorded as a claim until assessed.

Req ID	Source	Requirement	Interpretation and scope	Verification	Status	Gap
R-014	Electronic records rule, audit trail clause	Secure, computer-generated, time-stamped audit trail recording operator entries and actions that create, modify, or delete records.	Applies to the application database and the instrument-side acquisition log. Excludes the read-only reporting layer, which creates no records.	Test case TC-014, configuration inspection	**Partially satisfied**	G-003
R-015	Electronic records rule, audit trail clause	Record changes shall not obscure previously recorded information.	Prior values retained and viewable in change history for all regulated fields.	Test case TC-015	**Satisfied**	-
R-018	Electronic records rule, audit trail clause	Audit trail retained at least as long as the subject records and available for review and copying.	Retention configured to match record retention. Export path for review confirmed.	Configuration inspection, retention policy review	**Satisfied**	-
R-022	Electronic records rule, access clause	System access limited to authorized individuals.	Unique named accounts, no shared or generic logins, role-based permissions reviewed quarterly.	Configuration inspection, account review record	**Satisfied**	-

Req ID	Source	Requirement	Interpretation and scope	Verification	Status	Gap
R-026	Electronic records rule, authority clause	Authority checks to ensure only authorized individuals may use the system, sign records, or alter a record.	Distinct permissions for acquire, analyze, modify template, review, and approve. Administrator role held outside the analyst group.	Role matrix review, negative test cases	**Partially satisfied**	G-009
R-031	Electronic records rule, copies clause	Ability to generate accurate and complete copies in human-readable and electronic form.	Export must preserve the audit trail alongside the record. Vendor asserts support; assertion not yet tested.	Test case TC-031 (not executed)	**Gap**	G-007
R-037	Electronic records rule, signature clause	Signed records shall contain the printed name of the signer, the date and time, and the meaning of the signature.	All three elements rendered in the human-readable output, not only stored in the database.	Test case TC-037, output inspection	**Satisfied**	-
R-044	Electronic records rule, training clause	Persons who use the system have the education, training, and experience to perform their assigned tasks.	Role-linked training records, verified current before account activation.	Training record review	**Not applicable to this package**	-

5. Risk rating rubric

Risk ratings are worthless if each person assigns them by instinct. The rubric below is applied to every gap, and the rating drives remediation sequencing rather than the other way around.

Rating	Criterion	Remediation expectation
High	Affects the integrity or attributability of released records, or would be a citable deficiency as it stands.	Remediation planned before the next release cycle. Interim control documented if remediation cannot be immediate.
Medium	A control exists but is incomplete, undocumented, or not consistently applied. Detectable in audit, defensible with explanation.	Remediated on the current improvement cycle with a named target date.
Low	Documentation or process clarity issue with no effect on record integrity.	Batched into scheduled procedure maintenance.

6. Gap register, field definitions

Field	Definition
Gap ID	Issued once, referenced from the matrix row that opened it.
Linked Req	The requirement the gap sits against. A gap with no linked requirement is a to-do item, not a gap.
Description	What is actually missing, stated as a condition rather than as a task. 'Log not covered by review procedure' rather than 'update the procedure.'
Risk	Per the rubric above, with the rating rationale recorded where it is not self-evident.
Remediation	The action that changes the condition. Separate from the verification that proves it changed.
Owner and target date	Named person, dated. A gap without both is a gap nobody is closing.
Verification of closure	What evidence will demonstrate closure, defined when the gap is opened rather than when it is closed, so the bar cannot move.
Status	Open, remediated pending verification, or closed. The middle value exists because the two are routinely conflated, which is how gaps get closed without evidence.

7. Gap register, worked extract

Gap	Req	Description	Risk	Remediation	Owner	Verification of closure	Status
G-003	R-014	Instrument-side acquisition log is enabled but is not covered by the periodic audit trail review procedure.	**Medium**	Amend the review procedure to include the acquisition log; define frequency and reviewer role.	Quality systems owner	Re-inspect procedure and confirm one completed review cycle on file.	**Open**
G-007	R-031	Export function has not been tested for audit trail inclusion. Vendor assertion on file, unverified.	**High**	Execute TC-031 against a record with a known change history; compare export against source.	Validation lead	Executed test case with evidence attached, reviewed and approved by a second person.	**Open**
G-009	R-026	Analyst role retains template modification rights, so analysis configuration can change without change control.	**High**	Split the permission; move template modification to a restricted role under change control.	System owner	Role matrix re-inspected and a negative test confirming analyst accounts cannot modify templates.	**Remediated, pending verification**
G-011	R-022	Two dormant accounts remained active past the departure date of their holders.	**High**	Deactivate the accounts; add a departure trigger to the quarterly access review.	System administrator	Deactivation confirmed in the access record, and one subsequent review showing the trigger applied.	**Closed**

Gap	Req	Description	Risk	Remediation	Owner	Verification of closure	Status
G-014	R-018	Audit trail export was verified manually once but no procedure requires it to be repeated after upgrades.	**Low**	Add a post-upgrade verification step to the change control checklist.	Validation lead	Checklist revision issued and applied to the next upgrade record.	**Open**

8. How this behaves under audit

- An auditor picks a requirement and walks it to evidence, or picks evidence and walks it back to the requirement it serves. Both directions resolve, which is the entire reason to maintain a mapping rather than a checklist.
- A requirement marked not applicable carries a written justification. Silence in that column is treated as an unanswered requirement, and it is the first thing an experienced auditor scans for.
- Gaps are visible rather than absorbed. A live system showing no open gaps usually means the tracker is not being used, and a reviewer reads it that way.
- Partially satisfied is preserved rather than rounded. A tracker that only contains satisfied and gap has been managed for appearance, and it will not survive a sampled walkthrough.
- Closure is evidenced by verification performed by someone other than the remediator, the same second-person principle that governs record review.
- Every row carries a date and an owner, so the state of the system is reconstructable at any past point, not only as of today.

9. Anti-patterns this structure is built against

Anti-pattern	What it looks like
The status-column tracker	Requirements with a red, amber, or green cell and no evidence reference. Communicates mood rather than state.
The folder pointer	Evidence recorded as a directory path. Nobody can tell which artifact, which version, or whether it still says what it said.
The rounded-up row	Partially satisfied quietly recorded as satisfied because the remaining scope is small. This is the single most common way a tracker becomes untrue.
The orphan requirement	A requirement that reaches no evidence and no gap. It is invisible in every review until an auditor samples it.
The self-closed gap	Remediated and closed by the same person, with the closure evidence being their assertion that they did it.
The frozen baseline	A tracker completed once and never re-examined, describing a system that has since changed underneath it.

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