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Digital Calibration Certificate as part of an Ecosystem

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Abstract

Many companies still use paper-based calibration systems, which means they are missing out on the benefits of a paperless calibration system. By using a digital calibration certificate there will be no need for paper certificates anymore. The Digital Calibration Certificate has been developed since 2017 and the aim is to create an international DCC format for the entire field of metrology.

In this research, the possibilities of establishing a new DCC ecosystem were investigated as well as how the ecosystem should be realized. It was also investigated what the benefits and disadvantages are of either a closed or open DCC ecosystem. The research method for the technical part in this thesis work was mainly based on case studies of several proof of concept implementations related to the DCC schema. The second way data was collected was by using a qualitative research method to collect empirical data with semi-structured interviews.

The results shows that the current version of the DCC schema can be used in a closed ecosystem where one company controls both the generation and reading of the DCC. But to use it in an open ecosystem with multiple actors, a few issues must be solved and there is also a need for alignment between the DCC and the calibration management system. The DCC ecosystem should be open for the contractors and external labs as the highest benefit will come from including them to the ecosystem. For the users of calibration management software, a closed ecosystem is also acceptable since they rely on that they can continue to use their current software also with a closed system.

Language: English
Key Words: Calibration, Certificate, Digitalization, Paperless, Ecosystem, Standardization

EXAMENSARBETE

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Abstrakt

Många företag använder fortfarande pappersbaserade kalibreringssystem, vilket innebär att de går miste om fördelarna med ett papperslöst kalibreringssystem. Genom att använda ett digitalt kalibreringscertifikat kommer det inte att behövas papperscertifikat längre. Digitala kalibreringscertifikat har utvecklats sedan 2017 och målet är att skapa ett internationellt DCC-format för hela området inom metrologi.

I denna forskning har det undersökts vilka möjligheter det finns med att etablera ett nytt ekosystem för digitala kalibreringscertifikat och hur ekosystemet ska realiseras. Det undersöktes också vilka fördelar och nackdelar det är med antingen ett slutet eller öppet DCC-ekosystem. Forskningsmetoden för den tekniska delen i detta examensarbete baserades huvudsakligen på fallstudier av flera POC implementeringar relaterade till DCC-schemat. Det andra sättet att samla in data på var genom att använda en kvalitativ forskningsmetod för att samla in empiriska data med semistrukturerade intervjuer.

Resultaten visar att den nuvarande versionen av DCC-schemat kan användas i ett slutet ekosystem där ett företag kontrollerar både generering och läsning av DCC. Men för att använda det i ett öppet ekosystem med flera aktörer måste några problem med anpassning mellan DCC och kalibreringshanteringssystemet lösas. DCC ekosystemet bör vara öppet för entreprenörer och externa laboratorier eftersom den största nyttan kommer från att inkludera dem i ekosystemet. För användare av programvara för kalibreringshantering är ett slutet ekosystem också godtagbart, eftersom de förlitar sig på att de kan fortsätta använda sin nuvarande programvara även med ett slutet system.

Språk: Svenska

Nyckelord: Kalibrering, certifikat, digitalisering, papperslös, ekosystem, standardisering

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Nimike: Digitaalinen kalibrointitodistus osana ekosysteemiä

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Tiivistelmä

Monet yritykset käyttävät edelleen paperipohjaisia kalibrointijärjestelmiä, minkä seurauksena he menettävät paperittoman kalibrointijärjestelmän edut. Digitaalisen kalibrointitodistuksen käyttäminen mahdollistaisi paperisista kalibrointitodistuksista luopumisen. Digitaalista kalibrointitodistusta on kehitetty vuodesta 2017 lähtien ja sen tavoitteena on luoda kansainvälinen dataformaatti kalibrointitodistuksille koko metrologian alalle.

Tässä tutkimuksessa selvitettiin, mitä mahdollisuuksia on perustaa uusi DCC-ekosysteemi ja miten ekosysteemi tulisi toteuttaa. Myös suljetun tai avoimen DCC-ekosysteemin etuja/haittoja tutkittiin. Opinnäytetyön teknisen osan tutkimusmenetelmä perustui pääosin tapaustutkimuksiin useista DCC-skeemaan liittyvistä proof of concept toteutuksista. Lisäksi kvalitatiivista tutkimusmenetelmää hyödynnettiin tutkimuksessa empiirisen tiedon keräämiseksi puolistrukturoiduilla haastatteluilla.

Tulokset osoittavat, että DCC-skeeman nykyistä versiota voidaan käyttää suljetussa ekosysteemissä, jossa yksi yritys hallitsee sekä DCC:n luomista että lukemista. Avoimessa ekosysteemissä, jossa on useita toimijoita, on ratkaistava muutama ongelma, ja myös DCC:n ja kalibroinnin hallintajärjestelmän välinen linjaus on tarpeen. DCC-ekosysteemin tulee olla avoin urakoitsijoiden ja ulkopuolisten laboratorioiden käyttöön, sillä suurin hyöty on niiden sisällyttämisestä ekosysteemiin. Kalibroinnin hallintaohjelmiston käyttäjille suljettu ekosysteemi on myös hyväksyttävää, sillä he luottavat siihen, että he voivat jatkaa nykyisen ohjelmistonsa käyttöä myös suljetussa järjestelmässä.

Kieli: Suomi
Avainsanat: Kalibrointi, todistus, digitalisaatio, paperiton, ekosysteemi, standardointi

ABBREVIATIONS

AI	Artificial Intelligence
API	Application Programming Interfaces
BIPM	Bureau of Weights and Measures
CFR	Code of Federal Regulations
CMS	Calibration Management System
CODATA	Committee on data for science and technology
DCC	Digital Calibration Certificate
DCR	Digital Calibration Request
DT	Digital Twin
D-SI	Digital-SI
E2E	End-to-end
FDA	U.S. Food and Drug Administration
FS	Full Scale
GMP	Good Manufacturing Practice
GUM	Guide to the Expression of Uncertainty in Measurement
HART	Highway Addressable Remote Transducer
IEC	International Electrotechnical Commission
ISA	International Society of Automation
ISO	International Organization for Standardization
IT	Information Technology
JCGM	Joint Committee for Guides in Metrology
JSON	JavaScript Object Notation
NIST	National Institute of Standards and Technology
NMI	National Metrology Institute
PaaS	Platform-as-a-Service
POC	Proof of Concept
PTB	Physikalisch-Technische Bundesanstalt
QA	Quality Assurance
RC	Release Candidate
R2B	Research-to-Business
SaaS	Software-as-a-Service
SI	System of Units
TAR	Test Accuracy Ratio
TUR	Test Uncertainty Ratio
VIM	International Vocabulary of Metrology
W3C	World Wide Web Consortium
XML	Extensible Markup Language
XSD	XML Schema Definition

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1 Introduction

Not so long ago companies kept all records on paper. If you wanted to share information, you showed physical documents, or sent papers by fax. Then when computers became popular most businesses started to convert paper records to digital computer files. This process of converting information from analog to digital is called digitization. The process of using digitized information to make data access easier and more efficient is called digitalization. Kasenally (2018) says that when doing a digital transformation, you need to work not only on the technology, but also on the leadership, culture, and mindset to deliver a customer experience that give them more value of using your products than ever before. Then when all pieces fall in place, you got a true Digital Transformation.

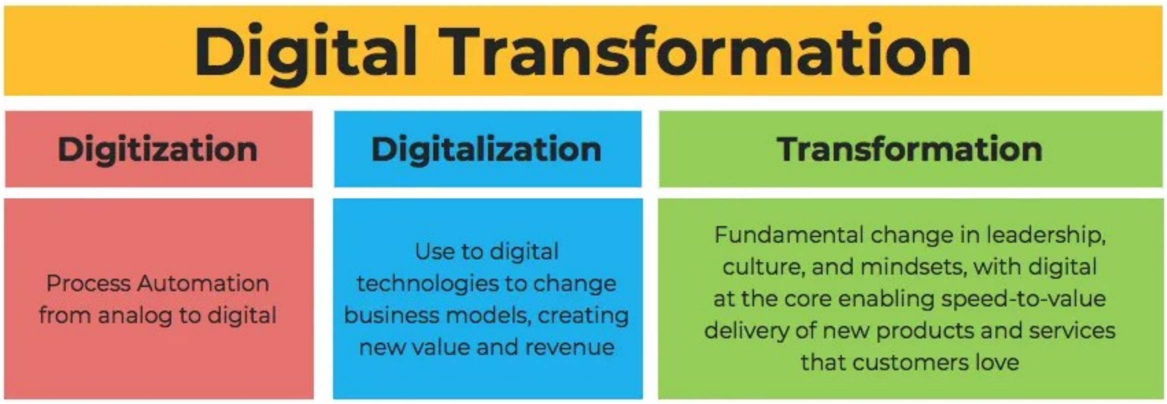


Figure 1. Definition of Digital Transformation. (Kasenally, 2018)

Digital transformation is by Salesforce (2020) described as the process of using digital technologies to create new (or modify existing) business processes, culture, and customer experiences to meet changing business and market requirements. This research focuses on if the Digital Calibration Certificate is technically ready to be used by the process industry and if the process industry is ready to switch from analog paper certificates to a Digital Calibration Certificate ecosystem where the certificates can be shared digitally between the actors. Both objectives are important parts in the digital transformation that the process industry faces.

1.1 The client

The client for the master’s thesis is Beamex Oy Ab. Beamex develops and manufactures calibration equipment and software and was established in 1975 by four instrument technicians. Beamex focus is to use technical insight to develop products and services that improve the customers' calibration processes. With close to 50 years of experience in manufacturing and developing calibrators, systems, and services, Beamex is a trusted advisor for continuous process improvement. Beamex has a comprehensive ecosystem of calibration solutions that covers everything from field calibration to workshop calibration, calibration management, and services. The company belongs to Sarlin Group Oy Ab and got subsidiaries in among others USA, UK, France, and Germany. Currently more than 12,000 companies in 139 countries are using Beamex products to calibrate process instruments and manage calibrations. (Beamex, 2021).

1.2 Background of the problem

Many companies still use paper-based calibration systems, which means they are missing out on the benefits of a paperless calibration system. Our consumption of paper is higher than it needs to be, especially since there are technologies, software, and electronic devices readily available today that makes the use of paper unnecessary. E.g., by using a digital calibration certificate there will be no need for paper certificates anymore.

The handling of paper-based calibration certificates is very time-consuming. The paper-based calibration certificates need to be sent to several people for approval but with a paperless digital system the workflow improves dramatically. They who need to sign calibration certificates can share or access electronic records simultaneously from a common database. Beamex (2012) claims that with electronic records the cost and time associated with printing copies of paper documents is also eliminated, as well as the cost of filing and storing those paper records. With digital calibration certificates it is much easier to analyze data. History trends can be shown faster and more reliable, which means cost savings for the business. Beamex (2012) also says that calibration intervals can be optimized for instruments that are performing better than expected. But to do all this we need a common standard for the calibration certificate, and we also need a platform where process industry, calibration service providers and instrument vendors can meet to share their data. That's why we need a digital calibration certificate ecosystem.

Hackel et. al (2017) says that the aim is to create an internationally recognized Digital Calibration Certificate (DCC) format, and that the DCC is to be established as an exchange format in the entire field of metrology. Since the DCC developed by Physikalisch-Technische Bundesanstalt (PTB) is based on the "ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories" standard it will fulfill the requirements for accredited laboratories, but we also need to find out if it is suitable for field calibrations in the process industry.

1.3 Problem description

This first thing this thesis will investigate is if there are technical or compatibility issues that need to be addressed before the standardized DCC can be used in field calibrations by the process industry. The thesis will investigate possible issues related to either the DCC schema or related to the clients' products. The DCC defined by PTB (Hackel et. al, 2017) is based on SI units, the international vocabulary of metrology (VIM), the GUM, the CODATA table, and ISO/IEC 17025. In the technical part the researcher needs to find out if there are any issues in the DCC definition that makes it difficult to map the calibration results from the clients' products to the DCC or vice versa.

The second thing that the research will address is if there is a possibility to establish a new Digital Calibration Certificate ecosystem, and it will also be researched if the customers prefer an open or closed ecosystem. The ecosystem will be part of a digital transformation that each customer needs to embrace to be able to receive and send digital calibration certificates. An ecosystem also needs to turn data into value for everyone that is participating. Can the client as a company establish a Digital Calibration Certificate ecosystem that creates value for the customers? Is there any specific benefits or disadvantages with either a closed or open DCC ecosystem?

Rogers (2016, p. 244) states that the leaders need to ask themselves the following questions:

"Do we look to create value exclusively through our own products?" or
"Do we look to create value through platforms and external networks?"

Two other important questions to ask are:

"Is our data strategy focused on how to create, store and manage our data?" or
"Is our data strategy focused on how to turn data into new value?"

According to Rogers (2016, p. 243) these questions are designed to measure the degree to which an organization has adapted its strategic thinking to the digital reality, and to measure the organization's ability to use new strategic principles and successfully drive change in business. So, you can say that the more we focus on the second question in each statement the better the digital transformation from paper-based calibration certificates to digital ones will go.

Through the client's history the focus has been more on the first question in each statement. The client good at creating products, got the best calibrators in the world and customers can store all kind of measurement data in the databases. But what the client now needs to focus on is to build a unique DCC ecosystem where the company can connect customers, industries, all internal departments, sellers, and buyers to share their calibration data with each other and to turn that data in to new value for everyone that is joining the ecosystem. But Rogers (2016) also claims that digital transformation is not all about technology, it is also about strategy and new ways of thinking. Even more important is that we focus on creating a better user experience and more value for the customers when doing the digital transformation.

1.4 Research questions

The Digital Calibration Certificate has been developed since 2017 and the aim is that metrology institutes and calibration laboratories worldwide could in the future use digital calibration certificates instead of analog versions. Most of the DCC research has so far been related to national metrology institutes (NMIs) and accredited calibration laboratories. The client works with field calibrations in the process industry, and we need to focus on that area. There are still few real-world applications for the DCC, but this research will investigate if the standardized DCC can be used in the process industry as part of a DCC ecosystem/platform. The research questions in this thesis are as follows:

- **What** are the possibilities to establish a new Digital Calibration Certificate ecosystem and **how** should the ecosystem be realized?
- **What** are be benefits/disadvantages of either a closed or open DCC ecosystem?

In the scope of the first research question, it will be investigated if the DCC is technically ready to be used by the process industry. The researcher will also try to find out if there are technical gaps in current products that need to be solved before the DCC can be taken in use. In the research the standardized DCC defined by PTB in Germany will be used. The researcher will also through semi-structured interviews investigate what kind of knowledge is needed and what the customers are expecting from the ecosystem.

In the second research question the definition of a closed ecosystem means interaction between the client's customers, partners, software, and equipment only. If the ecosystem is open, then all actors in calibration industry can join, and 3rd party applications can also interact with the ecosystem. The research will in addition try to find out what kind of data the customers are willing to share, and what kind of analysis they are expecting from the data in the ecosystem.

1.5 Purpose of the research

The main purpose of the research is to identify the technical needs and gaps for the client, customers and the DCC standard related to creating a DCC ecosystem. The research will also focus on determining the customer readiness for joining a DCC ecosystem and will also try to find out what kind of digital transformations the customers have already done. The research will be done by use of case studies (proof of concepts) and through interviews as qualitative research. The research is limited to process industry needs and is most likely excluding National Metrology Institutes, accredited and non-accredited laboratories.

1.6 Structure of the thesis

The thesis is divided into six chapters. Chapter one which is presented above introduces the background of the problem, the research questions, and the purpose of the research. Chapter two focus on understanding the theory behind digital calibration certificates and platform ecosystems. In chapter three some of the current research related to the thesis topic is reviewed. Chapter four focuses on describing the methodology for the research, which in this thesis is qualitative research including both case studies and semi-structured interviews. In chapter five the result of the research is presented. Finally, chapter six presents the discussion and conclusions of this thesis and gives recommendations for future work and research.

2 Theoretical framework

In this chapter relevant theory related to the background and definition of the DCC will be presented. The theoretical framework chapter will also describe platforms, ecosystems, and the calibration procedure in the process industry.

2.1 Digital calibration certificate (DCC)

According to PTB (2020) the conventional calibration certificates could soon be a thing of the past and metrology institutes and calibration laboratories worldwide could in future use digital calibration certificates (DCC) instead of analog versions.

The analogue calibration certificate has so far rarely generated a surplus value for a company since the data obtained during the calibration are time-consuming and error prone. But the calibration of measuring instruments is an essential pillar for correct and comparable measurements and manufacturing in industry (Hackel et. al, 2017).

Hackel et. al (2017) says the aim is to create an internationally recognized DCC format. This standard is to be established as an exchange format in the entire field of metrology. Based on the DCC, exchange formats should be developed in legal metrology, for digital type examination certificates and for the “digital twin” (DT)

According to Hackel et. al (2017) a digital calibration certificate (DCC) serves for the electronic storage, the authenticated, encrypted, and signed transmission, and the uniform interpretation of calibration results. Under the leadership of the Physikalisch-Technische Bundesanstalt (PTB), a concept is being developed that will allow these data to be handled in the future.

As with the analogue calibration certificate, the following norms and guidance notes are also applicable to the DCC: the SI units, the international vocabulary of metrology (VIM), the GUM, the CODATA table, and ISO/IEC 17025

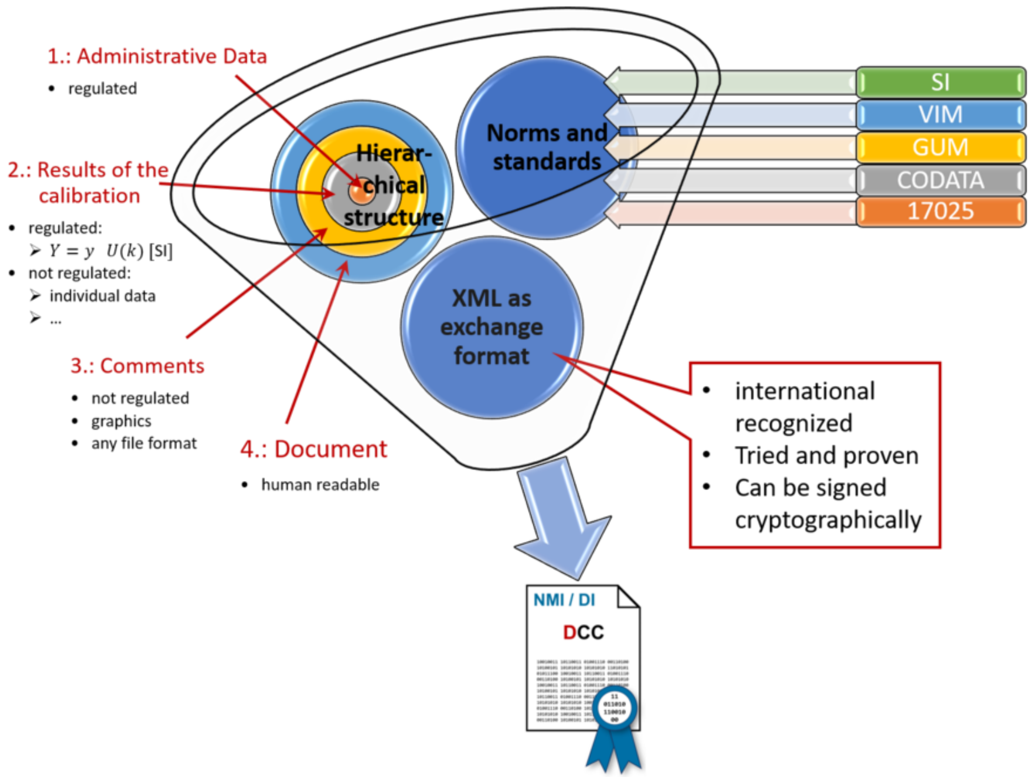


Figure 2. Overview of DCC schema structure. (Hackel et. al, 2017).

The general structure of a DCC is subdivided into four areas: administrative data (regulated area), measurement results (partially regulated area), comments (not regulated area), and document (additional area)

• Administrative data: This area is mandatory and fully regulated. It contains essential data of general importance such as the name of the measurement object, calibration laboratory, reference number, date and all other administrative data usually found on the first page of an analogue calibration certificate.

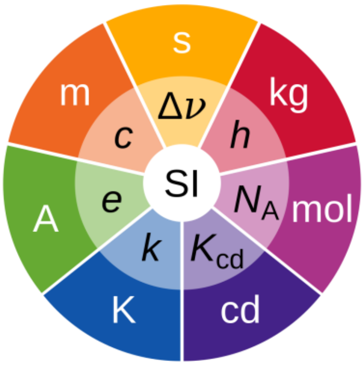
• Measurement results: This area is mandatory and partially restricted. It contains all measurement results provided with the calibration certificate. All measurement data which are of legal relevance must be expressed in the SI.

• Comments: This area is optional and not regulated. It allows adding any digital information which according to the calibration laboratory should also be transferred.

• Document: This area is optional but recommended: It contains a digital copy of the analogue calibration certificate and provides users with a convenient access to a human readable document.

2.1.1 International system of units

The International System of Units, the SI, commonly known as the metric system has been used around the world as the preferred system of units since it was established in 1960. The SI system determinates seven base units (meter, kilogram, second, ampere, kelvin, mole, and candela) and 22 derived units. The base units are derived from constants of nature.



Defining constant	Symbol	Value	Unit
hyperfine transition frequency of Cs	$\Delta\nu_{Cs}$	9 192 631 770	Hz
speed of light in a vacuum	c	299 792 458	m s^{-1}
Planck constant	h	$6.626\ 070\ 15 \times 10^{-34}$	J s
elementary charge	e	$1.602\ 176\ 634 \times 10^{-19}$	C
Boltzmann constant	k	$1.380\ 649 \times 10^{-23}$	J K^{-1}
Avogadro constant	N_A	$6.022\ 140\ 76 \times 10^{23}$	mol^{-1}
luminous efficacy	K_{cd}	683	lm W^{-1}

Figure 3. The seven SI base units and their defining constants. (BIPM, 2019).

The definition of the SI units is established in terms of a set of seven defining constants. The complete system of units can be derived from the fixed values of these defining constants, expressed in the units of the SI. These seven defining constants are the most fundamental feature of the definition of the entire system of units (BIPM, 2019).

The definitions of the SI units represent the highest reference level for measurement traceability to the SI. Metrology institutes around the world establish the practical realizations of the definitions to allow for traceability of measurements to the SI. The numerical values of the seven defining constants have no uncertainty (BIPM, 2019).

2.1.2 International vocabulary of metrology

The terminology in the DCC is based on the "International vocabulary of metrology — Basic and general concepts and associated terms (VIM)", which is a set of definitions and associated terms given for basic and general concepts used in metrology.

VIM is developed at an international level by the most important standardization bodies, metrology organizations and accreditation laboratories. The goal of VIM is to provide the basic elements to allow any operator interested in measurements and their respective results to use a clear and unique language, to avoid misunderstandings of both technical documents and measurement results. The terminology should be used not only in a technical context, but also for commercial purposes.

This vocabulary is meant to be a common reference for scientists and engineers, including physicists, chemists, medical scientists, as well as for both teachers and practitioners involved in planning or performing measurements, irrespective of the level of measurement uncertainty and irrespective of the field of application (JCGM 200:2012).

VIM is intended to promote global harmonization of terminology used in metrology. The present vocabulary refers to metrology, the "science of measurement and its application". It also covers the basic principles governing quantities and units (JCGM 200:2012).

2.1.3 Guide to the expression of uncertainty in measurement

GUM is short for "Evaluation of measurement data — Guide to the expression of uncertainty in measurement". This Guide establishes general rules for evaluating and expressing uncertainty in measurement that are intended to be applicable to a broad spectrum of measurements (JCGM 100:2008).

When an instrument is calibrated, the measurements should be traceable back to a common standard such as the international system of units (SI). You cannot have a traceable measurement without uncertainty, which means we must estimate it and show it in each step of the traceability chain.

Estimating measurement uncertainty is one of the most challenging tasks that metrologists or calibration technicians face, but calibration laboratories around the world use the GUM method to estimate measurement uncertainty. The word "uncertainty" means doubt, and "uncertainty of measurement" means doubt about the validity of the result of a measurement.

When reporting the result of a measurement of a physical quantity, it is obligatory that some indication of the quality of the result to be given, so that those who use it can assess its reliability. Without such an indication, measurement results cannot be compared, either among themselves or with reference values given in a specification or standard (JCGM 100:2008).

2.1.4 Committee on data for science and technology

Every four years, the Committee on data for science and technology (CODATA) issues recommended values of the fundamental physical constants. The values are determined by a least-squares adjustment, based on all the available theoretical and experimental information. The selection and assessment of data is done with the support of the CODATA task group on fundamental constants (NIST, 2017).

The purpose of the CODATA task group on fundamental physical constants is to periodically provide the scientific and technological communities with a self-consistent set of internationally recommended values of the basic constants and conversion factors of physics and chemistry based on all the relevant data available at a given point in time (CODATA, 2020). Some of the fundamental constants in the CODATA table is e.g., the speed of light in vacuum and the Planck constant.

2.1.5 Standardization

According to Wikipedia (2021) standardization is the process of implementing and developing technical standards based on the consensus of different parties that include firms, users, interest groups, standards organizations and governments. Standardization can help maximize, e.g., compatibility, safety, or quality. In social sciences, the idea of standardization is close to the solution for a coordination problem, a situation in which all parties can realize mutual gains, but only by making mutually consistent decisions.

The International Organization for Standardization (ISO, 2021) says standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent, people such as manufacturers, sellers, buyers, customers, trade associations, users, or regulators.

2.1.6 ISO/IEC 17025

The ISO/IEC 17025 (ISO, 2017) is an internationally recognized quality standard and sets the general requirements for the competence of calibration and testing laboratories. According to its introduction, the standard contains all the requirements that testing, and calibration laboratories must meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

The standard covers audit management, quality systems and technical competence and formally recognizes compliance by issuing a certificate of accreditation.

2.1.7 Extensible markup language

The DCC is provided in the Extensible Markup Language (XML) format. XML was developed by the World Wide Web Consortium (W3C) and was published in 1998.

Hackel et al. (2017) says that a major advantage of XML is its machine readability. In addition, XML is also basically readable for a human being. It is also very important that XML is a long-term storage data format. This is of importance because the files must still be readable in several decades.

The DCC must follow a specific XML Schema Definition (XSD), that specifies how to formally describe the elements in an XML document. According to Wikipedia (2021b) the schema can be used by programmers to verify each piece of item content in a document, to assure it adheres to the description of the element it is placed in. In the schema the different data types for the XML elements are also defined. Common datatypes can be, e.g., string (text), double (numeric value) or boolean (true/false).

Dominik et al. (2006) states that the semantics defined in a schema can be used as an exchange or serialization format for data used in an application. They continue that it is important to clearly define the languages syntax and semantics, like the definition of public methods or functions in libraries, so that the producer and consumer of XML documents have the same understanding of the document. This means that if the schema is ambiguous it will result in many different interpretations of the XML.

2.1.8 Digital-SI

The DCC XML scheme also implements another XML schema called the Digital-SI (D-SI). This is a data model for machine-readable transmission of metrological data in digital applications. It provides a trustworthy and common understandable interface for the exchange of metrological data based on the SI (International System of Units). The XML data format is designed to support metrological framework conditions for the communication of metrological data that are given by the International Vocabulary of Metrology (VIM), the Guide to the Expression of Uncertainty in Measurement (GUM) and CODATA listings of fundamental physical constants. Currently the Digital-SI (D-SI) XML exchange format for metrological data is of version 2.1.0

According to Hutzschenreuter (et al., 2019) units that are not listed in the SI brochure are not recommended for a machine-readable data exchange, and some of these unrecommended non-SI units are used mainly by particular groups, often to meet specialized requirements. So as a limitation, non-SI units can only be accepted if the measured quantities are specified in parallel using SI base units or if the non-SI units are accepted for use with the SI by the BIPM. Data such as NaN and INF are not permitted as they have no metrological significance.

Mustapää et al. (2020) says that the concept and original XML schema for the D-SI data model was developed as a solution for unambiguous and machine-readable presentation form of metrological data. The D-SI format requires that each numerical measurement value must be combined with the corresponding unit. The format is based on the SI unit system as it is the most used unit system worldwide. However, since several other measurement units are also widely used in different applications, the format also supports the inclusion of non-SI units in addition to the corresponding SI unit.

2.2 Platforms and ecosystems

Lewrick et al. (2018, p. 240) says that there is nothing revolutionary about business ecosystems and already in the 1990s, James Moore described business ecosystems as economic communities supported by various organizations and individuals that are in interaction—he compares ecosystems with organisms of the business world. Ruokonen (2021) states that platform ecosystems are ecosystems built around data platforms, which make data available not only for the organization itself but for various stakeholders, including customers, vendors, and subcontractors. Ruokonen (2021) continues that in an ecosystem, companies work together towards a common goal, creating value both for the end customer and each other.

With new digital ecosystems you can rewrite the business models and make it possible to revolutionize processes, value streams, and transactions. Lewrick et al. (2018, p. 242) states that what is important with digital business ecosystems is to think increasingly in decentralized structures.

To create an ecosystem and continue from the digitalization phase to digital transformation phase the first step would be to decide on a cloud platform. Euronovate (2020) says that by adopting cloud solutions, companies can integrate new forms of technologies that speed up, automate, and improve business, such as artificial intelligence, machine learning, big data analytics, and Internet of Things (IoT). Since these technologies require heavy computational power and storage space, cloud computing is a good solution to integrate these technologies.

When starting up a new platform or ecosystem there is always a risk that you do not get your existing customers to move from the old on-premises software to the cloud software. If they evaluate a new cloud platform, they may also evaluate some competitor's platform at the same time. The key here is to provide a migration tool that can import all their old data into the new system, because in this business measurement history is of high importance.

There is also a risk that customers do not want to store their data in a cloud solution, they are used to having all their data on their own servers. This may require quite some work to change the mindset and culture of an old-fashioned customer that still want to keep data on-premises. According to Continuity Central (2019) majority of security leaders say that cloud is safer than on-premises. But to really attract the customers you also need to add something new, something that gives them more value.

The value for the customers in this platform will in the future come from the analysis and AI. There are lot of possibilities when you can collect data from hundreds of customers and then do analysis and make decisions based on AI. Let’s say that a customer uses a sensor in their factory and some manager decided that the technician need to check the accuracy once a month by connecting a calibrator to verify that the sensor measures the correct value. If the sensor is not correct it must be adjusted to the correct value. But how do you know that once a month is enough? Or is it too often and you do unnecessary work? In a cloud platform you may have the same sensor in use by hundreds of customers, and you can then analyze the drifting in different environments. It may be that the sensor only needs to be checked once a year when used in 20°C, but if it is used in some process where the temperature rises to 100°C it may need calibration twice a month. The system can maybe also estimate mean time between failure and even suggest a replacement for a better sensor. The more data that is in the system, the smarter it will be, and this is going to save both time and money for the customer.

Mustapää et al. (2020b) states that the current way of handling calibration and metrological data is due to lack of standards that would allow a higher level of digitalization. The traceability of measurement-instruments is verified with calibration certificates that are currently either paper documents or pdf-files. This means that many of the processes where calibration data is handled still need human operations. It will require a lot of co-operation between companies and authorities to get a successful global DCC standardization.

The risk is that the standardization process will take a long time since many companies and authorities in different countries must agree on the file structure first. But there will also be lot of opportunities when the DCC standard is ready. As a company that is in this project from the beginning, the client can start delivering and receiving the digital calibration certificate before many others. There will be no human errors involved and since the certificate is digitally signed the customer can trust that no one has been altering the data. Herbert (2017) says that in digital transformation common technologies and standardization got huge benefits, and that it also means people across the company can build up expertise in the technology and learn advanced features. But this standardization is part of a digital transformation not only for us, but for the whole process industry.

Most of us are familiar with the ecosystems created by Apple or Android since both companies have created successful ecosystems for apps and peripheral devices. While Apple decided to have a closed ecosystem where you need Apple products to successfully use the system, then Android on the other hand has chosen to have an open system that can integrate with almost any device on the market. Both ecosystems got loyal followers and it is not easy to convince an Apple user to start using something else even if they know they got more freedom and choices with some other ecosystem. But how do we know what is best for the customer, is it an open or a closed ecosystem? And are the same things important both in consumer and business ecosystems?

Gordon (2020) says that in the world of software computing, an open platform is a software program that has provision for:

- open application programming interfaces (API)
- flexible scope to use the software for purposes other than as it was intended
- open-source code that can be edited by users to tailor it to their needs
- free adoptability - usage without going through official channels
- adaptability - editing functionality of specific features

By providing any of the five factors stated above, it makes a software program an open platform. Software that does not have any such provisions are called closed platforms. Gordon (2020) also states that all open-source platforms are open platforms, but that not all open platforms are open-source. An open platform can be using software components that are both open and closed. An open platform allows for certain components of its software to be edited, modified, and adapted to different functionalities. This allows for innovative use of software applications.

Heimala (2021) claims that the transition to open ecosystems requires a change in mindset from companies because the management can no longer pay attention just to their own company as before. According to Tiwana (2014, p. 111) platforms can be open or closed to varying degrees, with most platforms neither completely open nor completely closed. Heimala (2021) states that open ecosystems do not have an owner or a defined organization and that in an open ecosystem, networks are more flexible and innovative than in closed ecosystems.

Governance is something that is used to control how open or closed an ecosystem is. Tiwana (2014, p. 279) says that governance is the way a platform owner influences its ecosystem. With governance you can apply the decision rights, control, and pricing policies in the ecosystem. One of the most important control mechanisms is the gatekeeping control. With gatekeeping you can decide who is allowed to connect to the ecosystem. But the ecosystem owner not only decides who can connect but also what they can do once connected. For application developers there must of course be a predefined interface to which they can connect. Tiwana (2014, p. 111) states that standardized platform interfaces are the key to opening a platform's architecture. If a platform is open it means that a third party can access its information by using its interfaces to build applications that connects to the platform.

The interfaces to a platform must be clearly specified, standardized, documented, and stable to be useful to app developers. Tiwana (2014, p. 111) states that the platform's visible information and interfaces should be comprehensively and precisely documented and leave no room for misinterpretation by app developers.

Tiwana (2014, p. 113) also says that an industry standard is a detailed specification that is agreed on by multiple players in the industry. Platform owners who maintain control over a de facto platform interface standard can enjoy considerable market power for long periods without getting under the skin of antitrust regulators.

One of the challenges for a platform ecosystem is the business model, how do you make profit on it? Well at least Tiwana (2014, p. 128) claims that it is important to set separate prices for access and usage. Ruokonen (2021) says the main ingredient of a platform ecosystem is data, something that many companies have realized that they possess in massive amounts. Over the time it will be the data in the platform that generates a large part of the revenue. The idea behind this is to use data to align and coordinate the entire end-to-end value chain.

2.3 Calibration in process industry

This chapter will describe the calibration procedure in process industry.

2.3.1 Calibration

There are almost as many definitions of calibration as there are methods. According to ISA's The Automation, Systems, and Instrumentation Dictionary, the word calibration is defined as "a test during which known values of measurand are applied to the transducer and corresponding output readings are recorded under specified conditions." Cable (2005, p. 1) says that the definition includes the capability to adjust the instrument to zero and to set the desired span. An interpretation of the definition would say that a calibration is a comparison of measuring equipment against a standard instrument of higher accuracy to detect the accuracy of the instrument being compared.

Usually when calibrating an instrument, it is checked at several points throughout the calibration range of the instrument. Cable (2005, p. 1) states that the calibration range is defined as the region between the limits within which a quantity is measured by stating the lower and upper range values. The limits are defined by the zero and span values where the zero value is the lower end of the range. Span is defined as the difference between the upper and lower range values. The calibration range may differ from the instrument range, which refers to the capability of the instrument. A common test point distribution is 5 up/down, which means that you check the instrument at the following points: 0%; 25%; 50%; 75%; 100%; 75%; 50%; 25%; 0% of span.

By definition: Calibration is a comparison of two measurement devices or systems, one of known uncertainty (your standard) and one of unknown uncertainty (your test equipment or instrument). Calibration can briefly be described as an activity where the instrument being tested is compared to a known reference value, i.e., calibrator. Traceability is the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of calibrations all having stated uncertainties (Beamex, 2012).

The primary reason for calibrating is because even the best measuring instruments lack in absolute stability, in other words, they drift and lose their ability to give accurate measurements. This drift makes recalibration necessary.

2.3.2 Tolerances and error limits

Instruments are calibrated to a specified tolerance, or error limit that it is also called. Cable (2005, p. 2) says the permissible deviation from a specified tolerance value may be expressed in measurement units, percent of span, or percent of reading. It is most common to define the tolerance in measurement units (SI units), but e.g., pressure transmitters are also calibrated according to percent of span (full scale), and flow transmitters according to percent of reading. The measurement error is calculated according to the unit of the tolerance limit, if any calculated error is greater than the tolerance limit then the calibration is failed, otherwise passed.

Output error calculated in measurement units:

$$E_{Oabs} = O - O_{ideal} \tag{1}$$

Where:

E_{Oabs}	is the calculated absolute output error for a calibration point.
O	is the measured output for a calibration point.
O_{ideal}	is the theoretical output value at a calibration point.

Output error calculated in Percent of Span:

$$E_{O\,span} = \frac{O - O_{ideal}}{O_{fs} - O_{zero}} \times 100\% \tag{2}$$

Where:

$E_{O\,span}$	is the calculated output error (percent of span) for a calibration point.
O	is the measured output for a calibration point.
O_{ideal}	is the theoretical output value at a calibration point.
O_{fs}	is the theoretical output value at Output 100% (full scale).
O_{zero}	is the theoretical output value at Output 0%.

Output error calculated in Percent of Reading:

$$E_{O\,rdg} = \frac{E_{O\,abs}}{|O_{ideal}|} \times 100\% \tag{3}$$

Where:

$E_{O\,rdg}$	is the calculated output error (percent of reading) for a calibration point.
$E_{O\,abs}$	is the calculated absolute output error for a calibration point.
O_{ideal}	is the theoretical output value at a calibration point.

2.3.3 Traceability

Cable (2005, p. 4) says that all calibrations should be traceable to a nationally or internationally recognized standard. Metrological traceability is an important part of any calibration. One of the best ways to understand an instrument's measurement performance is to assess its accuracy. The instrument should be calibrated against an SI-traceable reference to ensure the quality of measurement data.

National Metrology Institutes (NMI) create SI units with detailed and analyzed uncertainties. The units are then transferred to secondary standards (e.g., to accredited laboratories) for use in calibrations. The traceability chain for industrial instruments is established through calibration against the secondary standards. The more calibration steps there are between the SI unit and the manufactured instrument, the greater the measurement uncertainty is. Ideally, the chain of traceability in calibrations should be as short as possible for demanding applications. If the traceability chain is broken at any point, any measurement below that cannot be considered reliable.

In the BIPM's International Vocabulary in Metrology (JCGM 200:2012) metrological traceability is defined as a property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations.

Traceability is according to Beamex (2012) defined by several elements:

(a) an unbroken chain of comparisons to a national or international standard

(b) measurement uncertainty

(c) documentation

(d) competence

(e) reference to SI units

(f) re-calibrations

Traceability is a declaration stating to which national standard a certain instrument has been compared.

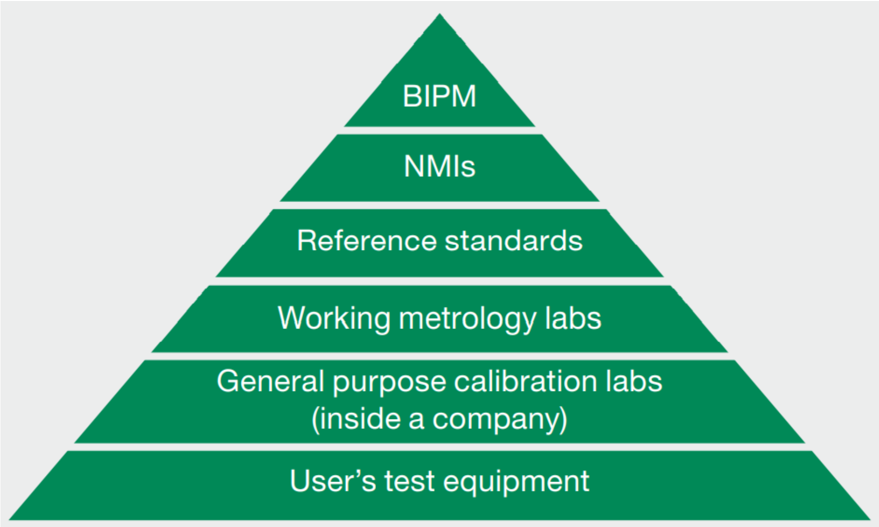


Figure 4. Traceability pyramid. (Beamex, 2012).

2.3.4 Measurement uncertainty

Measurement uncertainty is defined in VIM (JCGM 200:2012) as the parameter characterizing the dispersion of the quantity values being attributed to a measurand based on the information used. According to Beamex (2016) you should not really make any measurements unless you are aware of the related uncertainty. When doing measurements the uncertainty can come from many different sources, such as the reference measurement device (e.g., a calibrator) used for making the measurement, from environmental conditions, from the technician making the measurements, and from many other origins.

Uncertainty can also be called the doubt of a measurement. All the measurements we make for our calibration got some doubt and we need to know if the measurement is good enough for our purpose. Uncertainty should not be mixed up with measurement error, the error is the difference between the measurement of the device that you are calibrating compared to the measurement of the reference (calibrator). But without knowing the uncertainty of the measurement the error does not have a meaning.

The combined uncertainty is mostly also multiplied with a coverage factor (k) to get a higher confidence level of the results. Beamex (2016) claims that most often the combined uncertainty is multiplied with 2 (k=2 or 2 sigma). When the coverage factor k=2 is used we get a confidence level of 95%. This is according to Beamex (2016) done because we are dealing with statistical data and according normal (Gaussian) distribution

95% of the results are within the 2-sigma range. Different k values give the following confidence levels:

- k=1 = 68% confidence level (68% of the results are within)
- k=2 = 95% confidence level
- k=3 = 99.7% confidence level

Usually when you calibrate an instrument you compare it to a tolerance limit, this means that there are limits to within the calibration result is considered being passed, and outside that is considered being failed. There are however different interpretations how the uncertainty should be considered when deciding the Pass/Fail.

In the picture below, the diamond shape shows the measurement result, and the line above and below indicates the uncertainty for that measurement:

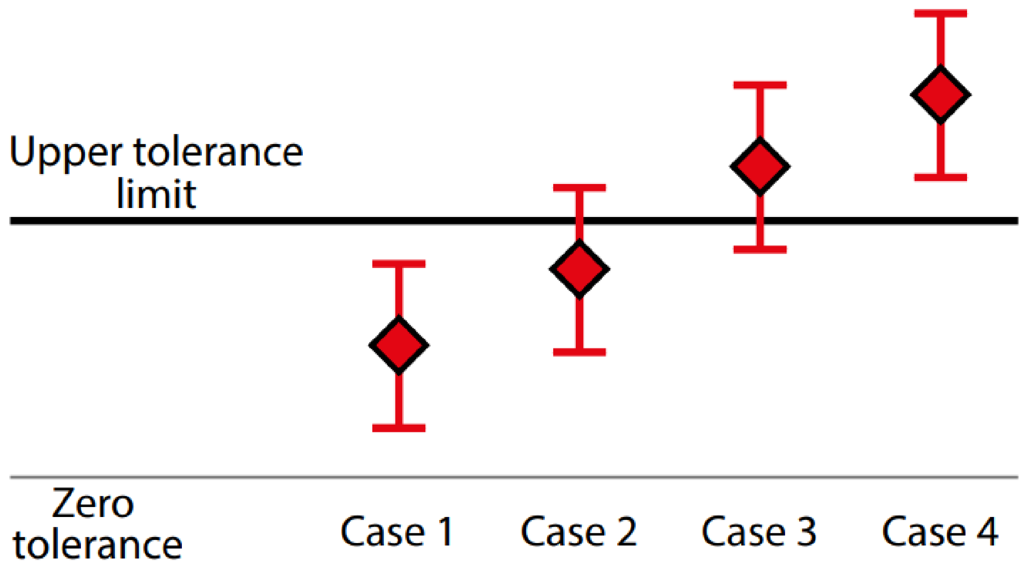


Figure 5. Measurement results with uncertainty. (Beamex, 2016).

Case 1: This is within the tolerance limit, even when uncertainty is taken in account. So, this is a clear "Pass" result.

Case 4: The result is outside of the tolerance limit, even when uncertainty is taken in account. So, this is a clear "Fail" result.

Case 2 and Case 3: Without uncertainty case 2 is within the tolerance limit, while in case 3 it is outside. But taking the uncertainty into account, we can't really say if the result is passed or failed, so these cases are undefined.

2.3.5 Calibration software

Both ISO 9001 (2015) and the FDA (CFR 21, 2022) state that calibration records must be maintained, and that calibration must be carried out according to written, approved procedures. Documentation is an important part of a calibration management process. Today when producing paper is having a big environmental impact the trend is to move towards paperless offices. If the calibration management software includes the right features, it is possible to manage calibration data on the computer without producing any papers.

With proper calibration software, maintaining instrument data and doing the calibrations can save a lot of effort, money, and time. A complete calibration management system for the process industry includes both calibration management software and documenting calibrators. In the calibration management software, you can define the process plant and all the devices and instruments that need to be calibrated. When an instrument is due for calibration the software will alert the users so that it will be calibrated in time. It may also be that the calibration request (work order) is coming from another system, if this is the case then the calibration results must also be returned to that system when the calibration is completed and approved. Today there is no standardized system to return the results to external systems, the industry is quite much implementing their own solutions in each factory.

The common way to use calibration software is as an on-premises installation, that means that you will have everything installed on a computer or server inside the factory. To use on-premises software you need to be logged in to a computer that is part of the organization's computer network. But as part of the current digitalization this way of using software is rapidly changing. Today more and more companies want to use cloud-based software, they don't want to be responsible for installations and maintenance of the servers. With cloud-based software you can usually log into the system from anywhere in the world, and that will give the companies a lot of flexibility, and the possibility to analyze calibration data from several factories in real time. According to Beamex (2012) every type of process plant, regardless of industry sector, can benefit from implementing specialized calibration management software. When all calibration records are safely stored in a database it will result in new possibilities for analyzing calibration data and improving your processes.

In calibration software an instrument is defined as anything that need to be calibrated or otherwise periodically checked. Usually, an instrument is built up from a position and a device that contains functions and calibration procedures. A position (also called a "tag") is the instrument's location seen in plant plans and drawings. Typically, it is the symbolic name for the function that is needed at a particular place in the plant, e.g., "TT" is the symbolic name used for a temperature transmitter. A device is the physical instrument installed into a position. It realizes the function defined by the position. Devices are occasionally removed from a position, e.g., for maintenance. The function describes the instruments physical properties, such as input/output quantity and the input/output span. The procedure on the other hand describes how the Instrument should be calibrated, e.g., the allowed tolerance (Error Limit) and what kind of test points are used during the calibration.

2.3.6 Calibrators and references

Many of today's process calibrators are so to say documenting multifunction calibrators. The calibrators, or references as they are also called, can calibrate many different process signals. It is common to have a calibrator that calibrates pressure, temperature, and electrical signals, including frequency and pulses. In addition, modern calibrators can also communicate with HART, Profibus or Foundation Fieldbus transmitters, and they can also be used for configuring these smart transmitters.

When a technician wants to calibrate an instrument with a documenting calibrator, he sends the instrument data from the calibration management software into the memory of the documenting calibrator. All needed information is sent to the device, both instruments measurement ranges and calibration procedure with required error limits, so no printed paper is needed. The calibration data is saved in the calibrator's memory, and there is no need to write anything down. The calibrator can automatically decide if the calibration was passed or failed immediately after the last calibration point was stored. The technician does not need to manually do any calculations in the field, and the calibrator can also advice if the instrument needs to be adjusted.

When creating a calibration certificate for the instrument calibration, then the calibrator is indicated as the reference. Based on the specification for the used reference (calibrator) you can calculate the uncertainty for each calibration point. Usually, you want to have a reference that is 4 times more accurate than the instrument that you are calibrating. This is called test accuracy ratio (TAR), but even more important is the test uncertainty ratio (TUR). According to Bennett (2005) a 4:1 TUR is the point to which most high-quality calibration labs strive. It is the point at which the level of in-tolerance probability stays at 100% the longest, with the best economic benefits. Bennett (2005) also says that the reason for the recommendation of minimum TUR's (such as 4:1 or 10:1) from quality standards is to ensure that the calibration process can provide a high level of confidence that the instrument is operating within its design specifications.

3 Literature review

The focus in this research is to acknowledge a better understanding on if and how the current version of the DCC can be used in an ecosystem by the process industry. Compared to accredited calibrations that are performed in laboratory environments most of the calibrations in the process industry are field calibrations. This chapter will point out some of the current publications related to the DCC. The theoretical background is presented in the previous chapter called Theoretical Framework.

3.1 Digital calibration certificate

Most companies today work on new technologies, but also on the leadership, culture, and mindset of the employees to deliver a customer experience that give them more value of using their products than ever before. This is also happening in the process industry, but Marques et al. (2019) says that the results of calibrations are still linked to printed documents and manual transcription which makes it difficult to connect to information systems and industrial automation. Furthermore, Mustapää et al. (2020) says processes of handling calibration data have mostly been dependent on manual work as the current calibration certificates lack machine readability.

To share calibration results faster between the actors we need to digitalize the calibration data. According to Marques et al. (2019) the purpose of digital calibration certificates, is not only the transformation of a physical format to a digital one, but mainly the application of the real digitalization concept, i.e., the use of digital technologies to change a business model and supply new opportunities with added value.

Marques et al. (2019) also states that the development of a system to exchange digital calibration certificates will allow customers to receive and analyze certificates faster, and that will reduce execution times and costs associated to the metrological confirmation process, as well as to avoid human error and their consequences.

To be able send and receive digital calibration certificates between different actors the format must be standardized. Mustapää et al. (2020) states that the lack of a standard for machine-readable digital calibration information, which would cover the whole calibration chain from national measurement standards all the way to low-cost sensors, has limited the use of calibration information, largely because of the incompatibility issues between different systems. Marques et al. (2019) says that all future work requires definition, test, and acceptance through consensus. They continue that future work must also consider the results of field, factory, and test laboratories, allowing for a full connection between reference SI units and results.

From the statements above we can conclude that the DCC standardization and machine readability are important parts if we want to include actors from the whole calibration chain. Mustapää et al. (2020) also says that with a standardized DCC format the amount of manual work can be drastically reduced, which both reduces the time and costs required for the calibration data management while simultaneously offering a significant improvement in data integrity.

For the highly regulated pharmaceutical companies the data integrity is also of high importance. Wikipedia (2022c) describes data integrity as the maintenance of, and the assurance of, data accuracy and consistency over its entire life-cycle and is a critical aspect to the design, implementation, and usage of any system that stores, processes, or retrieves data. Most of the pharmaceutical companies follows an acronym called ALCOA+. Schniepp (2019) says that data supporting the quality and safety of product must meet the ALCOA+ elements to avoid regulatory citations for data integrity issues. The first A in the acronym stands for Attributable and means that the data generated or collected must be traceable back to the individual who generated the information. Neyezhmakov et al. (2021) says the possibilities of digital calibration certificates significantly improve the traceability of measurements in comparison with the traditional paper certificate, but that the form and content of DCC, however, are still not clearly determined and require deep study. The rest of the letters in the acronym stands for (Schniepp, 2019):

- Legible: The data recorded must be readable and permanent.
- Contemporaneous: The results, measurements, etc. must be recorded at the time the work is performed.
- Original: Original or source data are the record, report, notebook etc. where the data point was initially recorded.
- Accurate: The data recorded must be complete, consistent, truthful, and representative of facts.

- Complete: Information that is critical to recreating and understanding an event. This would include any repeat or reanalysis performed on a laboratory test sample.
- Consistent: The data are presented, recorded, dated, or time-stamped in the expected and defined sequence.
- Enduring: The data or information must be maintained, intact, and accessible throughout their defined retention period.
- Available: The data or information must be able to be accessed at any time during the defined retention period.

The ALCOA+ statements need to be handled in the standardized DCC ecosystem so that the pharmaceutical industry can take it in use.

3.2 Ecosystem

Mustapää et al. (2020) says that there are still several challenges in global digitalization of metrology and its infrastructure, before introduction of DCC-based data exchange systems are totally viable in real industrial applications. Both Mustapää et al. (2020) and Nummiluikki et al. (2021) states that metrology is currently going through a transition from paper-based calibration certificates to DCCs that will enable fully digitalized calibration management processes. Furthermore, they say that the digitalized processes provide network effects to the players in the ecosystem that can be utilized with a shared platform. For the ecosystem collaboration to work, certain level of standardization is needed for the shared processes, the unambiguous DCC data format, and the infrastructure.

One of the benefits of having a DCC platform is that all the data that goes through the platform can be automatically validated. Neyezhmakov et al. (2021) says the rapid growth in the number of calibrations requires the automation of both the calibration procedure itself and machine-readability for the automatic analysis of calibration certificates. Mustapää et al. (2020) says the largest benefits of DCC validated data can be found in applications where data quality and trustworthiness are critical for the process, such as in the manufacturing systems in pharmaceutical industry and in data sharing between autonomous vehicles. It is also very important the validation is automatic and Marques et al. (2019) claims that the automatic validation of the results presented in a calibration certificate is highly facilitated with the use of machine-readable code.

One of the most interesting publications related to DCC ecosystems is a paper published by Nummiluikki et al. in 2021. In this publication they propose a platform to handle the delivery of DCCs as well as the connection between calibration certificate issuers and users. The functional components of the proposed DCC platform by Nummiluikki et al. (2021) will cover: creating a standard format digital calibration certificate (DCC), signing a DCC, transferring a DCC to the recipient(s), receiving a DCC and importing the DCC data to receiving system for further processing. Laine & Uusitalo (2021) states that digital platforms offer flexibility in business processes and networking allowing actors to develop innovative solutions at the customer boundary, and whereas traditional firms create value within the confines of a company or a supply chain, digital platforms utilize an ecosystem of autonomous agents to co-create value. Nummiluikki et al. (2021) however says that the digital calibration certificate (DCC) alone will not enable all possibilities of digitalization. Furthermore, they state that a fully automated calibration process that enables automated communication of DCCs needs to be interoperable. The process will require a solution which supports the integration between the senders' and receivers' systems.

Laine & Uusitalo (2021) says that while promoting cost-efficiency and system simplification, closed platforms limit both network diversity and open competition, leading to lower value-creation potential. They continue that closed platforms create value but tend to be limited in both scope and market penetration. Openness at the demand and supply side is critical to building a diverse ecosystem.

An open Business Ecosystem is a conceptual model described by Laine & Uusitalo (2021):

The ecosystem

- has no owner
- has no defined organization
- is open to all actors
- is fully market-based
- is driven by open and shared data

Nummiluikki et al. (2021) states that digital platforms enable value creation and revenue models that differ significantly from traditional business models by creating new interactions between producers, producers and consumers, and consumers. A main feature of platforms is to create data from the interactions on the platform. Laine & Uusitalo (2021) also says that one of the fundaments of ecosystem economy is that of open and shared data between actors. Data creates transparency and visibility, enabling horizontal cooperation opportunities between actors over business sector boundaries. Nummiluikki et al. (2021) says that a shared platform will enable system integration efficiencies with multiple calibration customers or partners and that the DCC infrastructure will improve the traceability of the certificate as all the certificates are stored in a shared platform. The definition of shared data is according to Laine & Uusitalo (2021) the actual data fields and formats shared through data interfaces that form a basis for business connections with other actors.

4 Methodology

This chapter focuses on describing the methodology of the research, which in this thesis is qualitative research including both case studies and semi-structured interviews.

Pratt (2020) says that a proof of concept (POC) is an exercise in which work is focused on determining whether an idea can be turned into a reality. Pratt (2020) also states that in software development, a proof of concept would show whether an idea is feasible from a technology standpoint. A proof of concept is meant to determine the feasibility of the idea or to verify that the idea will function as envisioned.

According to Ahlin (2019) semi-structured interviews are a qualitative approach to collecting data and that they begin with a set of standardized questions which are asked of multiple respondents. She continues that this research method is useful for understanding viewpoints of key stakeholders because it allows the respondent to participate in the process and discuss concerns related to the research questions that are of primary importance to people working in that environment.

4.1 Case studies by using proof of concept

The research method for the technical part in this thesis work is mainly based on case studies of several proof of concept implementations related to the DCC schema. With help of the proof of concept implementations the researcher is investigating if a standardized DCC can be created and transferred between several actors in the calibration industry.

According to Sekaran and Bougie (2016, p. 98) case studies focus on collecting information about a specific object, event, or activity, such as a particular business unit or organization. Sekaran and Bougie (2016, p. 98) also says that the idea behind a case study is that to obtain a clear picture of a problem one must examine the real-life situation from various angles and perspectives using multiple methods of data collection

McCombes (2019) states that a case study is an appropriate research design when you want to gain concrete, contextual, in-depth knowledge about a specific real-world subject. Crowe et al. (2011) says that a case study approach can offer additional insights into *what* gaps exist in its delivery or *why* one implementation strategy might be chosen over another. McCombes (2019) also adds that case studies tend to focus on qualitative data using methods such as interviews and observations.

Crowe et al. (2011) states that when reporting findings, it is important to provide the reader with enough contextual information to understand the processes that were followed and how the conclusions were reached. They continue with that in a collective case study, researchers may choose to present the findings from individual cases separately before combining across cases.

4.1.1 POC 1

The first proof of concept related to DCC that the researcher participated in started in August 2020 with a kick-off and planning meeting.

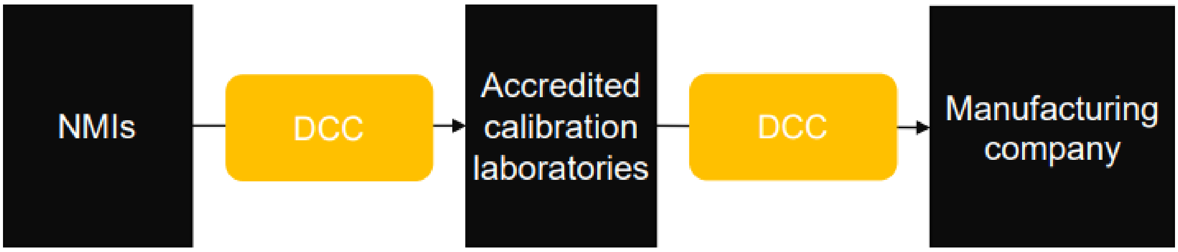


Figure 6. Initial plan of first proof of concept.

The main participants in the POC 1 were an NMI, an accredited calibration laboratory and a manufacturing company that uses the client's software. The whole project was coordinated by a research-to-business (R2B) project from Aalto University that was specialized in the DCC. All the participants in this POC were from Finland. The first main target for the POC was to build and validate a practical solution for DCC creation and usage in the calibration chain. The second target was to understand the benefits of DCC and implementation realities in the participants own processes and tools, and in the communication chain. The client's part of the POC was to create a DCC parser that could import the calibration certificate into the manufacturing company's database.

For optimal benefits it was stated that the DCC format and security solutions should support both standardized calibrations by the accredited laboratories and the industry specific field calibration needs.

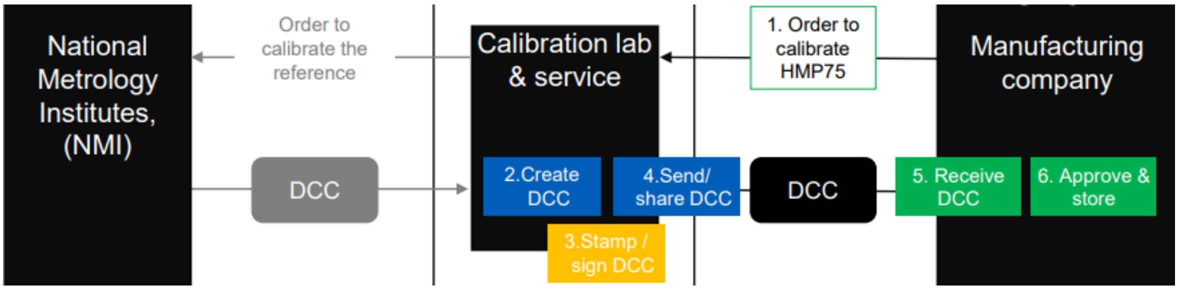


Figure 7. Overview of actual setup of first proof of concept.

The main scope was to create a DCC for a handheld humidity and temperature meter (HMP75). The "humidity and temperature meter" is designed for spot-checking and field calibrations, and the manufacturing company use it as a reference when calibrating their process instruments. In the first tests we had two DCCs created individually mimicking the real-life use case. One of the DCC's were created by the NMI by using the Aalto R2B projects DCC input form and the other DCC was developed by the accredited calibration laboratory.

In the real-life use case, the manufacturing company order a calibration for the HMP75 from the accredited calibration laboratory. The calibration laboratory then again got their references calibrated by the NMI. The DCC must be traceable to the previous actor in the calibration chain.

The client created a DCC parser based on the DCC they received from the calibration laboratory. When the DCC was received to the Manufacturing company the data in the DCC was mapped to the client's calibration software and the results were stored in the database. When the calibration supervisor approves the calibration results, a custom-made script created a new HMP75 reference in the database and the measurement uncertainties were updated to the reference. The DCC version 2.4 was used in this project.

4.1.2 POC 2

The second Proof of Concept related to DCC that researcher participated in started in April 2021. This POC was quite like the first one but with participants from both Finland and Germany. The main participants in the POC 2 were a German NMI, a German accredited calibration laboratory and a German (global) end user from the highly regulated process industry that uses the client’s software. The whole project was coordinated by the German end user.

The main objective for the end user in this project was a proof of concept that can be used for further development for using DCC in Pharmaceutical Industry. With this POC it should be possible to have a showcase which can be used as a prototype for a further DCC implementation. It must also be proven that the DCC can be imported into the calibration management system.

In the POC it was stated that to meet efficiency and compliance targets it is crucial to use technologies which support us by transferring calibration certificates in an electronic way. It will make vendor-done calibration results faster available, processable (trending) and substitute the common paper-based calibration certificate. With that it will avoid discontinuity in documentation processes and reduce errors during manual transferring data from paper to electronic system. It was also noted that the DCC initiative strives to set the global standard of electronical data exchange process for calibration data between calibration service providers and pharmaceutical industry to fully digitalize the E2E calibration process. This will ensure data integrity, increase compliance, and add value to product safety.

The End user said that all calibration documentation provided by external contractors are typically delivered on paper or as a pdf-file. In this case digitalization means scanning paper and attaching it as PDF to the inhouse Calibration Management System (CMS) or entering the data manually into CMS. The issue with current calibration certificate approach is that paper based calibration certificates received from vendor could be lost or are not easy to retrieve. With scanned documents calibration data is not processable anymore, you get no equipment history, and no history trending is possible. It is also a time consuming and error prone process to transfer Calibration results manually into that Calibration Management System, both for archiving and data retrieval. With these media breaks you get both data integrity and compliance issues.

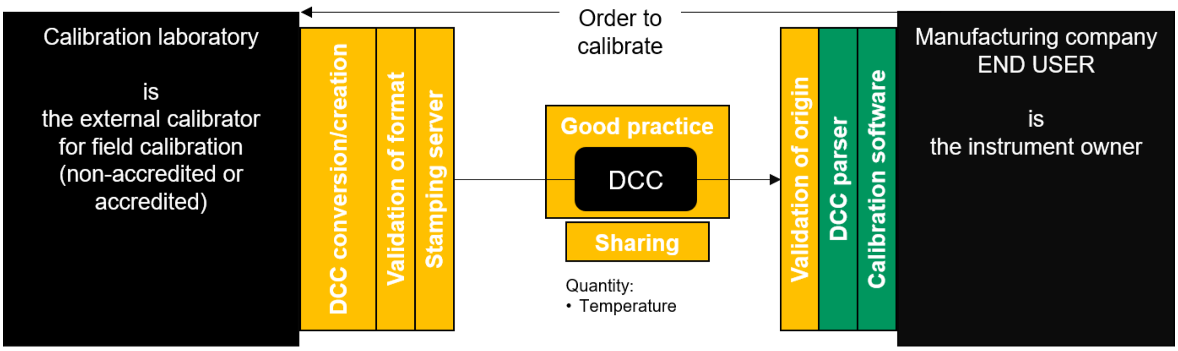


Figure 8. Overview of the setup of the second proof of concept.

The scope of POC 2 was to build a DCC for temperature calibrations. The goal was to use the official version of DCC v3.0 in this POC, but it was not finalized in time, so we decided to use a release candidate called DCC v3.0-RC2 instead. In the real-life case the End User sends an order to calibrate an instrument to the calibration laboratory and they create a DCC for accredited calibration results. The setup of secure data transmission through a sharing platform was handled by the Aalto R2B project. To get parallel execution in the project the NMI created example DCCs that could be used to create the DCC Parser as long as the calibration laboratory created their DCC. When the DCC was imported to the End Users calibration software the results were evaluated based on the human readable format in the user interface.

4.1.3 POC 3

The third proof of concept related to DCC that researcher participated in started in November 2021. This is an in-house POC that is using software developed by the client only. The project was at first defined as a software development project for students at Aalto university, but the students decided to go for another project so instead an external developer were hired.

The first phase of the project included to generate DCC's based on results that were already stored in a cloud-based calibration management system. The calibration results were extracted from the database and stored as JSON files. We then created a standalone software that converted the JSON files to DCC-XML files. We tested with several instrument configurations until we were satisfied with the DCC files.

In the second phase we created a DCC parser that could read the generated files. The DCC parser were then integrated into a on-premises calibration management system. By using the parser, it was now possible to import the DCC files to the on-premises software.

In the third phase we integrated the software made in phase one into the backend of the cloud solution. When new calibration results are stored into the cloud database the software will automatically generate a DCC file and add a download link for it to the user interface.

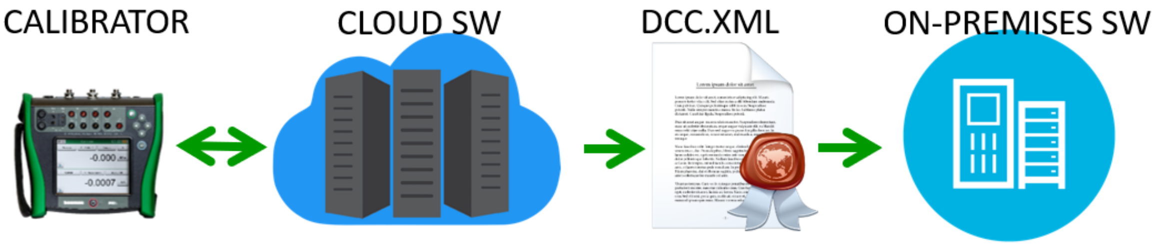


Figure 9. Overview of the third proof of concept setup.

In the full POC scenario we first create similar instrument setups both in the cloud-based software and in the on-premises software. The instrument in the cloud software is then sent to a calibrator where calibration results are created. The results are then received and stored in the cloud software and an DCC is automatically generated. The DCC is then downloaded to a computer where the on-premises software is installed. With the on-premises software you then import the DCC, the calibration results are then linked with the instrument that we had previously created. Finally, a human readably certificate is printed.

In this POC we first started with DCC v3.0.0, but during the project DCC v3.1.0 was released and we updated all our software to use that version. The scope was to support all instrument configurations that can be handled by the calibrator, so combinations of pressure, temperature or electrical quantities should be supported.

4.2 Qualitative research using interviews

The second way data was collected for this thesis was by using a qualitative research method. This method was found suitable for this thesis as it focuses on researching the possibilities to establish a DCC ecosystem based on customer feedback. The collected data is in the form of words based on semi-structured interviews, which is descriptive for qualitative research. Keller and Conradin (2019) says that by using this type of data collection, the interviewer has worked out a set of questions beforehand but intends the interview to be conversational. They also state that the interviewer can give explanations or leave out questions that may appear redundant.

The interviews were used to collect the empirical data through four semi-structured interviews. Empirical means that the information is based on experience. The plan was to interview five persons with experience of DCC, but in the end there were only four persons that accepted to be interviewed.

The interviewees were asked for example about what kind of knowledge is needed to create an DCC ecosystem. All the interview questions can be found in appendix 1. The interviews are presented anonymously in this thesis work and each interviewee has been identified as interviewee1 to interviewee4 to present each of interviewee's views on the questions. The interviewees will be later referred to with the letter and number combination i1-i4 in the text to follow.

The interview questions were initially defined by the researcher, but feedback on the questions were also collected from several people working at both Product Management and R&D. Based on the feedback the interview questions were adjusted to better fit the scope of the research questions.

The semi-structured interviews were held by using Microsoft Teams, and later the recording was automatically transcribed in Microsoft Stream, which is a secure enterprise video service where you can manage your videos. All the transcripts were manually corrected to correspond with the recording.

5 The results of the study

In this chapter the results of the study will be presented. The results from the case studies present technical or compatibility issues that need to be addressed before the standardized DCC can be used in field calibrations for the process industry. The interviews present answers related to establishing a new Digital Calibration Certificate ecosystem. The ecosystem will be part of a digital transformation that each customer needs to embrace to be able to receive and send digital calibration certificates.

5.1 Case studies

This chapter will describe the findings from the different proof of concepts projects that were used to investigate the technical issues in this research. Each POC is handled in a separate chapter and then a summary chapter will recap the most important findings.

5.1.1 POC 1

In POC 1 we tested the implementation of DCCs in an agile project to better understand the industry’s requirements and to enable fast implementation when the DCC schema is finalized. The main participants in the POC were an NMI, an accredited calibration laboratory and a manufacturing company that uses the client’s software. The whole project was coordinated by a R2B project that was specialized in the DCC.

Findings in DCC:

1. In the first tests we had two DCCs created individually simulating the real-life use case. But with two different DCC interpretations, it was not possible to import both into the calibration software without errors or special tailoring in the DCC parser.

2. DCC Schema v.2.4.0 enables several ways to represent the data which challenges the interoperability and unambiguity without precise guidance.

    a. The number of content elements is not restricted, the meanings and differences of these elements are unclear

b. Various ways to insert measurement data challenges the receiving end machine readability

c. Recursion in measurement data enables unclear use of the schema

d. Open string fields. Possible solution: Enumeration fields instead of string fields

3. The D-SI is not supporting resolution for numerical values, e.g., 15.000 will be stored as 15 in the XML. This is due to that the data type double is used.

4. It is not possible to define references for each measurement point, this means that you cannot know if the reference is changed for some measurement point. (Fixed in DCC 3.0)

5. References should have a dedicated field for calibration date and/or calibration due date, it is important to know if the reference is calibrated in time.

6. Dedicated field for statement of conformity in measurement metadata is missing, it must be possible to tell if the calibration is passed or failed. (Fixed in DCC 3.0)

Findings in calibration software:

1. From the calibrations software's point of view this was not an ideal POC since the DCC for HMP75B is a reference used by the manufacturing company. The calibrations software's main purpose is to manage calibrations for process instruments, but the calibration results for references are not directly supported.

2. When the DCC for the HMP75B was imported to the calibration software the results were stored in the structure for the process instruments. But instead, the references used to Calibrate the HMP75B were imported to the calibration software's reference database.

3. The DCC for the HMP75B contains two different quantities (humidity and temperature). To support two quantities two different functions are needed in the calibration software, which then must be imported as two different positions. This means that the results from one single DCC are split up into two places.

4. In the DCC the uncertainty for the calibration is calculated, there is however no interface in the calibration software that imported uncertainties. In this case the uncertainties were mapped to the note field and then later used by the script to add uncertainties to the HMP75B.

5. In the DCC the error for each calibration point is calculated, the calibration software is however not using the already calculated error, instead the error is recalculated based on the measurements.

6. There is no interface in calibration software that can import certificate numbers. Instead, the calibration software is generating a new certificate number for each imported calibration result.

7. To get the HMP75B as a reference in the calibration software database a custom script must be created. This must be handled separately in each customer database.

5.1.2 POC 2

In the second proof of concept, we evaluated the transfer of an accredited temperature calibration from a calibration laboratory to the end user. The main participants in POC 2 were a German NMI, a German accredited calibration laboratory and a German (global) end user from the highly regulated process industry that uses the client's software. The whole project was coordinated by the German end user.

Findings:

1. Certificate number cannot be imported to the calibration software. There is no interface in calibration software that can import certificate numbers. Instead, the calibration software is generating a new certificate number for each imported calibration result. (This is a similar finding as in POC 1)

2. Uncertainty cannot be imported to the calibration software, instead the uncertainty is shown in the Note field. In the DCC the uncertainty for the calibration is calculated, there is however no interface in the calibration software that imported uncertainties. (This is a similar finding as in POC 1)

3. The DCC contains different error limits for each point. This is not supported in the same way in the calibration software, instead the error limit must be recalculated for a specific range. The range is defined by a change point + the error limit that is valid above that point.

4. Undefined resolution for numerical values, which means that trailing zeroes are missing. The D-SI is not supporting resolution for numerical values, e.g., 15.000 will be stored as 15 in the XML. This is due to that the data type double is used. (This is a similar finding as in POC 1)

5. In the DCC the name of the same reference is written differently for different calibration points, this causes duplicate references to be created when importing the DCC to the calibration software.

6. In the DCC the ambient (environment) conditions are given according to accreditation, which is then given as an upper and lower value. The calibration software expects it to be a single measured value that is given at calibration time.

7. In the original paper certificate, the used references got Due Date, Equipment number, Certificate number and Traceability defined, these are however not in the DCC.

5.1.3 POC 3

In the third POC we evaluated the generation and transfer of the DCC from a cloud-based calibration management system to a on-premises calibration management system. The instrument in the cloud software was sent to a calibrator where calibration results were created. The results were then received and stored in the cloud software were an DCC was automatically generated. The DCC was then downloaded to a computer where the on-premises software was installed. With the on-premises software we imported the DCC, the calibration results were linked to the instrument and finally, a human readably certificate was printed.

Findings:

1. When receiving results from the calibrator to the cloud software a certificate number is generated, but this certificate number cannot be imported to the on-premises calibration software. Instead, the on-premises calibration software is generating a new certificate number for each imported calibration result. (This is a similar finding as in POC 1 and POC 2)

2. No uncertainty is calculated by the cloud software, so the generated DCC is missing this information. But since the references are transferred correctly to the on-premises software the uncertainty will be calculated when the DCC is imported.

3. Both the cloud software and on-premises software handles error limits as over the full span of the instrument, but in the DCC it must be given for each test point. This requires that when the DCC is generated the error limits must be calculated for each point, and when receiving the DCC parser must validate if there are multiple or just one error limit for the instrument span.

4. The DCC schema uses the D-SI schema for numerical values and units, this schema is based on the SI unit standard. Unfortunately, percent values are not part of SI and e.g., error calculated in % of Span and % of Reading is not supported without special definition in the DCC. This may cause mismatch between systems since it must be specified the same way in all systems.

5. Undefined resolution for numerical values, trailing zeroes are missing. The D-SI is not supporting resolution for numerical values, e.g., 15.000 will be stored as 15 in the XML. This is due to that the data type double is used. (This is a similar finding as in POC 1 and POC). During POC 3 we however changed the datatype in the source code for numerical values from double to string to preserve the resolution. The generated XML can be parsed with both double and string.

6. The calibrator used in POC 3 can indicate if a measurement point is unstable or if there is some electrical error like current overload. This information is possible to add to the DCC, but it not part of any standard and will not be recognized by other systems.

7. To be able to import a DCC for an instrument that is undefined in the receiving system a Digital Calibration Request (DCR) is needed. With this information you can create the instrument setup before receiving the calibration results. The DCR is planned to be part of DCC v.4.0.0, but before that instrument setups must be manually created when transferring DCCs between different systems.

8. The DCC Schema v.3.1.0 still enables several ways to represent the data which challenges the interoperability and unambiguity without precise guidance. This is meant to be solved by Good Practices templates but will require separate implementations for each quantity.

5.1.4 Main lessons learned from the POCs

During the time when the three different proofs of concepts were executed the DCC schema has evolved from version v2.4.0 to v3.1.0. Several of the issues addressed in the first POC has been addressed but there are still issues that need to be solved. One of the most important is that the resolution of the numerical values must be preserved. The second main issue is that the schema must be more strictly defined, it is still too flexible and ambiguous to make it machine readable between different producers and consumers of the DCC. In the calibration management software, it must be possible to import pre-generated certificate numbers, currently a new certificate number is generated when the DCC is imported. Another issue is that the measurement uncertainty cannot be imported, the uncertainty is currently re-calculated when the DCC is imported. To calculate the uncertainty the measurement references and their specifications must exist in the database.

5.2 Interviews

In this chapter the results of the semi-structured interviews will be presented. The interview questions are presented in appendix 1 and the different viewpoints are exemplified by using selected excerpts from the interviews.

The interviewees were all persons with previous knowledge of the DCC and calibration management. The interviewees were all representing organizations that are using calibration management software on daily basis. Two of the interviewees were in Germany and two of them in Ireland. The interviewees had the roles of:

- IT program manager (i1)
- Main user of calibration management system (i2)
- Management system owner (i3)
- Technical subject matter expert (i4)

The organizations that the interviewees represent have tens of sites that together are doing 100000 – 170000 calibrations each year per organization, of which a large part is done by external contractors or laboratories.

5.2.1 Ecosystem collaboration

The interview questions that contributed to this theme were as listed in appendix 1:

2. How do you see the role of your organization in the development of new DCC ecosystem?

4. Who would be the most important partners in a DCC ecosystem be, and how should these actors work together?

5. What kind of needs do you have for this kind of platform/ecosystem?

7. Should the collaboration in a DCC ecosystem be lead or managed by someone else than the client? Why/why not?

To get a working ecosystem you need a lot of collaboration between the different actors in the ecosystem. When the interviewees were asked about how they see their role in the development of a DCC ecosystem they all had the opinion that they want to contribute to the development. They want to participate actively in testing and both in developing a computerized solution and in the design of the DCC. One of the interviewees says that they know what they want from a process point of view and what overall legal authorities' requirements that need to be solved. The same interviewee also said that they got good IT expertise, and that they want us to understand how to make a good solution which is scalable, interoperable, and which also will serve for a good global utilization rate.

"We want to contribute actively to testing and developing of an appropriate computerized system solution. We know what we want from process point of view and what overall legal authorities' requirements that need to be solved. We also have good IT expertise and try to contribute also on that side. We want to make you understand the concept so that we at some point of time have a good solution which is scalable, interoperable, and which also will serve for a good global utilization rate." (i1)

"We want to be active participants in the development and the design of the DCC" (i4)

One of the main reasons to participate in the development is to get the right functionality in the DCC. The interviewees also want to collaborate and share their knowledge related to technical and process challenges. One of the interviewees says that it is important that their organization provides feedback and says how they want it, because the worst thing if the DCC is not at all like they wanted it.

"Going into a collaboration working on the given technical and process related challenges how to organize and how to set up a DCC process best for process industry and pharmaceutical industry." (i1)

"I see the role of our organization and people like me contributing and getting our say in there because the worst thing for something like this to happen is all of us to turn around afterwards and say how did this come about? None of us wanted this!" (i2)

"We want the opportunity to be in the design so that we can kind of get it to work the way we wanted to." (i4)

In the ecosystem it is also important to have the correct partners. The following thoughts were given about who the most important partners are. The interviewees feel like PTB will be the main partner as they are driving the standardization for a global DCC format. Other important partners are of course the solution providers, but also the third parties that will add the end-to-end capabilities to the ecosystem. There is a common understanding that PTB, who is the main developer of the DCC, is the most important actor in a DCC ecosystem. But when the standard is ready for use then the software providers, calibration service providers, contractors doing calibrations and externals labs are also mentioned as important actors. There is also an idea that the ecosystem should be held together by a foundation or a board of people from different organizations. The foundation can be made up of representatives from companies, universities, and vendors to make sure that the rules and standards are held together. It is important to have a stable and reliable platform, and the standard must be followed and adopted by all the actors.

"So, PTB as the main partner in driving a global standardization for DCC formats, PTB is definitely the one to drive it from a global strategic point of view." (i1)

"I think the key people are the PTB, the owners of the standard and then the software providers. So, the software providers and then the third parties that do the work are also going to have to adopt that in there, because otherwise you're not going to have end-to-end capability." (i4)

Since the DCC is planned to be a global standard there will be many different needs for an ecosystem of this type. One of the interviewees says it needs to be a cloud-based solution provided as a Platform-as-a-Service. Then it also must be a sustainable and reliable solution that is scalable on a global level.

"So, the clear strategy for any new solution we need to bring in is from the IT strategy point of view that we need to focus on platform-as-a-service, it needs to be cloud-based and it should be a strategic solution or service provider. It needs to fulfill our vendor assessment and strategic approach to act as a sustainable and reliable solution or service partner on a global level and provides a good scalable solution which is ready to grow with us." (i1)

ALCOA is discussed in chapter 3.1 and one interviewee says that if the DCC ecosystem follows the ALCOA principle then it will cover their needs, and then it must also be secure. One thing that several of the interviewees says is that the ecosystem must be financially easy to access, preferable free to use. The platform must also be technically easy to use, and especially for the contractors or third-party calibration providers. The use cases for the DCC are mostly related to when others than the own staff are performing the calibrations, and it would then be best to only have one platform where all customers and contractors can connect. One interviewee says that to get a successful industry platform there should be a template of the DCC for the industry, and no big alignment should be needed between the contractor and the customer. The contractor should not need to access to the customers calibration management system, instead they should use their own computers and software and return the calibration certificate as a DCC.

"Good easy answer is we just look at ALCOA, I mean that probably covers everything. And then it needs to be secure, and it needs to be an open system that's free for all to use. But ALCOA sums it up beautifully" (i2)

"I think to have a successful industry platform it should be as simple as possible. So, it starts with the template of the DCC for industry. No big alignment that should be done between the contractor and the customer. So, the DCC as it is at the moment can be used, but it needs a lot of alignment work between contractors and customers. So that's why first it's needed that we have a very clear and detailed not too interpretable DCC, so that it's really easy to handle the DCC." (i3)

"Basically, I think it's third-party calibrations where we physically send stuff, so for example, if we send a device to you to calibrate it, that would be a scenario where you could send us back our calibration certificates via DCC instead. The other scenario being where vendors come to our site to perform work, but we don't give them access to our systems, so they may be using their own computers and their own software." (i4)

When asked about if the collaboration in a DCC ecosystem should be lead or managed by someone else than the client, then there was many of the interviewees that said that the ecosystem should not be led by the client or by only one company. The opinion is that it should be led by someone independent, and that the ecosystem must attract also other companies and contractors than they who are using the clients' products. The client should concentrate on creating interfaces and functionality to the platform. One of the interviewees on the other hand said that he sees no reason why the client cannot lead it, and that it must be driven by the industry. But it is important that the ecosystem is based on an open standard and that the standard is followed precisely. One interviewee says that we need to have one agreed ecosystem standard and that is what it makes it so difficult.

"*Clear message, yes, it could not only be the client, but the client is then maybe one player, in terms of developing and providing a kind of DCC ecosystem at one point of time.*" (i1)

"I don't think it can be led by one company, it needs to be led by somebody independent and it needs to have the buy in from big hitters in in calibration software" (i2)

"My idea was that it would not be the client. I would prefer somebody independent. I think ideally the client should concentrate on their tasks for creating interfaces to this platform and they should be very carefully in not designing a client only platform." (i3)

"I think a platform by the client would work for us. But you have to see how to attract contractors." (i3)

"There's no reason to say that it shouldn't be led by the client, because without industry driving it, it won't go anywhere. But that doesn't mean that the client should go off building the green flavor of DCC that only talks to green approved vendors right, so it has to be done to a standard because I think the biggest part of my concern about this is how we ensure effectively that it's an open standard." (i4)

5.2.2 Ecosystem value

The interview questions that contributed to this theme were as listed in appendix 1:

3. How would a DCC ecosystem give value to your organization?

8. If (shared) calibration data is anonymized in the DCC ecosystem, what kind of shared data analysis would you expect?

10. If the client creates a DCC ecosystem, would you prefer it to be an open or closed DCC ecosystem? Why?

To attract customers to an ecosystem the ecosystem must provide them with some value. When the question how a DCC ecosystem would give value to the customer was asked one of the reoccurring answers was to improve data integrity. As discussed in chapter 3.1 the standardized DCC format will give a significant improvement of data integrity. One of the other reoccurring answers was that contractors and third-party calibration providers don't need access and training for the customers calibration management system if they can instead provide them a DCC. Another important thing is to avoid media breaks and that you don't need to scan papers or import PDFs manually to your system. By having all data digitally, it is also easier to do analysis and trending of the data. There is however some arguing if the DCC will save any money or not, while some says productivity will increase with less administration, others say that they don't see any huge cost savings.

"*Is basically about recording data, documenting results, and a manual transfer into our system landscape and this is error prone. This is a lot of work*" (i1)

"It's difficult when the contractor comes on site right to hand them a device and say OK, enter your results here because your results are going into the CMS. There's one the contractor needs, or the third party needs access to your IT systems, then it needs access to our CMS. Then it needs training and all of that." (i2)

"It's quite difficult to get your third party, people importing data into something like our CMS and any digital system? Something like the DCC would be fantastic where you could pre send the work." (i2)

"We have sites that are like 80% or 90% third party managed for calibrations and those sites can't go to the CMS because a lot of the things I've just sort of cyber security etc. It will be a great solution to it. Well actually you stick with your own systems, and you just send us the DCCs, and we have all the information that we want in our own central repository that then contributes into big data that then contributes into analysis with other systems etc." (i2)

"One of our highest targets is to have the best data integrity which is possible. So, our first requirement for this ecosystem is that we have less media breaks." (i3)

"The next one is that these data can be handled in our systems later, so we can do some trending, some analysis and so on. This is the next benefit that we have, and not to forget financial benefits that we have because handling paper or handling PDFs costs you a lot of money because somebody has to do that through this administration." (i3)

"I think the benefit is in productivity, compliance, and the capability to have your data accessible and readable. We know the issue is third party is providing your work either on a piece of paper or on a PDF, and you either scan the piece of paper or whatever." (i4)

"Productivity benefit in terms of not having to scan PDF's and attach them if the DCC can be automatically imported. That saves us several steps in our review process. It is more from the compliance productivity and a data availability side of things, not really in any cost saving. We don't really see a huge cost saving." (i4)

Since analysis and trending is one of the things that will give value to the customers the interviewees were also asked what kind of shared data analysis they would expect if the calibration data were anonymized in the DCC ecosystem. One of the common answers was to optimize the calibration interval but also to determine the reliability of certain instruments. Also, the pass/fail rate, trending, drifting and the speed of the work is interesting to some of the interviewees. An example on when analysis would be useful is when you are getting new process instruments and you can check which one is the most reliably by help of the analysis in the ecosystem. There is however a big concern among a few interviewees that device manufacturers don't want their instruments to be analyzed and it may be that a vendor that is ranked lower than another will not be accepting the results. One of the interviewees also said that they have not been thinking about sharing data like this, and that they think that their own data is enough for themselves, but for smaller companies this kind of data sharing can be beneficial. Another concern is that if the calibrations are not performed the same way, then they cannot be compared, so the calibration methodology must be taken in account when doing any analysis.

"To share calibration results and do a risk-based approach for future improved calibration cycles on same kind of instrument in the same process environment so that there is a kind of high-level comparison between across industries and across companies using the same type of instrument from the same vendor in a similar process. So that you can say hey, if it fails, not here 100 times why it should fail on our side and therefore maybe we can then reduce the calibration cycles, and this will then be a potential for cost savings all over." (i1)

"We can analyze this data, great for end user point of view. It's fraught with danger as a proposition, though. Because, like what if some vendor didn't like the results and challenged the results of that output?" (i2)

"We did not think of sharing data like this before, but this is, I think in the big data world this is typical and normal. And when we go more for cloud solutions and platforms it could be that let's say it's in the end it's very natural to share data like that." (i3)

"Determining your appropriate tolerances and determining your appropriate intervals of calibration. I mean, if you could go to some DCC supported shared data network where you can basically go, I need to buy a new pH meter for the labs. Which one should I pick?

And you can then go on to the DCC and see there's 10,000 calibrations that have happened on pH meters, and clearly that one is the most reliable." (i4)

"Imagine the blowback from the vendors that are down on the bottom of the list, right? So I mean, I don't know how that would work." (i4)

In terms of if the interviewees prefer that the DCC ecosystem is either closed or open there was a clear understanding that all preferred it to be open. The reason they prefer the ecosystem to be open is so that the service provider and external labs can connect their calibration management solutions to the ecosystem. Many of the interviewees also said that a closed ecosystem is also okay for them since they are already customers of the client, and they rely on that they can continue to use the same software also with a closed system.

"Clear message, I would expect you to make it as an open one. So, with an open API and the reason why is as I said, our target and our business cases are based on that we would like to onboard all our service providers for field and external lab calibrations into that ecosystem. And this can only happen if this is an open standard, because they also have their own calibration management solutions, and they can only do it if this is an open standard." (i1)

"It's just better if it's open, but actually the closed option isn't too bad either, and the client might at some stage make a complete open API." (i2)

"So, I would go for the open. Yeah, so the closed would work for us because for us it does not make a difference, because the client is our partner so that's why we cannot do it without them." (i3)

"We provide an open or maybe a closed standard, or a client only standard. But If people provide their data in specific format, it can be imported into our CMS. You know it's better than nothing, but the preference would be an open standard." (i4)

5.2.3 Ecosystem development

The interview questions that contributed to this theme were as listed in appendix 1:

6. What kind of knowledge and competences are needed to create a DCC ecosystem?

11. What development do you expect to see before you are ready to start using the DCC ecosystem?

12. Technical questions related to some current DCC findings.

To create an open DCC ecosystem will require both deep knowledge and competence from the calibration industry. According to the interviewees' calibration process knowledge, process expertise and IT expertise are among the things you need to understand when building an DCC ecosystem. But it is also about having the right network and the right connections. One of the interviewees said that if you can fulfill the pharmaceutical requirements that are one of the highest regulated industries then you can do it for anybody else. One of the interviewed persons thinks that coding will not be the hardest part but coming up with the idea and designing it will be tough. The understanding on what data you should transfer and designing the system for best efficiency, value, quality, and data integrity is also very important.

"It's about, having the right network, the right connections and talk to the right industries and to the right stakeholders. Because it's, as you often said, if you can fulfill the pharmaceutical requirements as one of the highest regulated industries, you can do it for anybody else." (i1)

"Coding the solution probably isn't the toughest bit in the whole thing. Coming up with the idea and designing it out in paper first is probably the hardest part" (i2)

"You need to have a knowledge of the calibration process. How is calibration done. What data are needed there. You should also have a basic understanding of GMP." (i3)

"Yeah, so this so understanding for calibration. For the data which have to be transferred for the quality of the data and especially also for data integrity." (i3)

"An IT understanding of the required data to be transferred." (i4)

Before the DCC ecosystem can be taken in use there have to be development both on the standard and on the calibration management software. The interviewees were asked what kind of development they expect before they are ready to start using a DCC ecosystem. The most common answer was that the standardization of the DCC schema must be approved and agreed with the industry. It is also important that the system is properly tested and validated, and here the importance of ALCOA is also mentioned. A few of the interviewees says that they want a commercial off the shelf solution and that it should also be an open cloud solution, offered as Software-as-a-Service.

"Fully standardized and fixed DCC Schema and structures in place as agreed across industry standards for our major measurement types like temperature and flow" (i1)

"Another prerequisite is that we need to have a commercial off the shelf, a platform-as-a-service solution in place as well as the sharing platform for transfer of DCC. And we need to have the client as our strategic partner for calibration solution to be ready to import any kind of DCC for any type of measurement we want to do. And it needs to be validated, that's really important." (i1)

"Organizations like mine are ready, right and except for, testing, testing, testing, testing, testing, and testing is it secure? But that means it's a cyber secure and testing the whole ALCOA patch and so we would run through. Yeah, we will run through a whole round of unit testing and user acceptance testing." (i2)

"First of all, we need to have a standardized system in the company to really make benefit out of the handling of calibration data. So, the bigger the company, the more standardized it should be." (i3)

"I think you have to start with the standard being approved and then adopting it into your system. Digital transformations needed well. I think. We are on a path now towards the cloud as much as possible. We are looking to software as a service." (i4)

During the three proofs of concepts, we have found a few technical issues. One of them is that the data type for numerical values is not allowing trailing zeroes to be transferred in the DCC, and the other issue is that percent values are not supported since percent is not defined in the SI unit standard. In process industry it is however common to calibrate instruments in % of Span, % of Reading or % of Load. The interviewees were asked what these issues means to their organization. One of the thoughts were that if this is a limitation of the DCC then their own calibration procedures and limits must be adjusted accordingly. But on the other hand, a few of the interviewees said that these issues are showstoppers and cannot be accepted. The argument is that zero is a number and must be treated the same as all other numbers. There is a concern that if you need to explain that your calibration results are missing zeros for some auditor or for the FDA then you will be in big trouble. The interviewees also agreed that % of span and % of reading are fundamental units in calibration and fully utilized in the process industry. They do not think that the industry will change the way they calibrate their instrument just because the DCC is not supporting a specific unit. One of the interviewees clearly pointed out that you must calibrate the instrument in the units for which it is configured.

"The only way we could do it, then if this means we need to adjust our calibration procedures and process limits, accordingly, because of limitations given by the system capabilities." (i1)

"So, it would mean non-acceptance of the system. Zero is a number and needs to be treated exactly the same as any number, it's no difference. It's important because it's the view of auditors" (i2)

"If you're explaining to an auditor, you're losing. If you're explaining how this number in front of you is not actually the number in front of you, that there's a couple of zeros, or there's doubt about zeros, are we not sure if the zeros should have been there, or if the system took off the zeros or added zeros? You're losing, you're losing massive and you're losing fast! Yeah, the number should be the number that's imported, and it should be stored like that." (i2)

"For the vast majority of things, we use absolute values anyway, but they're fundamentally in calibration, percent of span and percent of reading. But I mean the argument is that percentage of span is fully allowable and absolutely utilized. Industry is not going to change for some doctor in the PTB. No, and we are not going to go back and change." (i2)

"They are showstoppers at this point. I would say it depends on probably a lot of different elements, but on principle, the second one is a is a much bigger issue than the first, but both of them really." (i4)

"You have to calibrate it in the units for which it's configured, you have to. There's no other way to do it, right? So, you know if the manufacturer or the process demands that it uses some engineering unit that isn't SI, then you have to calibrate it in that. And if that locks you out of using a DCC, then to me that's a weakness of the DCC" (i4)

5.2.4 DCC alternatives

The interview questions that contributed to this theme were as listed in appendix 1:

9. If the DCC fails to be standardized, what other possibilities do you see to digitally transfer calibration certificates between actors in an ecosystem?

11a. What kind of digital transformations related to calibration have your organization already done?

13. Is there something else you want to add?

There is always a possibility that the standardization of the DCC will fail, or that it will not be taken into use by the industry. The interviewees were asked what other possibilities they see to transfer calibration certificates between actors in an ecosystem. One possibility that they see is to have a closed ecosystem on a different level with close cooperation between calibration solution service providers, the customers, and the contractors. But there will be limitations and they may not be able to bring in all the contractors or the service providers doing calibration services for them. Another possibility that they see is to have mobile devices with a manual entry application installed. From this application the calibration results could be transferred trough some secure cloud application to their core system. One of the interviewees says that they must go back to PDFs and send them with email or cloud storage (e.g., dropbox). But the same person believes that the DCC will be successful and that it is important to transfer the certificates without any media breaks. Another interviewee says that if the DCC fails they can only use vendors that uses the same calibration management system as them if they want the results to be automatically transferred into their system. But with this system it will be hard to onboard new vendors and they will be locked to the same system. There may also be problems validating a system like this. An open standard with all the compliance questions answered is much easier to sell, both to internal QA and to FDA and other inspectors.

"I still would see the possibility to do it on a different level as a closed DCC ecosystem which is then for a certain calibration management system solution only. In a close cooperation between the calibration solution service providers, the customers, and the contractors. Then in terms of contractors we need to consider that we will not manage to bring all our service partners in there doing calibration services for us." (i1)

"The obvious one is bMobile, where bMobile is made freeware." (i2)

"To have a data transfer without any media breaks, so if this fails fully and there will be no DCC because nobody wants to work with the DCC, then we have to go back to PDFs that we send by email or have a drop box." (i3)

"An open standard with all the compliance questions answered as part of that open standard is much easier for us to sell, so internally I mean not just to internal QA but to the FDA and other inspectors." (i4)

At the end of the interview the interviewees were asked an open question about if they still want to add anything related to the DCC. One of the reoccurring topics were what kind of time schedule they can expect from the DCC ecosystem and what will be the next steps. It was suggested that to get a fast start it may be better to start as a closed ecosystem and then when the system is stable it can be opened. Then you have a production proof of concept to show to the market. It would be possible to show the overall concept and that it is technically on a mature level that ensures the security, integrity standards and complies with the regulations on the highest level.

It was also a concern that many companies are just waiting for something to happen without participating actively in the DCC collaboration. One interviewee said that at some point of time, you must think about how to set up a platform that is attractive to everybody, and that you should not wait too long with this. Another interviewee said that they are really interested to see in what directions this goes but that they have been paperless along time already, including doing automatic approval of calibrations. The same interviewee says that they got a massive efficiency from going from paper based to paperless and going from manual review to automated review, so there is a big potential in a system like this. But what they would want is the system to tell them that they're calibrating the instruments too frequently or not frequently enough. They also want the system to tell them which instruments that are deficient. Based on the data the system should tell if the failure rate is higher on one type of instruments as it is on other ones.

"Maybe it could also be a fast approach to start with a closed ecosystem, based on the level of influence we have and based on the level of control we best can do. We will build it up as a closed ecosystem for DCC processing. To say we start with our customers in a more closed environment, anticipating the standards so that at a certain point of time we can open it up and be ready market." (i1)

"At some point of time you have to think about how do we setup this platform that is attractive to everybody and so on? And you should not wait too long with this, so I would be interested to hear something about that." (i3)

"I'm really interested to see where this goes right. We really want to take the next steps with calibration. We've been using our CMS for. 10-12-14 years, something like that, right? We've been paperless all that time. We've been doing automatic approval of calibrations all that time." -i4

When asked what kind of digital transformations the organizations have already done related to calibrations one of the interviewees said that they are already using a paperless system with automated review and that they got a massive efficiency from that compared to a paper-based system. Initially they used to have a lot of arguments with the quality assurance department, but now when the system is proven to work there are no more arguments. Another interviewee described the process from one of the POCs that they have now implemented into their development environment.

"Like we got a massive efficiency from going from paper based to paperless and going from manual review to automated review. We're now comfortable with that. We've brought not just our craftsmen along, but we've brought our quality organization along as well. They're completely sold on it. We used to have arguments with them about it. You can't possibly automate a review. You can't possibly go paperless? How is the electronic signature fully captured? How was your data integrity ensured? All that stuff is put to bed. We're not having those arguments anymore; QA is completely onboard with us now." (i4)

6 Discussion and recommendations

The main purpose of this study was to identify the technical needs and gaps for the client, customers and the DCC standard related to creating a DCC ecosystem. The research focused on to determine the customer readiness for joining a DCC ecosystem and was trying to find out what kind of digital transformations the customers have already done. The research was done by case studies that presents technical or compatibility issues that need to be addressed before the standardized DCC can be used in field calibrations for the process industry. The semi-structured interviews present answers related to establishing a new Digital Calibration Certificate ecosystem.

6.1 Discussion

As stated in chapter 1.4 there are still few real-world applications for the DCC, but this research investigated if the standardized DCC can be used in the process industry as part of a DCC ecosystem. The goal was to find out what the possibilities are to establish a new Digital Calibration Certificate ecosystem, how it can be realized, and what are the benefits or disadvantages of either a closed or open DCC ecosystem?

In the scope of the first research question, it was investigated if the DCC is technically ready to be used by the process industry. The researcher also tried to find out if there are technical gaps in current products by the client that need to be solved before the DCC can be taken in use. In the second research question the definition of a closed ecosystem means interaction between client approved customers, partners, software, and equipment only. If the ecosystem is open, then all actors in calibration industry can join, and 3rd party applications can interact with the ecosystem also. In the interviews the researcher also tries to find out what kind of data the customers are willing to share, and what kind of analysis they are expecting from the data in the ecosystem.

The technical results build on three different proof of concepts that were executed with DCC schemas from version v2.4.0 to v3.1.0. A few of the issues reported in the first POC has been addressed but there are still issues that need to be solved.

1. *Issue with undefined resolution for numerical values*

Based on the three POCs the issue with undefined resolution for numerical values has been appearing in all versions of the D-SI schema that is used by the DCC schema. The reason for this is that the numerical datatype (see chapter 2.1.7) xs:*double* that is used in the schema is not supporting trailing zeroes. One of the reasons to use double is because of the scientific notation. According to Wikipedia (2022) scientific notation is a way of expressing numbers that are too large or too small (usually would result in a long string of digits) to be conveniently written in decimal form, e.g., to show 0.00000000751 as 7.51×10^{-9}. This is mainly needed for NMIs where the measurement uncertainty may be very small. Hackel et al. (2017) says that the representation of the measurement results is one of the most challenging tasks to be solved in the shape of the DCC. The reason for this is the variety with which measurement results are presented.

The researcher suggested to the developers of the DCC schema to use the datatype *xs:decimal* instead since that datatype is supporting trailing zeroes. But since the *xs:decimal* is only supporting values between $\pm1.0 \times 10^{-28}$ to $\pm7.9228 \times 10^{28}$ compared to $\pm5.0 \times 10^{-324}$ to $\pm1.7 \times 10^{308}$ for *xs:double* it was not accepted, since then it would not be possible to represent all constants defined in the CODATA table (see chapter 2.1.4). E.g., it is not possible to represent the Planck constant $6.62607004 \times 10^{-34}$ m^2 kg / s with *xs:decimal*. Another reason for not using *xs:decimal* is also that scientific notations are not supported with that data type. During POC 3 we however changed the datatype in the source code for numerical values from *double* to *string* to preserve the resolution. The generated XML that e.g., contains <si:value>25.000</si:value> can be parsed with both xs:double and xs:string, and the output is then either 25 or 25.000.

```
<dcc:quantity refType="/referenceValue">
  <si:real>
    <si:value>25.000</si:value>
    <si:unit>\degreecelsius</si:unit>
  </si:real>
</dcc:quantity>
```

Figure 10. Part of a DCC that shows a numerical value with SI unit.

By using a regular expression pattern (Microsoft, 2022), it is possible to prevent usage of unwanted characters in the *si:value* even if it is defined as *xs:string*. E.g., the following regular expression “[-+]?((\d*\.\d+)|(\d+\.\d*)|(\d+\.?))([Ee][-+]?\d+)?” will only allow numerical values with or without a scientific notation. The change of the data type did not compromise the interpretation of the values as the regular expression for representing numerical values remained the same.

One of the interviewees said that if this is a limitation of the DCC then their own calibration procedures and limits must be adjusted accordingly. But on the other hand, a few others of the interviewees said that these issues are showstoppers and cannot be accepted. Based on the interviews (see chapter 5.2.3) it is important to preserve the trailing zeroes in the DCC. The argument is that zero is a number and must be treated the same way as all other numbers. There is a concern among the interviewees’ that if you need to explain that your calibration results are missing zeros for an auditor or for the FDA then you will be in big trouble. When looking at missing zeros from ALCOA+ point of view (see chapter 3.1), it will not at least fulfil the requirements of Accurate and Complete:

- Accurate: The data recorded must be complete, consistent, truthful, and representative of facts.
- Complete: Information that is critical to recreating and understanding an event. This would include any repeat or reanalysis performed on a laboratory test sample.

2. *Importance of reference due date*

When doing a calibration, it is important to have traceable references (see chapter 2.3.3), and it is also important to know when the reference has been calibrated. The calibrators and references (see chapter 2.3.6) should have a dedicated field for calibration date and/or calibration due date in the DCC, it is important to know if the reference is calibrated in time. Currently there is no dedicated field for due date or calibration date in the *dcc:measuringEquipment* section.

```
<dcc:measuringEquipment id="" refType="" xmlns:dcc="https://ptb.de/dcc">
  <dcc:name id="">{1,1}</dcc:name>
  <dcc:equipmentClass id="">{0,1}</dcc:equipmentClass>
  <dcc:description id="" refId="" refType="">{0,1}</dcc:description>
  <dcc:certificate id="">{0,1}</dcc:certificate>
  <dcc:manufacturer id="" refId="" refType="">{0,1}</dcc:manufacturer>
  <dcc:model>{0,1}</dcc:model>
  <dcc:identifications>{0,1}</dcc:identifications>
  <dcc:measuringEquipmentQuantities>{0,1}</dcc:measuringEquipmentQuantities>
</dcc:measuringEquipment>
```

Figure 11. Part of DCC schema that describes the measuring equipment.

According to GMP 11 (2019) the calibration laboratory must have a program of documenting and monitoring calibration status, and schedule calibrations of the reference standards on the defined intervals. CFR 21 (2022) also states clearly that the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. This is needed to prevent the use of reference standards after their calibration due date. If an overdue reference is used in a calibration, it will most likely cause a deviation if found by an auditor.

3. Importance of non-SI units

The DCC schema uses the D-SI schema for numerical values and units, this schema is based on the SI unit standard (see chapter 2.1.8). Unfortunately, percent values are not part of SI and e.g., error calculated in % of Span and % of Reading is not supported without special definition in the DCC. Mass Flow Online (2022) says that the accuracy of mass flow instruments is specified in one of two ways, either accuracy as a percentage of full scale (% FS), or accuracy as a percentage of reading (% RD). It is also very common that pressure transmitters are calibrated in percent of span, e.g., Rosemount 3051 that is according to Emerson (2021) installed in over 7 million places got the accuracy defined in percent of span, and the percent of span value is also needed when calculating the calibration interval.

Hackel et al. (2017) says that the guidelines for the measurement results in the DCC are based on the standards of the BIPM but that units that are outside the SI can also be displayed, but irrespective of this, the data in SI is always valid. The DCC schema does support XML tags for defining non-SI Units, but this may cause mismatch between systems since it must be specified the same way in all systems, e.g., the non-SI units must be recognized also if different languages are used.

```
<xs:element name="nonSIDefinition" type="xs:string" minOccurs="0"/>
<xs:element name="nonSIUnit" type="xs:string" minOccurs="0"/>
```

In the process industry it is common to calibrate instruments in “% of Span”, “% of Reading” or “% of Load”. The interviewees also agreed that % of span and % of reading are fundamental units in calibration and fully utilized in the process industry. Based on the interviews (see chapter 5.2.3) the interviewees think that the industry will not change the way they calibrate their instruments just because the DCC is not supporting a specific unit. One of the interviewees clearly pointed out that you must calibrate the instrument in the units for which it is configured and that if percent of span is not supported it will be a showstopper for them. Hackel et al. (2017) however says what is strongly regulated is that the measurement results must be presented completely and only on the basis of the SI. The statements from Hackel et al. (2017) seem to be a bit contradictory, saying both that “units that are outside the SI can also be displayed” vs. “measurement results must be presented completely and only based on the SI”.

4. *DCC schema semantics*

The DCC Schema v.3.1.0 still enables several ways to represent the data which challenges the interoperability and unambiguity without precise guidance. The DCC schema needs to be stricter, but this issue is initially meant to be solved by Good Practices templates that will require separate implementations for each quantity. Currently PTB has been working on Good Practices for Temperature calibration, but we need to have more quantities added that are common for the process industry, e.g., pressure and flow, to validate if this is a good solution. Despite their technical differences, calibration certificates have a high degree of similarity. Gloger (2022) says that based on this similarity, it is possible to structure the DCCs in such a way that they can not only be read by the machines, but also executed and interpreted. There is however still development to be done until the DCC is fully machine readable. One possibility with the DCC schema is to add enumerations or so-called controlled vocabularies. According to Coates (2003) schemas can be made more manageable by separating volatile controlled vocabularies (enumerations) into their own vocabulary schemas. This means that you have a separate schema with terminology and tags that can be used in the DCC schema to make it less ambiguous and more machine readable. Wikipedia (2022b) states that in large organizations, controlled vocabularies may be introduced to improve technical communication. The use of controlled vocabulary ensures that everyone is using the same word to mean the same thing. Wikipedia (2022b) also says that this is one of the most important concepts in technical writing and knowledge management, where effort is expended to use the same word throughout a document or organization instead of slightly different ones to refer to the same thing. An example of when this would be useful is for the non-SI units where e.g., "% of Span" can be written in many ways.

5. *Support for importing DCCs for references*

From the calibration software's (see chapter 2.3.5) point of view neither POC 1 nor POC 2 were ideal since the evaluated DCCs were for reference standards. The calibration software's main purpose is to manage calibrations for process instruments, and hence calibration results for references are not directly supported. This is however a use case for most of the customers and therefore support for importing DCCs for references should at some point be added to the calibration management software.

6. *Importing measurement error and measurement uncertainty*

In the DCC the measurement error and measurement uncertainty (see chapter 2.3.4) for the calibration is provided for each calibration point, there is however no interface in the current calibration management software that imports the measurement error or the measurement uncertainty. Instead, they are recalculated by the calibration management software during the import. To calculate the uncertainty the used references and their specifications must exists in the CMS database. No properties in the DCC should however be recalculated when the DCC is imported, so this issue needs to be corrected in the calibration management software. There is however a use case when the uncertainty calculation is needed. E.g., the cloud software used in POC 3 does not calculate any uncertainty, so the DCC that is initially generated is missing that information. But if the references used in the DCC are transferred correctly to the on-premises software then the uncertainty will be calculated when the DCC is imported.

7. *Importing certificate numbers*

There is no interface in the calibration management software that can import certificate numbers. Instead, the calibration software is generating a new certificate number for each imported DCC. This functionality is based on that you usually receive calibration results from a calibrator and the certificate number is generated when the results are stored in the database. To fully support importing of DCCs the calibration management software must however be able to use the certificate number that is given in the DCC. This issue must be corrected in the calibration management software.

8. ***Different way of handling error limits***

Both the cloud software and on-premises calibration management software define error limits (see chapter 2.3.2) over the full range of the calibrated instrument. The DCC however contains separate error limits for each point. This is not supported in the same way in the calibration management software, instead the error limit must be recalculated for a specific range that is defined by a change point + the error limit that is valid above that point. This causes extra logic when generating or reading a DCC. It requires that when the DCC is generated the error limits must be calculated for each point, and when importing the DCC-parser must validate if there are multiple or just one error limit for the instrument range.

9. ***Environment conditions***

The uncertainty of a measurement is most likely affected by the environment conditions. In the DCC the environment conditions are supposed to be given according to the laboratory accreditation, which is then given as an upper and lower value. The calibration management software expects the environment data, such as temperature, air pressure and humidity to be a single measured value that is measured at calibration time. When calibrating in process industry the temperature may vary a lot between different locations in the factory, and therefore additional uncertainty must be added if e.g., the device temperature is far from normal room temperature. To have a comparable and traceable uncertainty the measured environment conditions must also be given in the DCC.

10. ***Vendor specific calibration details***

The calibrator used in POC 3 can indicate if a measurement point is, e.g., unstable or if there is some electrical error like current overload. This information is possible to add to the DCC, but it not part of any standard and will not be recognized by other systems. Most likely vendor specific details about measurement results cannot be used if we want to use the standardized DCC.

11. *Digital Calibration Request*

To be able to calibrate or import a DCC for an instrument that is not previously existing in the receiving calibration management system a Digital Calibration Request (DCR) is needed. According to Jageniak (2021) a digital calibration request contains the requirements for the calibration process that a customer places on a calibration laboratory. This is an addition to the administrative data in the DCC. Hackel et al. (2017) says that the administrative data fields are fixed, and that the information is usually on the first page of an analogue calibration certificate. The data is used to identify the calibration laboratory, the calibration object, and the calibration customer. Jageniak (2021) says that in addition, administrative information is communicated to be able to assign the request unambiguously, e.g., to the customer as well as to the calibration laboratory. With the information in the DCR the calibration provider will know how to perform the calibration, and you can also setup the instrument and its calibration procedure before receiving the DCC to a calibration management system. The DCR is planned to be part of DCC v.4.0.0, but before that instrument setups must be manually created when transferring DCCs between different systems.

12. *Ecosystem collaboration*

The interviewees said that the ecosystem should not be led by the client or by only one company. The opinion is that it should be led by someone independent, and that the ecosystem must attract also other companies and contractors than they who are using the clients' products. Nummiluikki et al. (2021) also states that the ideal option is that an independent company develops and operates the DCC platform under the supervision and approval of a calibration authority, and that this allows neutral collaboration with all the stakeholders. There is also an idea that the ecosystem should be held together by a foundation or a board of people from different organizations. In chapter 2.2 Heimala (2021) states that open ecosystems do not have an owner or a defined organization. Nummiluikki et al. (2021) on the other hand says that if the DCC platform achieves ecosystem-wide support, it is important to discuss who owns, manages, and administers the DCC platform. The platform operator must enjoy wide trust by the industrial users, the calibration vendors, and the authorities (such as NMIs) in the traceability chain of calibration. One of the interviewees on the other hand said that he sees no reason why the client cannot lead it, and that it must be driven by the industry. The interviewees feel like PTB will be the main partner as they are driving the standardization for a global DCC format. There is a common understanding that PTB, who is the main developer of the DCC, is the most important actor in a DCC ecosystem. But as soon as the standardization work is ready there will be little work left for an organization like PTB in an industrial DCC ecosystem. The main role of PTB is to standardize the DCC, not to make a commercial ecosystem. If the client is not leading the work in the ecosystem, they should concentrate on creating interfaces and functionality to the platform. Creating functionality for calibration management software is one of the client's core competences.

13. Ecosystem Value

To attract customers to an ecosystem the ecosystem must provide them with some value. One of the most important things according to the interviewees is to improve data integrity. As stated in chapter 3.1 data integrity is of high importance for the highly regulated pharmaceutical companies. Most of the pharmaceutical companies follows an acronym called ALCOA+ to assure the data integrity. Schniepp (2019) says that data supporting the quality and safety of a product must meet the ALCOA+ elements to avoid regulatory citations for data integrity issues. Neyezhmakov et al. (2021) also says that using a specific data storage format in DCC significantly reduces manual work, which in its turn, reduces the time and cost required to manage calibration data while offering significant improvements in data integrity. One of the other reoccurring answers was that contractors and third-party calibration providers don't need access and training for the customers calibration management system if they can instead provide them a DCC. Another important thing is to avoid media breaks and that you don't need to scan papers or import PDFs manually to your system. By having all data digitally, it is also easier to do analysis and trending of the data. This supports the statement by Neyezhmakov et al. (2021) that says machine-readability makes it possible to effectively assess the traceability of measurement results, since it contains data on the entire chain of calibrations up to the national measurement standards. Neyezhmakov et al. (2021) continues with that having all the information about the calibration chain available and linking DCC sensors to the data they provide can ultimately be used with improved analytics and decision making.

14. Trending and analysis

One of the common answers on what gives value to the ecosystem was trending and analysis. The interviewees said that they want to optimize the calibration interval but also to determine the reliability of certain instruments. Also, the pass/fail rate, trending, drifting and the speed of the work is interesting to some of the interviewees. An example on when analysis would be useful is when you are getting new process instruments and you can check which one is the most reliably by help of the analysis in the ecosystem. Nummiluikki et al., (2021) says that a shared DCC platform will enable wider use of calibration data. Sharing non-critical and anonymized data within the ecosystem improves the data quality for any individual user as, e.g., uncertainty information can be compared against a larger peer group. There is however a big concern among a few interviewees that device manufacturers don’t want their instruments to be analyzed and it may be that a vendor that is ranked lower than another will not be accepting the results. One of the interviewees also said that they have not been thinking about sharing data like this, and that they think that their own data is enough for themselves, but for smaller companies this kind of data sharing can be beneficial. According to Nummiluikki et al., (2021) all partners would still have full control of their data and ability to decide what data can be shared or sold to the ecosystem partners.

Another concern is that if the calibrations are not performed the same way, then they cannot be compared, so the calibration methodology must be taken in account when doing any analysis. Neyezhmakov et al. (2021) says the implementation of DCCs into practice will allow the use of calibration data for analysis by machine learning methods in artificial intelligence systems. So, by learning the system the calibration methodology the analysis will be much more reliable. The way the analysis data is shared must however be agreed on with the different actors in the ecosystem, this means that the analysis part in the ecosystem will be partly closed. Nummiluikki et al. (2021) says the shared DCC platform would also enable calibration data markets outside the ecosystem in the future. Sharing or selling anonymized data could bring added value to all partners within the community. One example by Nummiluikki et al. (2021) is that instrument owners could sell their calibration data to the instrument manufacturers that could use the data to boost their product development and ability to offer optimal products to their customers based on the customers' needs and that this would help the instrument owners select the instruments that fulfil their requirements the best.

15. Open or closed ecosystem

In terms of if the interviewees prefers that the DCC ecosystem is either closed or open there was a clear understanding that they preferred it to be open. The reason they prefer the ecosystem to be open is so that the service provider and external labs can connect their calibration management solutions to the ecosystem. Many of the interviewees also said that a closed ecosystem is also acceptable for them since they are already the clients' customers, and they rely on that they can continue to use our software also with a closed system. As written in chapter 2.2 Tiwana (2014) says that platforms can be open or closed to varying degrees, with most platforms neither completely open nor completely closed. This is probably the way to go, with a more closed solution for the calibration management and analysis, and an open system for the contractors that provides the ecosystem with DCCs. Several of the interviewees says that the ecosystem must be financially easy to access, and preferable free to use. The platform must also be technically easy to use, and especially for the contractors or third-party calibration providers. This correlates with what Nummiluikki et al. (2021) says, to enable the ecosystem-wide collaboration in metrology, the solution needs to be easy and cost-efficient to take in use by any organization and institute regardless of their level of digitalization and resourcing.

To create an open DCC ecosystem will require both deep knowledge and competence from the calibration industry. According to the interviewees' calibration process knowledge, process expertise and IT expertise are among the things you need to understand when building an DCC ecosystem. But it is also about having the right network and the right connections. Heimala (2021) states that in an open ecosystem, networks are more flexible and innovative than in closed ecosystems. One of the interviewees said that if you can fulfill the pharmaceutical requirements that are one of the highest regulated industries then you can do it for anybody else. The understanding on what data you should transfer and designing the system for best efficiency, value, quality, and data integrity is also very important. But even if some part of the ecosystem is more closed it is important that the ecosystem is based on an open DCC standard and that the standard is followed precisely. We need to have one agreed open DCC standard and that is what makes it so difficult.

16. Ecosystem Development

Before any ecosystem can be taken in use the standardization of the DCC schema must be approved and agreed with the industry. It is also important that the system is properly tested and validated, and that the importance of ALCOA is taken in account. A few of the interviewees says that they want a commercial off the shelf solution and that it should also be an open cloud solution, offered as Software-as-a-Service. On the other hand, one of the interviewees says it needs to be a cloud-based solution provided as a Platform-as-a-Service. Since the DCC is planned to be a global standard there will be many different needs for an ecosystem of this type, but most likely it will be a SaaS solution rather than a PaaS solution, since then the customer organizations don't need to develop any software themselves.

According to the interviewees the platform must be technically easy to use, and especially for the contractors or third-party calibration providers. The use cases for when the DCC is needed are mostly related to when others than the own staff are performing the calibrations, and it would then be best to only have one platform where all customers and contractors can connect. One interviewee says to get a successful industry platform there should be a template of the DCC for the industry, and no big alignment should be needed between the contractor and the customer. This will require that we first create several good practices templates and then align them into one single template that is suitable for the process industry. When the DCC is aligned and agreed on the contractor do not need to access to the customers calibration management system, instead they can use their own computers and software and return the calibration certificate as a DCC.

If a global open ecosystem fails to be established one possibility that the interviewees see is to have a closed ecosystem on a different level with close cooperation between calibration solution service providers, the customers, and the contractors. But there will be limitations and they may not be able to bring in all the contractors or the service providers doing calibration services for them. Another possibility is that the contractors have mobile devices with a manual entry application installed. From this application the calibration results could be transferred trough some secure cloud application to their core system. The usage of a mobile manual entry application is something that can work in parallel with the DCC also, this way the generation of the DCC happen within the ecosystem and the contractor will only send the raw data to the ecosystem. Another interviewee says that if the DCC fails they can only use vendors that uses the same calibration management system as them if they want the results to be automatically transferred into their system. But with this system it will be hard to onboard new vendors and they will be locked to the same system. The point is that the customers of the DCC ecosystem wants to have the DCCs provided from contractors and external laboratories independently of what kind of calibration software they use. One interviewee said that at some point of time, you must think about how to set up a platform that is attractive to everybody, and that you should not wait too long with this.

17. Limitations and biases

In this study there has been no research related to the signing or validation of the digital certificates. The interviewees were also all from the pharmaceutical industry and the results are therefore biased toward that industry sector. The needs for NMIs and calibration laboratories has also not been researched, although mentioned several times in the discussions.

6.2 Conclusions

In this research it was studied if the DCC is technically ready to be used by the process industry. The first research question was to find out if the client can establish a Digital Calibration Certificate ecosystem and how it should be realized. The scope of the second research question was to find out the benefits or disadvantages of either a closed or open ecosystem.

6.2.1 Digital calibration certificate schema

The current version of the DCC schema can be used in a closed ecosystem where one company controls both the generation and reading of the DCC. But to use it in an open ecosystem with multiple actors the issue with undefined resolution for numerical values must be solved. Support for reference due dates and measurement results based on non-

SI units must also be added. The DCC schema semantics must also be improved to achieve full machine readability.

6.2.2 Calibration management system

It is fully possible to connect the evaluated calibration management systems to a DCC ecosystem. The parsing and importing of DCCs has been proven several times in the three different POCs, but to achieve full support the importing of measurement error, measurement uncertainty and certificate numbers must be improved. Automatic generation of DCCs were also proved in POC 3. From a long term view the CMS must also support importing of DCCs for references and calibrators, since that is a common use case for process industry.

6.2.3 DCC to CMS alignment

There are a few issues that will need alignment between the DCC and the calibration management system. The most important one is how the different ways of handling error limits should be solved. Now the DCC requires a separate error limit for each test point, while the CMS handles the error limit over the full instrument range (or sub-ranges). Another thing to align is whether the environment conditions are based on accreditation or if they are measured at calibration time. Some calibrators may provide additional information about calibration results, such as if the test point is stable or not. For failed points there may also be indicated that there was e.g., an electrical overload. These are vendor specific details that cannot be standardized but must be agreed on between customer and contractor if needed.

6.2.4 Ecosystem

Even if the opinion is that a DCC ecosystem should be led by some independent organization, there is no reason why the client cannot lead it. The main role of PTB is to standardize the DCC, not to make a commercial ecosystem. If the client is not leading the work in the ecosystem, then they should concentrate on creating interfaces and functionality to the platform.

The ecosystem should be offered as Software-as-a-Service platform. For the pharmaceutical companies the data integrity is of high importance in the ecosystem. It is important to avoid media breaks and that you don't need to scan papers or import PDFs manually into your system. The DCC ecosystem should provide a solution so that contractors and third-party calibration providers don't need access and training for the customers calibration management system. The use cases for when the DCC ecosystem is needed are mostly related to when others than the organizations own staff are performing the calibrations.

By help of the DCC ecosystem it should be possible to optimize the calibration interval and to determine the reliability of certain instruments. Also, the pass/fail rate, trending, drifting and the speed of the work can be analyzed. The way the analysis data is shared must however be agreed on with the different actors in the ecosystem, this means that the analysis part in the ecosystem will be partly closed. It will however be a big disadvantage if the data analysis part in the ecosystem stays closed for a long time, as the main ingredient of a platform ecosystem is data. As discussed in chapter 2.2 Ruokonen (2021) says that in an ecosystem, companies should work together towards a common goal, creating value both for the end customer and each other.

The DCC ecosystem should be open for the contractors and external labs as the highest benefit will come from including them to the ecosystem. For the users of calibration management software, a closed ecosystem is also acceptable, since they rely on that they can continue to use their current software also with a closed system. This is probably the way to start, with a more closed solution for the calibration management and analysis, and an open system for the contractors that provides the ecosystem with DCCs. The open side in the ecosystem must be financially easy to access and technically easy to use. But even if some part of the ecosystem is more closed, it is important that the ecosystem is based on an open DCC standard and that the standard is followed precisely, approved, and agreed with the industry. The use of a mobile manual entry application is something that can work in parallel with the DCC, in this way the generation of the DCC can, if necessary, take place within the ecosystem because the contractor sends raw data to the ecosystem.

Some customers already started their digital transformation by internally using a paperless calibration management system with automated review, and they say that they got a massive efficiency from that compared to a paper-based system. Initially they used to have a lot of arguments with the quality assurance department, but now when the system is proven to work there are no more arguments. With help of the DCC ecosystem they can achieve the same also with external contractors and laboratories. When the standardization of the DCC schema is approved and agreed with the industry, and when the ecosystem is properly tested, validated, and fulfills the ALCOA+ requirements they will be ready to join.

6.2.5 Proposal of a DCC ecosystem

By help of POC 3 we can conclude that we have the competence to both generate and import DCCs based on the standardized DCC schema, and that the DCC can be transferred between different calibration management systems. To create a closed ecosystem with only products by the client would be possible with the current DCC schema since we can then control the generated data from end-to-end. But to create a fully open ecosystem the DCC still needs improvements, at least the resolution issue, the handling of non-SI units and the schema semantics must be improved. On the calibration management system side, the importing of DCC must be able to use the raw data and no recalculation should be performed.

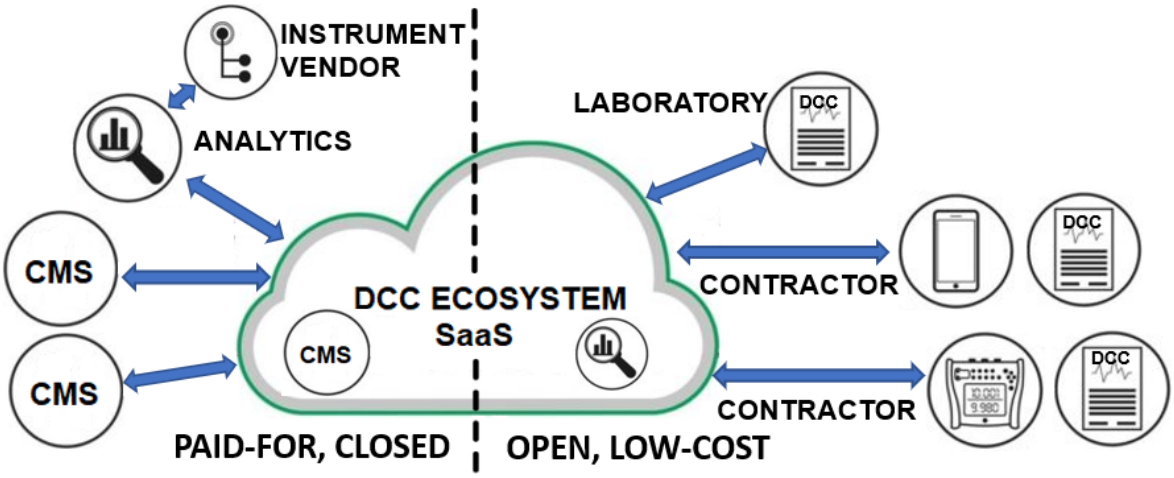


Figure 12. Overview of a proposed DCC Ecosystem, Software-as-a-Service

The conclusion of this research is that the DCC ecosystem can be split in to two sides and depending on your organizations role you can either access the low-cost and open side, or the paid-for and closed side. One of the most important things with the DCC ecosystem is to get the contractors and external laboratories to join, their access to the ecosystem needs to be open and cost effective. On the open side there may also be some basic statistics tool for e.g., number of transactions per contractor and turnaround time. To join the DCC ecosystem with an advanced calibration management system you would need to financially compensate for access, but then you will also get access to advanced analytics such as instrument drifting, calibration interval optimization and pass/fail rate of different instruments. The instrument vendors can also provide analytics tools to the ecosystem and in return they get statistics on how their instruments are used.

In the proposed DCC ecosystem the CMS owners will send a digital calibration request to the ecosystem that will then be routed to the correct contractor or laboratory. When the calibration is ready, a DCC will be returned into the ecosystem for validation, and if it is okay, it will be transferred to the CMS that sent the DCR. This way there will be no media breaks and a high data integrity will be achieved. There is still a hesitation to share data between CMS owners, even if the data is anonymized, and therefore the analytics is on the closed side. But to get full advantage of the ecosystem the analytics module should in the future be moved to the open side.

6.3 Recommendations and future research

Based on the conclusions further research is recommended both to validate and to find solutions to the findings in this study.

1. DCC schema

To use the DCC in an open ecosystem with multiple industrial actors the issue with undefined resolution for numerical values and the issue with measurement results based on non-SI units must be solved. Support for reference due dates also need further investigation. The DCC schema semantics must also be improved to achieve full machine readability, one suggestion is to include controlled vocabularies based on process industry needs. It is recommended that these issues are researched further by help of case studies with process instruments, e.g., by creating a good practices DCC template for a Rosemount 3051 pressure transmitter.

2. DCC to CMS alignment

There are a few issues that will need alignment between the DCC and the calibration management system. The most important one is how the different ways of handling error limits should be solved. Now the DCC requires a separate error limit for each test point, while the CMS handles the error limit over the full instrument range (or sub-ranges). One recommendation is that the error limit is defined in more detail in the DCR, e.g., some pressure instruments can have the accuracy specified as % of Span + % of Reading, and from that limit the point specific error limit can be calculated in the DCC.

3. Integration of contractors and external laboratories

The use cases for when the DCC ecosystem is needed are mostly related to when others than the organizations own staff are performing the calibrations. Further research is needed on how to integrate the contractors and external laboratories to the ecosystem.

4. Analysis and shared data

It is concluded that it will be a big disadvantage if the data analysis part in the ecosystem is closed, as the main ingredient of a platform ecosystem is data. We need further research on what calibration data needed for analysis that the ecosystem customers are willing to share, and what kind of mutual agreements the different actors in the ecosystem are expecting before they are willing to share their calibration data.

5. DCC for references

To take full advantage of the DCC ecosystem the calibration management system must also support importing of DCCs for references and calibrators, it is recommended that support for this is added in a near future since it is a common use case for the process industry to send their references to an external laboratory and then expecting a DCC back.

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APPENDIX 1.

1. Introduction

    a. Permission to record the interview. Interview is confidential.

    b. Explanation of the thesis topic. What & why.

    c. Can you tell a bit about yourself, your role, and your organization?

2. How do you see the role of your organization in the development of new DCC ecosystem?

3. How would a DCC ecosystem give value to your organization?

4. Who would be the most important partners in a DCC ecosystem be, and how should these actors work together?

    a. What kind of partners are you looking for in this ecosystem?

    b. With whom should your organization collaborate to create innovation and new business? Why?

5. What kind of needs do you have for this kind of platform/ecosystem?

    a. What kind of goals do you have for it?

    b. What value can a DCC ecosystem give to your organization?

6. What kind of knowledge and competences are needed to create a DCC ecosystem?

7. Should the collaboration in a DCC ecosystem be lead or managed by someone else than the client? Why/why not?

8. If (shared) calibration data is anonymized in the DCC ecosystem, what kind of shared data analysis would you expect?

    a. How do you see the importance of shared calibration data?

    b. What kind of data can be shared with the ecosystem members?

c. If there is an API to access shared data, how would you make use of it?

9. If the DCC fails to be standardized, what other possibilities do you see to digitally transfer calibration certificates between actors in an ecosystem?

    a. What if other industries accept the standardized DCC, but it is lacking functionality for your organization?

10. If the client creates a DCC ecosystem, would you prefer it to be an open or closed DCC ecosystem? Why?

    a. Closed = Client approved customers/partners/software/equipment only

    b. Open = All actors in calibration industry can join (open API?)

11. What development do you expect to see before you are ready to start using the DCC ecosystem?

    a. What kind of digital transformations related to calibration have your organization already done?

12. Technical questions related to some current DCC findings:

    a. If the resolution of numerical values cannot be stored in the DCC, what would that mean to your organization?

    b. If the calculated error cannot be given in percent in the DCC, e.g error in % of Span, % of Reading or % of Load, what would that mean to your organization?

13. Is there something else you want to add?