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Advancing Digital Quality Infrastructure: Transforming Laboratory Processes for Enhanced Efficiency and Reliability

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Abstract – **The digital Quality Infrastructure (QI) holds significant potential for ensuring and enhancing the accuracy, reliability, and efficiency of laboratory processes. Establishing digital QI tools and processes and the integration into the larger digital QI ecosystem however comes with many technical and organizational challenges at the laboratory but also larger system level. This paper presents solutions of a digital QI tool set that are being developed within the German initiative QI-Digital, our own experiences in the implementation of Digital Calibration Certificates (DCCs) as eAttestation in our laboratory, as well as the structured process we have been establishing to engage with the laboratory community to support adoption of the digital QI**.

I. INTRODUCTION

The digital transformation of laboratories is a critical component of the broader shift towards a digital Quality Infrastructure (QI). As key components of the QI system, laboratories need to be integrated into the evolving digital QI ecosystem.

The initiative QI-Digital seeks to develop solutions for a modern, digital QI that allows for smarter and automated quality assurance [1]. This paper introduces some of the QI-Digital tools that are most relevant for laboratories — such as SMART standards and Digital Quality Documents—and shares insights from implementing the Digital Calibration Certificate (DCC) in BAM's accredited calibration laboratory. As intensive stakeholder engagement is crucial to successfully establish these tools in practice, the paper continues to describe our structured stakeholder approach. Finally, the paper synthesizes key learnings and provides recommendations.

II. BACKGROUND

A. Digital Transformation in Laboratories

An international study by BAM across 15 countries worldwide [2] revealed that most conformity assessment bodies (CABs), including laboratories, are still in early stages of digital maturity, with limited adoption of digital technologies.

While there are many projects and initiatives under keywords like Lab of the Future or Lab 4.0 [3], laboratories are not just some type of organization, but a central corner stone within the QI system – a perspective that needs specific consideration. Both, the digitalization of QI and laboratories are closely interconnected and must therefore be driven in close coordination.

To address this, BAM, supported by the German Accreditation Body DAkkS and the VUP (the German Association of Independent Laboratories), hosted the workshop series "*Digital Quality Infrastructure in Testing and Calibration Laboratories – From Trend to Daily Business"* with over 100 participants. The aim was to identify specific needs and challenges and elaborate a vision of digital QI in laboratories [4, 5]. Section IV provides deeper insights and recommendations derived from this stakeholder dialogue. In the following we will present the concept of a digital QI, its building blocks and their implications for laboratories.

B. Digital Quality Infrastructure

The traditional system of quality assurance and infrastructure is still largely document- and paper-based and involves a great deal of manual, bureaucratic effort. The QI-Digital initiative, led by key German QI institutions, seeks to shift towards a data-driven, automated and networked quality assurance system that meets the needs of an increasingly digital economy [1].

The transformation goes far beyond the mere digitalization of existing processes –the initiative strives towards a genuine paradigm shift in the QI to a smart, interconnected QI ecosystem that encompasses modern methods as well as tools embedded in standardized digital platforms and technologies. The following section presents core tools and components of this digital QI ecosystem and how laboratories can benefit from it.

III. DIGITAL QI-ECOSYSTEM FOR LABORATORIES

A. Digital QI-Toolbox

The digital QI offers significant potential for improved efficiency and error reduction in daily laboratory routines. Specifically machine-readable versions of standards and quality documents, integrated in digitally connected processes, can play an important role.

SMART Standards

Standards define the requirements that products and processes need to fulfill. SMART Standards convert them from a human-only- into a machine-readable form allowing to feed them directly into laboratory systems and workflows. This way, limit and tolerance values can be imported automatically, and test or measurement parameters are loaded without manual re-typing, and automatically cross-checked with the latest version of the standard. Every result is tagged with that version—greatly enhancing traceability and efficiency and reducing errors [6].

Quality documents

Quality documents such as test reports, certificates of conformity, calibration certificates, or reference material certificates, are part of the daily routine in laboratories. Today, they are still issued as paper forms or static PDFs, which makes handling them a tedious effort. Media breaks create duplicate work, increase the risk of typos and version mix-ups, and make every subsequent review time-consuming. Thus, a range of quality related documents are currently being transformed in machine-readable format.:

- The Digital Calibration Certificate (DCC) [7] is an XML-based calibration certificate that consolidates all technical and administrative calibration data and meets ISO / IEC 17025 requirements.
- A Digital Certificate of Conformity (D-CoC) [8] is the machine-readable, structured counterpart to the paper-based Certificate of Conformity under the EU's New Legislative Framework. It consolidates every conformity assessment detail—modules, revisions, regulatory notes—into a unified data model that supports automated processing and plausibility checks.
- Digital Reference Material Documents (DRMD) [9] are machine-readable certificates based on ISO 17034 that encapsulate all key reference-material information—administrative data, certified and uncertified properties with uncertainties, and statements like handling and use, safety information or metrological traceability—within a unified XML schema.

Seamless integration of digital QI documents into laboratory, production and quality assurance processes requires standardized semantics and ontologies, and solutions for trustworthy verification [10]. The envisioned **DX Schema** [11] provides a unified, modular framework, from which many digital QI documents can be derived. Core fields in the schema — such as issuer, scope, applicable standards, validity period, and cryptographic signature—are harmonized across all document types, yet each schema still allows domain-specific extensions [10].

Digital certificates can feed directly into a company's data-management or ERP system, allowing automatic compliance checks and true end-to-end traceability—essential e.g. for the Digital Product Passport (DPP). Benefits include lower administrative burden, seamless data exchange across global value chains, and a single, trustworthy source for various stakeholders.

Digital Accreditation Symbol and eAttestation

To verify the authenticity of quality documents from accredited conformity assessment bodies, the German accreditation body DAkkS has introduced the **digital accreditation symbol** [12]. Embedded in digital certificates, this machine-readable, advanced electronic seal confirms the issuing body's accreditation and enables real-time validation of integrity and authenticity of the entire certificate data. This turns digital certificates into tamper-proof "**eAttestations**" that integrate seamlessly into digital workflows.

B. Digital Ecosystem for QI

For digital QI tools to deliver their full value, they must operate within a cohesive ecosystem. This requires harmonized semantics, standardized data management and sharing, and integration across platforms and stakeholders. The latest developments towards industrial international data spaces and the Asset Administration Shell (AAS), make such a digital QI ecosystem possible.

- **Data Spaces** offer a federated, open infrastructure for sovereign data exchange based on common agreements, rules and standards. They form a data ecosystem, on the basis of which data and services can be made available, networked, shared, validated and used in a trustworthy manner. This increases security, data protection, transparency, and trust, but also efficiency, scalability and adaptability [13] – making it a valuable option for laboratories and their stakeholders.
- The **AAS** (in accordance with the IEC 63278 series) as an administration shell for the digital twin represents each asset digitally and offers great potential for standardized data collection and documentation. It plays a key role in connecting QI systems to Industry 4.0 environments. The standardized AAS sub-models are being developed in the Industrial Digital Twin Association (IDTA) that also has a working group (No. 02065) for digital quality documents [14].

C. Use Case Scenarios: Digital QI for Calibration Laboratories

The following section illustrates practical experiences in the implementation of the DCC in the accredited calibration laboratory of BAM. We discuss the specific steps taken and the benefits realized in daily routines [15].

The accredited calibration lab specializes in three main areas: force, temperature, and electrical quantities. With a staff of three, approximately 200 certificates are issued per year within the accredited scope. Until recently, every Pt100 resistance-thermometer calibration resulted in a PDF certificate that technicians had to create, layout, export, and e-mail to customers—followed by manual data re-entry into the laboratory's quality-management system (QMS) and the customer's asset database. With the introduction of the DCC in our laboratory, the certificate generation can be automated and no longer end with paperwork.

Implementing a DCC for temperature quantities, specifically resistance thermometers calibrated according to the DKD-R 5-1 rule, the laboratory has further been a pilot laboratory for the digital accreditation symbol, allowing for piloting the eAttestation.

Digital calibration workflow

To establish a fully digital workflow in our laboratory, we followed several steps [15]:

1. *DCC template creation*

The first step was the creation of a DCC template based on the DCC scheme provided by PTB. This XML-schema was developed to be suitable for miscellaneous calibrations (*e.g.* from simple weight pieces to complex network analyzers) and is by now accepted as a world-wide standard for machine-readable calibration certificates. [7,16] The DCC template is specific to our laboratory and the calibration method, including placeholders for metadata and measurement data, making the middleware's task of gathering and matching information straightforward.

2. *Creation of a standardized data structure / interface between DCC and any existing calibration software*

A standardized data structure must be created for the interaction between the software with which the calibration is performed and the software with which the calibration data is to be written to the XML sample (middleware). LabVIEW and Python were used in our case. Harmonization between the DCC template (XML), the user interface (e.g. LabView) and the middleware (e.g. Python) are important.

3. *Write data to the XML template*

Measured calibration values, together with the metadata captured in LabVIEW (identifiers, dates, item descriptions, customer information, and more) are transferred to the middleware, which then automatically fills the corresponding placeholders in the XML template. This fully automated workflow ensures that DCCs are generated with both high efficiency and accuracy.

It may be necessary to make slight changes to the DCC structure for specific options within a procedure. In the case of temperature calibrations, a crucial feature is the toggling of the display item, distinguishing between resistance thermometers with a display and bare temperature probes like Pt100, which require a conversion of resistance measurement values into temperature – and accordant information in the DCC. Our DCC software is able to handle both and also supports multiple item calibrations with the automated creation of individual DCC files. All generated DCCs can be readily validated against the DCC schema in the authorization process, *e.g.* with an XML editor, to ensure that the architecture defined there is adhered to.

4. *Signature and eAttestation*

To ensure that the DCC is securely protected against subsequent changes and that the origin of the data can be authenticated, the finalized and approved XML is provided with a digital signature or an electronic seal.

As an accredited laboratory, we apply a digital accreditation symbol to every DCC, enabling recipients to verify our current accreditation status electronically. The German accreditation body DAkkS supplies a certificate file that cryptographically seals each DCC, much like an electronic signature. When the document is validated, this seal instantly shows whether any data have been altered, authenticates the issuing laboratory, and signals if the sealing certificate has been revoked or was expired.

In our simple yet powerful DCC demonstrator for thermal process monitoring, the software automatically validates every incoming certificate's accreditation symbol by checking three criteria: data integrity (no alterations), issuer authenticity, and the laboratory's current accreditation status. Only when all three checks pass is the DCC admitted to the process-control system.

Once accepted, the application extracts the metrological data, performs a linear regression on the temperature calibration points, and applies the resulting calibration function to correct the raw sensor readings. It then expands the certificate's uncertainty budget with additional contributions—such as those arising from the correction itself, long term stability and sensor hysteresis—and recalculates the process-specific acceptance limits accordingly, all in real time.

The result is a one-click workflow that turns a DCC into an instant source of metrological traceability and delivers a quality-assured process conformity assessment.

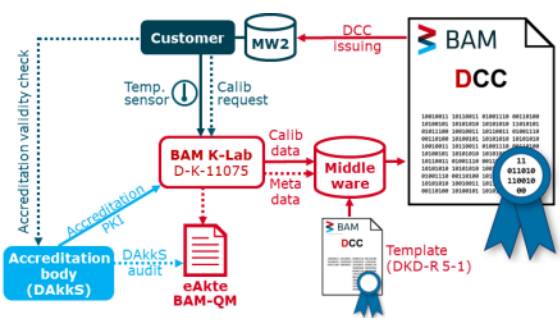

Figure 1 – Process for the automated generation of accredited DCCs (eAttestations) in the BAM calibration

laboratory.

Customer perspective: use at a technical facility

In order to demonstrate the added value of DCCs also on the receiver side, a simple DCC demonstrator for the use case of thermal process monitoring was developed. [17] Upon DCC reception, the software validates the XML-structure and the electronic seal, verifies the major administrative data (*e.g.* performance date and calibrated range), reads out its metrological data, performs a linear regression of the temperature calibration values, uses the obtained calibration function to correct the raw sensor readings, extends the DCC measurement uncertainty values with further contributions (e.g. from the correction and the hysteresis) and adjusts the process-defined acceptance limits to account for the measurement uncertainty, all in real-time. Hence, it automatically utilizes a DCC to obtain metrological traceability and a quality-assured process conformity assessment, practically at the push of a button.

Our next step is to extend the use case to the laboratory's customer. Specifically, we plan to issue DCCs for selected temperature sensors that are then used at our hydrogen refueling station test platform in designated sample processes. In that scenario, the DCC data are automatically fed into the process control technology (PCT) of the refueling station, evaluated and the measurement data from the sensors are linked in real time with the metrological information from the respective DCC.

This enables the corrections required for metrological traceability to be carried out and the measurement data to be quality-assured. The PCT thus carries out a continuous conformity assessment of the processes that are running, which is also quality-assured and therefore reliable thanks to the inclusion and correct further processing of the DCC information, including the measurement uncertainty.

The entire process of transferring, verifying and correctly integrating the metrological information from the calibration of the sensors is therefore fully automated and no longer ties up highly qualified personnel and other resources for the operator of a technical facility. Thus, automation enhances efficiency and accuracy, with significant time and cost savings for companies by accelerating processes and conserving resources. This, together with the increased safety due to the avoidance of errors from manual data transfer and processing, is the decisive added value for users of digital metrology and the DCC.

IV. DIGITAL QI FOR LABORATORIES: STAKEHOLDER DIALOGUE AND ACTIONS

A. Requirements from laboratories' perspectives and recommendations

To better understand the requirements and obstacles of a digital QI from laboratories' perspective, BAM, DAkkS and VUP conducted a series of four stakeholder workshops (see Section II A). The discussions led to specific recommendations to support the digital transformation across the laboratory ecosystem [4, 5].

Overall, participants identified two core **benefits**: improved efficiency (through faster, error-reduced processes), and increased appeal to skilled professionals (through automation allowing focus on demanding tasks). This frees up resources for further optimization, innovation, and the creation of new (digital) business models.

Yet, laboratories also face **hurdles in four areas** along which distinct **recommendations** have been deducted meant to support laboratories [4, 5]:

- **Knowledge and Networks**: The complexity of digital transformation makes orientation difficult. Laboratories need accessible guidance, best-practice examples, and cross-sector networks that connect them with IT providers, regulators, and researchers. Practical training is essential to build confidence in using new tools.
- **Tools and IT Architecture**: Digital tools must be user-friendly for non-IT staff and compatible with existing systems. Open-source solutions with well-documented APIs and strong data protection standards are crucial for trust and adoption.
- **Regulatory Frameworks**: Existing standards and regulations must be updated to accommodate digital processes. Simplified procedures, legal clarity, and standardized interfaces will improve interoperability and acceptance.
- **Business Development**: Adoption will accelerate when leadership sees clear returns. Practical implementation blueprints and collaborative spaces for co-developing business models can help translate digital potential into measurable value.

The workshop results reveal that the rollout of a digital QI will not succeed through technology development alone but needs practical support, dialogue and transfer efforts. Laboratories need strong partner networks, ready access to information for sound decisions, and hands-on help with implementation—and they are eager to collaborate. Addressing those needs, we have taken next steps by launching the "LabHub".

C. Building and strengthening the laboratory community: LabHub

Building on the insights from the dialogue process, BAM, DAkkS and VUP jointly drafted a concept for a "LabHub" addressing the identified needs and recommendations. Meant to support the digital transformation in laboratories, it represents a one-stop shop for **knowledge, training, and collaboration** on digital topics, including but not limited to QI. Implementing the digital QI in laboratories will be one important aspect of the LabHub. Yet, to ensure its adaptability and integration in the manifold other areas of digital transformation of the laboratory ecosystem, the scope needs to go beyond QI.

Making key resources for the digital transition at large accessible to laboratories is at the core. To this end, a website shall be established with curated information at a glance, including how-to notes and demonstrators; a wiki of best practices and experiential know-how; an academy offering online and on-site courses and workshops; information on funding schemes; a "toolbox" of ready-to-use software kits, guidelines; as well as a steady stream of push-and-pull updates delivered via the website, a newsletter, and social media.

LabHub is also meant to orchestrate events and networking sessions, such as within the annual QI-Digital Forum, industry gatherings like the VUP annual meeting, other conferences by associations, and specialized formats (for example, Accreditation Conferences).

It could also help advancing technological development and transfer them into deployable solutions by hosting collaborative development environments—business camps and innovation labs, plus "Co-Development Circles" in which developers and users refine tools together, as recommended by recent studies.

There are many organizations, initiatives and projects working on different but oftentimes also very similar aspects around Lab4.0, Lab of the Future, Smart Labs, etc. To create transparency, overcome silos, identify interfaces between all those initiatives, BAM, DAkkS and VUP have invited such stakeholders to join forces in the LabHub. In a Kick-off Workshop in April 2025 participants have pledged their support in turning the idea of a LabHub into action. The next steps involve mapping relevant initiatives and projects, exploring their synergies and intersections, mapping their contributions along the laboratory's process chain, and aligning data formats.

In addition, communication with the target group is actively promoted. Alongside the development of the web platform, this also includes talks and presentations as well as further co-operation with other potential partners, particularly at an international level (e.g. with Eurolab).

V. CONCLUSION AND OUTLOOK

The transition to digital Quality Infrastructure (QI) marks a major step forward for laboratories, offering enhanced efficiency, accuracy, reliability and safety. As both beneficiaries and key contributors, laboratories must be actively involved in shaping and implementing digital QI solutions. This paper has outlined the core components of a digital QI toolbox—such as SMART standards, and machine-readable quality documents—as well as the respective ecosystem and has demonstrated their practical application in an accredited laboratory setting.

However, technology alone is not enough. Real progress requires actual implementation and seamless integration across the entire ecosystem of laboratories. To support this, a structured stakeholder engagement process was presented that helped to better understand laboratory needs and promote adoption. The newly launched LabHub aims at connecting stakeholders, foster collaboration, and accelerate the uptake of digital tools—transforming isolated efforts into a coherent, interoperable, and future-ready QI landscape. This will help transfer digital QI solutions into everyday value for laboratories, paving the way for a fully interoperable, future-proof QI.

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