



Document Coverage Analysis Report

ISO/IEC 17025 - Documentary Pre-Assessment

67%

Audit Readiness

Automated documentary coverage assessment — expert interpretation according to ISO/IEC 17025

Audit Risk

HIGH

Critical Findings

1

Not Covered

1

Partially Covered

1

Analyzed Document

Type	PROCEDURE - DOCUMENT CONTROL
Title	Document Control Procedure
Reference	PROC-001
Version	2.0
Language	English

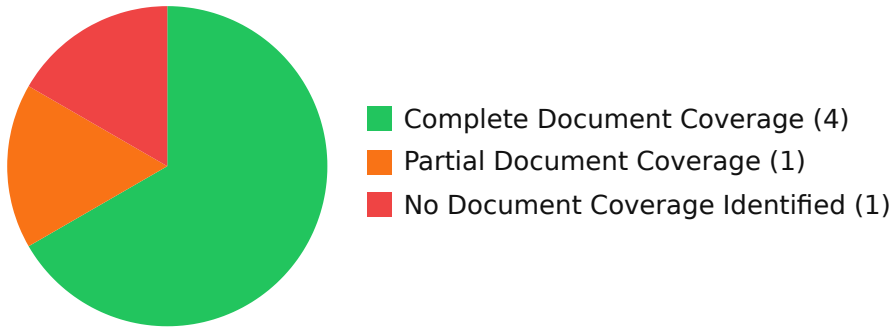
NormAICheck Analysis

Date	16-06-2026
Analysis ID	NAC-20260616-145002- 6MDR
Version	v1.0
Scope	1 document

Automated document analysis — decision-support tool, not a certification statement

Executive Summary

Coverage Distribution



DOCUMENTARY RISK : HIGH

The document analysis reveals a total of 6 rules, with 4 fully covered, 1 partially covered, and 1 not covered. The areas of strength include document approval, identification, version control, and update processes, all demonstrating a structured approach. However, the lack of coverage in records control presents a significant gap, as no evidence was found for retention, protection, or defined retention periods. This gap poses a risk in demonstrating compliance during audits. The overall maturity level is estimated as Intermediate, reflecting a need for improvement in specific areas.

Priority Actions

- **Define and formalize retention policies for records, specifying duration, access, and protection measures.**
- Establish procedures for the protection of records, including security measures and access controls.
- Clarify responsibilities for records management to ensure accountability and traceability.

Requirements Mapping

MD-01

Complete Document Coverage

Document approval

Covered Elements : 3 / 3

Severity : High

Priority : High

MD-02

Complete Document Coverage

Document identification and version control

Covered Elements : 3 / 3

Severity : High

Priority : High

MD-03

Complete Document Coverage

Document update and revision

Covered Elements : 3 / 3

Severity : Medium

Priority : High

MD-04

Partial Document Coverage

Document distribution and accessibility

Covered Elements : 1 / 2

Severity : Medium

Priority : Medium

MD-05

Complete Document Coverage

Obsolete document management

Covered Elements : 2 / 2

Severity : Medium

Priority : Medium

MD-06

No Document Coverage Identified

Records control

Covered Elements : 0 / 3

Severity : High

Priority : High

Complete Document Coverage**Document approval****Document Coverage Level : Complete Document Coverage**

All expected elements are identified in the documentation.

Identified Document Elements : 3 / 3

Normative Severity : High

Attention Priority : High

Observed Document Elements

- ***“Procedures shall be approved by Management. Forms may be approved by the Quality Manager.”***
Source :
Document Control Procedure — 6.4 Approval Levels
- ***“Approval workflow: Author Quality Manager. Management Distribution Each stage shall be completed before proceeding to the next.”***
Source :
Document Control Procedure — 6.2 Approval Workflow — p.5
- ***“Forms may be approved by the Quality Manager. Major revisions shall always require full management approval.”***
Source :
Document Control Procedure — 6.4 Approval Levels
- ***“Procedures shall be approved by Management. Forms may be approved by the Quality Manager. Major revisions shall always require full management approval.”***
Source :
Document Control Procedure — 6.4 Approval Levels

Documentary Observation

The document includes three elements related to approval: it states that a document cannot be issued until it has been approved by an authorized person, identifies the responsible roles for approval, and defines the approval workflow. The approval workflow is detailed in section 6.2, specifying the sequence of approvals required. Additionally, section 6.4 outlines the hierarchical approval levels, confirming that major revisions require full management approval.

NormAICheck Analysis

The presence of three documented elements regarding approval demonstrates a structured approach to document management. The explicit identification of responsible roles and the defined approval workflow enhance the ability to demonstrate compliance during an audit. However, the absence of any non-covered elements indicates a comprehensive coverage of the requirement. This thorough documentation supports effective governance and reduces the risk of procedural lapses during audits.

Document Coverage Level : Complete Document Coverage

All expected elements are identified in the documentation.

Identified Document Elements : 3 / 3

Normative Severity : High

Attention Priority : High

Observed Document Elements

- ***“All changes are recorded in a revision history log. The revision history specifies: author; date;”***
Source :
Document Control Procedure — 7.4 Revision History — p.7
- ***“Each document shall have a unique identifier. The document coding system is: MQ-XXX Quality Manual PROC-XXX Procedure WI-XXX Work Instruction FRM-XXX Form Duplicate document references are not permitted.”***
Source :
Document Control Procedure — 7.1 Unique Identification — p.6
- ***“author; date; version;”***
Source :
Document Control Procedure — 7.4 Revision History — p.7
- ***“The revision history specifies: author; date; version;”***
Source :
Document Control Procedure — 7.4 Revision History — p.7

Documentary Observation

Three elements related to document identification and version control are present, including unique identifiers, version numbers, and defined version management rules. Each document has a unique identifier as specified in section 7.1. The revision history log records changes, including author and date, as detailed in section 7.4. Additionally, each document includes a version number and revision date, as outlined in section 7.2.

NormAICheck Analysis

The presence of unique identifiers allows for clear tracking of documents, which is essential for audit trails. The documented revision history ensures that all changes are traceable, reducing the risk of using outdated versions. The defined version management rules provide a structured approach to document updates, facilitating compliance during audits. Overall, the comprehensive coverage of these elements supports effective document control and minimizes potential discrepancies in operational references.

Complete Document Coverage**Document update and revision****Document Coverage Level : Complete Document Coverage**

All expected elements are identified in the documentation.

Identified Document Elements : 3 / 3

Normative Severity : Medium

Attention Priority : High

Observed Document Elements

- ***“All changes are recorded in a revision history log. The revision history specifies: . author;”***
Source :
Document Control Procedure — 7.4 Revision History — p.7
- ***“Each document shall be reviewed at least once per year. The review frequency is annual.”***
Source :
Document Control Procedure — 9.1 Review Frequency — p.9
- ***“All changes are recorded in a revision history log. The revision history specifies: author;”***
Source :
Document Control Procedure — 7.4 Revision History — p.7
- ***“All changes are recorded in a revision history log. The revision history specifies: .”***
Source :
Document Control Procedure — 7.4 Revision History — p.7

Documentary Observation

Three elements related to document review and revision are present. The documents are reviewed at least once per year, as stated in section 9.1 Review Frequency. All changes are recorded in a revision history log, which specifies the author and the description of the change, as detailed in section 7.4 Revision History. The revision history log includes multiple entries confirming the traceability of document changes.

NormAICheck Analysis

The presence of three documented elements allows for a complete demonstration of the requirement during an audit. The systematic evidence of annual reviews and structured revision history ensures that the process is well-defined and traceable. The absence of any non-covered elements indicates a strong capacity to demonstrate compliance. The organization of the documentation supports the effective management of document updates and revisions, minimizing the risk of oversight in the review process.

Document Coverage Level : Partial Document Coverage

Some expected elements could not be identified from the analyzed documentation.

Identified Document Elements : 1 / 2

Normative Severity : Medium

Attention Priority : Medium

Observed Document Elements

- *“Applicable documents are accessible to all relevant users. Documents are available through: the Quality Intranet;”*

Source :

Document Control Procedure — 8.1 Accessibility — p.7

- *“Applicable documents are accessible to all relevant users. Documents are available through: .”*

Source :

Document Control Procedure — 8.1 Accessibility — p.7

- *“This procedure defines the methods for the creation, approval, identification, distribution, review and archiving of documents within the DemoLab Analytics management system. The objective is to ensure that applicable documents are available, appropriately identified and used in their current approved version.”*

Source :

Document Control Procedure — 1. Purpose

- *“distribution of controlled copies; communication through document distribution lists. Distribution is performed after approval.”*

Source :

Document Control Procedure — 8.2 Distribution

Documentary Observation

One element related to document distribution methods is covered, while the element regarding accessibility is not fully addressed. Three pieces of evidence confirm that applicable documents are accessible to users, including references to the Quality Intranet. The distribution methods are defined with three supporting excerpts detailing the processes involved in document distribution. However, the absence of a formal statement on the accessibility of applicable documents limits the completeness of the coverage.

NormAICheck Analysis

The coverage is partially complete due to the lack of documentation on the accessibility of applicable documents, which is critical for demonstrating compliance in an audit. The presence of three evidential elements regarding distribution methods indicates a structured approach, yet the missing element on accessibility creates a gap. This insufficiency may lead to challenges in proving that all relevant users can access necessary documents during an audit. Formalizing the accessibility criteria would enhance the documentation and mitigate risks associated with audit scrutiny.

Complete Document Coverage**Obsolete document management****Document Coverage Level : Complete Document Coverage**

All expected elements are identified in the documentation.

Identified Document Elements : 2 / 2

Normative Severity : Medium

Attention Priority : Medium

Observed Document Elements

- ***“Obsolete documents are identified using the marking: OBSOLETE This marking shall be clearly visible on the document.”***

Source :

Document Control Procedure — 10.1 Identification — p.10

- ***“Obsolete documents may be archived in a dedicated document archive repository. Archiving preserves document history while preventing the unintended use of superseded versions.”***

Source :

Document Control Procedure — 10.2 Archiving

- ***“A document replaced by a newer version or withdrawn from operational use. An obsolete document shall not be used to perform laboratory activities.”***

Source :

Document Control Procedure — 4.2 Obsolete Document

Documentary Observation

Two elements related to obsolete document management are present, specifically identification and removal or archiving. The document states that obsolete documents are identified using the marking: OBSOLETE, which is clearly visible on the document. Additionally, it mentions that obsolete documents may be archived in a dedicated document archive repository, preserving document history and preventing unintended use of superseded versions.

NormAICheck Analysis

The presence of structural evidence for both identification and archiving of obsolete documents allows for a complete demonstration of the requirement during an audit. The clear marking of obsolete documents ensures that they are not used in laboratory activities, which mitigates risks associated with outdated information. The documented procedures for archiving further support the integrity of document management practices. Overall, the comprehensive coverage of the elements indicates a well-structured approach to managing obsolete documents.

No Document Coverage Identified**Records control****Document Coverage Level : No Document Coverage Identified**

Some expected elements could not be identified from the analyzed documentation.

Identified Document Elements : 0 / 3

Normative Severity : High

Attention Priority : High

Observed Document Elements

- ***“Version: 2.0 Effective Date: 01/01/2026 Next Review Date: 01/01/2027
Classification: Controlled Internal Document Approved by: General Management
Distribution: All Personnel Status: Effective Revision History
VersionDateAuthorDescription 1.015/03/2024S. MartinInitial release
1.122/06/2024A.”***

Source :

Document Control Procedure — DOCUMENT CONTROL PROCEDURE

Documentary Observation

No elements related to the retention of records are documented, as evidenced by the absence of any records retention policy. There is no documentation indicating the protection of records, which is a critical aspect of records control. One element regarding retention periods is defined, as indicated by the presence of a document control procedure that mentions a version and effective date, but it lacks specific retention details.

NormAICheck Analysis

The absence of documented evidence for the retention and protection of records indicates a significant gap in the ability to demonstrate compliance during an audit. The single element regarding retention periods is insufficient, as it does not provide a comprehensive framework for records management. This lack of documentation creates a high risk of non-compliance being identified during an audit, as there is no clear demonstration of how records are managed and protected. The inability to show retention and protection measures could lead to serious implications regarding data integrity and security.

Documentary weaknesses have been identified at this stage of the analysis.

Analysis Conclusion

The document is partially ready for audit due to the lack of coverage in records control. While the majority of requirements are met, the absence of defined retention and protection measures for records introduces a critical risk. The structure of the documentation shows a good level of coherence, but the missing elements indicate a need for further development. To mitigate audit risks, it is essential to establish clear retention policies and protection measures for records. This will enhance the overall compliance framework and ensure that all documentation is adequately managed. Immediate actions should focus on formalizing these missing elements to achieve a higher level of audit readiness.