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Transition to DCC-based calibration management: findings from proof-of-concept investigations

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Abstract **– The introduction of standardized data formats for measurement and calibration data such as the digital calibration certificate (DCC) will enable further automation of calibration-related processes. This will open new possibilities for optimization of calibration processes in industrial applications. This paper describes some of the challenges and possibilities related to the transition to DCC-based calibration processes and management in the process industry. The findings presented are based on case examples and proof-of-concept projects from the process industry, in which automation of a calibration process is pursued using a combination of systems from multiple providers. The investigations and findings also suggest that parts of the DCC data structure could potentially be beneficial also for other applications, in which exchanging of calibration data is needed, but system integration is otherwise challenging due to lack of a suitable harmonized data structure.**

I. INTRODUCTION

Calibrations are an essential part of quality management of any industrial process that is dependent on measurements. Traditionally the results of a calibration have been documented in a calibration certificate that also contains detailed information on how the calibration has been performed. Due to their significance for quality management of any process that is dependent on measurements and thus the accuracy of the measurements, the contents of a calibration certificate have been standardized. As a part of the digitalization efforts around metrology and quality infrastructures, definition of a standardized format for a digital calibration certificate (DCC) and development of associated processes have been one of the key areas of development within the metrology community in recent years [1,2].

Digitalization of calibration related processes have many benefits but achieving them can require comprehensive changes in current processes and systems. Due to this expected that the transition will need to be done incrementally, e.g. as presented in [3]. A major benefit is improvement in cost-efficiency, as there are various direct and indirect costs associated with calibration, and reductions in the lead time of performing a single calibration quickly add up when the number of instruments requiring calibration increases. Availability of the calibration data in an easily usable format allows its use for analytics-based decision making and optimization of the processes, e.g., optimization of calibration intervals and tolerance analysis [4,5].

Digitalization also plays a big role in improving information security and data integrity, as manual work steps have a chance for human error, e.g., in data entries, and are thus considered a compromise for data integrity, which is a highly regulated topic, e.g., in the pharmaceutical industry [3]. A key factor in efficiency and security improvements is the possibility for better system integration as a standardized format for calibration data minimizes the need for bespoke system to system integration, which can become complex to maintain long term as the systems involved are being updated [6].

Ideally, the availability of unambiguous calibration data also allows more extensive network benefits within metrology ecosystems of customers, service providers, instruments manufacturers and other organizations [7]. This is one of the reasons for investigations on the establishment of metrology data spaces [8].

Achieving all the benefits of digitalization is still depending on more extensive harmonization and establishing more specifically defined ways of using the DCC in different applications [9]. This has led to efforts in defining good practices and guidelines for correct use of the DCC for different fields of metrology, e.g., by technical committees of the German Calibration Service (DKD) [10,11]. An important part of these efforts is the definition of XML attributes, i.e., refTypes, which are needed for ensuring correct interpretation of data. Such guidelines are already available, e.g., for weighing instruments [12,13]. The need for more specific semantics of the calibration data has also generated interest in the use of ontologies in more detailed descriptions of different data that are included in a DCC [14].

This paper presents an overview of technical investigations and testing based on use cases from the pharmaceutical industry. The presented part of the work focuses mostly on the end-user's side of the calibration process and calibration management. The work on the proof-of-concept implementations has not been finalized by the time of writing this paper, so the paper focuses mostly on presenting the investigated use cases, challenges identified so far and possible solutions to these challenges. Good practices and comprehensive lists of refTypes for the quantities and instrument types were not yet available at the time the work started. To overcome this some additional refTypes are used for testing purposes, and in this regard the solutions used proof-of-concept implementations will likely have some limitations for more generalized use in other cases.

II. CALIBRATION PROCESSES

Calibrations of high-precision measurement instruments are traditionally performed by calibration laboratories, to which the customers send their instruments to be calibrated. However, in industries such as process industry, the number of instruments at a single facility can be very high meaning that it is more efficient to calibrate instruments on-site if the tolerances for the measurements allow it. It is also common practice that larger companies with more annual calibrations outsource on-site calibration services to external calibration service providers. When calibrations are due, a technician from the service provider comes to perform the calibration on-site at the customer's facility, either using equipment from the service provider or customer. In general, the calibration processes used in the industry tend to follow mostly the same steps regardless of whether the calibration is performed on-site or at a laboratory.

The process can be considered to begin when the customer, i.e., the instrument's owner, requests a calibration to be done by the service provider. Once a calibration has been requested, the service provider needs to confirm that the requested calibration can be performed, and the customer and service provider agree on the calibration procedure and other practical details.

When everything has been agreed on the actual calibration is then performed. If the calibration is to be performed at a laboratory, the instrument to be calibrated is sent to the service provider. After that the actual calibration is performed and a calibration certificate is issued and sent to the customer. If the calibration was performed at a laboratory, the instrument is also sent back to the customer.

Upon receiving the calibration certificate, the customer will need check that calibration procedure etc. match the agreed procedure. Typically, the calibration is then approved on the calibration management system and the results are imported into the system and the original certificate is archived.

III. OPERATIONAL AND INFORMATION TECHNOLOGY SYSTEMS

In the industry systems used at factories, power plants or other kind of facilities are categorized into operational technology (OT) systems and information technology systems (IT). The main difference between of the two is the connectivity. Typically, OT systems such as supervisory control and data acquisition (SCADA) are used in an isolated local environment. Many typical OT systems have been designed with the assumption that systems are isolated, and thus their security may heavily depend on that. In addition, OT environments are typically not as well suited for regular updating of systems. This can lead to the systems having severe vulnerabilities if they were exposed to a cyberattack. Respectively, IT systems are intended to be interconnected so the approaches used for ensuring security are very different.

Introduction of industry 4.0 and internet of things (IoT) has meant that nowadays there are more interest towards converging IT and OT systems partially to enable more flexible use of data within organizations. However, there are several challenges related to the converging of IT and OT systems, most of which are related to ensuring the security of the OT environment.

IV. PROOF-OF-CONCEPT OVERVIEW

The proof-of-concept projects used as the basis for these investigations are focusing on two different use cases. The first use case is related to conventional calibration processes involving a customer and a service provider or instrument manufacturer. The second case is related to a more experimental use case where the use of the DCC's data structure is used to exchange calibration results between an automated calibration system and calibration management system developed by different companies. In both cases there are two essential functionalities for the calibration management system: importing calibration data from a DCC and generating and sending a calibration request. The main difference of cases is that in the first case the DCC is received from outside the OT environment where the calibration management system is running, whereas in the second case the systems involved are OT systems.

A. Importing calibration data

The first step of the implementation has been developing a simple solution for importing data from a DCC into a calibration management system to enable further testing. As a first iteration, the importing functionality was based on a file manager view where the user can browse for the DCC file that is to be imported. While this kind of approach is simple to implement, it is by no means ideal or particularly practical, as the process still involves several manual steps. This kind of solution used alone can still save some time in the process, if the data would otherwise have to be entered manually into the calibration management system.

Ideally, the importing process is done without needing to specifically browse and select a file to be imported. This requires that the results to be imported are transitorily saved in a specific location and are clearly identifiable so that a result can be automatically assigned to the correct instrument in the calibration management system's database. However, when the DCCs are to be received from a third-party IT system, e.g., via an Application Programming Interface (API) or a cloud service, into a calibration management system operating in an OT environment, additional security measures are needed to secure the OT environment.

B. Calibration request

Capability to create and send a digital calibration request (DCR) that is similarly structured file as a DCC will benefit different use cases. For industry, DCR is considered as a necessary part of the calibration process as it provides additional assurance in the calibration's conformity to the end-user's procedures. The most common use case for the DCR is requesting calibration from a service provider. In these cases, the DCR will be handled in a similar way whether the service provider is going to perform the calibration on-site or at an external laboratory.

One new opportunity that DCR can also bring is the ability to have the newly ordered instrument calibrated according to the customer's own procedure by the manufacturer. In industrial application instruments are often used in very specific operating ranges and have their calibration procedures defined accordingly. For these reasons, the calibration certificates provided by the manufacturers may not be that useful for the customers if the used calibration procedure uses different calibration points. For these reasons the customers may end up recalibrating brand-new instruments according to their own procedures. Thus, the DCR can in the best case help get rid of these kinds of seemingly unnecessary calibrations. When the calibration management system is considered, it is a relatively infrequent use case when compared to re-calibrations of existing instruments. In this case some of the data that is typically considered necessary for requesting calibration is also not available yet, so the requesting process must be possible also without it.

In the second use case presented, the requirements for calibration request are somewhat different, as the DCR is mainly needed to provide the instructions for the automated calibration system for performing the calibration, meaning that the process itself is much more straightforward. In this case the benefit from the use DCR is mainly making the operation of the calibration system less dependent on manual operation, which still is an important part of improving the efficiency of the calibration process as a whole.

C. Overcoming challenges in the IT-OT convergence

In the transition to a DCC-based calibration process, the IT-OT convergence quickly becomes a challenge when the exchange of the DCCs and DCRs is done using IT systems, as calibration management systems are typically OT systems. As such, multiple layers of security precautions are necessary. One of these approaches is implementing separate system between the interface and the calibration management system as a buffer between the IT and OT environments. This allows the validation of the received DCC before it is imported into the calibration management system, ensuring, e.g., that only DCCs corresponding to the original request are imported. Another important part of the security solution is access management for the interfaces, so that only the specified users or organizations can access the interface. Similarly, also electronic signing or sealing of the transferred files and verification of the signatures and seals is essential to ensure the integrity and authenticity of the files.

V. FINDINGS FROM THE INVESTIGATIONS AND PROOF-OF-CONCEPTS

Although the implementation is still at an early stage, there have already been some findings and challenges, for further investigations would be beneficial.

A. Adding instruments to calibration management system based on a DCC

DCCs contain some of the information that are typically also needed in calibration management systems. This means that there is a possibility to make adding new instruments easier if the instrument is delivered with a DCC from the manufacturer. Examples of such data include information for identifying the instruments such as the manufacturer name, model designation and serial number, or information on the technical specification or performance of the instrument.

B. Using partial DCCs for transferring calibration data

Since the DCC has been defined to be compliant with various standards and regulations regarding accredited calibrations, meaning that a lot of administrative data is considered as mandatory in the DCC schema. In industrial applications, in which a calibration would be performed on-site, some of the mandatory data in the DCC might not be relevant, but a standardized data format would still be needed to handle the communication between instruments or systems from different manufacturers or providers.

There are a few different approaches how the DCC, and possibly also the DCR, could be used to overcome the lack of a more suitable data format. The first way would be to include any data that the automated calibration system is not capable of generating itself into a partially filled DCC file so that the calibration system would be capable of filling the desired parts. Alternatively, the calibration result could be provided by the calibration system as a partially incomplete DCC, consisting of the minimum information required for successfully importing the data into the calibration management system. If a complete DCC would be required, any missing data could be included by the calibration management system so that the result could be exported later as an official document.

C. Non-SI units and conversions

From the beginning, the definition of the DCC has been strongly tied to the parallel development of the D-SI. The main purpose of the D-SI is to cover the units included in the SI system as defined by the BIPM. Thus, the DCC is also primarily supporting the use of SI units. Following this requirement and other best practices can be very impractical if the existing instruments or systems used in the industry do not natively support SI units. Extending the scope of the D-SI to cover all other units as well is not really a realistic option either. Instead, some alternative approach would be needed as the DCC also needs to cover the use of non-SI units. Currently, it is recommended to be done by including a definition for the used non-SI units in the DCC, but so far there is not an established database containing for the definitions, or any other kind of a harmonized naming practice for the non-SI units for use with the DCC. A more harmonized way of doing it would be needed to make DCC really support all applications of metrology. A similar approach as with the definitions of refTypes could be used for the most common units for different quantities.

Another challenge with the current versions of the DCC and D-SI is that when a measurement result is presented using two different units, there is not a clear distinction of the which value is the original value, and which value is a conversion. This issue arises especially in cases where the conversion would require additional significant digits or a higher resolution than the originally measured or indicated value to maintain a comparable level of accuracy. For any further use of the data, the original measurement value and the converted value should be clearly distinguishable.

As the DCC is intended to be a globally applicable standard, it should cover all different fields of metrology and the associated industrial applications. There are plenty of use cases where the use of a non-SI unit has become a common practice and forcing a change to that is not going to be feasible with the introduction of the DCC alone.

VI. CONCLUSION

The development of the DCC has reached a stage where its use in industrial applications can be considered realistic as good practices are agreed on and being published, although there still some needs for refinement. The transition to a fully digitalized DCC-based calibration processes will require significant revising of the current calibration processes. Having a strict separation of OT and IT systems may require even organizational changes before the DCC can be taken into use in an ideal way, as the DCC-based processes can be considered to require some degree of convergence of IT and OT systems.

The DCC and D-SI have been defined for specific purposes, but at least from the industry’s perspective there are also other potential uses for them in applications where calibration data is being transferred, and a corresponding standardized data format does not exist. However, using DCC data structure in a way that would be deviating from the general guidelines for the use of the DCC and D-SI. This suggests that there would be use for a more generic data structure for calibration data that would use the same structure as the DCC for the measurement results, but with less restrictions.

There are many industrial applications where non-SI units have become the de-facto standard measurement unit, and to make the DCC truly universally applicable standard for calibration data, some additional harmonization for non-SI units is also needed. This could be a guideline for labelling conventions, or more ideally a quantity specific database for commonly used non-SI units similarly as there already are for refTypes.

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