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FMEA for TCal: Risk Analysis in Compliance to EN ISO/IEC 17025:2017 Requirements

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Abstract: Touchless Calibration (TCal) is introduced at XXII IMEKO Congress in Belfast (UK, 2018) as a future development in calibration metrology, and to be implemented in calibration laboratories which are EN ISO/IEC 17025:2017 accredited, with a need to be risk assessed. The chosen method for risk assessment originally applied in this contribution is FMEA, which is widely accepted in industries such as aviation and automotive. In this paper, the overall process of risk determination and FMEA analysis for metrology of electric quantities and its results are presented and discussed.

I. INTRODUCTION

Touchless Calibration (TCal) is a contribution of Metrology 4.0 to the manufacturing industry as part of Industry 4.0 initiative. TCal is a new concept first presented on IMEKO XXII congress in Belfast, (UK) in 2018 [1] and the comparative uncertainty analysis against classical calibration was presented at Joint IMEKO TC1-TC7-TC13-TC18 Sympositum in St. Petersburg (Rusia) in 2019 [2]. This is a concept presented in Figure 1, where the manufacturers do not need to send their sensors/instruments for calibration to the laboratory, but they can simply digitally connect to the calibration laboratory and do the calibration in own premises.

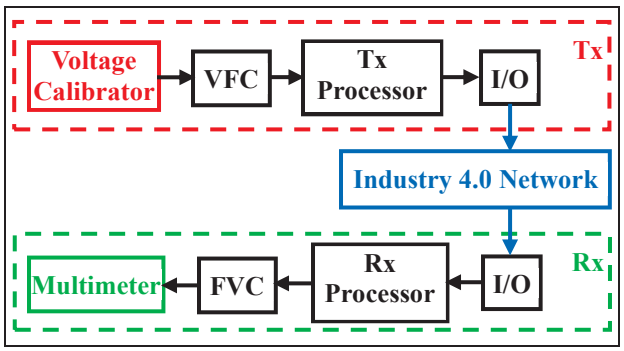

Fig. 1. TCal for voltage calibration

Most of the calibration laboratories tend to be accredited according to EN ISO/IEC 17025:2017 [3] in which in clause 8.5 (Actions to address risks and opportunities), but also throughout the overall content of the standard, the preventive approach of "risk-based thinking" is adopted.

"Risk-based thinking" is proactive approach in managing possible deficiencies and mistakes/errors which can happen during the calibration process. It is proactive approach which was first introduced in the Quality Management Systems in ISO 9001:2015 standard as a requirement.

This was novel approach in the Quality area, but it was in line with the studies over incidents and accidents data (especially in Risky Industries) which showed that many times, the quality shortcommings, deficiencies and failures can produce safety consequences [4]. In addition, there is "rule of the tumb", that the first step in improving the Safety, is the improvement of the Quality.

As a novel approach introduced in EN ISO/IEC 17025:2017 [3], there are still many misunderstandings of the application of the concept by the laboratories. The emphasis is to predict all possible non-conformities during calibration (measurement, testing, etc.) processes in the laboratories. So, the laboratory has to to establish a List of Hazards which could endanger the processes of calibration, measurement and testing in its own premises. When accomplished, for each of them there is a need to calculate the frequency (probability) as well as the impact of its occurance. This is a process of converision of Hazards into Risks [4].

Establishing the Risks for any of the Hazards means that the knowledge what, when and how can deviate, is present as "risk-based thinking". An opportunity for elimination of the risks and/or to mitigate them, is created. Elimination and/or mitigations apply to frequency and to consequences: there shall be efforts to decrease the frequency of happening and, if it happens to eliminate or mitigate the consequences.

This is in compliance to the proactive approach in Safety Management with intention to provide preventive and

corrective actions [4] regarding the possible shortcommings or deficiencies to the overal calibration process and to promote the approach of continual improvement as a philosophy in calibration.

Considering that the TCal is a novel concept in development, this contribution proposes the Failure Mode and Effect Analysis (FMEA) as a method for application "risk-based thinking" approach. In this paper only the risks which can affect the uncertainty of calibration are considered.

II. COMPARATIVE ANALYSIS FOR TOTAL RISKS

It is important to understand that a risk is calculated by mathematical means (statistical and probability rules). To calculate the frequency statistics has to be used. As statistics apply to data, a problem can arise as usually each calibration (measurement, testing, etc.) process in the laboratories is a company secret, and in general, there is lack of data. It means that laboratories should start recording each shortcoming or deficiency which can arise during their operation. All the records of these events which are affecting the calibration processes shall be used as data, to establish the frequency and consequences to the calibration process.

If there is enough data, statistics will help the establishment of the probability of happening of each of the risks. The probability must be accompanied by the particular probability distribution.

To make comparison of the total risks (a sum of all risks for particular system or process) between the classical calibration and TCal, a correct approach has to be applied. The total risks of classical calibration without using particular method have to be compared. Considering that different laboratories use different methods, using an approach independent from the method is most adequate.

For comparing the risks of classical calibration and TCal there is a need to take into consideration the Fig. 2. And Fig. 3, where the different steps of classical calibration and TCal are presented [2].

In Fig. 2 And Fig. 3, NMI ST stands for National Metrolgy Institute Standard, ALS for Accredited Laboratory Standard, ILS for Internal Labratory Standard, CWS for Company (Working) Standard and UUT for Unit Under Test.

The Fig. 2. deals with the traceability chains in classical calibration and Fig. 3 with the traceability chains in TCal, and it is used to calculate Type A uncertainties for the both calibrations [2]. The same figure can be also deployed to determine the total risk for both calibrations.

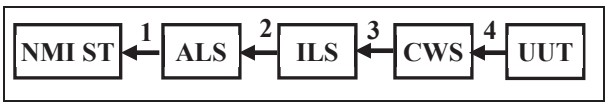

Fig. 2. Traceability steps for classical calibration

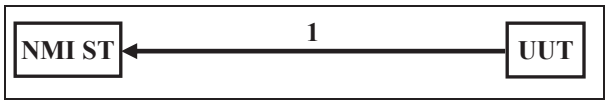

Fig. 3. Traceability steps with TCal

Each of these steps in classical calibration has particular risks of potential non-conformities and all these risks are associated with particular probability distribution.

To calculate the total risk using all these distributions, it is necessary to calculate the convolution among them. So, the total risks R_{tot} for classical calibration, expressed as summarized probability distribution for each individual step presented in Fig. 1, is:

$$R_{tot} = R_1 * R_2 * R_3 * R_4 \quad (1)$$

where

$$(R_1 * R_2)(t) = \int_{-\infty}^{\infty} R_1(\tau) \cdot R_2(t-\tau)\, d\tau \quad (2)$$

and $*$ stands for operation of convolution, the R_1, R_2, R_3 and R_4 are the particular individual risks (for steps 1, 2, 3 and 4 from Fig. 2, respectively) that something will deviate during execution of the steps 1, 2, 3 and 4, respectively in the Fig. 2. In this particular case, in order to calculate the total risk, the convolution should be executed three times in total.

The probability distribution for each step is not precisely known, but it is clear from the theory of statistics that the convolution of these risks, in most of the cases, will produce a fat-tail distribution [5]. Fat-tail distributions have increased total risks compared to Gaussian distribution in the tails of the curves. So, less expected hazards tend to have higher probability of appearance in fat-tail distributions than in Gaussian distributions. In general, the total risk for classical calibration, due to the fat-tails produced by convolution, will be with higher certainty than the total risk calculated for TCal.

III. FMEA INTRODUCTION

The theory explained in paragraph II is a scientific approach. In industry, the method of calculating the risk contains modificatios from the one explained in paragraph II. There, other diverse methods are used, and one of the most frequently applied is the Failure Mode and Effect Analysis (FMEA).

FMEA is a semi-quantitative method, not for mathematical calculation of the risk, but to provide information when, how and where to produce preventive and corrective qualitative measures to eliminate and/or to mitigate the risks present in industrial processes and operations. It is a bottom-up, inductive (semi-quantitative) analytical method which analyises the effects of single failure of the component, process or function of the system or subsystem. It is very useful for exhaustive listing of all

potential faults and failures and it is standardly used in automotive industry [6], [7] and in aerospace [8].

The first standard which introduced the FMEA was, the U.S. military standard MIL-STD-1629, published in 1949 as a procedure, and later standardized in 1974. Even before standardization, many industries adopted these methods in their processes. This standard was later updated as MIL-STD-1629A [6]. In practice, the FMEA is used in a rather unstandardized way considering that few FMEA engineers can produce different values for performances of the same process which is analysed by FMEA. NASA and its partners started to use FMEA in 1960s and since then it was used in many aviation and space programs (Apollo, Viking, Voyager, etc.). It triggered the use of FMEA in the civil aviation industry, especially in designing aircraft. In 1970s it spread also to automotive industry, beginning with the Ford Motor Company [7].

FMEA, as a safety engineering method, is aimed at identifying and classifying potential failure modes and their effects on the system. This helps in defining and implementing actions to avoid these failures. So, it is a method not considered only for detection of causes for faults of equipment and/or failures of operation (processes, actions, etc.), but it is used also to measure the effect of preventive and corrective actions undertaken to improve the situation, i.e. mitigations.

Failure mode is actually how the failure of the system is observed. In general, it describes how the failure occurs. Effect analysis is investigating the consequence of the failure in the system functioning (process, operation, activity, etc.).

FMEA should be launched at the beginning of implementation of every new system, process, method or operation. If the FMEA is already conducted, then every future change in the system (process, operation, activity, etc.) should trigger another checking of data comprised in previously prepared FMEA.

The main application of FMEA is to classify the effects of potential failure modes by their severity (SEV), frequency (FREQ) and detection (DET), and subsequently to determine the preventive and corrective actions needed to eliminate or mitigate these failures or consequences. The planning of actions may be determined by calculating the risk priority number (RPN) for each failure, as:

$$RPN = SEV \cdot FREQ \cdot DET \qquad (3)$$

where, SEV is the severity (how strong is the effect on the system), FREQ is the frequency (how often it could happen) and DET is the detection (how easily the failure can be detected).

The case of higher RPN than the initially established criteria, provides an argumented reason for an intentional change in the form of preventive or corrective action(s) to improve the system (process, operation, activity, etc).

IV. FMEA CRITERIA OF TCAL

As it can be seen from the equation above, the RPN can be calculated by simple multiplication of the determined values of SEV, FREQ and DET. To determine these values particular criteria have to be prescribed and although there are few options for calculation of the RPN mentioned in [9], the classical approach is used in this contribution.

The criteria which are used in this particular case for SEV, FREQ and DET for TCal are given in the Table 1.

Table 1. Criteria for SEV, FREQ and DET

SEV

Value	Cat.	Description
1	No effect	No effect on the calibration process
2	Minor effect	Slight increase in uncertainty and traceability can be established
3	Major effect	Considerable increase in uncertainty and traceability can be established
4	Critical	Uncertainty is on the limit or/and traceability cannot be established
5	Catast-rophic	Uncertainty is high or/and traceability cannot be established

FREQ

Value	Cat.	Description
1	Never	Never happened
2	Rare	Happen only in 1% of calibrations per year
3	Occasional	Happen only in 5% of calibrations per year
4	Probably	Happen only in 10% of calibrations per year
5	Frequently	Happen more than 10% of calibrations per year

DET

Value	Cat.	Description
1	Easy	Can be noticed immediately by observation before calibration starts
2	Not so easy	Can be detected after few different checks during calibration using observation
3	Medium	There is a need of simple tools and analysis to detect the problem
4	Hard	There is need of particular tools to detect the problem
5	Not detected	The nature of the problem is such as it cannot be detected without considerable tools, instruments and analysis

In determining these criteria, the following assumtions were considered:

- Customer has executed “relative” calibration and the corresponding tool (Sensor/Transducer) is received in the calibration laboratory in proper condition;
- Laboratory, itself, is self-equipped with everything needed for application of the TCal method (equipment for calibration, equipment for transmission of calibration and environmental data, etc.);
- Laboratory, itself, has established uncertainty and traceability of its measurement system and reference standards;
- Determining uncertainty is a Customer job, but the laboratory must provide data of its contribution to the uncertainty to the customer;
- Total uncertainty budget will be estimated by the Customer using method which is compliant with the method of calculating the uncertainty within the laboratory.
- Laboratory can provide a guarantee for the uncertainty and the traceability only for its part of TCal;
- Laboratory staff is trained for particular TCal calibration procedure.

In addition, the criteria for RPN should be provided and for its value, two main criteria are posed:

- If RPN for each row is equal or below 27, it is considered as acceptable. Everything else should be subject of improvement (preventive and/or corrective actions); and
- Any value of 5 for SEV, FREQ and DET is not acceptable and must be a subject of improvement.

V. FMEA FOR TCAL

FMEA must be executed by the person trained in FMEA and who is proficient in methods used in laboratory. This is not easy to achieve, so it is recommendable to appoint a person as Quality Manager (in compliance with EN ISO/IEC 17025:017) with high technical comptence in the laboratory activities, as in [4]. Alternativly, team efforts to produce and discuss FMEA are recommended.

The FMEA is not an one-time event. It must be mainatined continually, because any change in equipment, method or personnel must trigger reconsideration of the failure modes, failure effects and values inside the FMEA. All these changes happen in the laboratory with intentions for overall improvement, but neverthelless they provide benefits in some areas, they also introduce new failure modes or changes in the present faiulure effects. In the case of TCal, the FMEA will always vary primarily depending on the type of Sensor/Transducer and Sensor/Actuator chosen for conducting FMEA [1], [2].

The case study presented in this contribution for TCal is the one for voltage calibration, as presented in [2], which uses Voltage-to-Frequency Convertor (VFC) as Sensor/Transducer and Frequency-to-Voltage Convertor (FVC) as Sensor/Actuator as given in Figure 1 and in [1], the Table 2 for FMEA is produced considering the general applications of TCal. The terminology included in the Table 2 is in accordance with the concept of TCal described on Fig. 1. Also, the “relative” calibration between VFC and FVC [2] is not a part of the FMEA, because it is an activity which is to be executed in the company’s premises and there is no need for special type of equipment. The calculation of the TCal calibration uncertainty is a task of the laboratory’s client (the company), so the calibration laboratory itself is not affected by this issue.

As it was elaborated in [2] considering the uncertainties, there are some of the present failure modes and effects which apply in the same manner to classical calibration and there are new failure modes and effects, which are specific for concept of TCal. In conducting the FMEA for TCal, the emphasis was put only on the new failure modes and effects which are typical for TCal and they do not apply to classical calibration. The summerized FMEA for TCal is presented in Table 2.

VI. DISCUSSION

From the TCal FMEA presented in Table 2, it can be noticed that risks different from those in classical calibration are identified. The risks in the classical calibration are strongly connected to the equipment used in the NMI ST Laboratory and the chain of reference standards used for the calibration.

The failure modes and effects in classical calibrations arise from the multi-step traceability concept as each of the traceability chain steps contributes to the increased risk of non-conformity. TCal is provided only through a single hierarchical step which reduces considerably the total risks which are accumulating during classical calibration. So, the risk of non-conformity in classical calibration is considerably higher than in TCal.

The conducted FMEA is not very complex and 19 new failure modes which can produce 23 failure effects are identified. The critical failure modes are those with SEV equal to 5, and 14 such modes are detected. Six of them also achieve RPN higher than 27, and 8 of them are critical only because the SEV is 5. The RPN value higher than 27 is achieved only in 7 cases.

It is important to emphasise that FMEA cannot eliminate or mitigate all the risks. In risk management the concept of ALARP (As Low As Reasonably Practical) is applied, which is actually a cost-benefit analysis of elimination and mitigation of the risks [4]. Sometimes it is too costly to eliminate the risks considering that laboratories are economic entities. Costly measures to eliminate the risks will make the process of calibration unprofitable.

In general, the preventive and corrective actions chosen to eliminate/mitigate the risks must be proportional to potential impact of the risks to the measurement uncertainty. In the case of any type of calibration, decreased uncertainty provides better results.

Table 2. FMEA for TCal

Process	Failure Mode	Failure Effect	SEV	FREQ	DET	RPN	Action	SEV	FREQ	DET	RPN
Preparation	Proper connection of equipment in the Lab is not established	Calibration not executed	5	2	2	20	Check the connections thoroughly	1	2	2	4
		Calibration is not accurate	4	2	2	16					
	Equipment is not thermally adjusted	Calibration is not accurate	2	2	3	12					
	Connection with Customer cannot be established	Calibration not executed	5	3	3	45	Establish connection with customer	2	3	3	18
	Connection with Customer site is not reliable	Calibration not executed	5	2	3	30	Establish reliable connection with customer	2	2	3	12
	VFC/FVC is not functioning	Calibration not executed	5	2	3	30	Calibration should be cancelled	5	2	3	30
	VFC/FVC is not linear	Calibration is not accurate	3	2	4	24					
	Environmental conditions in the Lab are varying	Calibration is not accurate	3	3	2	18					
	Mains voltage is not stable	Calibration is not accurate	4	3	3	36	Use stabilized power supply	1	3	3	9
	Proper procedure is not used	Calibration not executed	5	1	2	10	Follow the procedure	1	1	2	2
		Calibration is not accurate	2	1	2	4					
	Proper equipment is not used	Calibration not executed	5	2	2	20	Calibration should be cancelled	5	2	2	20
		Calibration is not accurate	3	2	2	12					
Calibration	Lab staff is not trained for TCal method	Calibration not executed	5	2	3	30	Train the Lab staff	2	1	3	6
	Lab staff make mistake(s)/error(s) during calibration	Calibration not executed	5	2	3	30	Provide procedure with Error Proofing	1	1	3	3
		Calibration is not accurate	3	2	3	18					
	VFC stops functioning	Calibration not executed	5	2	2	20	Calibration should be cancelled	5	2	2	20
	FVC stops functioning	Calibration not executed	5	2	2	20	Calibration should be cancelled	5	2	2	20
	Lab equipment stops functioning	Calibration not executed	5	2	2	20	Change the equipment, provide back-up	2	1	2	4
	Customer is not receiving data (connection is good)	Calibration not executed	5	3	2	30	Fix the settings of the equipment, provide procedure for checking the settings	2	3	2	12
	Connection is lost	Calibration not executed	5	2	2	20	Establish alternate connection, provide back-up connection.	2	1	2	4
Finish	No confirmation from the Customer	Calibration should be repeated	5	2	2	20	Provide confirmation through alternate (back-up) channels	1	1	2	2
	There is error in calculation of uncertainty	Calibration result is not accurate	4	1	4	16					

In general, the preventive and corrective actions chosen to eliminate/mitigate the risks must be proportional to potential impact of the risks to the measurement uncertainty. For any type of calibration, decreased uncertainty provides better results.

Even with FMEA, residual risks continue to exist, but the level of their acceptance is considered by the laboratory. FMEA is a helpful tool because the risk impact can be easily quantified and appropriate actions will impose improved values for frequency and consequences of risks which could happen.

As it can be seen, the most critical modes are those where calibration should be cancelled and there are 4 such failure modes. All of them can happen during calibration phase and three of them are connected with stopping of proper operation of the VFC and/or FVC. It is understandable because these two circuits are fundamental for providing effectiveness of calibration.

Another critical aspect for TCal is the communication. However, this concept is proposed to be used in the scope of Industry 4.0 digital telecommunication network, as it is assumed that reliability of the network is extremely high and integrity of data is also very high. That is the reason that communication is not considered as particular critical failure mode. It does not depend on the laboratory, so only which laboratory and customer could do is to provide redundant communication between them.

The only critical failure mode with RPN higher than 27, which does not have SEV equal to 5, is the one where the stability of mains is not so good and it might affect the power supply of the equipment. However, this is a case which can easily be mitigated by using stable power supply which has to be provided as regular equipment.

All these newly identified risks for the TCal in the calibration laboratory are related to the specifics of TCal as a calibration approach diverse from the classical calibration. The conducted FMEA has identified the major risks and most of the particular measures to eliminate and/or mitigate risks. One of the outputs of the FMEA for TCal is that all the failure modes and their effects could be critical problems for TCal execution, but they could be solved with limited input resources.

VII. CONCLUSION

From the FMEA of TCal which is presented in Table 2, it can be noticed that risks different from those in classical calibration are identified and they are not so problematic.

The most critical modes are those where calibration should be cancelled and all of them could happen during the calibration phase. In addition, three of them are connected with VFC and/or FVC. These two circuits are fundamental for providing effectiveness of calibration and as such, they are critical. Their pairing is making difference between acceptable and unacceptable calibration. These two circuits are highest contributors in the uncertainty budget of TCal and particular attention should be provided during their manufacturing and pairing, i.e. through so called relative calibration.

Another critical aspect in TCal is the communication, but TCal as concept is used with Industry 4.0 digital telecommunication network, and it is assumed that reliability of the network and the integrity of calibration data is very high. So, the communication is not expected to fail and as such, is not considered as a particular critical failure mode.

In general, all FMEA issues can be easily solved and TCal is not introducing any problematic risks.

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