

Digital Calibration Certificate in an industrial application

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ABSTRACT

Rapid growth of automation in combination with digitalization generates increasing need for measurement data, provided by sensors, the interface between real and digital world. In Industry 4.0 scheme the measurement data, including the calibration information, flows through the whole production chain in digital format. The present study demonstrated a fully digitalized environment for the calibration data generation, transfer, and usage in a Proof of Concept (PoC) project. Various stages of the PoC and different information systems used by the partners Aalto University, VTT MIKES, Beamex, Vaisala and Orion are discussed. The developed and tested digital calibration certificate (DCC) solution and its components are described. The major findings of the project include further need of DCC standardization and good practice subschemas. Development of the DCC is ongoing worldwide and the big picture goes even beyond the DCC. It is not only a question of calibration certificates and related data transfer to digital and machine-readable format, but also how this data could be used effectively.

Section: RESEARCH PAPER

Keywords: Calibration; digital calibration certificate; traceability; metrology; digitalization; quality infrastructure

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1. INTRODUCTION

Western Europe was the third largest region in the measuring and control instruments market worth \$137.9 billion in 2020, accounting for 19.6 % of the global measuring and control instruments market, preceded and followed by North America at 27.7 % and Eastern Europe at 5.6 % respectively. The Western Europe measuring and control instruments market is expected to grow to \$188.59 billion by 2025. [1]

1.1. Need and benefits of DCC

Since only reliable measurement data enables reliable decision making, regular calibration of measuring instruments and the metrological traceability of these results are essential. Today calibration certificates are mostly paper documents or PDF files which require human operations in the calibration processes. With the help of the digital calibration certificate (DCC) [2], manual work with calibration certificates can be eliminated. This makes calibration processes faster and allows valuable human operators to concentrate on more valuable work. Data transfer and uncertainty calculations related to calibration results can be

performed automatically. Effective processes, calculations without human errors, automated reporting procedures and use of calibration data have indirect economic effects on the industry through better product quality.

In industrial production, the quality of products and processes is verified by measurements. Efficient quality inspection is essential to avoid defect propagation in the manufacturing chain. The target is to minimize waste in production as well as to ensure long lifetime to minimize waste due to premature end-product failure [3]. Fully digitalized cyber-physical manufacturing requires autonomous quality inspection and control processes as well as integration to digital design and digital quality certificates, including digital calibration certificates. These principles are also emphasized by Sustainable Development, where the production chain from raw material to recycling (or waste management) of the end-product can be digitally controlled with a Digital Twin. Key challenges and a potential future role of metrology in the digital age are discussed by Eichstädt et al [4]. The publication investigates algorithms, cyber-physical systems, FAIR data and metrology, and the role of metrology in the digital transformation in the quality infrastructure (DQI). The digital transformation of metrology is

a key enabler for DQI and adoption of advanced analysis methods like Artificial Intelligence (AI), Machine Learning (ML), and Big Data.

1.2. DCC as enabler for new innovations

Moving towards machine-readable calibration certificates aligns not only with the digitalization strategies of individual organizations but with more comprehensive initiatives such as the European Digital Strategy of the European Commission (EC) [5]. Providing a quality and traceability infrastructure for data-driven engineering in Industry 4.0, the Internet-of-Things, autonomous systems, etc., also requires machine-actionable calibration information, i.e., access and interpretation by computer systems. The DCC information can be directly transferred into other digital processes to optimize process control and hence get the benefits of the calibration data online. Thus, it can be utilized for digital workflows in measurement science, calibration, and industry.

New digital metrology innovation can be found e.g., from sensor networks (IoT) and *in-situ* self- or co-calibration techniques. Although already widely used and rapidly increasing, sensor networks have not been addressed in a metrologically sound and systemic manner. EMPIR project Met4FoF [6] developed an initial set of methods for the propagation of uncertainty through elementary pre-processing steps in ML for sensor network data. The project provided an agent-based approach to ML implementation and demonstrated the use of the D-SI, DCC and semantic information for the automated metrological treatment of sensor networks. However, in real-world cases, and particularly in very large-scale sensor networks, practical methods, software frameworks, and guidelines for the automated uncertainty and data quality evaluation, and semantic descriptions are not available yet. The recently established FunSNM project, financed by European Partnership on Metrology, will address on these issues.

1.3. Background

The International System of Units (SI) [7] provides a coherent foundation for the representation and exchange of measurement data. It also enables interoperability and reproducibility in all fields. The EMPIR SmartCom project [8] has defined Digital SI (D-SI) [9], where a data format for reporting measurement results in terms of a numerical value, associated unit, and uncertainty statement is described. However, the correct interpretation of this information is only possible by understanding the content of the SI system, and additionally the GUM [10] about the uncertainty, the VIM [11] about the metrological terms, and standards such as ISO/IEC 17025 [12] about the concept of metrological traceability and calibration. Thus, these terms and concepts together with their meanings need to be represented in a machine-interpretable way, in order to make a DCC machine-readable in a wider sense, and thus enable the new services and possibilities based on digital calibration data.

This publication presents results of a Proof of Concept (PoC) study of fully digitalized environment for calibration data. This work originates from the EMPIR SmartCom project [8]. The doctoral thesis of Mustapää [13] was partly done as a part of the project. However, the thesis conducted a broader investigation of metrology digitalization in industrial IoT systems. The thesis also discussed methods for secure data exchange and provided means for establishing trust between organizations in a fully digital environment. Furthermore, the master thesis of Riska [14]

provided insight into possibilities to establish a new DCC ecosystem and how it should be realized. It also investigated the benefits and disadvantages of either a closed or open DCC ecosystem.

Similar kinds of initiatives are currently studied globally. The most relevant to this work is the GEMIMEG II [15] project. The project aims at safe and robustly calibrated metrological systems for the digital transformation enabling secure, consistent, legally compliant, and legally acceptable end-to-end availability of information for the implementation of reliable, networked measurement systems in Germany [15]. The number of publications related to DCC has increased rapidly during the last years [16]. Gadelrab and Abouhogail [17] reviewed 17 research publications published in the period from 2018 to 2020 covering the topics “digital transformation in metrology” and “digital calibration certificates”. The publications report DCC requirements, conceptual studies, specific application implementations, security, etc., all relevant to this work as well. However, the authors are not aware of earlier publications that report PoC results focusing on interoperability of DCC data over the whole value chain.

1.4. Contributions of the present study

Many of the previous studies about the DCC and its applications have been rather focused on implementing the DCC in small scale. In the present study, we describe the results of a PoC project that tested a fully digitalized environment for calibration data generation, transfer, and usage. The goal of this project was to test and identify barriers for large scale implementation of DCC in a whole calibration value chain.

The members of the project consortium are organizations with a high number of calibration customers or calibration providers. Implementing a DCC in this kind of environment brings new requirements. For example, receiving DCCs through email from a small number of calibration providers might not be a problem, but receiving DCCs from hundreds of different calibration providers needs to be highly organized and automated. One of the core benefits of the DCC is that it mitigates manual processing of data between organizations. To realize the full potential of the DCC, the sending and receiving process between the organizations should also be automated. In this project, a data transfer platform was developed and tested in order to automate DCC transfer between the calibration service provider and the calibration customer.

Another important aspect of the project was to test the DCC in an environment with several different information systems through the whole calibration chain as shown in Fig. 1. Implementing a DCC in a multi operator, each having their own system, environment requires a well standardized protocol in order to be interoperable between different systems. In this project, the interoperability of the data transfer protocol, i.e., the DCC, was tested by importing DCCs generated by different systems into one calibration management system.

The aim of this Proof of Concept (PoC) was to implement the concept presented in [18] to demonstrate and investigate its feasibility. PoC is an effective way to test DCC in practice and gain experience. In addition, special attention was paid to the digital authentication of the data, data integrity and fulfilment of metrological traceability.

2. METHODS

In the project, two linked calibrations of a metrological traceability chain were chosen for the PoC. The calibrated device

was a humidity and temperature probe type HMB75B, manufactured by Vaisala Oyj. The studied traceability chain covers the metrological traceability from the SI to the end user working measurement standard. The chosen chain is not fully complete since it does not include the actual measurement results performed by the PoC end user in their real process environment. The PoC was executed with DCC version 2.4.0 [19]. The good practice template used in the project was collectively developed and agreed on by the partners in the PoC.

2.1. Project consortium

In Finland, a digital data ecosystem has been established with DCC in its focus. The group consists of research institutes, instrument manufacturers, calibration laboratories and end users, i.e., the whole value chain is represented. The common goal is efficient and extensive utilization of measurement and calibration data as well as increasing digitalization in this context. The pharmaceutical industry has been especially active in this field, and the current activities around the DCC are linked together through this sector.

In the PoC reported in the present study, the partners were Aalto University, VTT MIKES, Beamex Oy, Vaisala Oyj and Orion Oyj. Aalto University was the project coordinator and developed the data transfer platform and cloud components for DCC management. VTT MIKES is the National Metrology Institute (NMI) in Finland and provided the expertise of calibration certificates and traceability to the project. Beamex, an integrated calibration solution provider, was the calibration management system specialist and developer in the present project. Vaisala manufactures innovative measurement solutions for weather, environment, and industrial processes. The instrument containing humidity and temperature sensors was a product of Vaisala. They operated in the project as an accredited calibration service provider and a DCC receiving party. Pharmaceutical company Orion was the other DCC receiving party and the endpoint of the calibration chain.

2.2. Implementation and test setup

DCC management and exchange was tested by simulating a traceability chain which included three partners: VTT MIKES, Vaisala and Orion. The PoC concentrated on a humidity and temperature probe used by the calibration end user Orion. The simulation concentrated on the temperature traceability chain.

Each partner in the traceability chain had a different calibration management system (CMS). Calibration certificate generation in VTT MIKES is based on their proprietary in-house software together with Microsoft Office tools for data management and certificate templates. For their system environment, a manual DCC creation tool was estimated to be the easiest to implement in the project. In the future, the DCC creation can be implemented as a part of their current information management systems to increase automation in DCC generation, but for the PoC this was decided to be out of scope.

Vaisala had a dual role in the PoC as they both received a DCC from VTT MIKES and sent a DCC to Orion. Vaisala calibration services use a proprietary in-house calibration management platform. On the DCC receiving end of Vaisala, it was decided by the project consortium to test the manual receiving process. Receiving of the DCC was based on a human readable format of the DCC as described in section 3.2. As the certificate creation process is already highly digitalized within Vaisala's calibration management platform, automated DCC

generation was possible to test due to fully machine-readable data. Automated DCC generation was tested as a part of the calibration management platform as explained in section 3.1.

The DCC created by Vaisala was received by the calibration end user Orion. Orion uses a commercial off-the-shelf calibration management system, Beamex CMX. DCC import to the CMS was tested as a part of the Beamex CMX environment to enable automated import of calibration results from the DCC. The structure of the DCC import is presented in section 3.2. As each organization had their own CMS, the data transfer needed to be arranged through the organization boards. In the PoC, the data transfer was tested through a data transfer platform that was integrated into the systems used by the partners in the traceability chain. The data transfer platform enabled system-to-system integration of different CMS systems eliminating the need for e.g., emails as a transfer method.

2.3. Test procedure

Testing of the PoC solution was carried out in three phases. In the first phase, generating and reading the DCCs was tested with a peer-to-peer approach. The goal of the first testing phase was to demonstrate the capability of creating and reading a DCC with two separate approaches. First an example DCC was manually created using existing PDF certificates as a template. Once the first version of the DCC was created utilizing Notepad++, both the calibration service provider and the calibration customer reviewed and accepted the example. The example DCC compatibility with the DCC schema was also validated at this point. Next, the DCC example was frozen, and a copy was distributed to both parties to develop an implementation for DCC creation or reading.

After the development, a DCC was generated by the calibration service provider and sent to the receiving party of the calibration. At this point, the DCCs were delivered manually through email and without digital signatures. Next, the receiving party used the received DCC to import calibration results to their CMS. In the calibration between VTT MIKES and Vaisala, the calibration results were not automatically imported to the CMS. Instead, the DCC was tested with the human-readable format as described in section 3.2.

The next testing phase in the project was end-to-end testing. In the context of this project, it meant that both calibrations were executed following the required industry procedures and standards. At this time, the full data flow and all developed components were tested. The goal of the test phase was to establish a fully digital calibration process from generating a DCC in the calibration service provider's CMS to reviewing the calibration results at the calibration customer's CMS. The process included the following steps:

1. Calibration service provider generates a DCC from calibration management system.
2. Calibration service provider validates the DCC against the DCC XML schema.
3. Calibration service provider adds a digital signature to the DCC.
4. Calibration service provider uploads the DCC to the data transfer platform.
5. Calibration service provider shares the DCC with the calibration customer.
6. Calibration customer validates the digital signature in the DCC.
7. Calibration customer imports the DCC to their calibration management system.

8. Calibration customer reviews and accepts the calibration in their calibration management system.

The final testing phase in the project was interoperability testing. The goal of the testing phase was to test the interoperability of all the DCC generation and reading methods with each other. The test was conducted by generating a DCC with both the manual web form and the automated CMS DCC generation. These DCCs were then read with both the human readable format and the automated DCC CMS import.

2.4. Data security

For the calibration customer it is vital to ensure that the received calibration certificate is from the designated calibration service provider and it was not tampered by any third party. To ensure these objectives, the PoC solution was designed with a focus on digital authentication of data and data integrity. Digital authentication of data and data integrity were achieved with the combination of digital signature and user management.

Data integrity was ensured in the project with an XML Advanced Electronic Signature (XAdES) [20] based signature solution. XAdES signatures are compliant with European eIDAS regulation [21] which defines requirements for legally binding digital signatures. Digital signatures allow the calibration customer to validate that the received DCC was not modified in any way after it was accepted and authorized by the calibration service provider. In this project, digital signatures were tested as an organization level digital seals as described in section 3.1. In a production-ready implementation, the demo Public Key Infrastructure (PKI) should be replaced with another PKI. Requirements for such PKI are described by e.g., Pekka Nikander et al [22]. Some practical approaches for the PKI are presented by e.g., Tuukka Mustapää [13].

In the PoC solution, signing authorization was controlled through each organization's existing user management. In this project, Microsoft Azure Active Directory was used as the user management solution as all participants used it. Modern authentication solutions also have built-in audit trails that can record when and by whom a DCC was signed by.

The project consortium considered data integrity as the most important aspect of data security in the calibration process. Data confidentiality was also recognized as an important topic in the project. Still many consortium members did not consider calibration data confidentiality critical to the business operations, since it's difficult to misuse calibration data without the meta information involved in it. Data confidentiality was ensured by using Transport Layer Security (TLS) encryption when uploading and downloading data from the data transfer platform. Data was also stored encrypted at the data transfer platform.

3. RESULTS

The tested solution created a fully digitalized environment for the calibration data generation, transfer, and usage. The different components and organizations in the traceability chain were integrated to each other through the data transfer platform. As presented in Figure 1, the DCC generation tool in Vaisala and the DCC receiving in Orion's CMS were tested as a part of the organizations' existing information technology environment. Other components of the infrastructure were implemented as a part of the cloud-based data transfer platform. The calibration traceability chain was created through the DCCs. Each DCC includes all necessary information for traceability e.g., measurement data, deviation, uncertainty, and measurement references.

3.1. Components for creation

Manual DCC creation: Global adoption of the DCC format requires easy-to-use tools with low entry barrier. In the PoC, a web form was developed, based on the good practice format of the DCC, for manual creation of DCCs. The web form was developed using JSON GUI technology and it was integrated to the data transfer platform. The web form enabled easy creation of DCCs without any changes to the existing information systems.

Automated DCC creation: Another approach to DCC creation was a fully automated DCC creation from the CMS. The component was tested as a part of a laboratory calibration management platform. The component enabled creating a DCC automatically from the calibration management system database. Fully automated DCC creation mitigates human errors in the DCC generation and removes unnecessary work.

Format validation: DCC offers a framework for the calibration data that needs to be specified to a use case in question. Seamless interoperability requires that the use of the DCC schema and the good practice examples are commonly agreed and executed. To ensure this, DCCs need to be verified to make sure that the data format follows the commonly agreed guidelines. Format validation checks the data in the DCC against an XML schema, defined by the DCC schema and the use case specific good practice DCC, and highlights the possible differences. In the PoC, the format validation was implemented as a part of the signature service.

Digital signature: Calibration results need to be authorized by the calibration provider and secured during the transit. A cryptographical digital signature allows the calibration customer to trace the signature to the calibration provider and ensure that the data integrity of the calibration results is intact. In the PoC,

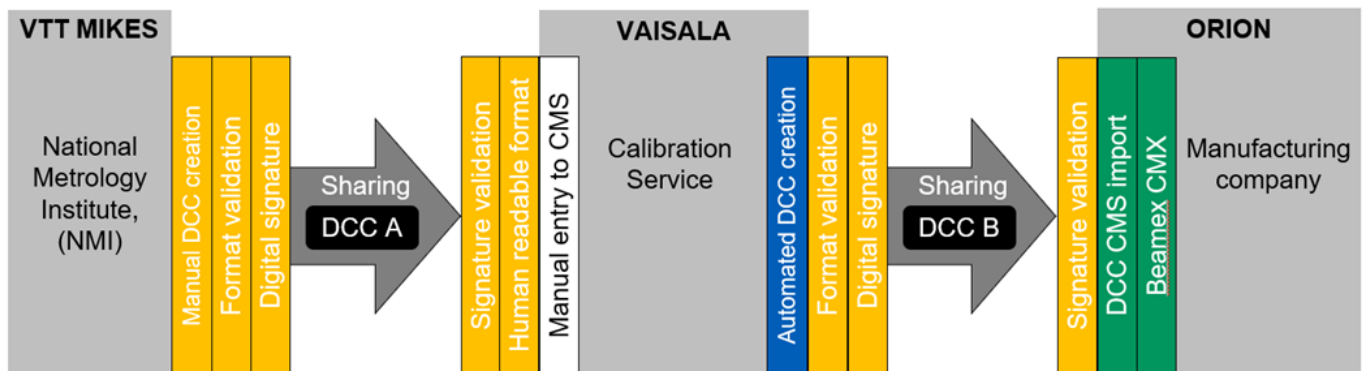


Figure 1. Data flow and components of the developed and investigated solution for digital calibration certificates (DCC). The color of the component indicates the organization that was responsible for the development. Yellow and dark grey components were developed by Aalto University, blue components by Vaisala and green components by Beamex.

XAdES based cryptographical digital seals were used. Digital seals are digital signatures that identify a group of people instead of one individual person. In the PoC, digital seals were used at organization level. Each organization had their own private keys for signature creation traceable by the demo Public Key Infrastructure (PKI).

3.2. Components for receiving

Signature validation: The calibration customer needs to ensure that the data included in the DCC is authenticated by the expected organization and has not been manipulated by third parties. This can be ensured by validating the digital signature in the DCC. In the PoC, the signature validation service was implemented as a part of the data transfer platform.

Human readable format: The DCCs need to be visualized to a human readable format to be used in manual processes. These can be e.g., manual transfer of data to a calibration management system or a manual review of calibration results. In the project, a human readable format was developed using XSLT and JavaScript technologies. The human readable format was used to manually review and transfer calibration results to the calibration management system of the accredited calibration laboratory. The human readable format also included a user interface for validating the digital signature.

DCC CMS import: Utilizing the calibration data in calibration management systems (CMS) requires data extraction from the DCC XML document to the CMS database. In the PoC, a DCC data parser was developed to enable fully automated and error resistant data transfer process for the calibration customer. The DCC data parser was integrated to the customer's CMS (Beamex CMX) as a separate driver that enabled import from local data storage or DCC data transfer platform. After the data import, the calibration result could be reviewed and accepted according to current calibration processes. Finally, the calibration result data can be utilized in the CMS as part of instrument analytics and asset management processes.

3.3. General components in the data transfer platform

DCC sharing: The data transfer was implemented through a data transfer platform used by all the partners in the project. The data privacy of each organization was achieved through multitenancy. The data transit between organizations took place in the platform through transferring the DCCs between tenants. The platform user management also allowed to add user and visibility rights to specific DCCs for other organizations in the platform.

DCC storage: The long-term storage of DCCs was outside the scope of this PoC but the platform approach enables several options. If both the calibration provider and the calibration customer use the platform for long-term DCC storing, there is no need for unnecessary data replication as the same document can serve both parties. Either party can also take control of storing their own DCCs. In case both parties have local storages for their DCCs, the platform can be used only for data transfer and no data will be stored in the platform.

User management: The user management in the tested solution was based on Microsoft Azure Active Directory (AAD). In the PoC, all the organizations used Microsoft AAD for user management. The data transfer platform was developed to support single sign-on (SSO) through Microsoft AAD. This allowed all organizations to use their existing authentication methods to authorize users to sign, transfer and manage DCCs in the data transfer platform. Microsoft AAD integration also

allows each organization to have full control of the users that can access their organization's data. As the platform's user authentication is integrated as a part of the organization's normal user authentication, the user rights to the platform can be added and removed automatically through normal employee onboarding and offboarding processes.

4. DISCUSSION

The PoC solution presented in the present study was designed for testing and demonstrating an example implementation of the DCC in an industrial application. The investigated solution and its components worked as expected in general and the test was considered successful by all consortium members. The PoC solution was considered effective and user friendly for executing calibration data exchange. The cloud-based platform offered a low entry level for organizations with less software development capabilities.

The development of the necessary components, excluding the custom components for generating and reading DCC from specific calibration management systems, as a part of the calibration data transfer platform lowered the effort to implement the DCC. All necessary integrations between the information systems were implemented through standardized application programming interfaces (APIs). Necessary integrations were user management integrations with the data transfer platform through AAD and CMS integrations with the data transfer platform.

The presented solution gives guidelines for the development of a production-applicable solution. Room for improvement was identified especially in the solution interfaces and in general robustness of the system. Furthermore, a production-ready solutions will require further development of the solution infrastructure and data security, as was discussed in section 2.4.

4.1. Challenges in the DCC implementation

Interoperability between different information systems requires a well-standardized and universal data format. The universal DCC format has been designed to provide a framework for representing calibration data. It enables various ways to insert measurement data and recursive data structures which challenge the receiving end machine-readability. Need for interoperable machine-readability sets tight requirements not only to the DCC structure but also to the overall harmonization of the calibration certificates' content, including common and fixed vocabularies, glossaries, and semantics content. As use case-specific needs and data formats can vary significantly, there needs to be a way to standardize the data in a more detail level.

To achieve use case level standardization, several good practice examples are currently being developed. The goal of the good practice examples is to standardize the representation of data, e.g., with a specific measurement quantity. The PoC was executed before widely adopted good practice examples were published, and there were several challenges to achieve an adequate level of interoperability. In the first tests, only the universal DCC schema was used to validate the created DCCs. As a result, the CMS data import failed to read both DCCs created with the manual web form and the automated DCC creator. The reason was identified to be different data structures in the two DCCs despite they both were compatible with the universal DCC schema. The finding highlights the importance of good practice examples and related good practice subschemas. The development of good practice subschemas should restrict

the use of the universal DCC schema to the level where use case specific requirements are fulfilled, and interoperability ensured.

In addition to the need for more precise standardization, also other technical findings were identified. The current version of the Digital SI (D-SI) does not support resolution for numerical values. For example, measurement result 1.00 will be saved as 1 in the XML which has implications e.g., to uncertainty calculations. Furthermore, calibration date or calibration due date of the reference instrument used in the calibration do not have a dedicated field in the DCC. These findings were considered critical for the implementation of the DCC by the project consortium members.

4.2. Remaining challenges and future work

The development of good practice examples should be intensively coordinated between different working groups to avoid the risk of divergence. Also, the total number of different good practice examples should be minimized, and same data structures applied to as many different use cases as possible, to ease the implementation of the DCC. Every additional good practice format will increase the difficulty to implement the DCC especially for organizations that operate with several types of measurements. The authors see finding the balance between the number of good practices developed and ensuring standardized data structures in the DCC as the core challenge for the DCC.

Wide reformation, like digital transformation, in a quite traditional calibration field will not happen in a second. And unfortunately, all stakeholders do not have resources to be involved in the development work. This leads to a situation where stakeholders do not have easy access to the latest development work, knowledge, and capabilities needed for DCC implementation. DCCs are currently developed mainly in a few large European metrology institutions and some forerunner industrial companies. Support for the digital transformation and implementation of DCCs is needed. Especially end user needs in different industrial operations need to be considered.

Our future work will include executing a new DCC PoC, exploring new possibilities to exploit DCC data, and validating business opportunities. The partners in the new PoC are VTT MIKES, Beamex, Lahti Precision, Orion, Vaisala, and Bayer. We will demonstrate mass and weighing instrument calibration cases. The PoC will examine a complete metrological traceability chain from the SI to the end user process. More information on the reported PoC and the future work is available from the authors.

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