Guidance Number:
063

Table I

Probability of Instrument Failure [MTBF = mean time between failures]

	Risk Level → Numeric Ranking →	Low (1)	Medium (2)	High (3)
History	This Instrument (The intent is to use history as an indicator of probability)	Have more than 2 years of records, history shows low rate of calibration OOT (MTBF > 24 months)	Have less than 2 years of records, history shows low rate of calibration OOT	Have no historical records, or records show MTBF < 24 months
	Identical Instrument (make and model)	Have 3 or more identical instruments (MTBF > 24 months)	Have 1 or 2 identical instruments (MTBF > 24 months)	Have no identical instruments to benchmark
	Similar Instruments (The concept is to determine if there are instruments of similar design and functionality utilized in the intended environment that may yield performance data for use as a predictor, i.e. show low risk based on demonstrated reliability)	Have several (e.g. 10) similar (in type, technology, range) instruments in similar environments (MTBF > 24 months)	Have a few similar instruments in similar environments (MTBF > 24 months);	Have no similar instruments in similar environments
Environmental	Temperature and Humidity (both operating and storage conditions)	Temperature and humidity are stable and are always within manufacturer's recommended range	Temperature and humidity vary, but always stay within manufacturer's range	Temperature and humidity are not known or may exceed manufacturer's range
	Power line / Electrical Disturbances	Instrument is non-electric	Instrument is battery powered or well-filtered and protected from power disturbances and lightning	Instrument is located in an electrically "noisy" environment, or may be susceptible to sags, surges, spikes, and severe electro-magnetic interference (EMI)
	Dust / Dirt / Chemical / Wash down	Instrument is located in a clean, dry, area that does not get washed down	Instrument is in a protected cabinet, or removed for area wash down, light dust, and no chemical exposure	Instrument is in an exposed, dirty environment subjected to frequent wash downs, or chemical exposure
	Vibration and shock	Instrument is permanently mounted in a stable environment	Instrument is portable and moved frequently, or may be exposed to occasional vibration or shock	Instrument is subjected to severe shock and vibration
	Physical Damage	Instrument is kept in a segregated or protected area	Instrument is located in a moderate traffic area and potentially susceptible to contact with equipment or personnel in transit	Instrument is located in a high traffic area and susceptible to contact with equipment or personnel in transit
Range of Use	Range of inputs the instrument is subjected to	Instrument is operated at a single fixed setting in the middle portion of its designed functional range	Instrument is operated at multiple settings throughout the middle 80% of its functional range	Instrument is operated at multiple settings across the entire functional range or at a fixed setting at the upper or lower limit of the functional range
Age	Infant mortality (start-up failure) or aging components	Instrument has been in service for >3 months but less than 5 years	Instrument has been in service for less than 3 months, or greater than 5 years	Instrument has been in service for over 10 years

Table II

Severity of Instrument Failure*

	Risk Level → Numerical Ranking* →	Low (1)	Medium (2)	High (3)
Human Safety	Instrument's criticality to plant safety	Instrument is not part of a safety system	Instrument is part of a safety system, but is redundant (secondary)	Instrument is a primary component of a safety system; no redundant instrumentation is deployed
Environmental	Instrument's criticality to the operating environment	Instrument is not part of an environmental system	Instrument is part of an environmental system, but is redundant (secondary)	Instrument is a primary component of an environmental system, no redundant instrumentation is deployed
GMP / Product	Impact of performance failure on product quality	Instrument is part of a "No Impact" system, failure to conform with performance specifications/expectations would not adversely impact the quality of product	Instrument is part of a "Indirect Impact" system or an "Indirect Component" of a "Direct Impact" system; failure to conform with performance specifications/expectations could adversely impact product quality, however, there is 100% testing/verification downstream in the process	Instrument is a Direct Impact component in a Direct Impact system with no downstream verification or testing; failure to conform with performance specifications/expectations could adversely impact product quality,
Production	Impact of performance failure on operational efficiency	Failure to conform with performance specification/expectations would not adversely affect production speed or efficiency	Failure to conform with performance specifications/expectations would adversely impact the speed and/or the efficiency of the operation	Failure to conform with performance specifications/expectations would cause a halt to production
Cost	The intent is to quantify the additional cost incurred by instrument performance failure	Performance failure results in no additional cost	Performance failure can be mitigated with minor additional resources	Performance failure results in major damage, additional failures, or the need for product rework or rejection
Energy	Impact of performance failure on energy consumption	Performance failure has no effect on energy efficiency and consumption	Performance failure causes a minor increase in energy consumption, or loss of efficiency	Performance failure causes a major increase in energy consumption or major loss of efficiency

*Note: A severity ranking of "Zero" [0] is possible. There are some potentially calibrated instruments that will have no impact if they are out of tolerance and are candidates for removal from the calibration program and subsequent categorization as "No calibration necessary" or "For reference only". Instruments in this category should be clearly labeled in the operation.

Table III

Detectability of Instrument Failure

	Risk Level → Numerical Ranking →	Low (1)	Medium (2)	High (3)
Automatic Operation	Automated verification of critical product characteristics/parameters	100% or continuous online inspection/analysis (PAT) of critical attributes/parameters; redundant stage release testing	Periodic online inspection/analysis of critical attributes/parameters redundant stage release testing	No automated online inspection/analysis of critical attributes/parameters, no stage release testing.
Manual Operation	Human interventions or audits to verify resulting product quality	100% or continuous online inspection/verification of critical attributes/parameters; with or without stage release testing	Periodic inspection/verification of critical attributes/parameters; with stage release testing	No inspections/verifications during the process and no stage release testing

Table IV

FMEA Ranking Criteria and Failure Scores using a Three Point Ranking System

Numerical Ranking	Probability of Risk (Table I) Criteria used: Instrument history, environment, range of use, & age	Severity of Risk (Table II) Criteria used: Impact on human safety, environmental, GMP/product, production, cost, & energy	Detectability of Risk (Table III) Criteria used: Automatic operation or manual operation, operator verification	Maximum Risk Score
1	Low	Low	Low	1
2	Medium	Medium	Medium	8
3	High	High	High	27

The following frequency period based on risk score is recommended:

Risk Score Examples	Overall Risk Description	Suggested Calibration Frequency Interval change
01	Negligible	Consider extending calibration interval up to 36 months
02	Very Low	Consider extending calibration interval up to 24 months
03-06	Low	Consider extending the calibration interval x2 (up to a maximum of 24 months) (i.e. 6 months ➔ 12 months)
08	Medium	Consider extending the calibration interval by a factor of 1.2x to 1.5x, (up to a maximum of 18 months) (i.e. 3 months ➔ 4 months, 12 months ➔18 months)
09-12	Med / High	Maintain the same calibration interval, (re-evaluate the risk score in 12 months)
18	High	Consider shortening the calibration interval by a factor of x .5 (i.e. 12 months ➔ 6 months)
27	Very High	Consider shortening the calibration interval to a very short period (i.e. 3 months) and consider re-engineering the instrument system to reduce the risk score

Examples of Instrument Calibration Interval Change Requests

The sample risk assessments below are to serve as "examples" only and used as illustrations of this approach. Actual situations require a Team assessment and review of local and site conditions.

Example #1:

Instrument: Temperature Transmitter

Application: Temperature transmitter on a circulation loop for WFI. Temperature is always maintained at 85 deg C, transmitter is located in a protected area that does not get washed down. Temperature transmitter is rated to handle the sanitizing temperatures for the system.

Basis for change:

Instrument Type	Inst. Class Critical?Y or N	Associated System	Probability of Occurrence	Severity of failure	Detectability of Failure	Risk Score (Failure Mode)	Recommended Calibration Period (Months) from table:	Basis for Change Calibration Interval: Medium probability of failure, medium severity, and medium delectability. Cautiously extend the interval, by a factor of x1.5
Temperature Transmitter	Y	WFI	2	2	2	8 (medium)	6 months	9 months

Example #2:

Instrument: Pressure Indicator

Application: Pressure indicator on a large reactor vessel. Need to assure positive pressure in the reactor, but maintain pressure below tank safety rating. Tank is washed down, goes through vacuum / pressure cycles, and occasionally goes over-pressure **(blows the relief).**

Basis for change:

Instrument Type	Inst. Class Critical?Y or N	Associated System	Probability of Occurrence	Severity of failure	Detectability of Failure	Risk Score (Failure Mode)	Recommended Calibration Period (Months) from table:	Basis for Change Calibration Interval: High (or unknown) probability of occurrence, medium severity, and high detect ability risk. Consider shortening the calibration interval based on the calculated risk (high).
Pressure Indicator	Y	Reactor	3	2	3	18 (high)	12 months	6 months

Example #3:

Instrument: Humidity Transmitter

Application: Ambient humidity sensor in a conditioned room. ***This transmitter is an alarm point only***. The Building Management System (BMS) controls the temperature and humidity, and a chart recorder records them, providing very easy detect ability of failure.

Basis for change:

Instrument Type	Inst. Class Critical?Y or N	Associated System	Probability of Occurrence	Severity of failure	Detectability of Failure	Risk Score (Failure Mode)	Recommended Calibration Period (Months) from table:	Basis for Change Calibration Interval: Since it is low probability and easily detected, consider increasing the calibration interval to 24 months.
Humidity Transmitter	**Y**	**Packout Room**	**1**	**3**	**1**	**3 (low)**	**12**	**24 months**

Example #4:

Instrument: O_2 Sensor

Application: Oxygen sensor detecting ***breathable*** concentration of O2 in an area using liquid nitrogen as a coolant. Typically these devices are covered by a LOPA (layers of protection assessment) evaluation to determine the safety factors.

Basis for change:

Instrument Type	Inst. Class Critical?Y or N	Associated System	Probability of Occurrence	Severity of failure	Detectability of Failure	Risk Score (Failure Mode)	Recommended Calibration Period (Months) from table:	Basis for Change Calibration Interval: Since the history of these devices is awful, and the severity is very high (human injury or death), and detect ability presents a high risk, consider decreasing the calibration interval to 3 months and re-engineering the detection system to mitigate the risks of single-unit failure.
O_2 Sensor	**Y**	**Reactor**	**3**	**3**	**3**	**27 (high)**	**6**	**3 months**

Example #5:

Instrument: **RPM Indicator**

Application: Direct drive gearbox from a synchronous motor.

Basis for change:

Instrument Type	Inst. Class Critical?Y or N	Associated System	Probability of Occurrence	Severity of failure	Detectability of Failure	Risk Score (Failure Mode)	Recommended Calibration Period (Months) from table:	Basis for Change Calibration Interval: Overall negligible risk, consider increasing the calibration interval up to 36 months.
RPM Indicator	**Y**	**Reactor**	**1**	**1**	**1**	**1 (low)**	**18**	**36 months**