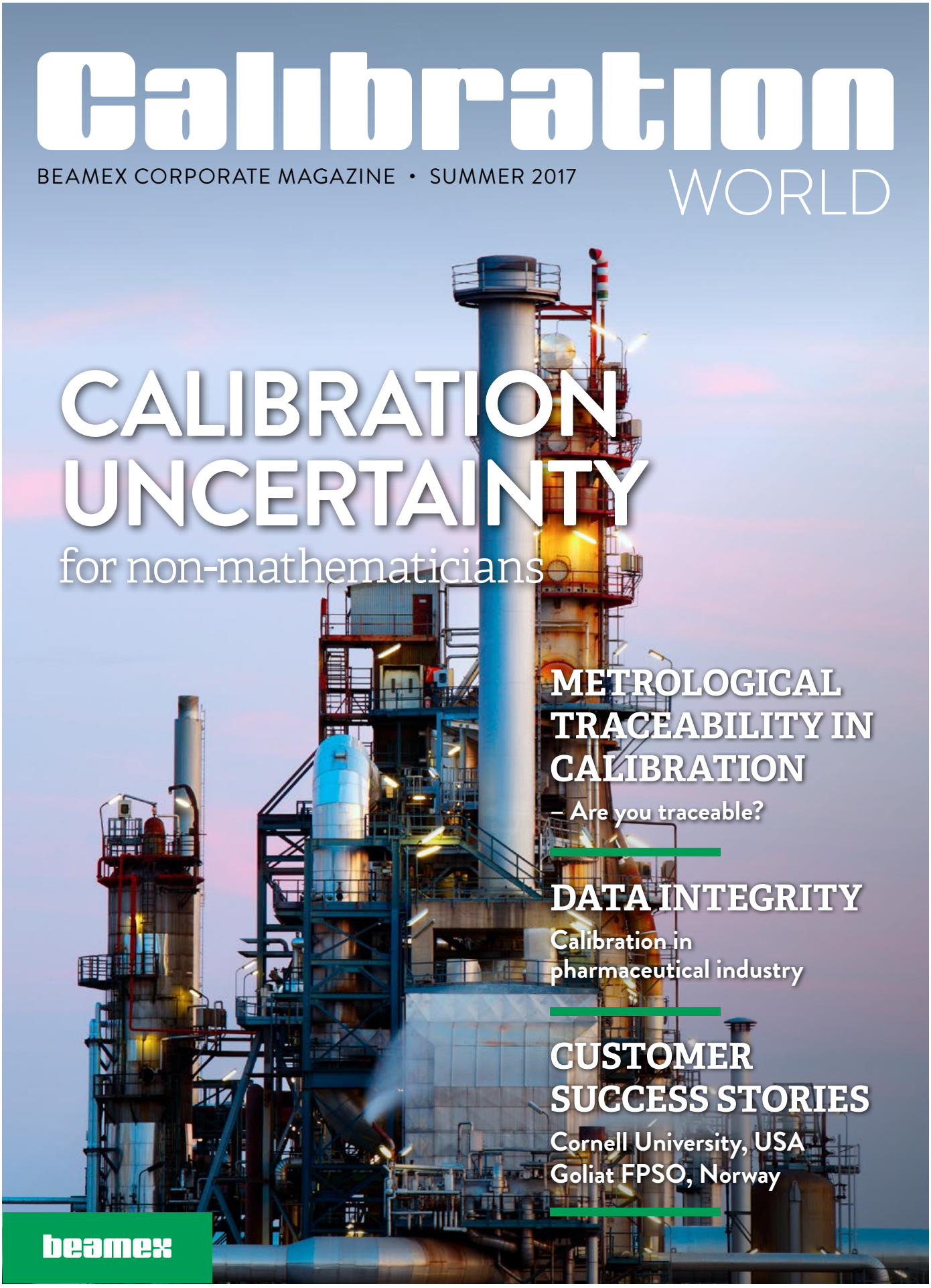
Calibration WORLD

BEAMEX CORPORATE MAGAZINE • SUMMER 2017



CALIBRATION UNCERTAINTY

for non-mathematicians

METROLOGICAL TRACEABILITY IN CALIBRATION

– Are you traceable?

DATA INTEGRITY

Calibration in pharmaceutical industry

CUSTOMER SUCCESS STORIES

Cornell University, USA
Goliat FPSO, Norway

beamex

CEO'S LETTER

Jan-Henrik Svensson
CEO, Beamex Group

In an ever-changing world, what do businesses need to think about when it comes to future success? Our new Beamex premises were inaugurated at the beginning of this year and even though this was a very important milestone for us as a company, I was personally even more energized by our workshop covering future technology and mega trends, and how we expect these to impact calibration. To summarize my thoughts a few months later on, I would state that there are (at least) three mega trends that will impact the way we work – even in our geeky calibration world:

Internet of Things, the connected factory, Smart Factory, Industry 4.0 – these all confirm that soon everything will be connected to the Internet, even calibrators. **Big Data** – manufacturing industries will increase efficiency and productivity by collecting, processing and measuring big data in real time. In the future, everyone will implement big data and predictive maintenance technologies in every area of manufacturing process including calibration. **Regulation** – increasing need for regulatory compliance will drive process industries to adapt new systems and processes to achieve compliance while still maximizing productivity and profitability. And of course, regulation has always been tightly coupled with calibration.

In an ever-changing world, is anything constant then? With all these thrilling changes happening, it is somehow calming for me to realize that some things do not change: calibration is, and will always be, about establishing trust; trust in data, trust in measurement and trust in traceability. As it happens, you can learn more about all the above mentioned in this issue of Calibration World. And if you're a more hands-on kind of person, you have the chance to improve your calibration know-how by participating in Beamex Interactive Workshop at Harvard University on August 2nd – 3nd where you will learn about best practices from calibration experts.

I am confident that we at Beamex are ready to assist you in welcoming these mega trends with open arms and to incorporate the changes they bring with them in a better way whenever you consider the time is right at your own plant. In this issue, you can read about how two very different customers – a U.S. university and the world's largest FPSO, Goliat – improved their calibration processes by implementing Beamex calibrators and software.

Enjoy your reading and remember that we very much appreciate your feedback on the magazine! You can contact us via our social media channels (Twitter, LinkedIn or Facebook), the Beamex blog, e-mail or why not give us a call.

CALIBRATION WORLD

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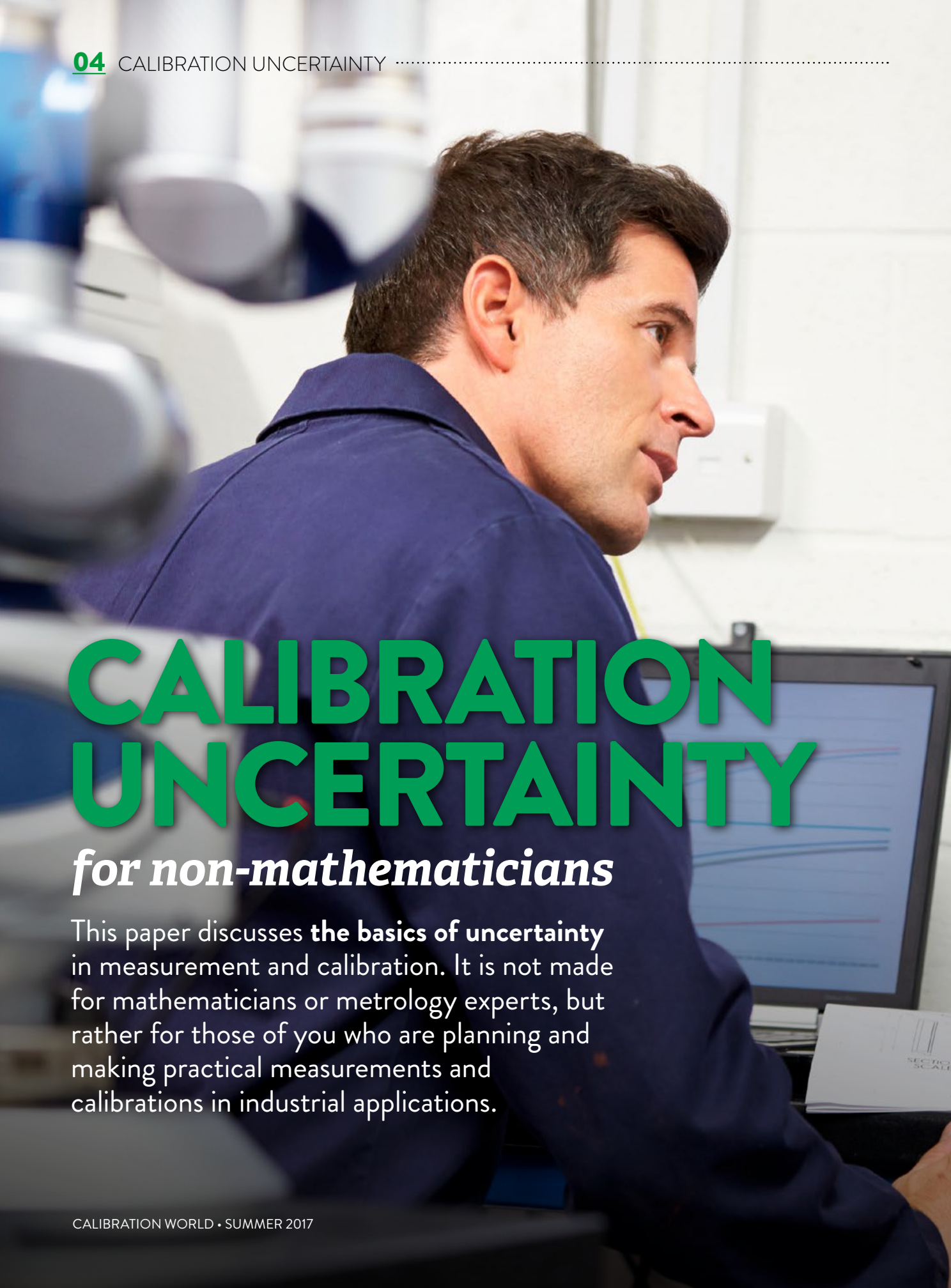

CALIBRATION UNCERTAINTY

for non-mathematicians

This paper discusses **the basics of uncertainty** in measurement and calibration. It is not made for mathematicians or metrology experts, but rather for those of you who are planning and making practical measurements and calibrations in industrial applications.


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PAPER

CALIBRATION UNCERTAINTY

for non-mathematicians

Being aware of the uncertainty related to the measurement is a very fundamental concept. **You should not really make any measurements unless you are aware of the related uncertainty**. Generally speaking, it seems that the awareness and interest of uncertainty is growing, which is great.

The uncertainty of measurements can come from various sources, such as the reference measurement device used for making the measurement, from environmental conditions, from the operator making the measurements, and from many others sources.

There are several calibration uncertainty guides, standards and resources available, mostly full of mathematical formulas, so in this article I will try to keep the mathematic formulas to a minimum.

This is a practical guide to gain some general understanding in the great world of uncertainty in measurements and calibrations.

CLASSIC "PIECE OF STRING" EXAMPLE

Let's start with an example to illustrate the measurement uncertainty in practice; the example is to give the same piece of a string to three persons (one at a time) and ask them to measure the length of that string. With no additional instructions given. They can all use their own tools and methods to measure it.

More than likely, as a result, you will get three somewhat different, such as:

- The first person says it is about 60 cm. He used a 10 cm plastic ruler, measured the string once and came to this conclusion.
- The second person says it is 70 cm. He used a three meter measuring tape and checked the results a couple of times to make sure he was right.
- The third person says it is 67.5 cm, with an uncertainty of ±0.5 cm. He used an accurate measuring tape and measured the string multiple times to get an average and standard deviation. Also, he tested how much the string stretches when it is pulled and noticed that this had a small effect on the result.

Even this simplified example shows that there are many things that affect the result of a measurement; the measurement tools that were used, the method/process that was used and the way the person did the job.

So, the question you should be asking yourself is:

When calibration work is performed at your plant, which of these three examples sound the most familiar to you?

What kind of "rulers" are being used at your site and what are the measuring methods/processes?

If you just measure something once without knowing the related uncertainty, the result is not worth much.

VERY SHORT TERMINOLOGY COURSE

Let's take a very brief look into the essential terms related to this subject.

So, what is the ***uncertainty*** of measurement? We can simply say that it is the "doubt" of our measurement, meaning that it tells us how good our measurement is. Every measurement we make has some "doubt", and we should know how much this "doubt" is, in order to decide if the measurement is good enough for the purpose.

It is good to remember that error is not the same as uncertainty. When we compare our device to be calibrated against the reference standard, the error is the difference between these two measurements. But the error does not have any meaning unless we know the uncertainty of the measurement.

So I would like to say that:

If you don't know the uncertainty of the measurement, don't make the measurement at all!

Too often we have seen, for example, that when a person is making an important temperature measurement in his process with, say, ±1.0 °C acceptance limit, and finds a maximum error of 0.5 °C, he is happy and says it "passes" and accepts the result. Although, after analyzing the calibration process, he could find that the total uncertainty of his measurement process is ±2.0 °C. So the way the calibration was done was not good enough for this application.

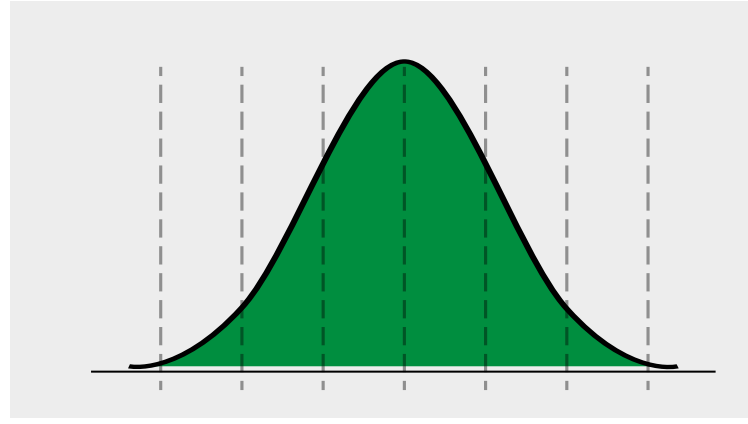
But ***as long as he did not know/care about the uncertainty, he could claim that it was a good "passing" calibration***, although in reality, it failed.

FROM MAKING A SINGLE MEASUREMENT TO KNOWING YOUR STANDARD DEVIATION

So, what should you do to start the journey towards being aware of all the related uncertainties?

The first simple, yet good, practice is that when you normally make a measurement/calibration once, try instead to repeat the same measurement several times. Most likely you will discover small differences in the measurements between the repeats. But which measurement is the correct one?

Without diving too deep into statistics, we can say that it is not enough to measure only once. If you repeat the same measurement several times, you can find the average and the standard deviation of the measurement. So you will learn how much the results can differ between repeats. This means that you can find out what is the normal difference between measurements.



PIC 1. Standard deviation of your calibration process.

It is suggested to make a measurement multiple times, even up to ten times, for it to be statistically reliable enough to calculate the standard deviation. These kind of uncertainty components that you get by calculating the standard deviation, are called the ***A-type uncertainty***. (***SEE PIC. 1***)

You may say: ***What???*** – Always repeating the same measurement ten times is just not possible in practice!

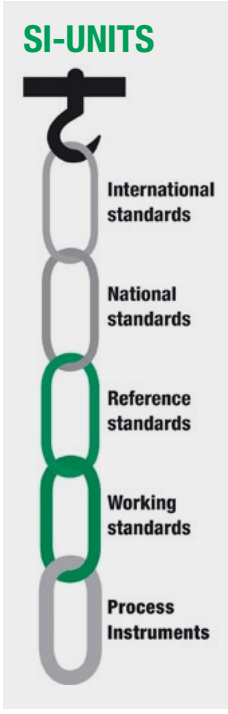
Luckily you don't always need to make ten repeats, but you should still experiment with your measurement process by sometimes making several repeats of the same measurement.

This will tell you what the typical deviation of that whole measurement process is and you can use this knowledge in the future as an uncertainty component related to that measurement, even if you just make the measurement once during your normal calibration.

Imagine that you would perform a temperature measurement/calibration multiple times and you would learn that there could be a ±0.2 °C difference between the repeats. Next time you made the same measurement, even if you made it just once, you would be aware that there is this ±0.2 °C possible difference. You could take this difference into account while not letting the measurement get too close to the acceptance limit.

So if you keep calibrating similar kinds of instruments over and over again, it is often enough to make the measurement just once and use the typical experimental standard deviation. Of course, you need to do your homework and make the measurements and the calculations to find out the typical standard deviation of that instrument type and that calibration process.

In summary, ***you should always be aware of the standard deviation of your calibration process – it is one part of the total uncertainty***.



PIC 2. One of the biggest sources of uncertainty comes from the reference standard (or calibrator) that you are using in your measurements/calibrations.

YOUR REFERENCE STANDARD (CALIBRATOR) AND ITS TRACEABILITY

Often, ***one of the biggest sources of uncertainty comes from the reference standard*** (or calibrator) that you are using in your measurements/calibrations. Naturally to start with, ***you should select a suitable reference standard for each measurement***. It is also important to remember that it is not enough to use the manufacturer's accuracy specification for the reference standard and keep using that as the uncertainty of the reference standards for years. Instead ***you must have your reference standards calibrated regularly*** in a calibration laboratory that has ***sufficient capabilities (uncertainty small enough)*** to calibrate the standard and to make it traceable. Pay attention to the total uncertainty of the calibration that the laboratory documented for your reference standard. Also, you should ***follow the stability of your reference standards*** between its regular calibrations. After some time, you will learn the true uncertainty of your reference standard and you can use that information as the uncertainty of your reference standard in your calibrations. (***SEE PIC. 2***)

OTHER UNCERTAINTY SOURCES

In the previous section I suggested that you repeat the measurement several times. But how about if you ask ***a few of your colleagues to repeat that same measurements?*** Do you all get the exact same results? Often there are some differences between the different persons making the measurement. So, does it mean that the person making the measurement also has an effect to uncertainty? – yes, it does. This is especially the case if the instructions are not at an appropriate level.

What if you make the same test and this time you ***use different kind of reference standards (calibrators) to make the measurement?*** Again, most likely you will find differences. If the reference standards have different levels of accuracy (uncertainty) you may even see relatively big differences. Often the reference standard (or calibrator) used to make the measurement can be ***one of the biggest sources of uncertainty!***

Different environmental conditions may add additional uncertainty in certain calibrations. If you need to read some form of analog display (analog gauge, temperature meter), you have limited ***readability***, i.e. you can only read it to certain accuracy and there is a possibility to read it incorrectly (wrong viewing angle) which ads uncertainty. In case of digital readouts, the ***resolution*** (number of decimals) is always limited, which causes uncertainty (you can only read to the last decimal).

There are different technical aspects in the calibration process, applications and quantities that create additional uncertainties. For example, in temperature calibration, it is imperative to wait long enough for the temperature to stabilize and to assure proper probe immersion into temperature block; in flow calibration you need to ensure a stable flow; in pressure calibration you must avoid any leaks and have a stable pressure, etc. Generally, any fluctuations or changes in the variable to be measured will cause additional uncertainty.

There are also some ***random variables*** that throw in some additional spices to the soup.

Also, you can use the e***xperimental standard deviation*** mentioned earlier as one uncertainty component.

So we can shortly summarize these additional sources of uncertainty:

- Device under test
- Reference standard (calibrator)
- Method/process for making the measurements/calibrations
- Environmental conditions
- The person(s) making the measurements
- Additional uncertainty components depending on the quantity being measured/calibrated

All of these above listed uncertainty components are referred as the ***Type B uncertainty***.

ADDING UNCERTAINTIES TOGETHER => COMBINED UNCERTAINTY

The type A (standard deviation) is something you can calculate, but often some of the various type B uncertainties needed to be estimated. Once standard deviation is calculated and the various Type B uncertainties are estimated, it is time to add them together. Before that you need to make sure that all uncertainties are in the same quantity/unit. Also, the uncertainties should have the same ***coverage factor / confidence level***.

When you add together uncertainty components that are independent from each other, don't just sum them all together, which would lead to the worst-case result. Instead, add the components together using the ***root sum of the squares*** method. That means, square each component, sum them together, then finally take the square root of the total sum. Although I said no formulas, maybe it is anyhow easier to understand this with a relatively simple formula:

Total uncertainty=

$$\sqrt{u_{(1)}^2 + u_{(2)}^2 + \ldots + u_{(n)}^2}$$

Where each "u" is one independent uncertainty component.

COVERAGE FACTOR/CONFIDENCE LEVEL

When uncertainty is determined, it is typically multiplied with a ***coverage factor (k)***. Most often the combined uncertainty is multiplied with 2 (k=2 or 2 sigma). This multiplication is done in order to have greater ***confidence level*** of the result. When the coverage factor of 2 is used, it equals a confidence level of 95% since we are dealing with statistical data. According to a ***normal (Gaussian) distribution***, 95% of the results are within the 2 sigma range. So in practice when using the 2 sigma, 95% of the results will be within the given uncertainty budget. Different sigma values give the following confidence levels: (***SEE PIC. 3***)

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

When you add different uncertainty components together, make sure they are all the same 1 sigma values before adding them.

EXPANDED UNCERTAINTY

Before the combined uncertainty component is published, you need to multiply the result with the selected sigma value in order to get the required confidence level. After you have done the multiplication, what you get is called ***expanded uncertainty***, i.e. uncertainty with certain confidence level included.

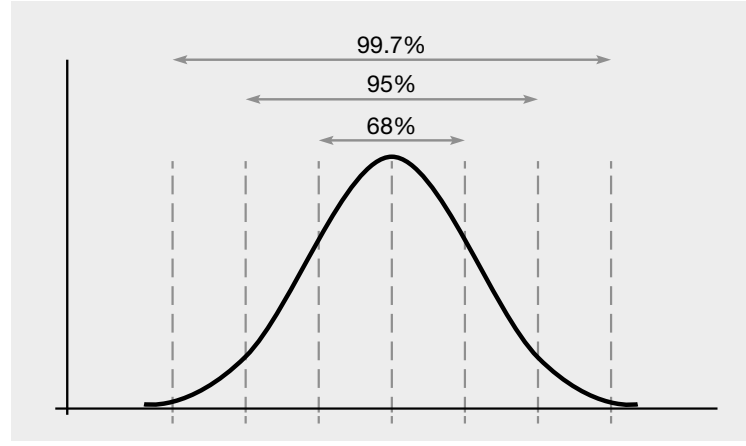
HOW TO EXPRESS UNCERTAINTY IN RESULTS OR CALIBRATION CERTIFICATE

In your calibration results, you should express the uncertainty as a ± value and also mention the coverage factor/confidence level. For example you can say that the temperature is: 20.5 °C with uncertainty ±0.1 °C (k=2).

COMPLIANCE STATEMENT – PASS OR FAIL

Most often the calibration of an instrument includes an acceptance criteria, i.e. there are limits within which the result is considered being ***passed*** and outside of which it is considered being ***failed***. There are different interpretations if/how the uncertainty should be taken into account when deciding for Pass/Fail.

Let's use some examples to study different cases. In the figure to the right, the diamond shape illustrates the measurement result and the line above and below indicates the total uncertainty for that measurement (***SEE PIC. 4***).



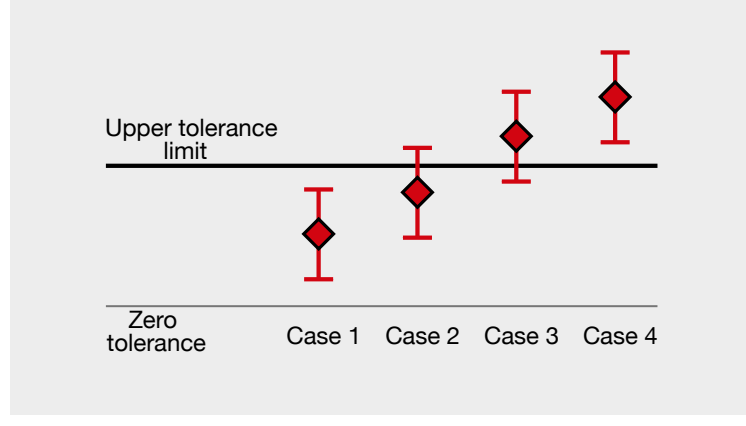
PIC 3. Normal (Gaussian) distribution.

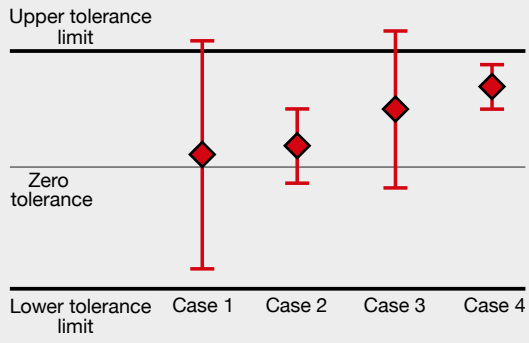
We can interpret the different cases above as follows:

- **Case 1**: This is pretty clearly within the tolerance limits, even when uncertainty is taken into account. So we can state this as a good "Pass" result.
- **Case 4**: This is also a pretty clear case. The result is outside of the tolerance limits, even when uncertainty is taken into account. So we can state this being a bad or "Fail" result.
- **Case 2** and **Case 3**: These cases are a bit more difficult to judge. Sure it seems that in case 2 the result is within the tolerance while in case 3 it is outside, especially if you don't care about the uncertainty. But taking the uncertainty into account, we can't really say this with confidence.

There are regulations (for example; ILAC G8:1996 - Guidelines on Assessment and Reporting of Compliance with Specification; EURACHEM / CITAC Guide: Use of uncertainty information in compliance assessment, First Edition 2007) for how to state the compliance of calibration. These guides suggest to state a result as "passed" only when the error added with

PIC 4. Most often the calibration of an instrument includes an acceptance criteria.





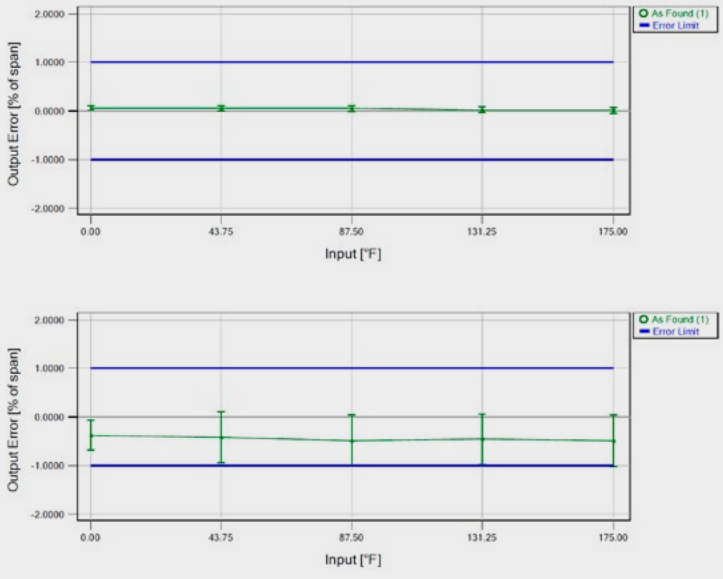
PIC 5. Uncertainty examples.

uncertainty is less than the acceptance limit. Also, they suggest to state "failed" only when the error added (or subtracted) with the uncertainty is bigger than the acceptance limit. When the result is closer to the acceptance limit than half of the uncertainty, it is suggested to be called an "undefined" situation, i.e. you should not state pass or fail.

We have seen many people interpreting the uncertainty and pass/fail decision in many different way over the years. In practice, the uncertainty is most often not taken into account in the pass/fail decision, but it is still very important to be aware of the uncertainty when making the decision.

UNCERTAINTY EXAMPLES

In the graphics below, there are some examples of what different uncertainties can mean in practice.



PIC 6. Real-life examples using two different calibrators.

> "How many times more accurate should the calibrator be, compared to the device to be calibrated?" While some suggestions could be given, there isn't really any correct answer to that question. Instead you should be aware of the total uncertainty of your calibrations. And of course, it should reflect to your needs!

The cases 1 and 2 have the same measurement result, so without uncertainty we would consider these being the same level measurements. But when the uncertainty is taken into account, we can see that case 1 is really terrible because the uncertainty is simply too large to be used for this measurement with the given tolerance limits.

Looking at case 3 and 4 it seems that case 3 is better, but with uncertainty we can see that it is not good enough for a pass statement, while case 4 is. (***SEE PIC. 5***)

Again, I want to point out that ***we need to know the uncertainty before we can judge a measurement result***.

Without the uncertainty calculation the above cases 1 and 2 look similar, although with uncertainty taken into account they are very different.

A REAL-LIFE EXAMPLE

Below is a real-life example where the same RTD temperature transmitter has been calibrated using two different calibrators. These graphics were produced using Beamex CMX calibration management software (***SEE PIC. 6***). You can easily see that in the first case,the results are very good and the green vertical uncertainty line is very short, indicating a very small uncertainty. In the second case, you can see that the result is a little bit worse, but the uncertainty of that calibrator is much worse.

Well, needless to say, that the first case is done with a Beamex calibrator... ;-)

Anyhow, when you see the uncertainty graphically it is very easy to notice the significance of it.

TUR / TAR RATIO VS. UNCERTAINTY CALCULATION

The ***TUR (test uncertainty ratio)***, or ***TAR (test accuracy ratio)***, is often mentioned in various publications. In short, this means that if you want to calibrate a 1% instrument and you want to have 4:1 ratio, your test equipment should be 4 times more accurate, i.e. having 0.25% accuracy, or better. Some publications suggest that having a TUR/TAR ratio large enough, eliminates the need need to worry about uncertainty estimation/calculation. The quite commonly used ratio is 4:1. Some guides/publications do also have recommendations for the ratio.

Most often the ratio is used as in the above example, i.e. just to compare the specifications of the DUT (device under test) and the manufacturer's specifications of the reference standard. ***But in that scenario you only consider the reference standard (test equipment, calibrator) specifications and you neglect all other related uncertainties***. While this may be "good enough" for some, calibrations, this system does not take some of the biggest sources of uncertainty into account. So it is highly recommended to make the uncertainty evaluation/ calculation of the whole calibration process.

We also get asked quite regularly: "How many times more accurate should the calibrator be, compared to the device to be calibrated?". While some suggestions could be given, there isn't really a correct answer to that question. Instead you should be aware of the total uncertainty of your calibrations. And of course, it should reflect to ***your needs!***

RESOURCES & SUMMARY

SUMMARY

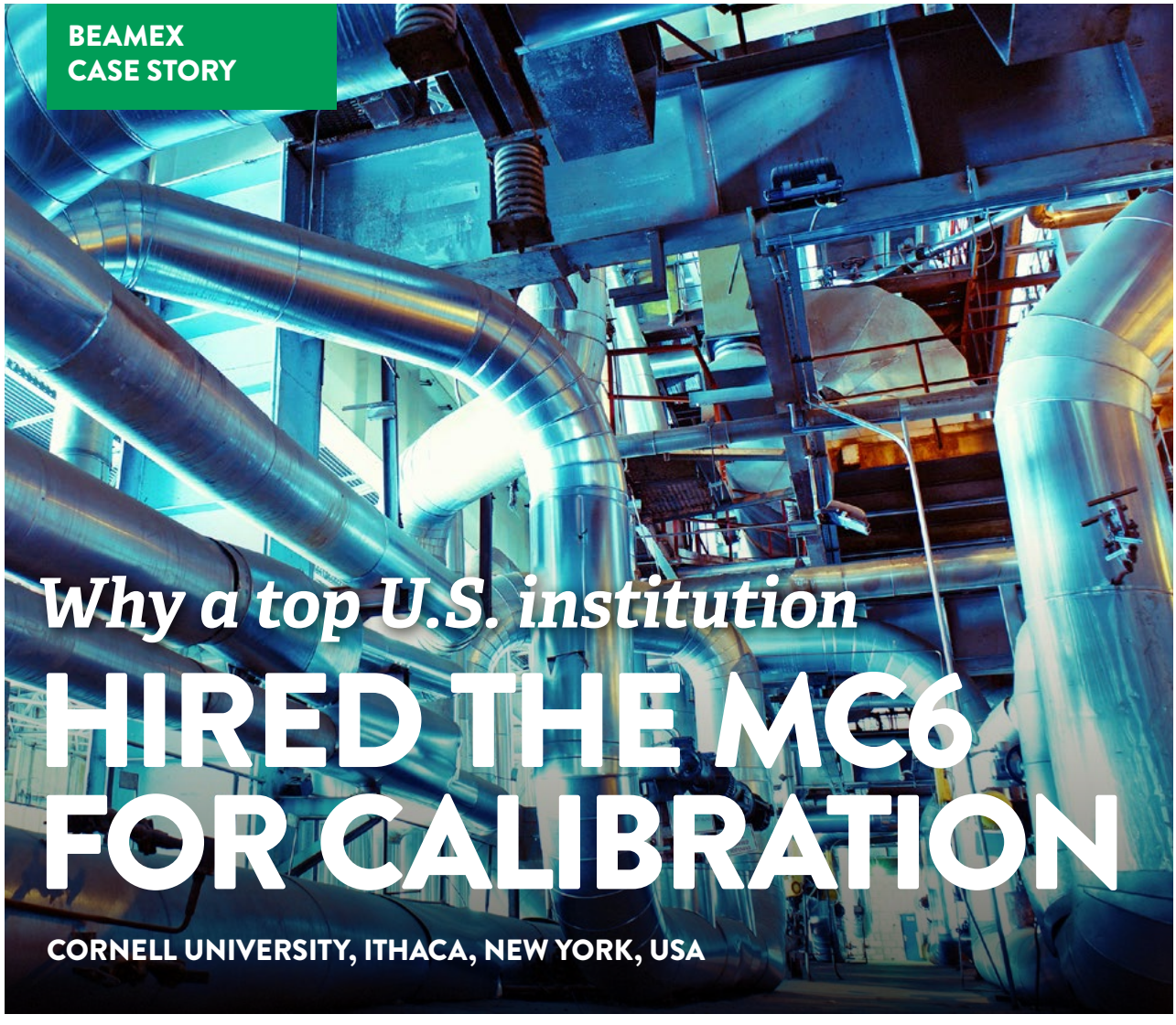
I hope this paper helped to give some practical understanding of the uncertainty subject.

To very shortly summarize the key take-outs of some of the main topics:

- Be sure to distinguish "error" and "uncertainty"
- Experiment by making multiple repeats of measurements to gain knowledge of the typical deviation
- Use appropriate reference standards (calibrators) and make sure they have a valid traceability to national standards and that the uncertainty of the calibration is known and suitable for your applications
- Consider if the effect of the environmental conditions have a significant effect to the uncertainty of your measurements
- Be aware of the readability and display resolution of any i ndicating devices
- Study the specific important factors of the quantities you are calibrating
- Familiarize yourself with the "root sum of the squares" method to add independent uncertainties together
- Be aware of the coverage factor / confidence level / expanded uncertainty, of the uncertainty components
- Instead, or in addition to the TUR/TAR ratio, strive to be more aware of all the related uncertainties
- Pay attention to the total uncertainty of the calibration process before making pass/fail decisions

If you have any comments or questions, and I hope you do, we are very happy to hear from you!

Contact us, **www.beamex.com**
or **marketing@beamex.com**



BEAMEX CASE STORY

Why a top U.S. institution HIRED THE MC6 FOR CALIBRATION

CORNELL UNIVERSITY, ITHACA, NEW YORK, USA

Located in Ithaca, New York, **Cornell University** is a private, Ivy League research university that is widely and consistently recognized as one of the top 10 research universities in the United States and one of the top 20 universities in the world. The school's mission is to make contributions in all fields of knowledge to help improve the quality of life in the state, the nation and the world.

Much has developed throughout the years since its foundation in 1865, including the property infrastructure. The university has created, maintained, and produced power and water for the campus for more than 100 years. Today, Cornell University's campus includes 608 buildings on more than 2,000 acres, enrolls 21,000+ students and employs 9,000+ faculty and staff.

CORNELL ENERGY RESOURCES

Cornell represents 1/1000th of the state of New York's electricity load, which makes an ideal test bed for sustainable energy solutions. The Central Energy Plant (CEP) provides all the power and energy services, like steam and chilled water. Additional facilities associated with CEP include:

Cornell Energy Resources

1. Central Heating Plant (CHP)
2. Combined Heat & Power Plant (CCHPP)
3. Co-generation facility (Co-Gen)
4. Lake Source Cooling (LSC)
5. Chilled Water Plant 3 (CWP3)
6. Water Treatment Plant (WTP)
7. Steam Condenser Building (SCB)
8. Maple Avenue Substation (MAS)

Kristopher Welfel, Senior Instrument and Control (I&C) technician, has worked in the maintenance field for over 20 years.

THE MAINTENANCE GROUP

Kristopher Welfel, Senior Instrument and Control (I&C) technician, has worked in the maintenance field for over 20 years. Currently, Kristopher, alongside a team of three additional I&C techs, maintains the 1,000+ primarily analog and HART transmitters and controls, including pressure, temperature, flow, differential pressure, level and switches, located throughout the CEP. Approximately 300 of the instruments are classified as critical and require documented calibration.

Not only is the group responsible for maintenance, but they are also responsible for commissioning. And last year, two new boilers were commissioned. Needless to say, this small group stays busy and works hard to execute all assignments in compliance with Cornell's high standards, known as the triple constraints: safety, reliability and efficiency.

In short, as Kris emphasizes, "I am extremely proud to work for Cornell and proud of the amount of work we execute with our small team. We maintain all the utility buildings with just our group, which is unfathomable to some people. We keep the systems not only running, but reliable, efficient and above all, safe."

CALIBRATION THEN AND NOW

A few years ago, while attending a training class at the International Society of Automation (ISA), Kris experimented with the Beamex MC6 field calibrator and communicator as well as temperature blocks. Upon using this advanced technology, he realized that there was an opportunity to utilize more robust solutions to help improve the CEP's calibration program. At that time, the CEP's process consisted of an assortment of equipment and technology:

- Handheld calibrator
- Handheld communicator
- Hand pump (pressure calibrations)
- Decade resistance box (temperature calibrations)
- Handheld computer with asset management software

Predominantly due to the amount of single-function equipment that had to be carried, it took 3 to 4 techs to perform a single calibration. As Kris describes, "the calibration wasn't so hard, it was just all the equipment we had to carry." Furthermore, these multimanned calibrations were then followed by tedious, manual entry work to get the calibration data, vital for documentation requirements, into the asset management software. The team found this work to be not only time consuming, which was a challenge for a small team already short on time, but also error-prone. Occasionally, calibration data was manually entered under the wrong instrument record, which caused data reliability issues. Keeping in mind the daily challenges at CEP and after experiencing this type of advanced

> So far, we've at least cut **the time in half** for most calibrations and seen the biggest difference with temperature calibrations. We've cut the time it takes to perform those by two thirds.

The automated flow of calirbation results from the calibrator to CMX mitigates human error.

technology while at ISA, upon his return to work, Kristopher was inspired and motivated to improve their processes. He began by outlining the objectives and specifications:

- Minimize the amount of equipment needed in the field
- Invest in reliable, accurate and easy to use equipment
- Utilize equipment that offers versatile and smart communication capability
- Investigate calibration software to store detailed data and allow for instrument trending
- Eliminate manual entry of data to save time
- Automate the process to reduce the risk of errors

After researching, requesting information, support, and quotations from major vendors, he determined that the Beamex integrated calibration solutions best fit their needs for several reasons:

- Multi-functional, "grab & go" capability of the MC6: calibrator and built-in HART communicator would allow them to take less equipment into the field
- User-friendliness and intuitive nature of the MC6 allowed the technicians to perform basic calibrations without any training.
- CMX calibration software allowed detailed data storage capability and history trending functionality that was not possible in their current asset management software
- Automated data flow of calibration results from the calibrator to CMX would mitigate human error

> "What used to take three or four of us to do in the past, can be done by one, maybe two of us now. **Just the Beamex MC6 alone**, is like having another technician on staff."

When Kris presented his case for the new hardware to management, there were glaringly easy-to-see benefits of how an all-in-one, multi-functional, reliable piece of equipment could help the I&C team. However, with an asset management software already in place, they did not immediately understand the need for calibration software. With some effort, he was able to communicate the functionality differences between an asset management software and calibration software. Ultimately, management realized that the existing asset management software was not designed for their calibration needs. There was more value in CMX from the automated data

flow to history trending reporting, to calibration certificate generation that an asset management software simply could not offer. As Kris simply articulates, "the hardware is great and it could be used without the calibration software. But, I couldn't imagine having to manually input the information into the asset management software like we used to. It would be a nightmare."

THE RESULTS

Sometimes it best to hear it straight from the source. Kris states, "so far, we've at least cut the time in half for most calibrations and seen the biggest difference with temperature calibrations. We've cut the time it takes to perform those by two thirds. Who knows where we will be a year from now. Just this morning, we had to commission two Fisher Control valves. The first one took a few extra minutes. The second one was done in a third of the time." This example illustrates the quick proficiency that comes from using the equipment on different types of instruments. He goes onto explain, "Before the investment in Beamex solutions, we had discussed hiring another I&C tech. A short time ago, I asked my boss if we were still planning to hire more help. He said, we already did; we bought the MC6. All joking aside, he is right--- what used to take three or four of us to do in the past, can be done by one, maybe two of us now. Just the Beamex MC6 alone, is like having another technician on staff."

CASE STORY IN BRIEF

CORNELL UNIVERSITY

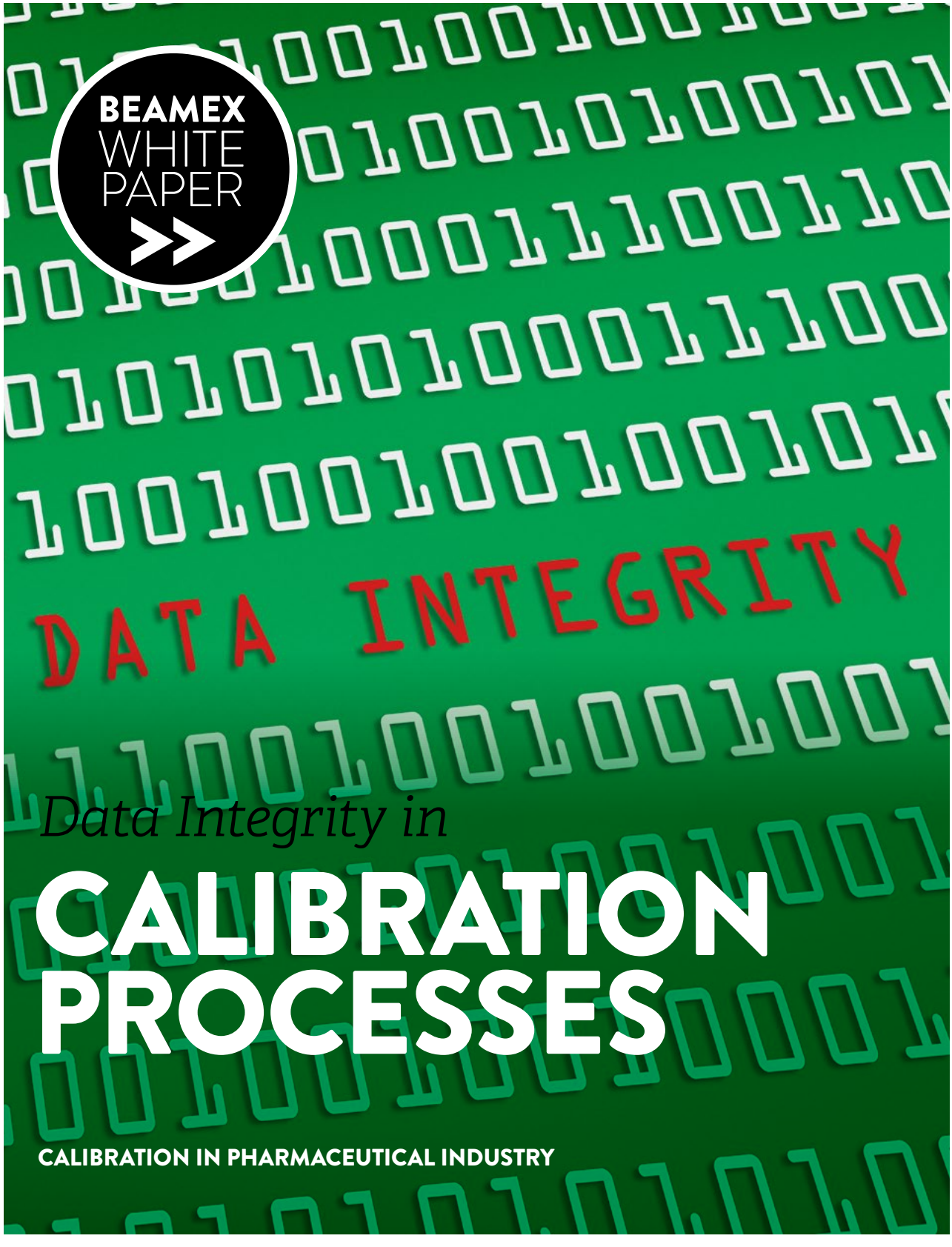
CORNELL UNIVERSITY
ITHACA, NEW YORK, USA

DESCRIPTION

- Beamex MC6 advanced field calibrator and communicator
- Beamex CMX calibration management software
- Beamex professional services: product training

MAIN BENEFITS

- User-friendly and intuitive integrated solutions allow ease of use for all technicians
- Automated documentation of calibration results minimizes the risk of human error and saves time
- All-in-one functionality of the MC6 requires less personnel to perform calibrations and less equipment to be carried into the field
- Improved data management and historical analysis functionality with a dedicated calibration software allows effortless record keeping and enables better strategic decision-making



Data Integrity in

CALIBRATION PROCESSES

CALIBRATION IN PHARMACEUTICAL INDUSTRY

As a concept, **data integrity** is by no means a new one, it has been around for several decades. Anyhow, in this article, we look at data integrity more from the calibration process point of view, and focus mainly on the pharmaceutical and regulated industry.

At first we take a look at the data integrity generally; what it is, why it is important and what a breach could cause. The ALCOA plus concept is also briefly discussed.

I remember in the early 90's when we had some pharmaceutical customers auditing us prior to a calibration software purchase, and data integrity was already then one of the normal topics discussed during such a supplier audit. So it is not a new topic.

IT'S ALL ABOUT TRUST

Often, when we buy an everyday product, we can quickly see if the product is operating properly, or if it is faulty. For example, if you buy a new TV and turn it on, you can quickly see if it working or not. But with different products it is not so easy to see if you have a proper product. This is especially the case with medicines. When you pick up a medicine, how do know that it is a product working properly according to design specifications? In most cases you can't tell that, so it is all about trust – you must be able to trust that the medicine you take is a proper one.

Data integrity is fundamental in a pharmaceutical quality system to ensure that products are of the required quality.

WHAT IS DATA INTEGRITY?

Data integrity is fundamental in a pharmaceutical quality system ensuring that products are of the required quality.

In every process, there is a lot of data produced. Data integrity is the maintenance of, and the assurance of the accuracy and consistency of the data over its entire life-cycle. It is a critical aspect to the design, implementation and usage of any system which stores, processes, or retrieves data. The term "data integrity" is widely used and has different meanings in different contexts. The term itself is pretty old and was initially used in computing. The integrity of the data collected and recorded by pharmaceutical manufacturers is critical to ensuring that high quality and safe products are made. To ensure the integrity of data, it should be protected from accidental or intentional modifications, falsification and deletion.

With many processes in the process industry, you cannot just simply test the final product to see if it is a proper one. Instead you must assure that the conditions during the process are correct in order for it to produce the right product. These critical conditions must be recorded and maintained to assure that they are correct. This is certainly the case in many processes in a pharmaceutical plant.

WHY IS DATA INTEGRITY IMPORTANT AT THE MOMENT?

Data integrity has recently risen to become an even more important topic than before.

With many processes, you cannot just simply test the final product to see if it is a proper one.

Data integrity related violations have led to several regulatory actions such as warning letters and import alerts. Actually, a large number of the recent warning letters issued by FDA are somehow related to data integrity.

As international regulatory agencies have more focus on data integrity, the FDA, WHOA and MHRA auditors have been trained to better recognize data integrity issues.

MHRA (Medicines & Healthcare products Regulatory Agency in UK) has recently released new guide "GMP Data Integrity Definitions and Guidance for Industry" (March 2015). There is a deadline set for pharmaceutical companies to comply at the end of 2017. Also, FDA has released "Data Integrity and Compliance With CGMP - Guidance for Industry" (April 2016). This is still in draft mode but has been on comment rounds. Both of these will naturally have an effect on the pharmaceutical industry. Sure, there has been guidance for the good manufacturing practice (CGMP) regarding data integrity related issues in the past, such as 21 CFA parts (210,211, and 212) but these newly mentioned updates will raise the focus.

One additional reason why more focus has been on data integrity is the increased use of mobile devices in calibration processes. This includes applications used in tablets and mobile phones. It also includes the increased use of documenting calibrators, which automatically store the calibration results in their memory and transfers this data to calibration software. Since the use of automated documenting calibrators will improve the business case of a calibration system, they are being more widely used. To learn more on what a documenting calibrator is and how it benefits the calibration process, please check the blog post: What is a documenting calibrator and how do you benefit from using one?

As results of all these, data integrity is getting more and more acute.

IMPACTS OF BREACH OF DATA INTEGRITY

The impact of breach of data integrity can be looked at the impact to customer and impact to the pharmaceutical company.

For the customer the impact can be that the medicine does not have the required effect, patient safety can be compromised and in the worst case it can even cause the loss of lives.

For the pharmaceutical company the impact can be; warning letter from FDA, bans of license to produce, negative reputation, loss of customer confidence, reduction of market share, and reduction of share price.

ACCIDENTAL / INTENTIONAL

A breach of data integrity may be accidental or intentional. Often there are computerized systems involved that handle the data so the users may not be aware of any issues in such systems. Certainly the majority of data integrity issues are accidental and non-intentional. However, in looking at some of the FDA warning letters, it indicates that in the very worst cases there has been even intentional falsifying of records.

MAIN STEPS TOWARDS BETTER DATA INTEGRITY

Many pharmaceutical companies seem to agree that the main steps towards better data integrity are:

- Better education and communication
- Detection and mitigation of risks
- Focus on technology and IT systems
- Governance of data integrity

Validation is also something that is a must for any computerized system in the pharmaceutical industry. It is good to remember that ANSI defines systems as: people, machines and the methods organized to perform specific functions. So it is not only the computer system that needs to be validated.

ALCOA AND ALCOA PLUS

The acronym ALCOA has been around since the 1990's, being used by regulated industries as a

framework for ensuring data integrity, and is key to good documentation practice (GDP). ALCOA relates to data, whether paper or electronic, and is defined by FDA guidance as:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

The ALCOA plus ads a few attributes to the list:

- Complete
- Consistent
- Enduring
- Available

A brief description of these attributes are included in the table to the right.

WHAT COULD CAUSE DATA INTEGRITY ISSUES?

Some practical and general things that could cause data integrity issues in any systems are lack of training, user privileges, poor or shared passwords, control of a computerized system, incomplete data entry, and lack of audit data records for changes and modifications.

THE FIRST TRAP TO AVOID FOR CONSUMERS – FRAUD DRUGS

Although not really a data integrity issue for the industry, this is an important point for consumers. People are buying more from the internet nowadays and you can also buy medicines from internet, but unfortunately you don't always get what you order. A huge amount of medicines bought online are frauds. Sometimes packaging is obviously inappropriate and it is apparent that the medication is a fraud. Unfortunately that is not always the case and people do, at times, consume fraudulent medicine. It is clear that the fraudulent medication does not provide the expected cure, but it is also a big risk for our safety and at its worse, it may be even lethal.

NEW REGULATION FOR PRODUCT PACKAGING TO AVOID FRAUDS

To better control fraud drugs, the European Medicines Agency (EMA) has recently introduced a new regulation that will require all prescription drug makers in all (but three) EU (European Union) countries to incorporate new safety features on their product packaging by February 2019. The regulation, which is part of a broader effort to combat falsified medicines in the EU, will require drug makers to add a unique identifier and an anti-tampering device to the packaging of most centrally authorized products. This naturally adds another burden and cost for the drug manufacturers, to build the systems to support this, but this will certainly be beneficial for the customers. Although this specific regulation is for the European Union area, it will have a global effect.

ALCOA	ATTRIBUTE	DESCRIPTION OF ATTRIBUTE
A	Attributable	Who performed an action and when? If a record is changed, who did it and why? Link to the source data.
L	Legible	Data must be recorded permanently in a durable medium and be readable.
C	Contemporaneous	All data should be recorded at the time the work is performed. All date and time stamps should be in chronological order.
O	Original	Is the document the original (raw) data? This should be the first time the information is recorded. In some cases, the original may not be available, but a "certified true copy" is available e.g., a copy may be from a thermal printer and photocopied to preserve the printing. It should be signed and dated with wording that this is a certified copy.
A	Accurate	This refers to the data being entered without errors or editing. If editing occurred, it must be properly documented, e.g., audit trail, traceable to original data.
+	Complete	All of the data generated is included in the analysis. This includes all runs, whether good or bad. In some cases data may not be used in an analysis, but it is addressed in a deviation or investigation and shown to be invalid.
+	Consistent	This refers to the consistent use of date and time stamps and that the data is collected/reported in the proper sequence (as expected).
+	Enduring	The original data is recorded in controlled records, e.g., controlled (numbered) worksheets, laboratory notebooks (bound) or electronic media.
+	Available	One can access the data throughout the lifetime of the record (and the associated retention period required).

People are buying more from the internet nowadays and you can also buy **medicines online**, but unfortunately you don't always get what you ordered.

CONCLUSION

Although the data integrity concept has existed for a long time, it has recently risen to be more acute due to the use of mobile tools and the added focus of regulatory agencies. Although in the end, the concept of data integrity is common sense – to assure the integrity of data throughout its life cycle – when practiced using various systems and tools it gets more complicated. Since the impacts of the breach of data integrity can be enormous, it is something that needs to be a high priority.

USEFUL REFERENCES

DATA INTEGRITY

21 CFR Part 11, Electronic Records; Electronic Signatures:

http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

MHRA GMP Data Integrity Definitions and Guidance for Industry, March 2015:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/412735/Data_integrity_definitions_and_guidance_v2.pdf

Data Integrity and Compliance with CGMP Guidance for Industry DRAFT GUIDANCE, April 2016:

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm495891.pdf

FDA warning letters are public and can be found here:

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

European Medicines Agency (EMA), recent regulation for product packaging:

http://www.raps.org/Regulatory-Focus/News/2016/02/09/24281/EU-Regulation-Requires-New-Safety-Features-on-Drug-Packaging-by-2019/

CALIBRATION BEST PRACTICES
INTERACTIVE WORKSHOP

Beamex to host a two-day hands-on

INTERACTIVE WORKSHOP

at Harvard University

INTERACTIVE WORKSHOP
AUGUST 2nd–3rd
AT HARVARD UNIVERSITY

Beamex is excited to host the Calibration Best Practices: Interactive Workshop, which will be held Wednesday and Thursday August 2–3 2017, at Harvard University in Cambridge, MA, USA.

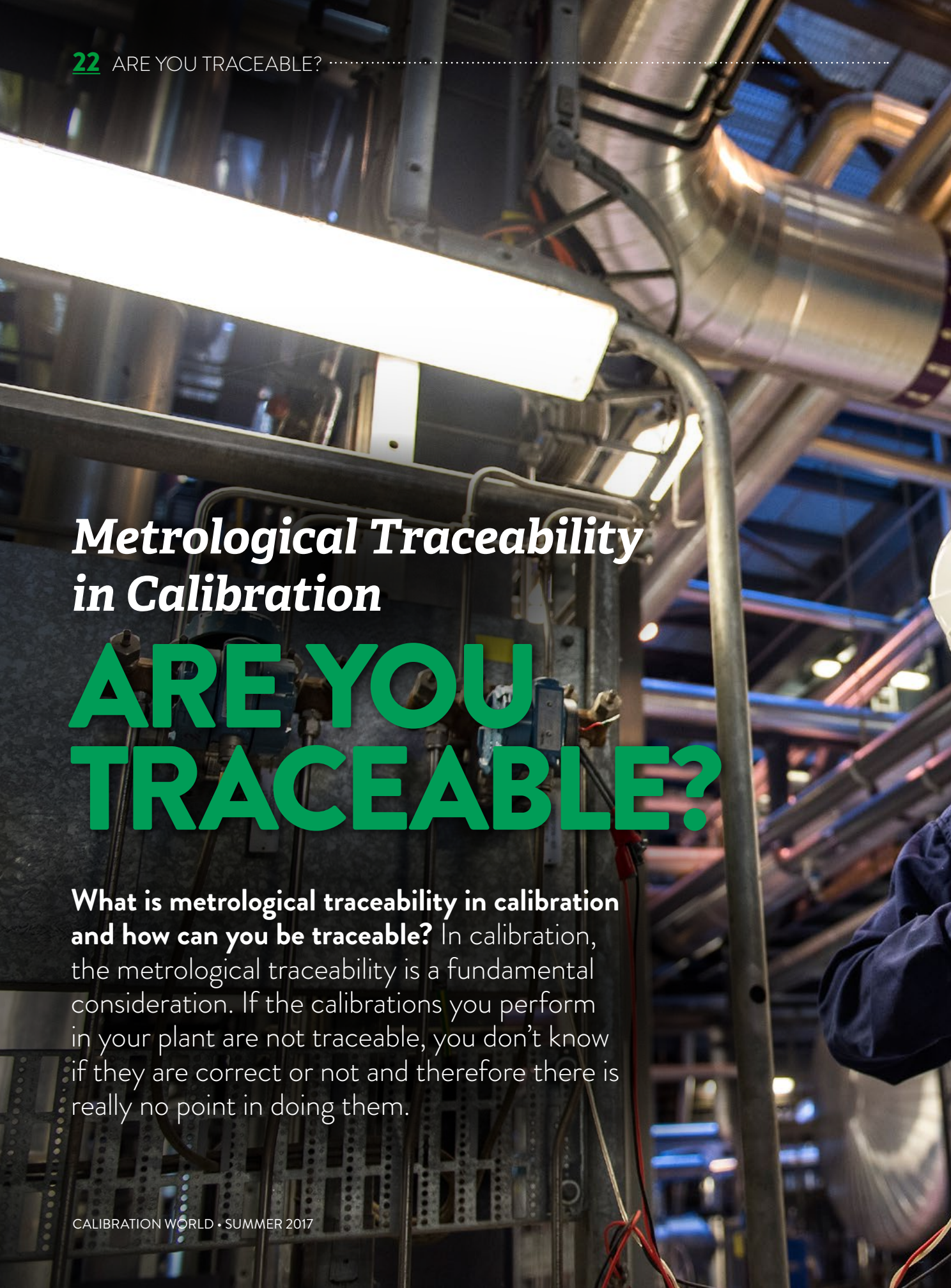
The workshop will explore the latest insights, trends and best practices for process plant managers, engineers and technicians seeking to improve calibration quality, safety, accuracy and efficiency. Experts with a combined 100+ years of calibration experience will discuss day-to-day challenges and how best to solve them through new and innovative strategies and advances in calibration technology—all designed to save time while achieving quality metrics and improving safety. Workshop participants will benefit from a highly interactive learning approach, providing the practical skills and know-how needed to improve daily maintenance processes and tasks.

The day of personalized instruction includes sessions like:

- Hands-on workshops (temperature and pressure calibration)
- How to eliminate calibration paperwork
- 5 insider secrets to integrating software systems
- Open discussion of complex calibrations

Registration includes access to all presentations, breakfast and lunch as well as a tour of the Blackstone Steam Plant. To reserve your spot, view details on the program, review a list of recommended hotels and more, visit the workshop website.

https://resources.beamex.com/interactive-calibration-workshop-2017



Metrological Traceability in Calibration

ARE YOU TRACEABLE?

What is metrological traceability in calibration and how can you be traceable? In calibration, the metrological traceability is a fundamental consideration. If the calibrations you perform in your plant are not traceable, you don't know if they are correct or not and therefore there is really no point in doing them.


Anders
BEAMEX
WHITE
PAPER

Metrological Traceability in Calibration

ARE YOU TRACEABLE?

In practice, you see terms such as **"Calibration Traceability," "Measurement Traceability,"** or sometimes just the word **"traceability"** is used, although it is formally most correct to talk about **"Metrological Traceability."**

Using just the word "traceability" may cause confusion as it relates also to many other contexts such as material traceability, document traceability, requirement traceability matrix etc.

In USA the ***"NIST traceability"*** is probably the most often used term. NIST (The National Institute of Standards and Technology) has adopted the VIM's (International Vocabulary of Metrology) international definition of metrological traceability, which is explained in the next chapter below.

Let's first take a look at the formal definition of metrological traceability and then discuss what you need to do in order to claim that the calibrations in your plant are traceable. (***SEE PIC. 1***)

FORMAL DEFINITION OF TRACEABILITY

The formal definition of metrological traceability:

> ***Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.***

This definition is based on the official definition in standards listed in the "references" chapter at the end of this article.

That definition sure has many fancy words, so I want to break it down to a level that is more practical and easier to understand.

CALIBRATION/METROLOGICAL TRACEABILITY CHAIN IN PRACTICE

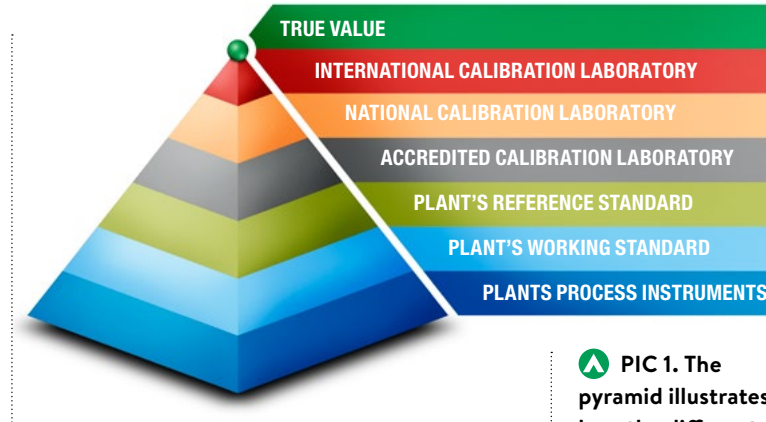
Let's take a look at what the metrological traceability and the traceability chain is in practice, in a typical process plant, looking from bottom to top:

- In your plant, you have many ***process instruments***, such as transmitters, that are calibrated regularly using your process calibrator, or similar measurement standard.
- The ***process calibrator*** is typically sent out to an external calibration laboratory for calibration, assuming it is the highest level reference standard in your plant.

PIC 2. The chain illustrates pretty well the fact that everything hanging below certain link is not traceable if that link is broken.

Alternatively, the process calibrator may also be calibrated internally in the plant, using a higher level reference standard.

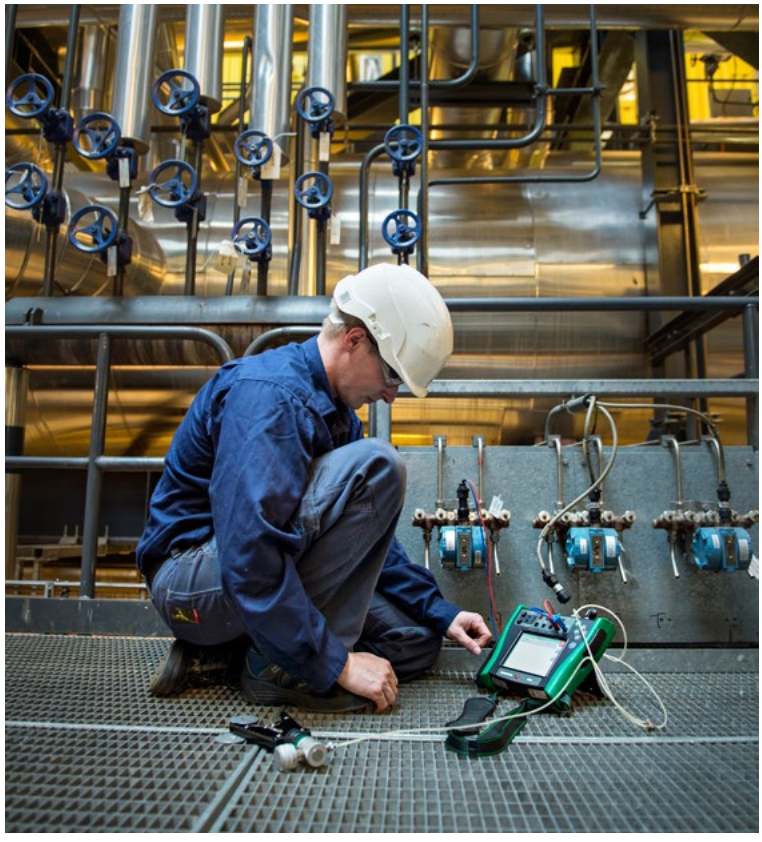
- The highest level ***reference standard(s)*** of your plant are sent out to an external calibration laboratory, preferably an accredited one, to be calibrated.
- The ***external calibration laboratory*** will calibrate their references to assure traceability to the National Calibration laboratory, or similar.
- The ***National Calibration laboratories*** work with international level laboratories and make comparisons with each other assuring that their calibrations are on the same level.
- The ***International level laboratories*** base their measurements on international comparisons, international definitions and realization of the International System of Units (SI system).



PIC 1. The pyramid illustrates how the different levels the traceability are located. As all your process instruments are located in the lowest level, their traceability is dependent on all the levels above.

The higher you go in the chain, ***the smaller the uncertainty*** is, or the better the accuracy is.

The above simplified practical example shows how a process measurement that you make in your plant is traceable up to an international level through an ***unbroken chain*** of measurements. The old worn-out saying "a chain is only a strong as the weakest link" is very much valid here. If any link in the chain is missing



It is good to remember that if the calibration is done without documented procedures in an environment without a Quality System, the calibration is not reliable and cannot be proven to be traceable.

(or overdue), all measurements below that level have no traceability and are subject to error.

There are conditions that need to be met before you can say that your process measurements are traceable, more on that in the next chapters.

WHEN CAN YOU CLAIM THAT YOUR MEASUREMENT IS TRACEABLE?

Timely calibrations

All the calibrations in the traceability chain have to be done on at regular intervals. It is not enough to have your reference standard calibrated once and then continue using it for years with re-calibrations. The calibration of any measurement device only remains valid for a stated period of time. Therefore, the ***traceability expires when the calibration expires***.

Every step needs to be documented

Every calibration in the traceability chain needs to be ***documented***. Not only does this mean that the calibration results are documented in the ***calibration certificate***, but also that the calibration procedure is done according to a ***written procedure*** based on the ***company's quality system***.

It is pretty clear that a calibration without a calibration certificate is not a proper calibration, and certainly is not a traceable calibration. It is also good to remember that if the calibration is done without documented procedures in an environment without a quality system, the calibration is not reliable and cannot be proven to be traceable.

Every step needs to include measurement uncertainty

As the definition says, it is also important that every calibration step in the traceability chain have the related ***measurement uncertainty documented***.

If the uncertainty information is missing from the calibration, you can't claim it is traceable. The main reason is that without knowing and documenting the uncertainty, you could calibrate an accurate measurement equipment with one that is less accurate. Or that the calibration procedure causes such a big uncertainty, that the calibration is neither good nor traceable.

CALIBRATIONS INSIDE YOUR PLANT

Typically the process plant's internal calibration activities are not accredited, meaning that they are not able to produce an accredited calibration certificate. This is perfectly fine, in most cases it is not reasonable or necessary to get accreditation. Sure you could use an external accredited calibration service that comes in and makes the calibration of your process instruments, but in most cases that is an overkill. This is assuming that your plant is following a quality system such as the ISO 9001 quality standard. In some regulated industries or critical measurements the accredited calibration of the process instruments may be worth the effort.

In the internal calibrations inside your plant, ***you can transfer the traceability*** from one reference to the next one, or to the process instruments, even multiple times in multiple levels. This is as long as the basic requirements are met, such as, but not limited to, the following:

- calibration results are documented in certificate
- there are sufficient procedures on how to perform the calibration
- there is a quality system
- the training and competence of workers are adequate and documented in records
- the uncertainty of the calibration is known and documented

EXTERNAL CALIBRATIONS – ACCREDITED OR NOT?

To get the traceability into your plant, send your reference standard(s) outside to an external calibration laboratory for calibration. ***Using***

an accredited calibration laboratory is highly recommended. It is not compulsory to use an accredited laboratory, but if you use a non-accredited laboratory you must ensure (audit) yourself that the laboratory is traceable, this means for example, but not limited to, the following:

- traceability of that laboratory is documented
- its quality system and proper procedures are in working order
- competence of workers is adequate
- uncertainty of the calibration is properly calculated
- uncertainty of the calibration is suitable for your use

To find out all the necessary information, it requires a ***very dedicated competence*** of the person performing the audit of the laboratory. If that is an accredited laboratory, you know that competent auditors are auditing the laboratory on a regular basis, ensuring everything is in order. ***So using an accredited calibration laboratory makes it all so much easier for you***.

However there is one thing that is always left to you, that is the last bullet in the above list – ***you must assure that the uncertainty of the laboratory used is suitable*** for your reference and for your needs. I have seen more than once an accredited calibration certificate where the ***total uncertainty of the calibration is bigger than the accuracy/uncertainty specifications*** for the reference calibrated.

So remember, even if you use an accredited calibration laboratory to calibrate your references, its uncertainty may not be suitable for your needs or small enough for you. There are many accredited calibration laboratories out there and they have different uncertainties they can offer. It is possible to get an accreditation for a calibration laboratory that has a big uncertainty, but of course that uncertainty will be documented in the certificate and in its scope of accreditation, so it is known and easy for you to find out. Anyhow, when you calibrate your reference standards, ***you must ensure that you use a laboratory that can offer good enough uncertainty for your needs***. If using an accredited laboratory you will know what the uncertainty of the calibration is. However, if using a non-accredited laboratory, that information remains a mystery. It is good to remember that it is not enough that the laboratory has some good reference standards, everything else must also be in order for the calibration to be traceable.

SUMMARY & REFERENCES

SUMMARY

To briefly summarize, let's take the definition of metrological traceability and what it means in practice: Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Shortly this means that in order to be traceable every calibration has to include:

- Calibration certificate
- Indication to the reference used and traceability
- Performed according to documented procedures
- An unbroken chain of calibrations
- Known measurement uncertainty
- Resource training/competence records
- Calibrations must not expire

USEFUL REFERENCES

- ISO/IEC Guide 99:2007, International vocabulary of metrology
- JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3rd edition
- ILAC P10:01/2013 - ILAC Policy on the Traceability of Measurement Results
- ISO/IEC 17025:2005
- ISO/IEC 9001:2008 and 2015
- ISO/IEC 10012:2003

BEAMEX CASE STORY

The world's largest cylindrical FPSO, GOLIAT, *appreciates Beamex calibration accuracy*

The platform, based on a proven cylindrical hull concept, is huge; 115 m wide, 100 m tall and weighs 64,000 tons.

Goliat is the largest cylindrical FPSO (floating, production, storage and off-loading unit) in the world. It is located offshore of Norway and is the first oil field ever moored in the Barents Sea.

Goliat is the largest cylindrical FPSO (floating, production, storage and off-loading unit) in the world. It is located offshore of Norway and is the first oil field ever moored in the Barents Sea.

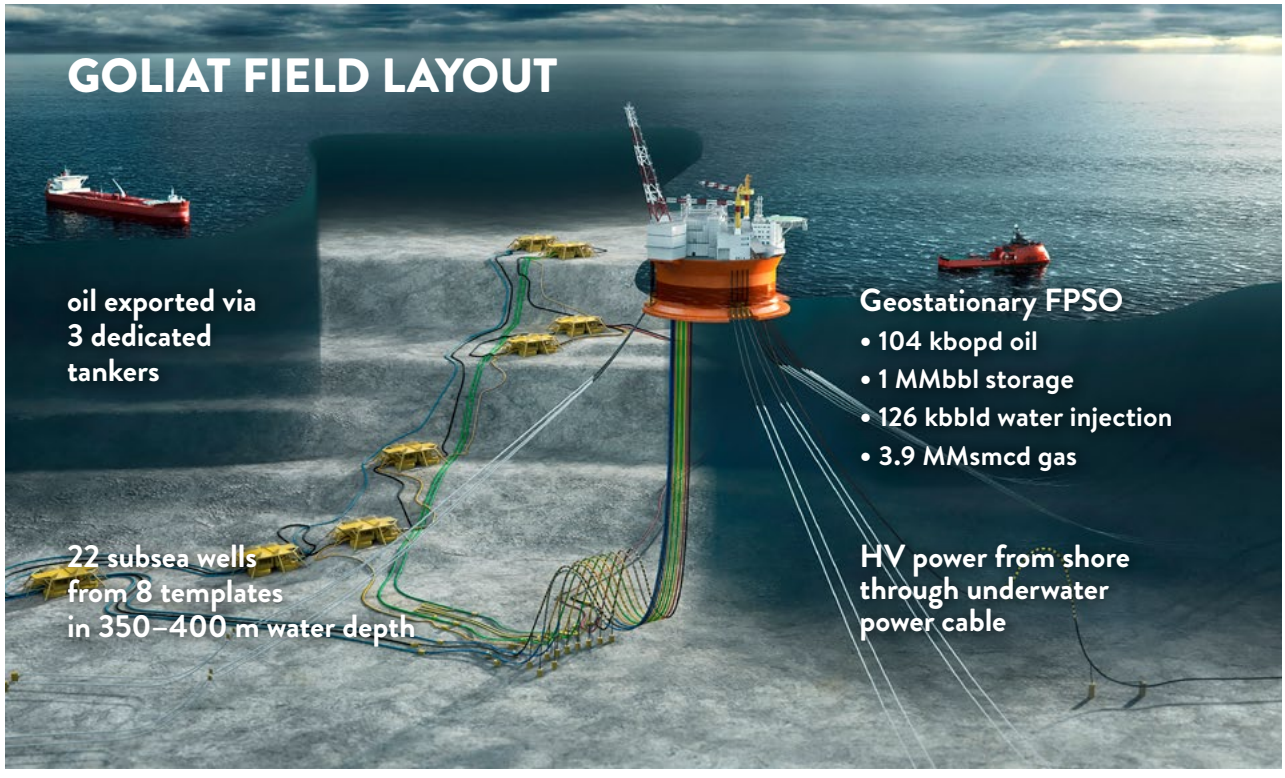
The platform, based on a proven cylindrical hull concept, is huge; 115 m wide, 100 m tall and weighs 64,000 tons. The platform concept is designed for operations under the challenging conditions encountered in the Barents Sea and introduced new winterization systems, among other things. It is also equipped to meet the strict environmental requirements stipulated for operations in the Arctic Ocean.

The Goliat field is operated by Eni who also owns the majority, 65%. The second owner is Statoil with 35% of the shares. The estimated recoverable oil reserves are 28 million Sm^3/ 174 million barrels and the estimated recoverable gas reserves are 8 billion Sm^3. The annual operating costs are approximately 180 million euros.

> We have only had Beamex calibrators for 1 ½ years and **we can already see the improvements** of the calibration process. It looks very promising. We are still in the learning phase, but so far, we are very satisfied."

ACCURACY IN FOCUS

All companies in Norway producing crude oil and gas are subject to very strict regulations on measurement of all hydrocarbons going in and out of their systems in conjunction with sale and custody transfer. This is being done in a fiscal



metering system. The results and the condition of the system shall periodically be reported to the Norwegian Petroleum Directorate. The fiscal metering system on board a production unit shall have a predictive maintenance and calibration program to ensure that the measured results at any time are within tolerances. Relatively large volumes and high value are at stake.

The metering station consists of metering systems for crude oil, fuel gas and flare and injection gas with different kinds of reference meters such as ultrasonic meters (USM), turbine master meters, orifice and cone meters. All of these are equipped with dual temperature and pressure transmitters as secondary references.

Accurate measurements are focused on throughout the entire supply chain; starting with a plan for development and operation and finishing with daily operations. When it comes to the Goliat project development and production phase, there have been three employees primarily working with ensuring the quality of fiscal metering, secondarily other process-related quantity and quality related measurements.

> We perform approximately 50 calibrations per year on fiscal equipment with the MC5-IS, but **we keep track of more 100 items in the Beamex CMX database.**"

MEASUREMENT UNCERTAINTY IS EQUAL TO HUGE FINANCIAL LOSSES

Calibration is a very essential task and plays a central role, as this is the reference point for taxes to the state and settlement between seller and buyer. Calibration is required by shareholders, customers and the Norwegian Petroleum Directorate (OD). "We perform approximately 50 calibrations per year on fiscal equipment with the MC5-IS, but we keep track of more 100 items in the Beamex CMX database," says Metering Technician Benjamin Rosnes.

When it comes to fiscal metering there are always major economic values at stake. Any measurement uncertainty in this system will mean that either party will experience a financial loss. Even small measurement errors can result in big financial losses. The seller and the buyer want to know exactly what is being delivered and received. The uncertainty for the calibrators needs to be 3–10 times less than the instrument that is calibrated. All calibrations are documented. Due to circumstances within fiscal metering it's very beneficial to avoid all kind of manual entry. The calibration intervals are set according to gov-

ernmental requirements and internal quality procedures.

INSOURCED AND AUTOMATED PAPERLESS CALIBRATION BRINGS BENEFITS

Beamex was the chosen supplier thanks to excellent references within calibration for fiscal metering in the oil and gas industry. "The Beamex calibrator is accurate and gives us the possibility to document our calibration records," describes Benjamin Rosnes. "Beamex MC5-IS is approved as an intrinsically safe calibrator which fits the tasks very well. It has great capabilities for calibrating pressure transmitters on the metering station. The documenting function makes it easy to document records within the measurement loop. In our instrument workshop we have a Beamex MCS100 calibration workbench for performing calibrations in the workshop. Two other MCS100 workbenches are used for electrical and electronic testing and maintenance. We also use the Beamex CMX calibration management software. We save all certificates that belong to the metering station, even for equipment that we do not calibrate ourselves." Eni has experienced cost savings and increased profitability thanks to calibrations being made on-site instead of outside the house. There have also been improvements in efficiency and productivity through automated calibration, both on an operative level as well as administrative.

The quality has been enhanced thanks to accurate measurements and an optimized calibration process. "We have only had Beamex calibrators for 1 ½ years and we can already see the improvements of the calibration process. It looks very promising. We are still in the learning phase, but so far, we are very satisfied," Metering Technician Benjamin Rosnes confirms.

CASE STORY IN BRIEF

GOLIAT FPSO

GOLIAT FPSO
NORWAY

DESCRIPTION

- Beamex MC5-IS intrinsically safe multifunction calibrator
- Beamex CMX calibration management software
- Beamex professional services: product training
- Beamex MCS100 test benches for Electro, Instrument and Telecom

MAIN BENEFITS

- Improved accuracy and quality
- Possibility to document records
- Paperless calibration
- Cost savings and increased profitability
- Improvements in efficiency and productivity

LATEST NEWS

BEAMEX INTRODUCES A DIRT AND MOISTURE TRAP

PROTECT YOUR PRESSURE CALIBRATION EQUIPMENT FROM CONTAMINATION

■ When performing pressure calibrations in the process industry process instruments often contain moisture and dirt. During the calibration, when decreasing or releasing the pressure, the air will flow from the device being tested (e.g. pressure transmitter) towards the pressure source bringing along any dirt from the transmitter. This dirt and moisture may be harmful for the precious calibration equipment, such as pressure pumps, pressure controllers or pressure calibrators.

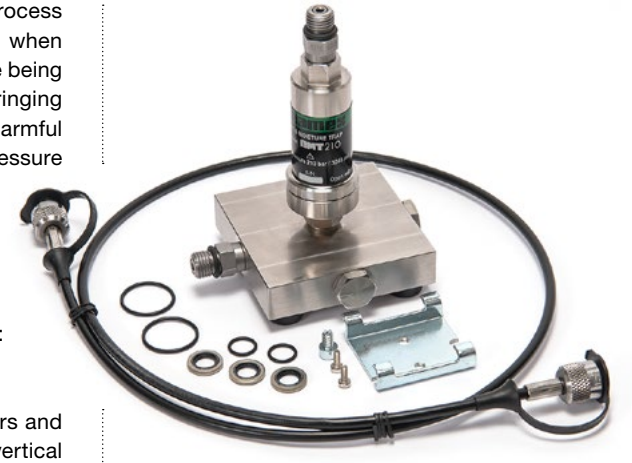
When a dirt and moisture trap is used, it will capture any dirt and moisture and prevent them from entering calibration equipment.

A trap also prevents cross-contamination between different pressure instruments devices being calibrated.

The Beamex DMT dirt and moisture trap is available in two versions:

- DMT40 for 40 bar / 580 psi
- DMT210 for 210 bar / 3045 psi

The DMT trap includes dedicated low or high pressure connectors and hoses as the standard. Also, a stand is included to keep the trap in a vertical position when placed on a flat surface. The stand works also as a manifold including three pressure ports. The stainless steal trap is simple to open for emptying and cleaning.



More info: **www.beamex.com/dmt**

New partner for LATVIA AND LITHUANIA

■ Beamex is happy to announce that we have appointed a new, exclusive sales distributor for the countries Latvia and Lithuania.

Operating since 1996, **Elintos matavimo sistemos** has had much experience in the measurement equipment field.

The contract was signed in Pietarsaari on May 23rd by Elintos director Vytautas Narbutas, and Beamex CEO Jan-Henrik Svensson.

We welcome Elintos to the Beamex family!

BEAMEX INTRODUCES
A PAPERLESS SOLUTION FOR MAINTENANCE INSPECTIONS

IN MAY 2016 Beamex introduced a new mobile, paperless solution for maintenance related inspection activities.

In today's process industry, there are various maintenance activities that need to be carried out at specified intervals, and the results must be documented. According to several surveys that have been conducted by Beamex many inspections are still done with a paper based solution, carrying paper in the field and making the notes with a pen. Research has also stated that in most cases, it is the same technicians that perform both the calibration and the inspection activities.

In addition to the new functionality introduced in the Beamex CMX software, Beamex also introduced an Android mobile application called "Beamex bMobile" that can be used to perform and document inspection activities on the factory floor.

The Beamex bMobile application is available from the Google Play store. The Beamex CMX software communicates with the Beamex bMobile application enabling a streamlined and fully paperless solution for maintenance inspections.

HOW DOES IT WORK?

When using the Beamex CMX software for inspections, you can plan and schedule all your activities and make detailed instructions for each inspection. When it is time to make the inspection, you can send the work orders from CMX to the mobile device—whether an Android tablet or Android phone—and go out into the field. While in the field, the Beamex bMobile application guides you through all the inspection activities, allows you to make the Pass or Fail decision and add notes. The test results are stored in the mobile device, and when you return to the office, you can upload the results into the CMX software. Using the mobile application, the results are automatically stored in the database, reports may be printed and the scheduling is updated.

For each asset, you can specify an individual list for checks to be done. For repeating procedures, you can create templates in CMX to easily access them later. Each procedure can include any number of individual checks. Each check includes the instructions for that check (what needs to be tested and how), a field for notes as well as a Pass, Fails and Skip result for that test.

LATEST NEWS

BUILDING A **BRIGHT FUTURE**

THE INAUGURATION OF THE NEWLY BUILT BEAMEX FACILITIES

■ On January 26th of this year, the inauguration of the newly built Beamex facilities in Pietarsaari, Finland took place. Boasting a new laboratory, expanded production space, additional office space for the sales, IT and finance departments, as well as a new auditorium, the facility expansion added 2743 m^2 (29,500 sq ft) to the existing 4427 m^2 (47,600 sq ft). The expansion project is not only an important milestone in the company's history, but also an investment in the future, as Beamex CEO Jan-Henrik Svensson explained at the opening ceremony.

"Investing 8 million euros into the facilities in Pietarsaari shows commitment and belief in Beamex customers, personnel and our strategy going forward. The inauguration of this facility expansion is therefore much more than celebrating our new premises, it also signals a new boost towards a bright future with more great colleagues, new innovations, satisfied customers and accelerated growth."

The day kicked off with a media event, followed by the opening ceremony for Beamex personnel and invited guests. Functioning as the ceremony inaugurators, Mr. Mika Lintilä, Finnish Minister of Economic Affairs, and Mr. Heikki Vappula, Executive Vice President at UPM Biorefining BA, had the honor of cutting the ribbon. Among the guests were Beamex customers representing various industries, politicians, national and international business media and the Beamex board of directors and owners.

"We're very happy that so many wanted to attend the inauguration and celebrate with us – we had guests travelling from as far away as Switzerland to be here. The number of media representatives was also the highest we've had at an event so far," Svensson declares.

On the agenda were also guided tours of the premises, after which the guests could mingle and network over coffee and cake. The day was wrapped up by an afternoon seminar with interesting presentations and discussions regarding the future of the industry. "Above all we wanted the day to be a networking-event, an opportunity to share information and exchange ideas around business growth. The whole program and the presentations were planned according to that theme," Svensson continues.

Guest speakers included Mr. Heikki Vappula and Mr. Bruce Oreck, public speaker and a former U.S. ambassador in Finland. Being able to adapt to rapid changes in the industry and technology, as well as the importance of including creativity when it comes to business success in the future were some of the charismatic American's main points. When talking about the next five years for Beamex at the seminar, CEO Jan-Henrik Svensson emphasized the importance of putting the customers at the center of the Beamex strategy.

"In terms of customers, what we want to be is a trusted advisor to them. We want them to understand that we can help and advise them on improving their process, and that we are more than just a vendor."

The positive feedback from the participants indicated that people enjoyed the event and felt it was worth attending. "The inauguration was more than just a celebration – those attending also got something out of the day. It was a positive kickoff for the future and for our ultimate goal – to be number one. How long it takes doesn't really matter, the path towards our goal is the most important. We will strive to do the right things along the way to get there and also learn from what doesn't work," CEO, Jan-Henrik Svensson concludes.

BEAMEX INTRODUCES A NEW CALIBRATION **PRESSURE AND VACUUM PUMP**

THE BEAMEX CALIBRATION PUMP FAMILY NOW INCLUDES 6 DIFFERENT CALIBRATION PUMPS

■ Beamex has expanded its pump range with a new calibration pump, the PGC. The pump can generate both pressure and vacuum, in the pressure range –0.95…35 bar / –13.7…510 psi.

The pump has a pressure/vacuum selector, so you can quickly go between positive pressure and vacuum. A fine adjustment is provided to accurately adjust the generated pressure or vacuum.

The new pump completes Beamex's range of pressure generation equipment. "Beamex is now able to supply a complete range of user-friendly calibration pumps for a broader range of pressure calibration applications," Beamex's Product Manager, Heikki Laurila, describes.

The PGC pumps comes in a carrying case as a complete kit, with a new dedicated 40 bar/580 psi pressure T-hose set provided with Beamex conical pressure connectors that are perfectly suited for use with Beamex calibrators.

More info: **www.beamex.com/pgc**

BEAMEX IN BRIEF

BEAMEX IS A LEADING worldwide provider of calibration solutions that meet even the most demanding requirements of process instrumentation. Beamex offers a comprehensive range of products and services - from portable calibrators to workstations, calibration accessories, calibration software, industry-specific solutions and professional services. Through Beamex's partner network, our products and services are available in more than 80 countries.

Learn more about Beamex calibration solutions
www.beamex.com

Find your local Beamex sales office
www.beamex.com/contacts

Interested in submitting an article to Calibration World?
Contact: henrika.granholm@beamex.com

Beamex blog provides useful and educational information for calibration professionals.

Blog for calibration professionals: **www.beamex.com/blog**

10,000+

times the most popular blog posts have been read

30+

blog articles published so far

40+

years of calibration experience

A few topics we have covered in our Blog:

- Temperature units and temperature unit conversion
- Calibration uncertainty for dummies
- Metrological traceability in calibration - Are you traceable?
- Pressure units and pressure unit conversion
- How to calibrate pressure gauges - 20 things you should consider

> *As an avid reader of your white papers I enjoy and welcome your experience within the industry.*

> *An excellent, educative, easy-to-understand video covering key topics of calibration and trimming of pressure transmitters.*

> *Thank you for describing and explaining data integrity in such a clear, easy to understand, way.*

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