Calibration and Management 4.0 An innovative approach in ionizing radiation metrology using Pandora IRTech software.

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Abstract. To solve the new metrological challenges related to the digital revolution, recently a series of projects have been created worldwide with the primary objective of promoting the new infrastructure for legal digital metrology: through the use of clouds to support conformity assessment processes, development of infrastructure for digital calibration certificates; research on the comparability of real and virtual measurements and work on assessment methods for machine learning and artificial intelligence. Objective: To present Pandora IRTech, a calibration and management software that uses concepts and technologies from the 4th industrial revolution. Pandora IRTech was built from a conceptual model derived from state-of-the-art studies and process and risk mappings. The model identified optimized structures and features for software development. Finally, the applications developed to optimize the calibration process and laboratory management in the current context of the digital revolution in metrology are presented and discussed.

Keywords: Software; Calibration 4.0; Metrology 4.0; Management 4.0.

1. Introduction

"...There is nothing more difficult than having something new at hand, and nothing more dangerous than to lead in new directions, or uncertain of success when taking the lead in introducing a new order of things"[1]. The sixteenth-century philosopher Nicolaus Machiavelli remains current, especially when the changes to a new path go through sectors such as metrology. In this context, there is the paradigm of the digital revolution, represented by the rapid transformation driven by digital technologies that fundamentally change how we live, work, and relate to each other. Today, one can see that in metrology, this revolution continues to evolve and shape the field, bringing both benefits and challenges to society.

The Fourth Industrial Revolution, also known as Industry 4.0, has radically transformed how organizations operate and manage their production processes. Industry 4.0 is characterized by the convergence of digital, physical, and biological technologies, and the digital revolution is an integral part of this transformation. The metrology universe is intimately inserted in this new way of operating and managing processes through the so-called digital revolution of metrology [2].

Due to the rapid advancement of digital transformation, 4.0 model-related technologies such as Artificial Intelligence (AI) methods are increasingly finding their way into the medical fields and presenting new metrological challenges. The applications of AI in the healthcare sector are motivated by the enormous potential for savings, increased benefits for patients, and the progress that can be achieved in measurement technology. AI can be, for example, the solution for dealing with the challenge of processing a large volume of data. Over a year, imaging procedures generate large volumes of information (data) that are humanly unfeasible for professionals to assimilate as new knowledge in a short time. AI may be helpful in the future to accelerate developments requiring many physicians with years of experience and a significant amount of time to assimilate the processed knowledge. In this circumstance, AI could process and update new information quickly. However, there is no formally recognized anchor of confidence for AI metrology in medicine [3].

In this context, the calibration of measurement equipment plays a crucial role in ensuring the quality and accuracy of the measurements performed by such instruments. The combination of calibration and Management 4.0 offers an innovative approach that integrates advanced technologies and intelligent systems to improve the efficiency and reliability of calibration processes. Moreover, processes become more efficient when combined with cloud computing, internet usage, virtual applications, and artificial intelligence.

In the field of metrology 4.0, the importance of mathematical and physical simulations and computer-based experiments is rapidly increasing. Such simulations can mimic both measuring devices and actual measurements, which can be referred to as a "virtual measuring instrument" Thus, the task of metrology in this scenario is to ensure confidence in the results obtained through simulation and that the calibration conditions are the same as for real measurements [3].

Recently, several projects were created worldwide (GEMIMeG-II, European Metrology Cloud, Met4FoF, Digital-SI Task Group, and SmartCom) to promote the new infrastructure for legal digital metrology; developing applications and infrastructure for digital calibration certificates - DCC; researching comparability of real and virtual measurements; and working on evaluation methods for machine learning and artificial intelligence [4]. And it is in this digital revolution paradigm Pandora IRTech was created and modeled with advanced 4.0 technology resources to optimize laboratory management and calibration processes. This paper aims to present the development of Pandora IRT applied to calibration labs.

2. Methodology

2.1 Modeling

The application software (Pandora IRTech) was developed from a conceptual model that was conceived from a state-of-the-art study [5] and a process mapping and risk identification study [6] in the metrology technique. Thus, the software was developed to meet the following user requirements: the operational requirements described in Table 1.

i. Practicality, accessibility, universality, and compatibility
ii. Own and easily manage database;
iii. Possess features with 4.0 technologies;
iv. Have applications for management and calibration activities.

Table 1. Software operational requirements

<table>
<tr><th colspan="2">Structure and Features with 4.0 Technologies</th><th>Management Applications</th><th>Calibration Applications</th></tr>
<tr><td rowspan="4">Cloud Computing
e
Database Systems</td><td>Artificial Intelligence</td><td>Order and job management</td><td>Integration of technical and administrative records
Automation of tasks
Calculation of errors and uncertainties
Traceability management</td></tr>
<tr><td>Data Science Analytics</td><td>Compliance,
Risk and opportunity,
Finances,
Production and
Client satisfaction management</td><td>Quality Controls</td></tr>
<tr><td>Cryptography & Digital Signature</td><td rowspan="2">Records control
Issuance of Digital Calibration Certificates</td><td rowspan="2">Raw data protection and
Conformance of the data to the XML Scheme standard</td></tr>
<tr><td>XML Scheme</td></tr>
</table>

2.2 Applications

The applications were created in the Power Apps software (Microsoft) to integrate the functionalities developed in Excel (for AI applications, calculations, and automation of the tasks); PowerBI (in the use of data science tools); Foxit Reader (in the encryption of the data), gov.br (advanced electronic signature) and the Notepad++ (32 bit) for adapting the data to the XML Scheme standard, standard for issuing Digital Calibration Certificates - DCC.

The programming language used to write the codes for automation tasks was Visual Basic for Applications (Microsoft), and the user interface language was Portuguese.

2.3 Validation

The software validation process verified its ability to meet the requirements and expectations defined for its operation. For this, the following approach was used: 1) operational requirements verification, 2) unit tests, 3) acceptance tests, and 4) security tests.

3. Results and discussions

3.1. Modeling

To be practical, accessible, universal, and compatible with other programs, the base chosen for the program was the spreadsheet, which can be run by Excel, one of the most used commercial software in the world that provides affinity to the user with a familiar interface. Through the Excel format, the user can incorporate spreadsheets with uncertainty calculations already existing in his organization without the need to host his data in third-party databases or having advanced knowledge in a programming language to manage them.

Pandora IRTech has characteristics and technologies used for Metrology 4.0, such as: artificial intelligence; cloud computing associated with a database system; data analysis by data science tools; encryption algorithms, and advanced digital signatures.

The software's primary structure is that of rule-based systems, one of the simplest methods for Artificial Narrow Intelligence (ANI) applications. The program works by reading and interpreting data entered into cells, which have been prepared to receive numeric or text data. In this system, a rule is always composed of a premise and a conclusion. The interpretation of these rules is made according to the logical value of the premises. If the value of the premises is actual, it follows that the conclusions are also valid.

- Basic case, where you have only one premise and one conclusion:
  IF < PREMISE > THEN < CONCLUSION >
- General case, where you are allowed to have multiple premises connected by the logical connector.
  IF < PREMISE1 > AND < PREMISE2 > OR < PREMISE3 >. . .
  THEN < CONCLUSION1>, < CONCLUSION2 >, < CONCLUSION3 >...

Cloud computing, also known as on-demand access via the Internet, allows users to access calibration and laboratory management data agilely. Cloud computing enables the control of documents and communication between physical twins (files stored on the local computer) and their digital twins (virtual copies hosted in the cloud). This way, the cloud can centralize and synchronize information, promoting greater efficiency and convenience in managing laboratory resources. Data is readily available on the Internet for designated users, backed up, and automatically controlled for revision history. Integrating a database system associated with cloud computing enables the efficient storage of administrative and calibration data that can be used for descriptive, diagnostic, predictive, and prescriptive analyses of the processes related to the quality system.

The original calibration certificate data (.xmls) is saved in PDF (human-readable) and XML (machine-readable) format. Later, when the XML Scheme standard is defined and operational in the country, it will enable the issuance of DCC that will consequently allow users (service providers, industries, regulatory bodies) to automate the critical analysis of the certificates.

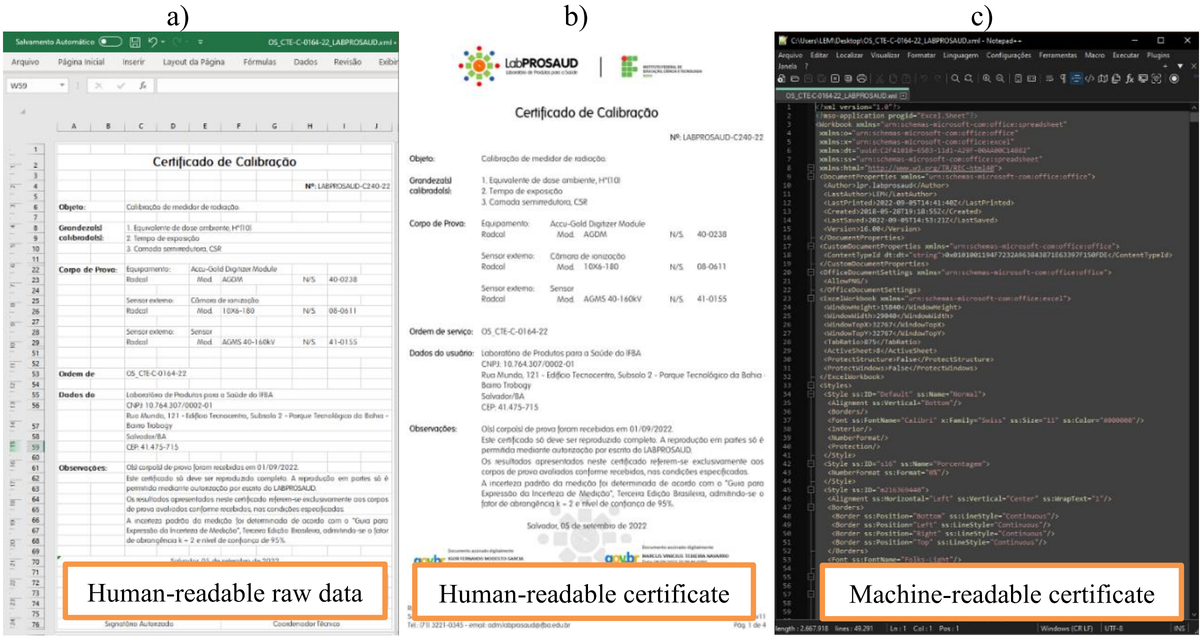

Figure 1. Calibration data in a) xlsm, b) PDF, and c) XML formats.

3.2. Applications for Management 4.0

The Business Intelligence (BI) approach analyzes the data stored in the database. This technology allows the user to identify trends, patterns, and anomalies in the data that might otherwise be difficult to identify. In addition, this application ultimately enables the identification of growth opportunities, improved process efficiency, and cost reduction. In this sense, a series of applications with easily integrated interfaces were created, which help to manage: orders and jobs (proposal, calibration report generation, and document and record control); risks and opportunities; compliance (regulatory and normative); production control; financial analysis, suppliers and training, and customer satisfaction evaluation.

Figure 2: Illustration of the application models for management (software language, Portuguese).

3.3. *Applications for Management 4.0*

3.3.1. Integration of technical and administrative records. According to the data from the service provision proposal approved by the client, the software was programmed to load all the administrative data from the calibration, automatically identifying all the instruments, quantities, and calibration ranges and parameterizing them according to the type of calibration certificate (accredited or not accredited).

3.3.2. Generation of calibration certificate models and spreadsheets. With the parameterization of the quantities, the software generates the spreadsheet models that will be used to calibrate each equipment quantity. The generated model contains the respective calibration certificates and a specific calculation sheet for each calibration.

3.3.3. Calculation of errors, uncertainties, coefficients, and statistical inferences of the calibrations. A spreadsheet is generated for each calibration. This generated spreadsheet contains a set of cells that organize the calibration data in a structured way in tables. When fed with data from the readings of the standard equipment and the equipment being calibrated, these tables automatically calculate errors, uncertainties, calibration coefficients, unit conversions, and statistical inferences to validate the calibration results and generate a graph that helps the technician analyze the calibration results.

3.3.4. Traceability management. Each standard used in the calibrations must be traceable and have its data updated on the calibration certificate. Although simple, this task is a critical requirement for ensuring calibration quality and can be systematically challenging to manage when many standards are used in the calibrations. For this reason, a code was written that manages all traceability of calibration certificates. This application automates verifying and updating the current traceability data for each standard by querying the laboratory's current calibration plan.

3.3.5. Quality controls. Statistical techniques such as control charts and variance analysis helps monitor the calibration processes' stability and identify any undesirable deviations or trends.

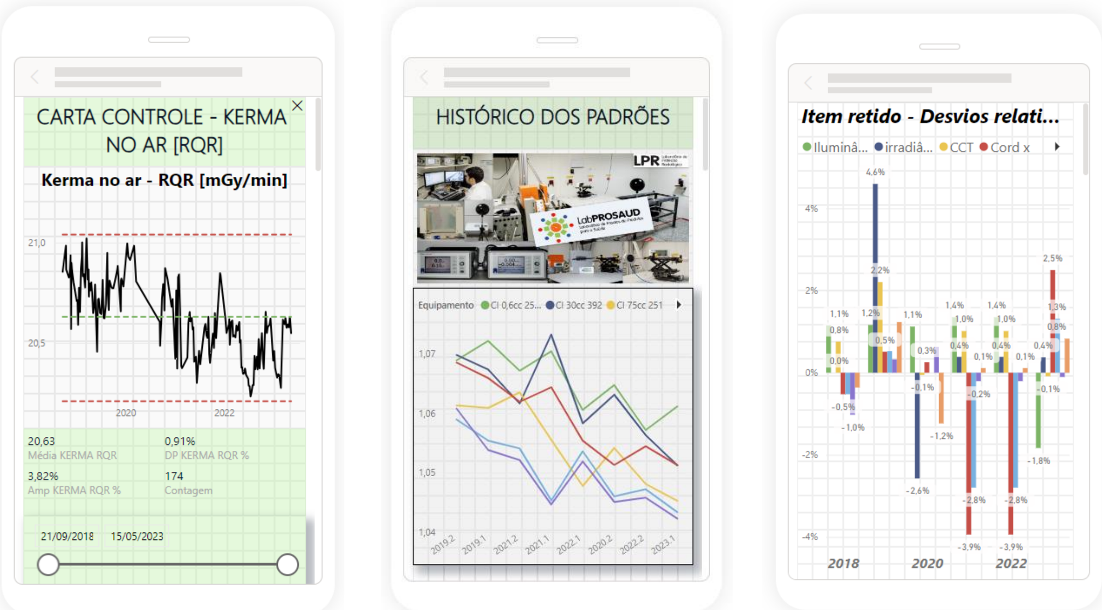

Figure 3: Illustration of the application models of quality control (software language, Portuguese).

3.3.6. Protection of raw data. According to ISO 17025:2017, all technical records must be guaranteed protection against alterations. Therefore, for the protection of raw calibration data, a code was written that allows the user to protect all relevant data and formulas from all calibration spreadsheets with a standard password in a single click. This function is handy for speeding up the process of protecting the calibration data of equipment with many quantities to calibrate that generate large volumes of data.

3.3.7. Protection of the calibration certificates. Calibration certificates (in PDF and XML format) are protected using the 128-bit AES algorithm, an advanced encryption standard for preventing document changes. The last layer of protection is the application of advanced electronic signatures. This signature is inserted in the certificate with the Gov.br platform (www.gov.br) that allows the user to sign a document in digital form from his Gov.br account. The document with the digital signature has the same validity as a document with a physical signature and is regulated by Brazilian Decree No. 10,543 of 11/13/2020.

3.4. Pandora IRTech Structure and Features

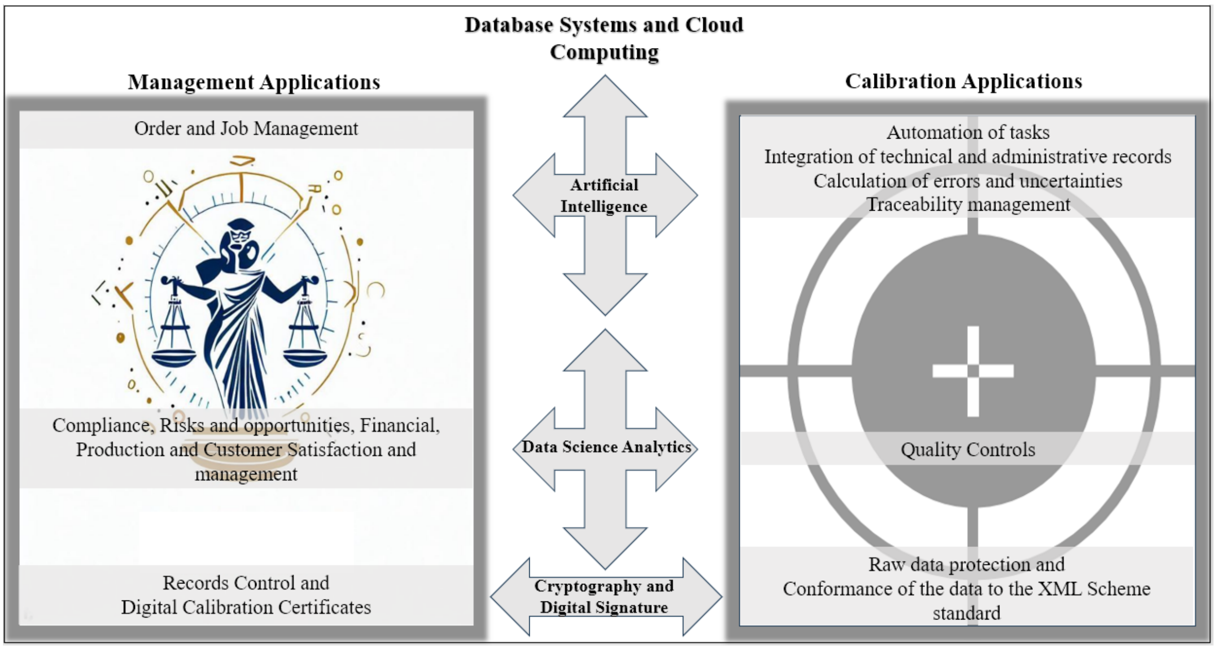

Figure 4: Illustration of the application models of quality control.

3.5. Validation

The validation was done in 3 stages. In the first stage, the compliance with the operational requirements was verified, which were: compliance with Table 1, chapter 7.1 (resources) of ISO 9001 [7], and Chapter 7.11 (data control and information management) of ISO 17025 [8].

In the second stage, the developer tests were performed. These were: unit testing to verify that each unit of the code worked correctly (these tests helped identify and correct implementation errors to ensure correct functionality); integration testing to verify that the different components of the software work correctly together; And finally, security testing was performed to identify and correct possible vulnerabilities and ensure that the software is protected against external threats. This involved performing penetration tests, vulnerability analysis, and verifying the security practices adopted.

In the last step, end users performed acceptance testing to verify that the software met their expectations and requirements. This included the execution of specific test cases, simulation of real scenarios, and validation of critical functionalities. Pandora IRTech began testing and was incorporated into Labprosaud's quality management system from 2021 to 2023. Since then, a general restructuring in all processes has been observed, especially in the organization and learning at the document level of the quality management system.

It is important to note that software validation is an ongoing process and should be iterative between developers and users to ensure that it is working correctly and meeting the changing needs of users.

4. Conclusions

In summary, the development and use of Pandora IRTech made the management and calibration processes of the laboratory where it was implemented more efficient. Among all the implemented changes, the radical reduction of raw data transcription in the technical records is worth mentioning with the unification of several spreadsheets in a single software, making the records more reliable and efficient.

The results show an innovative approach in the metrology of ionizing radiation and represent a significant advance in improving calibration processes. The combination of 4.0 technologies such as artificial intelligence, cloud computing, data science analysis tools, process automation, and compliance with the digital calibration certificate standard enables organizations to achieve higher levels of performance and quality.

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