Measurement Risk Documentation: A Comprehensive Guide

INTRODUCTION

As calibration/testing laboratories transition to risk assessment policies and procedures a question often asked is what constitutes an adequate documented risk assessment in terms of its content and use to justifying actions/in-actions. A solid foundation for understanding risk management can be drawn from NASA's NPR 8000.4B, 'Agency Risk Management Procedural Requirements':

> *'Generically, risk management is a set of activities aimed at understanding, communicating, and managing risk to the achievement of objectives. Risk management operates continuously in an activity, proactively risk-informing the selection of decision alternatives and then managing the risks associated with implementation of the selected alternative.'*

There are many documented risk assessments that can be found via internet searches which have commonalities such as a risk assessment statement and ranking of proposed corrective actions but typically exhibit wide variation in terms of specific content. This is not surprising given an industry accepted 'consensus' guidance for risk assessment content documentation has not been established. This paper will outline critical risk assessment topics one would expect/hope would be addressed in a documented risk assessment. These topics were derived from various publications, internet searches and the author's own experiences.

This paper assumes readers have a general understanding of risk assessment. Please note , this paper will not address the cornucopia of statistical methods used to determine risk criticality/impact as well as associated data requirements i.e. sampling, population distributions, etc.

1. RISK ASSESSMENT IDENTIFICATION STATEMENT

Let's start with some fundamentals risk assessment topics and build a check list one can use as an outline for documenting risk assessment. The first pre-essential topic for all risk assessment documentation is a concise risk assessment identification statement, ideally conveyed in a sentence or two providing a definitive reason for the assessment. Upon reading this statement a reader should have a clear understanding of a risk scenario's departure or possible departure from its intended, preferred state. Additional verbiage such as justification or substantiating details should be avoided and addressed elsewhere in the content of the risk assessment documentation in order to avoid shifting any focus from the statement's primary purpose of identifying the risk scenario.

1.1 Examples of Risk Assessment Identification Statements

a. Tuco 123FA production test noise failures
b. Assembler safety incidents on the rise
c. ACV reference standard repeatedly found out of tolerance

2. RISK ASSESSMENT IDENTIFICATION STATEMENT ASSUMPTIONS AND QUALIFICATIONS

As stated, a risk assessment identification statement is primarily used to convey a particular risk scenario. Risk assessment identification statement assumptions and qualifications identifies a specific risk scenario which differs from other scenarios in terms of context, constraints, presumed conditions, dependencies and other qualifying criteria to clearly define the risk scenario's uniqueness. Information presented in this section should be concise and logically presented to avoid confusion and reduce the chance of misconstruing the risk scenario with other similar scenarios. Should a risk scenario be difficult to uniquely identify in contrast to other scenarios, qualifying statements may be needed to clarify what the risk scenario is not. Generally speaking, this section should address the who, what, when, where and why's associated with a risk scenario which makes it unique.

2.1 Example of Risk Assessment Identification Statement Assumptions / Qualifications

Austin test lab (test station #2 configured with model 123XYZ, SN 4567), exhibited high failure rate for Tuco 123FA network boxes (batch 27) noise verifications per section 12.A of the Tuco 123FA test procedure (TS-01 Rev. 2).

These failures occurred on 13 March 2025, second shift, discovered by QA technician W. White for 16 units out of 22 tested. No other Austin Lab test stations exhibited high failure rates for Tuco 123FA network boxes (batch 27) noise verifications.

3. RISK ASSESSMENT DATA IDENTIFICATION

Risk data used in identifying/investigating a risk scenario should be uniquely identified to ensure the validity of subsequent risk analysis. Risk assessment data should include the equivalent of a pedigree linking the data to a specific risk scenario. This pedigree should identify the specific risk scenario, unique identification of the data, any restraints or mathematical computations associated with the data such as sampling, averaging, filtering, etc., data acquisition information as appropriate, and any influencing assumptions and/or interdependencies associated with the data.

3.1 Example of Risk Assessment Data Identification

Tuco 123FA network boxes (batch 27) noise verification data harvested from Austin Lab's factory verification reports, numbered 1001 thru 1023, for test points 11 thru 14. Data obtained via Heisenberg test software Rev 3 provided at two significant digits of resolution for 3 second unfiltered measurement windows.

4. RISK ASSESSMENT DATA ANALYSIS INFORMATION

As mentioned earlier, there is a multitude of data analysis methodologies for investigating risk assessment data as well as a variety of methods for determining priority and impact of corrective action candidates. Whenever risk data analysis is performed, any methodology used should be documented to the extent necessary to faithfully reproduce the analysis. Some data analysis information to consider.

1) Methods/mathematical computations used
2) Qualifiers, dependencies, assumptions, etc.
3) Reference data derived from lookup tables, handbooks, etc.
4) Impactful influences such as temperature, settling times, handling, etc.
5) Conclusions guidance derived from analysis if needed for better understanding

If data analysis methods used are proprietary or otherwise not readily available in the public domain they should be documented as to their intent, expected outcome(s) and ideally provided with associated validation information using appropriate data disclosing safeguards as needed

4.1 Example Risk Assessment Data Analysis Information

Analysis of Tuco 123FA network boxes (batch 27) noise verification data showed a linear offset increasing from the first to last units tested. Acceptance limit of -90dBm exceeded for the fifth to last unit tested. Average linear offset increase was 1.7dB for each sequential unit tested. Given the aforementioned, there is a high likelihood that the model 123XYZ, SN 4567 used to measure noise exhibited an unprecedented drift causing measured noise levels to steadily increase over time.

5. RISK ASSESSMENT CORRECTIVE ACTION(S) IDENTIFICATION, RANKING AND IMPLEMENTATION

Identification of corrective action candidates for a risk scenario can be derived from multiple sources such as risk data analysis, experimentation, simulations, insight gleamed from historical data, similar scenarios, published case studies and experience/knowledge of equipment operators, data analyst and end users. As viable corrective action candidates are identified, those candidates which for some reason(s) are not viable, such as being cost prohibitive or having an extremely low chance of success, should be captured (recorded) to reduce time revisiting them. The following are some issues which may need to be addressed when evaluating corrective action candidates.

- Personnel safety (always a top consideration)
- Catastrophic failures that can potentially cause surrounding damage
- Cost to implement
- Operating costs
- Ease of implementation

- Implementation timelines requirements
- Risk scenario life expectancy, example: imminent product end of life
- Resource dependencies (hardware, software, personnel, etc.)
- Insufficient, questionable data
- Probability of success
- Longivity of success
- Rework considerations
- Redesign, re-fixturing considerations
- Accessibility
- Maintainability
- Interactions and dependencies
- Stakeholders, operators considerations
- Environmental, social impact
- Proprietary, nondisclosure, legality considerations
- Regulatory, import/export compliance
- Certification, accreditation
- Technology availability
- Personnel availability
- Future operation/support considerations

Once viable corrective action candidates have been identified, their prioritization relative to obtaining an intended, preferred state can be inputted into a simple Action Priority Matrix diagram to help determine which corrective actions to focus on and in which order. This diagram typically has two axis with impact (low, medium, high severity rankings) on the vertical axis and effort, cost, etc., on the horizontal axis (low, medium, high rankings). Action Priority Matrices diagrams are often color coded to give a quick visualization of rankings. Selection of corrective action candidates rankings may be facilitated by assigning weighting factors to corrective action considerations (see above) for impact and effort/cost and tallying totals. Corrective action(s) selected for implementation may need additional documentation if not intuitively derived from the Action Priority Matrix assuming high impact, low effort/cost candidates are preferred.

Once one or more corrective actions have been selected for implementation, implementation plans need to be created and evaluated. Corrective action implementation plans should be well documented as to who, what, when, where and why's and of course clearly communicated to implementers, interested parties and stakeholders as applicable.

6. RISK ASSESSMENT CLOSURE

Realization of risk assessment closure is typically performed within a company's quality manual policy and procedures to ensure:

1) desired outcomes have been achieved and any subsequent actions such as monitoring or periodic review is performed

or

2) alternative/additional actions needed to be taken should desired outcomes not be achieved.

Again, as applicable, the who, what, when, where and why's of a risk assessment closure should be documented.

SUMMARY

A well-documented risk assessment is essential for helping ensure corrective actions are successfully implemented, or intentionally not needed/implemented, are clearly communicated and available for future referencing. This paper outlines some risk assessment topics that one would expect/hope be addresses in risk assessment documentation and provides a simple checklist of these topics.

MEASUREMENT RISK DOCUMENTATION CHECKLIST

- ✓ Risk Assessment Identification Statement
- ✓ Risk Assessment Identification Statement Assumptions and Qualifications
- ✓ Risk Assessment Data Identification
- ✓ Risk Assessment Data Analysis Information
- ✓ Risk Assessment Corrective Action(s) Identification, Ranking and Implementation
- ✓ Risk Assessment Closure

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