Simplifying Progress

A Systematic Approach for risk-based Determination of Test and Calibration Intervals, Tolerances and Safety Factors for Weighing Instruments

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1. Background & Motivation

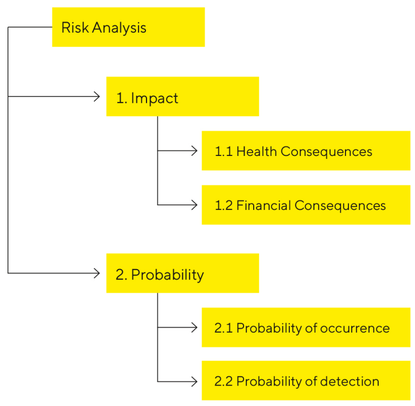
- Weighing results are critical for product quality, safety and compliance
- Fixed test | calibration intervals often ignore process-specific risks
- Increasing regulatory focus on risk-based approaches (e.g. ISO 9001)
- No regulatory guidance on
  - How can risk be quantified?
  - What would be the risk quantification for my application | process?
  - What are appropriate intervals, tolerances,... for my risk?
- Need to balance measurement reliability and cost-effectiveness

2. Objective

- Develop a systematic, risk-based methodology to determine
  - test intervals
  - calibration intervals
  - tolerances
  - safety factors
- Applicable to laboratory and industrial weighing processes
- Transparent, reproducible and standards-aligned

3. Risk-based concept overview

- Process-oriented risk management approach
- Risk defined as function of
  - Impact (consequences of erroneous weighing results)
  - Probability (likelihood and detectability of errors)
- Alignment with
  - ISO 9001 risk-based thinking
  - quality management principles



4. Risk assessment methodology

I

4.1 Impact Assessment

- Health-related consequences
- Financial consequences (including regulatory | compliance implications)
  - Health-related consequences are weighted twice as high as financial consequences

Probability That an Incorrect Weighing Result Goes Undetected	Detection Factor F_D
Low	1
Medium	2
High	3

P

4.2 Probability Assessment

- Probability of occurrence
  - Taking into account user-side mitigation actions (procedures, training, controls) and device features that reduce risk (e.g. auto-levelling, automatic internal adjustment, ionizer,...)

O

D

- Probability of Detection of errors

$$F_P = F_O \times F$$

Severity of Consequences	Category of Consequence	
	Financial F_I	Healthwise F_I
Not applicable	---	0
Low	1	2
Medium	3	6
High	5	10

Probability of an Erroneous Weighing Result	Occurrence Factor F_O
Low	1
Medium	2
High	3

5. Quantification & Risk indicator

- Scoring of impact and probability factors
- Calculation of a risk indicator as the product of impact and probability
- Risk indicator used as decision basis for
  - test intervals
  - calibration intervals
  - tolerance limits
  - safety factors

$$R = F_I \times F_P$$

Impact Factor F_I \ Probability Factor F_P	1	2	3	4	6	9
10	10	20	30	40	60	90
6	6	12	18	24	36	54
5	5	10	15	20	30	45
3	3	6	9	12	18	27
2	2	4	6	8	12	18
1	1	2	3	4	6	9

6. Assigning test | calibration intervals to risk indicator values

- Distinction between
  - Internal (i.e. performed by the user) routine tests
    - more often, less extensive
  - External (i.e. perfomed by an independent service provider) calibrations and tests
    - Less often, more extensive
- Choosing practical intervals
- Occasion-related tests | calibrations (e.g. after relocation, repair,...) should be conducted separately

R	Internal Performed Routine Tests	External Performed Calibrations and Tests
1 to 6	monthly	24 months
8 to 15	14-daily	12 months
18 to 30	weekly	6 months
36 to 90	every working day	3 months

7. Assigning tolerances and safety factors to risk indicator values

7.1. Define a required process accuracy

- Preferrably from an uncertainty calculation
- Alternatively, from the risk assessment:

Impact Factor F_I	1	2	3	5	6	10
Process accuracy / %	5	2	1	0.5	0.2	0.1

7.2. Define a safety factor as distance between action limit and warning limit:

Probability Factor F_P	1	2	3	4–6	9
Safety factor	1	2	3	5	10

7.3 Define warning (WL) and action limits (AL) based on the determined process accuracy (PA) and safety factor (SF)

AL=L*PA/2

where L is the test load and the division by 2 denotes the assignment of half the acceptable limit to each test (eccentricity, linearity, sensitivity, repeatability)

WL=AL/SF

- If the warning limit (WL) is exceeded, undertake a predefined action (call service,
  clean balance, reconsider process requirements,....)
- If the action limit (AL) is exceeded, disable the further use of the balance.

8. Benefits & practical impact

- Optimized weighing processes
- Increased measurement reliability
- Improved cost-effectiveness
- Better alignment with regulatory requirements
- Scalable and adaptable to different use cases
- Harmonized and comprehensible way to determine tolerances and intervals

Want to learn more?

- Download our respective white paper: