ACCREDITATION AND CHALLENGES OF A DIGITAL LABORATORY

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Keywords: accreditation, digitalization, laboratory, metrology, taxonomy, standard, management

ABSTRACT

Future of metrology necessitates a fundamental shift towards the digitalization of laboratory accreditation processes, which is reflected in already recognized need for digitalization of laboratories' Scope of Accreditation (SoA). This transition extends beyond the mere conversion of Calibration Measurement Capabilities (CMC) documentation into electronic formats. It involves developing and implementing standardized machine-readable documents to facilitate efficient access to accredited laboratories published methods and measurement uncertainties. Key steps towards this goal include the automation and continuous monitoring of laboratory processes, ensuring the ongoing accuracy and relevance of documentation, and optimizing customer-related activities. Adoption of a comprehensive lab management system incorporating such automation not only optimizes financial, human, and temporal resources but also enables laboratory personnel to focus on technical and research endeavours. This paper presents a detailed case study of a digital laboratory characterized by highly automated processes, providing insights into the practical benefits and challenges associated with this innovative approach to accreditation. The case study delves into the specific methodologies utilized for data management and quality assurance and the outcomes observed in terms of efficiency gains, resource utilization, and overall laboratory performance. Additionally, the paper discusses the broader implications of calibration and testing laboratories digitalization and outlines potential avenues for further research and development in this domain.

AKREDITACIJA I IZAZOVI DIGITALNE LABORATORIJE

Vukan Ogrizović

Ključne reči: akreditacija, digitalizacija, laboratorija, metrologija, taksonomija, standard, upravljanje

REZIME

Budućnost metrologije zahteva suštinski pomak ka digitalizaciji procesa akreditacije laboratorija, što se ogleda u već prepoznatoj potrebi za digitalizacijom obima akreditacije laboratorija. Ovaj prelaz se proteže dalje od puke konverzije dokumentacije o mernim mogućnostima etaloniranja u elektronske formate. To uključuje razvoj i primenu standardizovanih mašinski čitljivih dokumenata kako bi se olakšao efikasan pristup objavljenim metodama akreditovanih laboratorija i nesigurnosti merenja. Ključni koraci ka ovom cilju uključuju automatizaciju i kontinuirano praćenje procesa u laboratoriji, obezbeđivanje stalne tačnosti i relevantnosti dokumentacije i optimizaciju aktivnosti u vezi sa klijentima. Usvajanje sveobuhvatnog sistema upravljanja laboratorijom koji uključuje takvu automatizaciju, ne samo da optimizuje finansijske, ljudske i vremenske resurse, već i omogućava osoblju u laboratoriji da se fokusira na tehničke i istraživačke poduhvate. Ovaj rad predstavlja detaljnu studiju slučaja digitalne laboratorije koju karakterišu visoko automatizovani procesi, pružajući uvid u praktične prednosti i izazove povezane sa ovim inovativnim pristupom akreditaciji. Studija slučaja se bavi specifičnim metodologijama koje se koriste za upravljanje podacima i osiguranjem kvaliteta i uočenim rezultatima u smislu povećanja efikasnosti, korišćenja resursa i ukupnog rada laboratorije. Pored toga, u radu se razmatraju šire implikacije digitalizacije laboratorija za etaloniranje i ispitivanje i navode se potencijalni putevi za dalja istraživanja i razvoj u ovoj oblasti.

INTRODUCTION

Digitalization involves using digital technologies to transform a business model, leading to new revenue streams and value-creating opportunities. This process includes integrating digital tools and systems across various aspects of a business's operations, including management, communication, production, and customer service.

Digitalization is revolutionizing industries and society by driving innovation and disruption. It empowers startups with scalable, data-driven models that threaten established companies. True digital transformation goes beyond digitizing documents; it fosters an agile, innovative business culture leveraging advanced technologies like quantum computing, blockchain, and artificial intelligence. This transformation is crucial for productivity, competitiveness, and sustainable value. Despite significant efforts, many organizations struggle to succeed, highlighting the need for comprehensive digital fluency

and the adaptation of workforce skills. Embracing digitalization is imperative for navigating and leading the future's technological landscape [1].

In the context of metrology, digitalization points to a significant advancement in how measurements are taken, analyzed, and utilized. Digital technologies enable more precise, accurate, and reliable measurements, which are crucial for quality control and assurance in various industries. By integrating advanced sensors, data analytics, and automated systems, digitalization enhances the efficiency and effectiveness of metrological processes.

Digital metrology tools can provide real-time data, allowing for quicker decision-making and more responsive adjustments in production processes. This leads to improved product quality and consistency, as well as reduced downtime and waste. Furthermore, digitalization facilitates better data management and traceability, ensuring that measurement data is easily accessible, auditable, and secure.

The digitalization of metrology also connects closely with the concept of taxonomy in metrology. Taxonomy, the systematic classification and organization of measurements and standards, is essential for maintaining consistency and interoperability in metrology. With digitalization, taxonomies can be more effectively implemented and managed, enabling seamless integration of different measurement systems and standards across various industries. Digital tools can automate the classification process, ensuring that all measurement data is accurately categorized and easily retrievable.

BACKGROUND AND METHODS

Metrology taxonomy

Metrology taxonomy (MT) is a product of the Measurement Information Infrastructure (MII) effort [2], aimed to define, create, and implement a standard for expressing the laboratory's CMC and ISO/IEC 17025 SoA in a machine-readable format, easy to share between laboratories, proficiency testing (PT) providers, accreditation bodies, and National Metrological Institutes (NMI). XML is recognized as a format that is systematic, well-defined, with clear rules, and easy to implement and share.

MT comprises a set of aspects that are taken into account during the construction of the taxonomy specification:

- classification of measurement types:
  - physical: length, mass, time, electric current, temperature, luminous intensity, amount of substance,...
  - chemical: concentrations, pH levels, chemical compositions,...
  - biological: biological activity, cellular counts, and genetic material quantification,...
  - ...
- units of measurement:
  - SI
  - Non-SI
- measurement methods:
  - direct measurements
  - indirect measurements
- standards and calibration:
  - primary standards
  - secondary standards
  - reference materials
- measurement uncertainty:
  - quantifying uncertainty
  - standard uncertainty
  - expanded uncertainty.

The importance of MT is reflected, in the first place, in consistency, ensuring that measurements are consistent across different laboratories, industries, and countries. This is crucial for scientific research, international trade, and regulatory compliance. Also, interoperability is important in a way that it facilitates the integration and comparison of measurement data from different sources, which is essential for collaborative research, global supply chains, and cross-border regulatory frameworks. Standardization is another valuable aspect which provides a common language and framework for discussing and reporting measurements. Standardization bodies like ISO, IEC, and BIPM play a crucial role in developing and maintaining these standards. Finally, quality assurance helps in establishing and maintaining quality control processes in manufacturing and testing. Accurate and reliable measurements are critical for product quality and safety.

However, implementing a MT system is not without challenges. One of the primary difficulties is the lack of standardization across different laboratories and industries. Each organization may have its own way of describing measurement processes and results, leading to discrepancies in data interpretation. Harmonizing these diverse practices into a unified taxonomy requires extensive collaboration and consensus-building among stakeholders.

Another challenge is the complexity of creating a comprehensive and flexible taxonomy that can accommodate the wide range of measurements encountered in practice. The taxonomy must be detailed enough to capture all relevant information but also adaptable to new measurement techniques and technologies as they emerge. This balance between specificity and flexibility is critical for the long-term success of the taxonomy.

Despite of mentioned challenges, the benefits of having MT are numerous. By creating machine-readable documents, laboratories can automate many aspects of data management, from data entry and validation to report generation and archival. This reduces the administrative burden on laboratory staff and minimizes the risk of errors associated with manual data handling.

Digital taxonomy also enhances data traceability and transparency. Each measurement is recorded with a detailed metadata profile that includes information about the measurement conditions, instruments used, and the personnel involved. This level of detail ensures that measurement results can be accurately reproduced and verified, which is crucial for maintaining confidence in the data.

Furthermore, a digital MT facilitates interoperability between different systems and platforms. Laboratories can share measurement data seamlessly with clients, regulatory bodies, and other laboratories, promoting collaboration and ensuring compliance with international standards. This interoperability is particularly important in a globalized economy, where cross-border trade and regulatory harmonization are essential.

MT is an initiative opened for all laboratories and other players in the metrology field. It is an ongoing action, and involvement of more metrological experts is highly needed. Some specialized software tools are already created, in order to help and encourage metrologists to take part in this action [3].

Digitalization by software

During previous years, few software tools and services have been offered to laboratories, as possible solutions for partial digitalization of their procedures and processes. The ideas standing behind the particular Laboratory Information Management System (LIMS), as this type of software is called, their implementation, features, and focuses are quite different, but the common denominator for all of them is an effort to make laboratories' daily work easier. Here are some of the products available at the market.

LabWare LIMS [4] is a scalable LIMS solution that supports a range of laboratory processes, including sample management, test scheduling, and data reporting. Its base features are: sample tracking, instrument integration, workflow automation, regulatory compliance, and data analysis.

LabVantage LIMS [5] provides comprehensive laboratory management capabilities, focusing on automation, efficiency, and compliance. Its scope of features include: sample management, workflow automation, instrument integration, and electronic lab notebooks (ELN).

STARLIMS [6] offers solutions for laboratory management, including LIMS, ELN, and scientific data management systems (SDMS), such as sample and test management, instrument integration, workflow automation, and regulatory compliance.

Qualer [7] is a calibration and asset management software that helps laboratories automate calibration and maintenance processes, offering calibration scheduling, equipment tracking, compliance management, and automated notifications.

MET/CAL [8] is another calibration management software designed for automating calibration procedures and managing calibration assets. It is equipped with automated calibration procedures, asset management, compliance tracking, and reporting.

Beamex CMX [9] calibration management software helps in planning, managing, analyzing, and documenting calibration work, through calibration planning, automated calibration procedures, compliance management, and data analysis.

Labguru [10] offers a comprehensive lab management solution that includes ELN, inventory management, and project management capabilities, specifically: digital lab notebooks, inventory tracking, workflow automation, and data management.

LorisQ [11] is a cloud-based software solution designed to streamline the management of measuring instruments and calibration processes in laboratories and industrial settings. Its features comprise: equipment management, automated notifications, integration with service providers, predictive maintenance and data analytics.

CASE STUDY AND DISCUSSION

Laboratory staff, and particularly, quality assurance managers, need to handle both regular daily laboratory duties regarding measurements and communication with clients, and periodical activities related to the lab's scope of accreditation. This can be exhausting and error-prone. Therefore, full or, at least, partial automation of the laboratory processes could improve laboratory features a lot.

Generalizing the term "laboratory", it could be agreed that a laboratory is an entity with five distinctive functions of segments (Fig. 1):

1. **Methods**. Whether is it about a testing or calibration lab, the methods are something that the lab is recognized by in the community and within its customers
2. **Space**. Each method is performed in some dedicated space (indoor or outside in the field). Some methods require extremely rigorous conditions for the space where it is performed.
3. **Equipment**. Each method requires one or more pieces of equipment for its realization
4. **Staff**. Competent laboratory staff is an important element of the lab's quality
5. **Users**. Although users are not part of the lab staff, they are included in the lab's documentation system in many places. After all, without the users, the existence of the lab will not make any sense.

All items 1-5 have their dedicated place in laboratory's Document Management System (DMS) and are mutually connected.

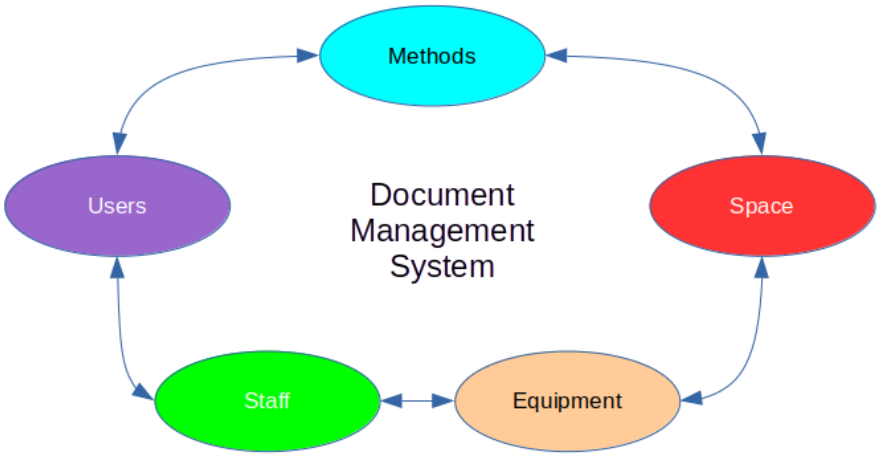

Figure 1: Contents of a document management system

The case study that would be presented here is based on a web service MetroLabIS [12], created specifically for laboratories accredited with ISO/IEC 17025 standard, aiming at the automation of laboratory processes.

Following basic entities from the scheme shown the Fig. 1, the motivation for creating this web service was to combine daily laboratory procedures with periodic accreditation activities into one smooth process, where the laboratory staff can concentrate on measurements and data processing, while all supporting and repeatable tasks will be performed fully- or semi-automatically by the software.

An accreditation cycle can be represented as a number of tasks organized in a circle flow (Fig. 2), beginning and ending with (re)accreditation, the yearly milestone of the lab's quality check. Activities presented in Fig. 2 are not performed daily, but rather at some specific spots in the time. Therefore, it is easy to miss some action that is necessary for the next external audit performed by the accreditation body. So, why not let some automation with the accreditation maintenance?

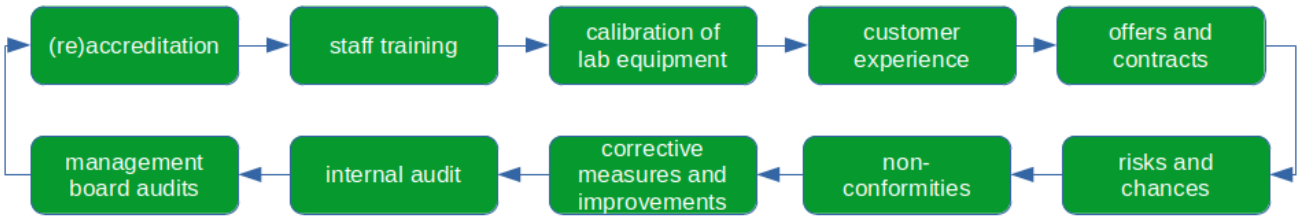

Figure 2: accreditation cycle

On the other hand, dealing with customers' requests and performing testing and/or calibration is something that the laboratory lives of. It is reasonable to put a focus on these daily actions, which requests an utmost care and dedication. Such daily engagement is, more or less, straightforward, and follows a linear structure depicted in Fig. 3. A customer places a request for testing or calibrating. A person in charge of the quality reviews and approves that request. Then, a laboratory staff performs measurements. When the measurements are complete, the lab authority creates and signs the testing report or the calibration certificate. When the document is prepared, it is delivered to the customer.

Figure 3: Testing/calibration actions flowchart

Automation of processing events and activities shown in Fig. 2 and Fig. 3 makes the core of MetroLabIS. The data model is arranged according to three guidelines:

1. **Minimal redundancy**. The relational model is designed to request minimum duplication of data.

2. **Maximal flexibility**. This includes data, models, reporting applicable to all types of laboratories, but, also, very adaptable and flexible design of laboratory's documents.
3. **Easy usage**. An intuitive web interface is adapted to the ISO/IEC 17025 standard, making it easy to follow the standard's requests.

User experience is treated in a manner that allows the users to access as easy as possible all segments of the MetroLabIS service:

1. **Model**. MetroLabIS is a cloud service, so 24/7 access is guaranteed to all users
2. **Access**. A responsive design makes comfortable utilization with all kind of devices, whether they are smartphones, tablets, laptop or desktop computers.
3. **Authority**. The laboratory authorities delegate access rights to the laboratory staff, so the responsibilities of the lab staff is rigorously controlled.

A special attention is paid to data security with MetroLabIS. There are four levels of security treatment (Fig. 4):

1. **Hosting provider**. The service is hosted by a proven and reliable hosting provider.
2. **Web server**. The web application itself is running on SSL powered web server.
3. **User management**. Laboratory's authorities can grant a wide scope of various rights to its staff, as well as, for their customers.
4. **Data backup**. Daily backups of all data are performed automatically, both locally, and on a remote server.

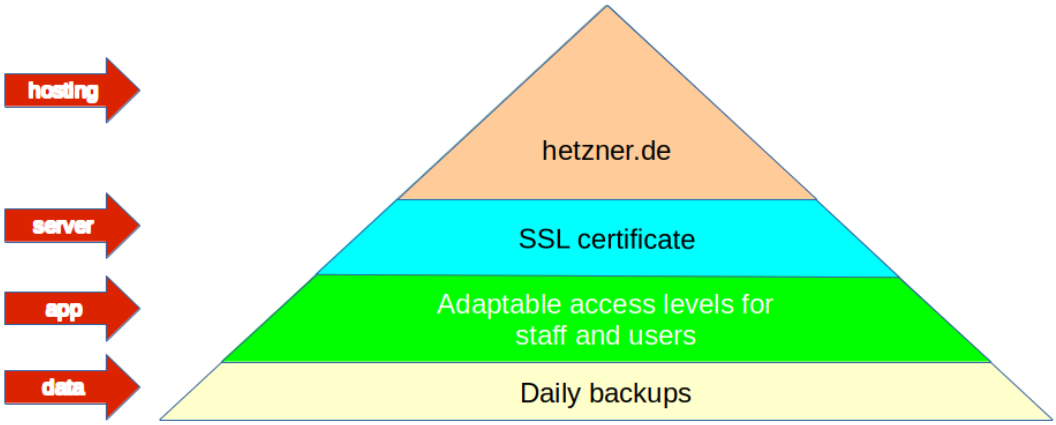

Figure 4: Data security

Laboratory DMS is based on a set of internal and external documents, each of them holding special kind of information needed either for daily activities, or accreditation purposes. MetroLabIS recognizes:

1. **External documents**. Everything that is not created in the lab (standard, technical manual, rulebook, or other reference document).
2. **Internal documents**. These documents contain data created within the lab, by the lab staff (request for testing/calibrating, handover protocol, measurement log, testing report, calibration certificate, (proforma) invoice, offer, letter, log, working manual).

Referring to the claim that MetroLabIS data model forces entering only necessary data respecting minimum redundancy, upon their creation, the internal documents are automatically linked with data that already existed somewhere else in the database. Data models for specific internal documents are created in accordance with ISO/IEC 17025.

Communication with lab clients is done, also, via MetroLabIS. The lab creates a profile for a customer with one or more customer's user accounts for accessing the service. After that, the customer can place

requests. When testing or calibrating, depending on the customer's request, is completed and a report or certificate is created, the customer logs in again and downloads the corresponding pdf.

In the same manner, the lab works with all other documents related to its accreditation. A flexible model for creating various tabular documents allows for handling non-conformity actions, internal and external audits, logs about lab staff and equipment and other documents of lab's management system.

CONCLUSION

Digitalization is revolutionizing industries by fostering innovation and disruption, empowering data-driven startups that challenge established companies. In metrology, digitalization enhances measurement precision and reliability, supporting quality control and process efficiency. The development of a MT is crucial for standardizing measurement data, ensuring consistency, interoperability, and quality assurance across industries. Despite challenges in standardization and complexity, MT provides significant benefits in data management, traceability, and collaboration, promoting global trade and regulatory compliance. The involvement of metrological experts and the adoption of specialized software tools are essential for advancing this initiative and ensuring the success of digital transformation in metrology.

Quality assurance managers and laboratory staff frequently face the dual challenge of handling daily measurement duties, client communications, and periodic accreditation tasks, which can lead to fatigue and errors. Automation of laboratory processes offers a significant improvement in efficiency and accuracy.

The MetroLabIS case study demonstrates a web service specifically designed for ISO/IEC 17025-accredited laboratories, integrating daily operational procedures with periodic accreditation activities. This integration allows laboratory staff to focus on critical tasks like measurements and data processing, while routine and repetitive tasks are automated, ensuring compliance and reducing the administrative burden.

MetroLabIS organizes laboratory functions by minimizing data redundancy, maximizing flexibility, and ensuring ease of use. Its cloud-based model guarantees 24/7 access, while responsive design facilitates use across various devices. The system's robust data security measures, including secure hosting, SSL-powered web servers, user management, and automatic data backups, ensure the protection and integrity of sensitive information.

Moreover, MetroLabIS enhances data traceability and transparency, allowing laboratories to seamlessly share measurement data with clients, regulatory bodies, and other labs. This interoperability promotes collaboration, supports regulatory compliance, and strengthens global trade frameworks. The comprehensive automation of accreditation cycles and daily tasks fosters an environment where laboratories can thrive, focusing on innovation and quality improvement while maintaining rigorous standards of operation. The involvement of metrological experts and the adoption of specialized software tools like MetroLabIS are crucial for advancing digital transformation in metrology and achieving long-term success.

While MetroLabIS effectively automates many laboratory activities, it addresses only a segment of the broader digitalization of a laboratory. It is not a comprehensive solution for a fully digital laboratory and digital certificates. However, it represents a significant step forward, offering a robust starting point for laboratories on their digital transformation journey.

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