CRA Technical documentation list

Document decision, responsible person and supporting documents in the editable Word document.

Own product or system identifier

Enter the version, date of reference, use or variant concerned and responsible body.

Set the variation limit

Identify product variant, software status and related documents.

Matching Evidence

Compare risk files, test results and technical documentation with the release.

Follow Version Change

Document open deviations and re-examination in the dossier.

Understanding the Example Decision

The fictitious process shows what facts the decision bears.

Test position	Observation and impact
Observation	The risk file and release note 3.3. The test report refers to version 3.2.
Decision	The gap is identified. Product release requires a documented version comparison and, if necessary, the re-test.
Negative test	Change the report to version 3.3, but leave the variant identifier blank. Check if the assignment is occupied.

Comparison with the situation at its own pace

What deviation does the result change? Which proof makes the difference visible?

Determine the examination, decision and follow-up date

The process is monitored, decision-making and verifiable next order with the same reference.

Agreed scale observation and evidence findings and test assignment

Responsibility, decision and release

Enter the text, date, responsible body, result and, where appropriate, follow-up or retest.