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Mapping of processes and risks in the digital transformation in metrology of ionizing radiation, a case study in X-rays air kerma calibration

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ABSTRACT

For the new metrological challenges of an increasingly digitized world, several countries are developing applications and infrastructure for Digital Calibration Certificates – DCC, researching the comparability of real and virtual measurements. Objective: to map the processes and risks related to the digital transformation of X-rays air kerma calibration. The Failure Mode and Effect Analysis - FMEA was used to quantify risks and is widely used in the aviation and automotive industry due to its reliability. The results presented a conceptual model for calibrating ionizing radiation quantities in the framework of new technologies and calibration 4.0 and comparing processes and risks. The conceptual model of calibration 4.0 comprises three main parts: a transmitter, the 4.0 communication network, and a receiver. Intelligent devices with configurations enable calibration data transfers by radio-frequency messaging in all these parts. Comparing risks in contemporary and calibration 4.0 processes, a slight reduction in the total risk can be observed. But new risks are unique to the 4.0 model, all with maximum severity, and how to mitigate them is still unknown. It is also possible to estimate that artificial intelligence and automation can significantly reduce measurement risks, identification, and error in the analysis and use of calibration certificates.

Keywords: **Metrology 4.0, calibration 4.0, X-rays; risks, management.**

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1. INTRODUCTION

The concept of management generally refers to a set of principles related to the functions of planning, organizing, directing, and controlling. It consists of working efficiently with the available resources to achieve the expected goals with the least possible expenses [1]. A quality management system integrates all processes, techniques, and strategies to ensure that products and services are delivered according to expectations [2]. In this context, it is observed that in recent years, management focused on quality has progressively gained greater relevance in the Metrology of Ionizing Radiation (MIR).

Recently a new management concept has emerged, the so-called management 4.0, which is a response to the demands of the 4th industrial revolution from the digital transformation. This type of management is based on environment virtualization, integrating areas, and monitoring data in real-time. For example, the article [3] presents several European initiatives to support the new industrialization of Europe, such as the German *Industry 4.0*, the French *Industry du Futur*, and the Portuguese *i4.0*.

In this scope of metrology 4.0, the importance of mathematical and physical simulations and computer-based experiments is rapidly increasing. If such simulations imitate real measuring devices and measurements, they can be called "virtual measuring instruments." In this context, the task of metrology is to ensure the reliability of simulation results if they are used in the same way as real measurements [4].

At the same time, it can be observed that the digital transformation process enables the emergence of new products and processes that push proven quality assurance measures to their limits. This is particularly evident in the case of complex products that dynamically change their state after being put on the market. To be reliable, a product would need to be tested several times during its life cycle, sometimes continuously, and even today, there are no definitive solutions for this. One example is the applications of machine learning in medical devices. Although several innovative medical products are currently being developed with a high share of software, only a fraction leaps into the healthcare market. Why have neural networks not yet been trained to evaluate the quality of individual mammography images? One of the main reasons is the lack of structured metrological processes as well an objective, verifiable, and reproducible validation of Artificial Intelligence (IA) technologies [4].

New projects worldwide (Digital-SI Task Group; SmartCom: European Metrology Cloud; GEMIMeG and Met4FoF) [5] are collaboratively developing applications and infrastructure for digital calibration certificates, researching the comparability of real and virtual measurements and also working on evaluation methods with scope for machine learning and artificial intelligence. Thus, aiming to support the country's technical and scientific development, this study aimed to map the processes and risks related to X-rays air kerma calibration.

2. MATERIALS AND METHODS

A state-of-the-art study described [6] discusses the evolution of an emerging research topic and systematically reviews [3], [5], [7]–[21]. The analysis of all these studies, together with the experience of the LABPROSAUD/IFBA laboratory experts, were used to identify the risks, build the process mapping of the contemporary calibration, and the flow chart projection of the future calibration.

For the quantification of risks related to the process, the Failure Mode and Effect Analysis - FMEA method was used [22] with the following sequence:

1. Defined the criteria (table 1);
2. The Risk Priority Number - RPN was calculated as the product of Severity x Occurrence x Detectability;

Note[1]: The value of Occurrence (O) is derived from the statistical analysis of the risk occurring in the studied environment. The values of Severity (S) and Detectability (D) are collected from the result of technical evaluation and a consensus of three or more experts. Preferably, the values collected for the risk analysis were obtained privately and independently. In the absence of these, typical values from the literature were used.

3. The RPN was classified according to the parameters defined in table 2;

Note[2]: The rankings of the ranges in table 2 are calculated by multiplying the variables. For example: (No effect or Lesser effect) x (Never or Rare) x (Easy or Not so easy) = Acceptable.

4. Were applied the corrective actions;
5. The RPN was quantified once again to evaluate the effectiveness of the corrective actions.

Table 1. Definition of criteria by the effect

Value	Effect	Description
Criteria for severity (S)		
1	No effect	No impact on the calibration process
2	Lesser effect	Minor effect on the calibration result (smaller than uncertainty)
3	Greater effect	Reasonable effect on the calibration result (proportional to uncertainty)
4	Critical	Significant effect on the calibration result (greater than uncertainty)
5	Catastrophic	Interruption of the calibration process
Criteria for occurrence (O)		
1	Never	Never happens
2	Rare	1% chance per year
3	Occasional	5% chance per year
4	Likely	10% chance per year
5	Frequent	>10% chance per year
Criteria for detectability (D)		
1	Easy	Can be easily detected by observation before starting the process
2	Not so easy	Can be observed after some process checks
3	Medium	It is necessary to use standard checking tools
4	Difficult	It is necessary to use specific tools
5	Not detected	It cannot be detected

Table 2. RPN classification

S	O	D	RPN	Classification	Treatment
1	1	1	1	Acceptable < 27	No corrective actions need
2	2	2	8		
3	3	3	27	Relevant 27 ≤ RPN< 64	Demands corrective action
4	4	4	64		
5	5	5	125	Unacceptable RPN > 64	Urgent corrective action required

Additional criteria:

1 Any RPN < 27 is a residual risk and can be addressed in the continuous improvement process.

2 If any criteria are 5, the RPN should be classified at least as "Relevant."

3. RESULTS AND DISCUSSION

3.1. Contemporary calibration

Figure 1 presents the macro-flow (an overview) of the contemporary calibration process, ranging from user requests to market surveillance by regulatory bodies. Except for the "calibration request" step, there is a direct interrelationship between the process members; in general, there are no multiple connections between them for the execution of the flow, which means that each process member performs its task independently.

Figure 1. The macro flow of the contemporary calibration process

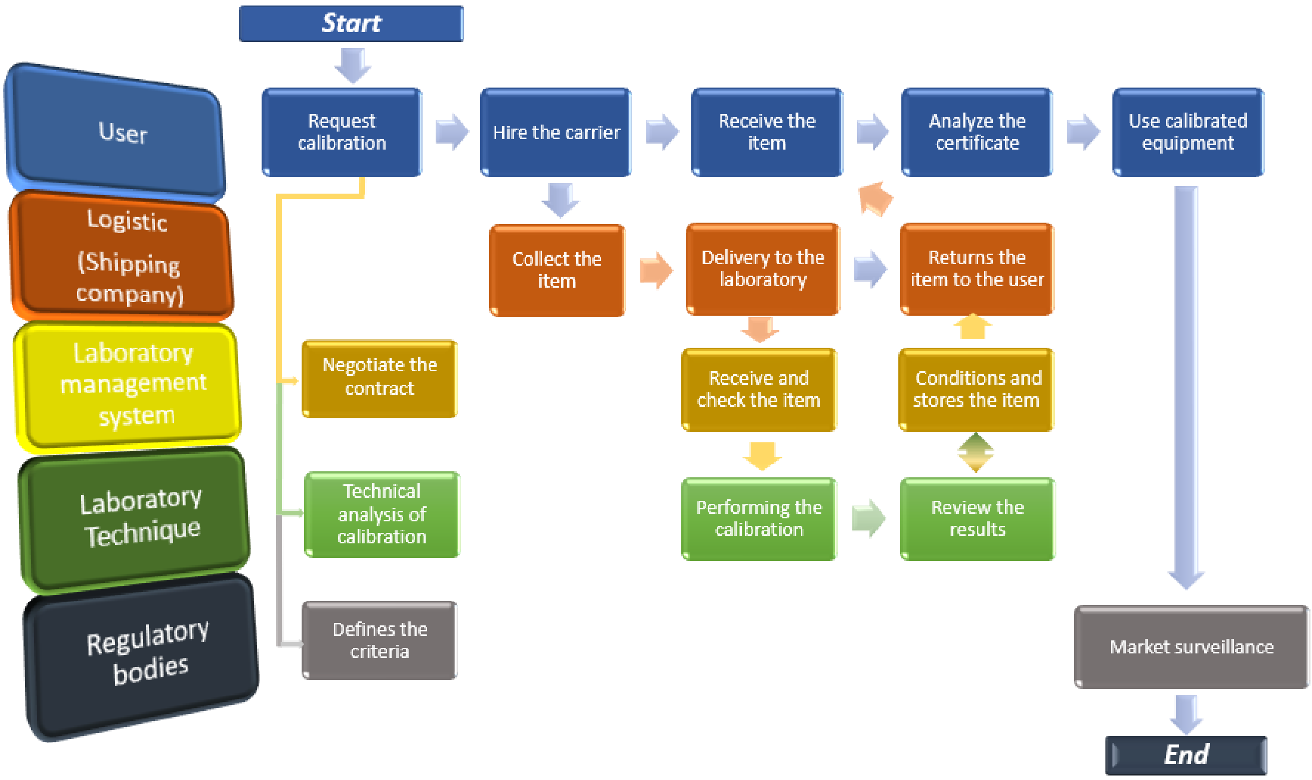


Figure 2 shows the mappings detailing the procedures related to the calibration of the kerma in the air, using the substitution method, according to the methodology [23], and mechanisms to guarantee the quality of the results required by [7]. There are 23 tasks to be performed, 15 of which are manual. The estimated total time was 1h30 per calibration. So, a calibration process for equipment with five ionization chambers is estimated at 7h30.

Figure 2. Mapping of the calibration process

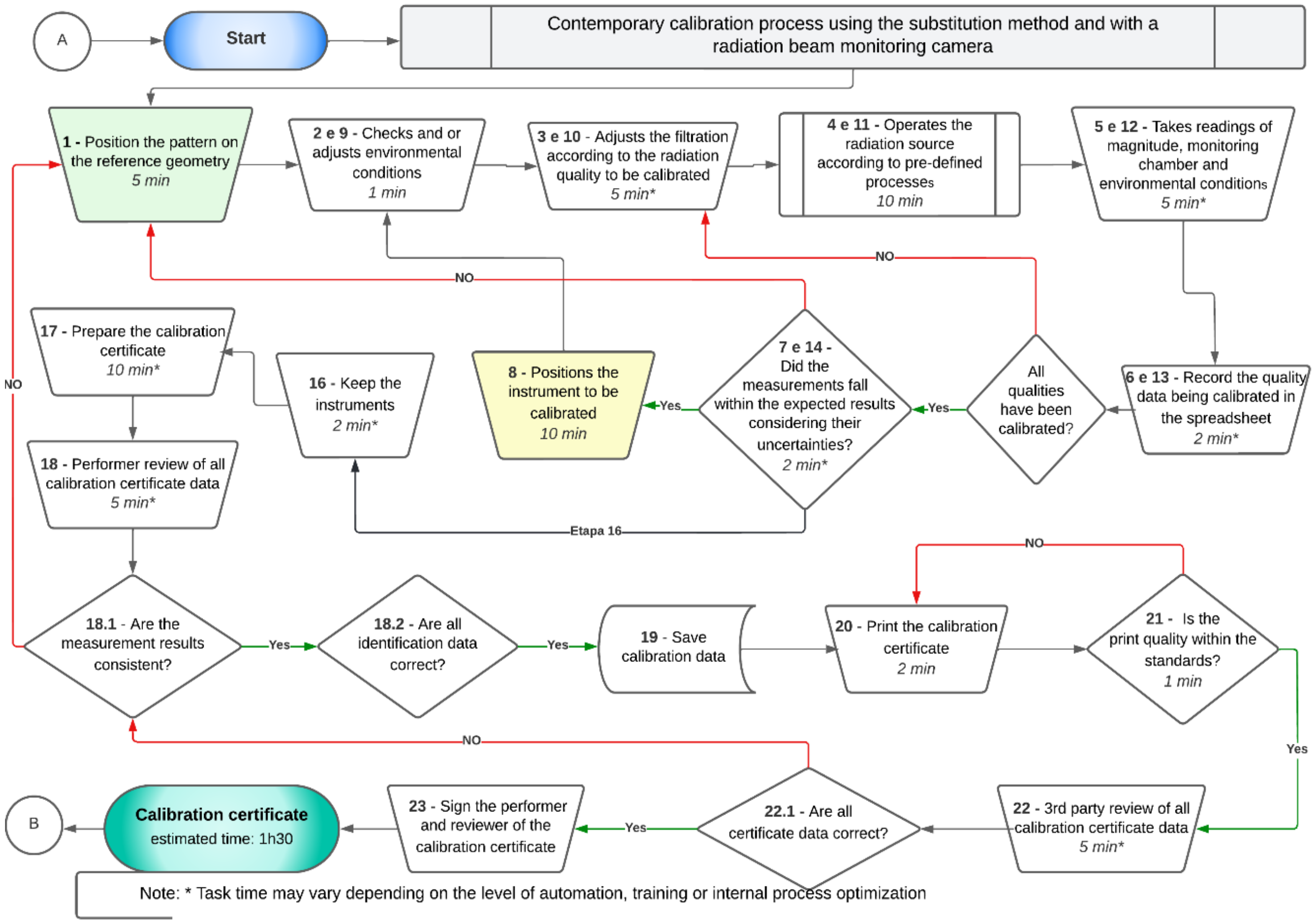


Table 3 shows the results of the statistics (O) and technique analysis (S and D). It identifies and quantifies the risks and their effects related to each agent in the contemporary calibration process at the place of study. The main risk identified was the error in the user's analysis and use of the calibration certificate. Its main vectors are complexity and number of quantities related to the area, lack of metrological user training, lack of metrological management of user equipment, manual certificate analyses process, complexity in the presentation of calibration certificate results, and cultural factors (perception of the meaning of the word “calibration” as “adjustment”).

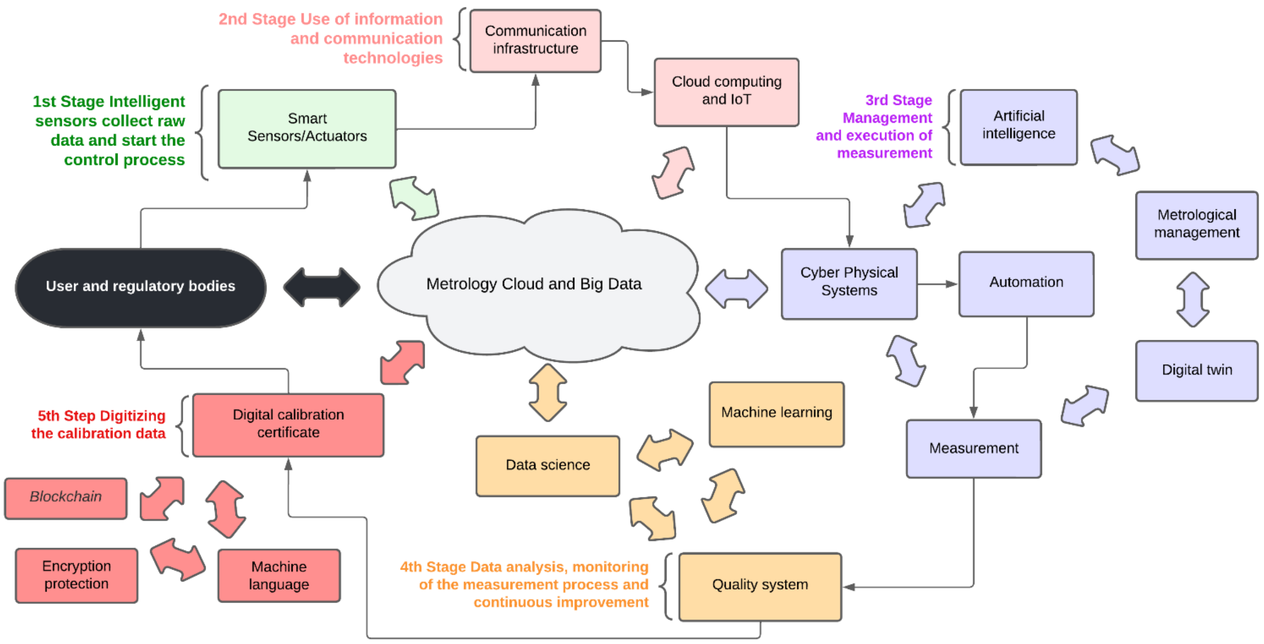
Table 3. Quantification of the risks of the traditional calibration process (FMEA).

Agent	Effect	Risk	S	O	D	RPN[1]	Actions	S	O	D	RPN[2]
User	Inaccurate calibration	Error in defining calibration criteria	4	2	2	16	User training and laboratory advice	3	2	2	12
		Error in the analysis and use of the CC	4	4	4	64		3	3	2	18
Logistics	Calibration not performed	Damage, loss, or theft of user equipment	5	3	3	45	Insurance and internal controls	4	2	3	36
		Excessive delay and calibration not performed	5	2	2	20		4	2	1	8
Laboratory management	Inaccurate calibration	Failure to comply with calibration requirements	4	3	3	36	Procedures for quality controls, internal and external audits	3	2	2	12
		Conflict of interest and confidentiality	3	2	3	18		3	1	2	6
		Receiving, handling, transport, and storage	4	2	3	24		4	2	2	16
	Calibration not performed	Break-in or theft of laboratory facilities	5	1	5	25	Security system	3	1	5	15
Laboratory calibration technique	Inaccurate calibration	Errors in calibration measurements	4	3	3	36	Procedures for quality controls, internal and external audits	4	2	2	16
		Errors in uncertainty calculations	4	3	4	48		4	2	4	32
		Errors in the calibration certificate information	4	3	2	24		4	2	1	8
		Equipment identification errors	1	3	3	9		1	2	2	4
		Unstable environmental conditions	3	3	3	27		2	1	2	4
	Calibration not performed	Patterns stop working	5	2	2	20	Reservation system	2	1	2	4
		User equipment does not work	5	3	2	30	No actions, calibration should be canceled	5	3	2	30
Regulatory bodies	Inaccurate calibration	Definition of calibration criteria	4	2	1	8	Team training	3	1	1	3
		Market surveillance error	4	2	4	32		3	2	2	12
					Total	***490***				***Total***	***242***

3.2. Metrologia 4.0

Figure 3 presents a relationship diagram that analyzes the interrelationship between the different members of the metrology 4.0 concept. It is crucial to explain the complex relationships because they serve as the basis for understanding the calibration 4.0 process. In the 1st stage, the smart sensors/actuators collect the raw data and start the measurement process. 2nd stage, information, and communication technologies are used (cloud computing, Internet of Things – IoT). In 3rd stage, the management and execution of the measurement take place through cyber-physical systems and automation, generating the measure that can have a direct or parallel action of AI with Digital Twin. 4th stage, the quality management system analyzes the data and monitors the process, continuously improving through data science and machine learning. In 5th step, the Digital Calibration Certificates - DCC is generated using blockchain, cryptography, and a markup language with rules for formatting documents (so that humans and machines can easily read them), for example, Extensible Markup Language – XML). These actions enable data protection and certificate parsing automation.

Figure 3. Metrology 4.0 relationship diagram



3.3. Calibration 4.0

Until the publication of this article, calibrations 4.0 for quantities related to ionizing radiation have not yet been performed out or published; however, observing the development of metrology in the European Union for electrical quantities [13], it is possible to estimate a conceptual model witch a macroflow (figure 4) and sketch a probable flowchart of the calibration 4.0 process (figure 5) for air kerma in X-rays.

Figure 4. Possible macroflow of the calibration 4.0

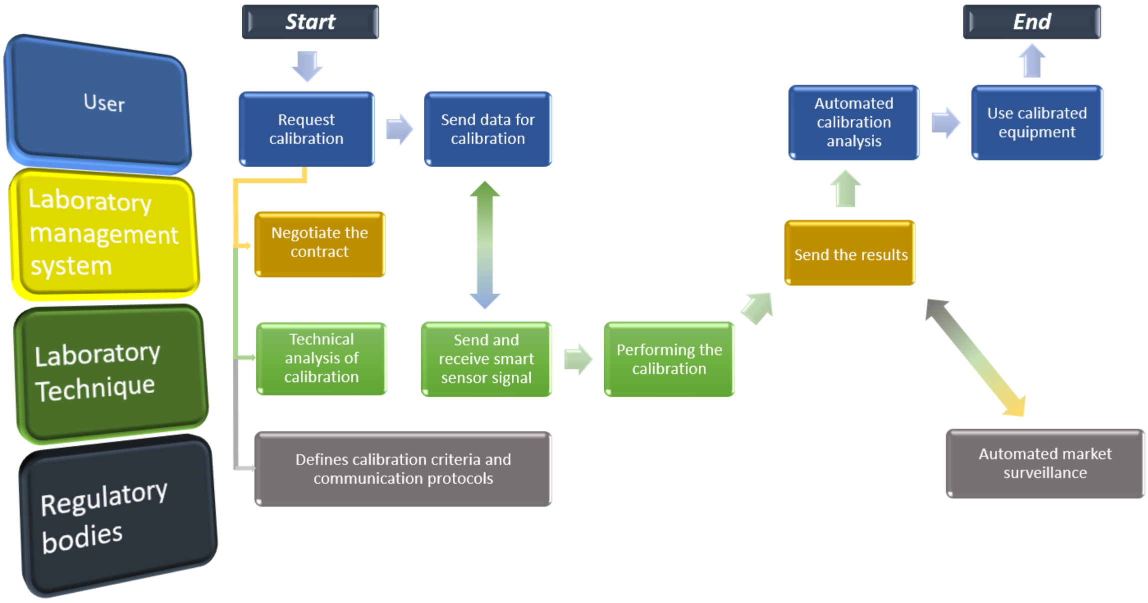


Figure 5. Flowchart of the conceptual model of calibration 4.0 for air kerma
Source: Adapted from Andonov [13]

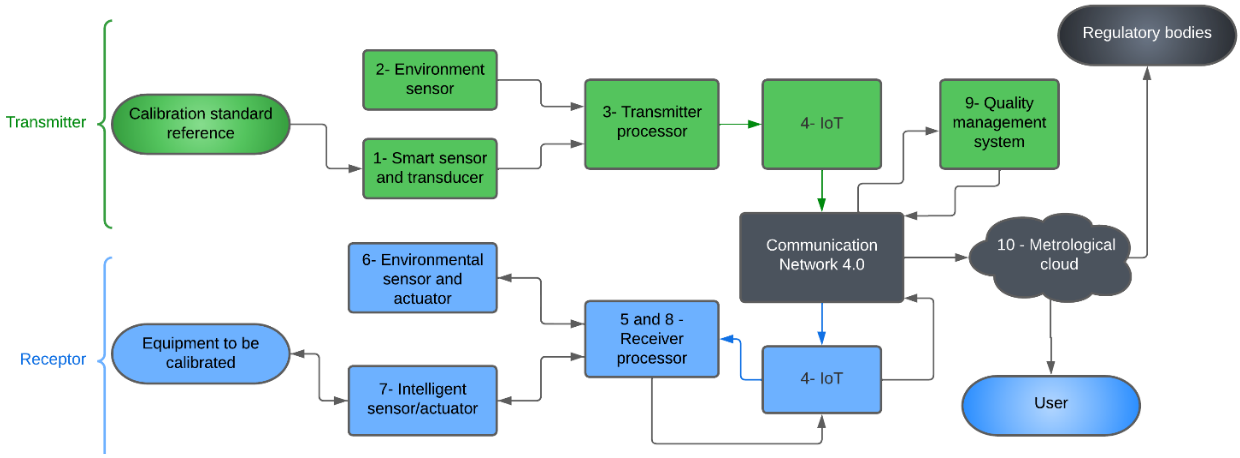


Figure 5 shows the macro-flow of the calibration 4.0 process. This system comprises three main parts: a transmitter (the calibration laboratory), a 4.0 communication network, and a receiver (the equipment to be calibrated). In all these parts, smart devices with configurations allow data transfer at high speed, reliability, and integrity. The process can be summarized as follows:

1- The reference standard (in the case of a would-be ionization chamber or solid-state sensor) is coupled to a smart sensor/transducer, which measures the reference value, transforms them into an electrical signal, and sends them to the transmitter processor.

2- The environmental sensor measures the ambient conditions and sends to the transmitter processor.

3- The transmitter processor synchronizes the electrical signals from the sensors and processes them in a radiofrequency calibration message.

4- The laboratory's IoT device sends the information using the 4.0 communication network to the receiver's IoT device.

5- The receiver processor checks the data for errors and divides it into calibration data and environmental conditions. The data is transformed into a format that will allow a comparison with the data obtained by the equipment to be calibrated. At the same time, the processor converts the environmental data into an appropriate format that will be sent as a signal to the environmental actuator sensor.

6- The environmental actuator sensor adjusts and maintains the environmental conditions to the same condition as the laboratory.

7- The intelligent sensor and actuator measure the values of the equipment to be calibrated and produce an electrical signal.

8- This signal is submitted to the receiver's processor and compared with the data from the reference standard. The difference between the data is recorded and processed to calculate instrument errors and uncertainty. If necessary, the intelligent sensor and actuator adjust some equipment parameters to be calibrated at the request of the receiving processor.

9- Then, the data is sent to the laboratory's quality management system, which analyzes and generates the digital calibration certificate.

10- At the end of the process, the laboratory sends the digital calibration certificate to the metrological cloud.

The [7] in clause 8.5, "Actions to face risks and opportunities, refers to the term "Risk-based thinking" which is a proactive approach in managing possible deficiencies and errors that may occur during the process; thus, even though there is still no calibration 4.0 for ionizing radiation area, table 4 presents the results of prospection of the quantification of risks related to this process.

Table 4. Quantification of risks related to the calibration 4.0 process (FMEA).

Agent	Effect	Risk	S	O	D	RPN[1]	Actions	S	O	D	RPN[2]
User	Inaccurate calibration	Error in defining calibration criteria	4	2	2	16	Automation	3	1	1	3
		[3]Error in the analysis and use of the DCC	4	1	4	16		3	1	1	3
Laboratory management	Inaccurate calibration	Failure to comply with calibration requirements	3	3	3	27	Improvement in the use of IA, automation, procedures for quality controls, internal and external audits	3	2	1	6
		Conflict of interest and confidentiality	3	2	3	18		3	1	2	6
	Calibration not performed	Break-in or theft of laboratory facilities	5	1	5	25	Security system	3	1	5	15
Laboratory calibration technique	Inaccurate calibration	[3]Errors in calibration measurements	4	2	2	16	Improvement in the use of IA, automation, procedures for quality controls, internal and external audits	4	1	2	8
		[3]Errors in uncertainty calculations	4	2	3	24		4	1	3	12
		[3]Errors in the calibration certificate information	4	2	2	16		4	1	1	4
		[3]Equipment identification errors	1	2	2	4		1	1	2	2
		Unstable environmental conditions	3	3	3	27	System backup	2	1	2	4
		Patterns stop working	5	2	2	20		2	1	2	4
	Calibration not performed	User equipment does not work	5	3	2	30	No actions, calibration should be cancelled	5	3	2	30
		[4]Laboratory personnel not trained for calibration method 4.0	5	2	3	30	Team training	2	1	3	6
		[4]Network communication error	5	2	2	20	Check connections, system backup	2	1	2	4
		[4]Transmitting processor error	5	2	3	30	No actions, calibration should be cancelled	5	2	3	30
		[4]Error in the receiving processor	5	2	2	20		5	2	2	20
		[4]Error in sensors/actuators	5	3	2	30		5	3	2	30
Regulatory bodies	Inaccurate calibration	Definition of calibration criteria	4	2	1	8	Automation	4	1	1	4
		[4]Market surveillance error	3	1	4	12		3	1	4	12
		Total				**389**					**203**
		Difference from the contemporary process				**-21%**					**-16%**

[3]It is estimated that the use of AI and automation can significantly reduce the occurrence rate
[4] Unique risks of the calibration 4.0 model [15]

For the quantification of the exclusive risks of the 4.0 model, it was used the value found in 4.0 voltage calibrations and published in [15]. As the data transmission technologies are likely to be the same between the calibrations 4.0, it is reasonable to estimate that these values are the current typical ones for the technology, so they can be used in a projection of the kerma calibration with X-rays or quantities that have similar measurement and physical processes such as the calibration of electrical quantities used in radiodiagnosis like (voltage and current in the X-rays tube). The quantification of the other risks in the projection of the calibration 4.0 as, for example, the error in the analysis and use of the certificate and calibration were estimated by consensus among the Labprosaud experts and discussed at the PTB international conference [24]. It is estimated that the use of AI, automation, and DCC can significantly reduce the occurrence of this risk since this analysis would be done only by machines, which mitigates the main factors related to the occurrence in estimating this risk.

Comparing the contemporary and calibration 4.0 processes, it was possible to observe a small reduction in the total risk. Still, there are new risks unique to the 4.0 model, all with a severity of 5, and how to mitigate them is still unknown. It is also possible to estimate that AI automation can significantly reduce the risks of measurement, identification, and error in the analysis and use of calibration certificates.

In the case of calibration 4.0, the risk level may vary significantly with the type of processor transmissor/receptor, sensor/actuator chosen, and the communication network's reliability and integrity. For this study, the effects of the actions to mitigate the risks from processors and sensors have not been estimated since there is no statistical data for them yet. Therefore, it is crucial to note FMEA is not a one-time event and should be re-evaluated whenever there are changes in equipment, people, or method.

Study limitations: risk is calculated by mathematical means (data statistics). As the calibration process is “company secrets,” there is a lack of “typical values” data; different laboratories use different techniques, so a particular independent approach would be the best way to do the risk analysis. Risk is different from risk perception. Although judgments must be made based on facts, cultural, religious, social, and political factors can influence the perception of risks among the agents involved. This means that these quantifications are limited to the current level of knowledge available about these risks and for this specific case study. However, since this is a pilot project, it can serve as a guide for future studies.

The risk analysis of this study corroborates that of [15] in which the agents involved in the calibration process are economic entities. The ALARA concept (as low as reasonably achievable) is applied in risk management. It is important to emphasize that residual risks and uncertainties continue to exist as long as actions are economically practical to mitigate them. Totally minimizing a risk or uncertainty is too costly. It may not be the best cost-benefit ratio, especially in resource-poor countries where other priorities for resource allocation may exist for economic development and the well-being of citizens and the environment.

4. CONCLUSION

The results presented a conceptual model for the calibration of processes involving some ionizing radiation quantities in the framework of new technologies and calibration 4.0 and a comparison between processes and risks. The conceptual model of calibration 4.0 is composed of 3 main parts the system will be composed of 3 main parts: a transmitter (the calibration laboratory), a 4.0 communication network, and a receiver (the equipment to be calibrated). The reference standard (an ionization chamber or solid-state sensor) will be coupled to an intelligent sensor/transducer to measure the reference value, transform it into an electrical signal, and send it to the transmitter's processor. The transmitter's processor will synchronize the electrical signals from the sensors and process them into a radio frequency calibration message. The IoT devices will exchange the data from the processors. Ultimately, the laboratory will send the digital calibration certificate to the metrology cloud that concatenates the user and the regulatory bodies.

The main identified risk of the contemporary calibration process was the error in the user's analysis and use of the calibration certificate. In the case of calibration 4.0, the level of risk varies significantly with the type of sensor/actuator chosen and with the reliability and integrity of the communication network. There are new risks exclusive to the 4.0 model and all with criterion 5 (interruption of the calibration process), which increases the need for control actions.

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