Kevin Silbereisen

Calibrations in Medical Device Development

Building a Foundation for Infor EAM

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The goal of this work was to conduct a study on calibration in medical device technologies and investigate how calibrations are performed on medical devices by looking at the workflow and tools available to GE Healthcare Helsinki.

Furthermore, this project was meant to prepare and possibly implement the Infor EAM system for managing the calibration equipment on GE´s Helsinki site. The intention was to replace the previous asset management system with the one provided by Infor which was already in use on multiple GE sites. This is due to risks that can be caused by outdated software.

Getting acquainted with the everyday calibration work and the software involved was essential and required cooperation with GE Digital´s Global Infor team. The transition would include to plan a schedule, migration parameters and then ensuring that all the information has been transferred correctly and completely by testing the data migrations from GAGEtrak to Infor EAM.

In the final stage after validating the data and documenting the results, the plan is to create training material for the users here in Helsinki. The project will then be completed on the official Go-live date for Infor EAM at the Helsinki site.

Keywords	Calibration, Infor EAM, Healthcare, Gas Mass Flow Meter, Measurements, Asset Management

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List of Abbreviations:

AL	Apulaite. Auxiliary Device. GE Healthcare Finland equipment class.
CCS	Clinical Care Solutions.
CE	Conformité Européenne. European Conformity.
CEN	European Committee for Standardization.
CENELEC	European Committee for Electrotechnical Standardization.
DBMS	Database management system. Software for maintaining, querying and updating data and metadata in a database.
EAM	Enterprise Asset Management. Software managing asset´s life cycle, location and other important information across departments.
EEA	European Economic Area.
EMA	European Medicines Agency.
EN	European Norm.
EU	European Union.
FDA	United States Food and Drug Administration.
FINAS	Finnish Accreditation Service.
GAMP	Good Automated Manufacturing Practises.
GEHC	General Electric Healthcare.
GMP	Good Manufacturing Practises.
HL	Huoltolaite. Maintenance Device. GE Healthcare Finland equipment class.

IEC	International Electrotechnical Commission.
ISO	International Organization for Standardization.
ML	Mittauslaite. Measurement Device. GE Healthcare Finland equipment class.
OOT	Out of Tolerance.
SFS	Suomen Standardisoimisliitto. The Finnish Standards Association.
UUT	Unit under Test.

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1 Introduction

Calibration is the basis of quality control and thus vital in complying to the numerous standards regulating various industries. The processes of calibration provide the means to ensure that instruments maintain their accuracy, by configuring an instrument to provide a specific result. This generally involves using the instrument to test samples of one or more known values and comparing them to a reference device.

The process itself is regulated by international enterprise specific standards, including the ideal result tolerance values of which a device is allowed to deviate from. A correctional process might be initiated in the case that the result of the calibration process is out of tolerance or is drifting too close towards it. These measures can be performed either externally or in an “in-house” laboratory.

General Electric Healthcare Finland Oy is GE´s Healthcare branch located in Vallila in Helsinki. GE Healthcare is one of the world´s leading medical technology companies. Formerly, they were known as Instrumentarium´s Datex-Ohmeda until General Electric acquired them in the year 2003. GE Healthcare Finland provides a wide range of services and products. This range includes but is not limited to patient monitors, clinical information systems and medical imaging equipment like X-ray-, Magnetic Resonance Imaging- and ultrasound devices [1].

This thesis was commissioned by GE Healthcare´s CCS Monitoring Solutions. Their Hardware department in Helsinki is also managing their in-house Calibration Laboratory which is planning on implementing a new management system for their calibrated devices. This is a necessary step because GAGEtrak, which is the current management software, is becoming increasingly outdated. This poses a potential quality risk which cannot be underestimated. Especially, since working in the healthcare technology environment means that GE Healthcare must follow strict regulations which get regularly checked in short-notice audits.

This inspired to investigate the calibration process in GE Healthcare Finland as a whole and, thus, is the content of this thesis. GE Digital´s international team was also included in the process of arranging the deployment of Infor EAM and consequentially the implementation of the Software in Helsinki. A collaboration with GE Digital´s Infor team was

deemed necessary for this work since they can give the guidance necessary to ensure that all necessary standards are upheld.

2 Regulations

Customer and user safety of medical devices is vital not only because of the physical harm that it can cause to the people. Moreover, it can do unrepairable damage to the manufacturers reputation and as a potential consequence mean the end of an entire company. This is especially true for enterprises dealing with healthcare applications. Here, they also need to consider the patient's safety, which have special needs due to their individual conditions. Thus, having standards and regulating institutes in place that ensure that quality and safety measures are met, this benefits all parties involved.

2.1 Institutions

Similarly, to many other aspects of a company which have official bodies inspecting them, ensuring that all necessary standards are held up, calibrations, as well as a means of quality assurance, have their own set of organizations. In the case of General Electric Healthcare, we are dealing with a very international company. This adds a bit more complexity, since, although standards have been adjusted and brought together via globalisation, there are still major international factors that need to be considered.

The United States food and drug administration might be rather well known even here in Europe but might be more associated to food regulations by many. However, as FDA they also inspect medical devices. Their office and their counter-part, the EMA, representing them and their values in Europe help establish a channel to the U.S. market. This fosters collaboration and ensures safety and quality for medical products in both regions.

The international organisation for standardisation, however, has arguably the biggest impact on GE in terms of standards. The international organization of standardization is a global federation of standardization with technical expertise; their committees are preparing ISO-standards and make them available for companies. Their members are an

international combination from over 160 countries. Founded in 1946 it has already established more than 21000 international standards in virtually every industry. [2.]

One exception being the standardization of electrical- and telecommunication engineering also known as CEN. The European committee for standardization, for its part, is a large-scale European standardization organization, which is in principle responsible for all non-electrical and telecommunications standardization. The European standards set out in the CEN are called EN standards.

The International Electrotechnical Commission is an international standardization organization for electrical and electronic equipment. The organization comprises 60 countries as full members and 23 associates. The CENELEC encompasses 33 countries in the EU, EEA, Turkey and Macedonia and is responsible for the preparation and approval of EN standards. International and European standardization organizations cooperate appropriately so that whenever possible, European standardization is used to make global standardization. 75% of the electrical EN standards are based on international IEC standards. [3.]

All European standards are enforced in the SFS standards in Finland and the conflicting ones are revoked. In Finland, SESKO is the Finnish standardization association for electrical engineering. Their tasks include the harmonization of European standards into the local markets. This often requires the need for new, purely national standards and eliminating standards which are virtually out of date but are in some cases still in practice.

2.2 Effective Standards

Standards are sometimes referred to as legislations. In this case they may become a priority or even a compulsory procedure ensuring that regulatory and compliance requirements are met. EU adjusted standards are European standards prepared by European standardization organizations which are drawn up based on the European Standardization Commission´s request. If the co-ordinated standard meets EU legislation, its references will be published in the Official Journal of the European Union. The purpose of co-ordinations is to support and assist manufacturers to comply with the requirements of EU directives.

Directives regarding the requirements of the most important safety, health, environmental and consumer protection requirements for products are commonly the result of these co-ordinated standards. According to this a product can in principle be traded across the EU if all standards and their essential safety requirements are met. On the other hand, this means that authorities cannot obstruct its freedom of movement. However, EU legislation must not conflict with the directives. Compliance with standards, however, is not mandatory. Products may also be manufactured with deviations from the standards, but in such a case the manufacturer must be able to demonstrate by some other means that the product complies with the essential requirements of the directives. [4, 86-87;6.]

The ISO 9001 is one of the world's most well-known standards and the most used management model due to its philosophy of constant improvement. It consists of requirements for quality management system, management responsibilities, resource management, product implementation, and measurement analysis. The ISO 9001 standard alone is not sufficient for the quality management of healthcare equipment. The compliance with ISO 9001 and its related certifications are useful to the manufacturer due to its value to customers and end users. [5.]

The Medical Device Regulations EEC 93/42 and 2017/745 define the safety-prudential requirements of medical devices sold within the European Union. These effective requirements apply to all Member States. The Directive is therefore intended to bring together the requirements of medical devices within the European Union. [7;8.] Following the definition of the term "medical device", this covers any instrument, materials or other equipment used either alone or in combination and the software necessary for their proper operation, intended by the manufacturer for the use of: [10.]

- disease: diagnosis, prevention, monitoring, treatment and/or alleviation
- disability: diagnosis, prevention, monitoring and/or relieving
- examining: anatomical or physiological modifications/replacements
- regulating fertility

Manufacturers of the medical devices are legally responsible that the requirements of the Medical Device Directives are met. Following ISO 13485 standard which describes

the requirements for Health Care Equipment including their supplies and quality management systems. In this regulation, detailed requirements are laid down for the manufacturers by regulatory authorities, clarifying the requirements for quality management systems to work within the framework of EU legislation [9].

The International Electrotechnical Commission standard IEC 60601 forms a family of essential technical standards that ensure the safety of medical electrical equipment. Major import countries for medical devices have been enforcing the standard for many years making it a widely accepted standard in the U.S., Canada, EU, Japan, Brazil, Russia and Australia. Manufacturers are advised to ensure that their products comply with the IEC 60601 in order to avoid being denied entry into these markets. The IEC 60601 at its core ensures that manufactures estimate for each applicable risk, the probability of occurrence and its severity and via this means ensure that no single failure poses an unacceptable risk to operators and most of all patients [16]. The IEC 60601 must be applied in conformance with ISO 14971 which is the international standard for application of risk management of medical devices. The requirements described in detail in this standard are frequently recognised as State of the art and thus are considered a pre-requisite for the commercialisation of electrical medical equipment by public health authorities.

The CE mark is an indication that the product is in conformity with the directive. The marks and, thus, the organizations behind it, are well established. It can be effortlessly identified by authorities and customers using these means and having it well visible on the product. Furthermore, the healthcare device may not be placed on the market in the EU and EEA without the CE marking. Other markets usually establish similar regulations, like the United States FDA 150k. By the mandatory CE mark, the manufacturer and the importer indicate that they are explicitly and exclusively responsible for ensuring that the healthcare appliance complies with all the requirements. The affixing of the CE marking requires that the appliance meets its essential requirements of the Healthcare Directive, and any other directives and legislations that apply to that type of healthcare device. [6;7.]

For the purpose of this study we are looking particularly at the case of calibrations in General Electric Healthcare in Helsinki. It is vital to consider the scale and reach of the company. Due to their roots in the United States, we also need to consider standards more applicable to their market of origin. The FDA is the primary authority in regulating and inspected medical equipment in the United States.

The requirements under FDA QSR 21 CFR have a particular impact which GE Healthcare needs to fulfil. It consists of requirements for quality systems. These requirements set the guidelines for methods of controlling the design, manufacture, packaging, labelling, storage, installation and servicing of all finished devices intended for human use, this way ensuring that the finished devices will be safe, effective and otherwise compliant with the Federal Food, Drug and Cosmetic Act. [11.]

Good Manufacturing Practice sets guidelines for good manufacturing practices of pharmaceuticals, the arrangements for pharmaceuticals and quality assurance and procedures to ensure that the pharmaceuticals meet all their requirements for manufacturing. The GMP as well as the GAMP for Calibration Management is essential in this study because it describes principles and suggests priorities for effectively meeting the calibration needs of the pharmaceutical industry and satisfying the requirements of the regulators.

2.3 Inspections

Auditing is an integral part of quality assurance for a company and especially for their calibration department. Audits inspect processes or quality systems to ensure compliance with applicable requirements. Audits can be performed in several ways and can first of all be split into internal and external audits but furthermore might also be broken down into following categories and such be conducted accordingly:

- Product Audit: Examining a product or service
- Process Audit: Verifying processes work within established standard parameters
- System Audit: A documented activity performed to verify a management system
- Documentation Audit: Confirming appropriate documentation procedures

However, it is not allowed to alter the initial purpose of an audit to verify compliance, conformance, or performance. In certain cases, audits may have specifically administrative purposes such as auditing documents, risk, performance or following up on completed corrective actions. Additionally, companies like GE Healthcare, belonging to a

high-risk category like pressure vessels, elevators and medical devices, in doing business in Europe get audited so that they comply with the CE requirements. Furthermore, customers might suggest that that their supplier must conform to ISO 9001 and ISO 13485, this requirement is also the case for GE. Successful audits then may conclude in such a manner that the company receives the appropriate certification stating the conformity [12].

2.3.1 Audit Phases

The auditee might not be aware of all the work that goes into preparing and conducting an audit, especially since most audits come on a rather short notice for the company. This is due to the inspection supposedly being a surprise and thus avoiding that the auditee might make special preparations, in order to conform to standards. The general activity of an audit can be described in four distinct phases which are necessary in order to conduct a successful inspection. These are as follows:

- Preparation: Necessary preparations to ensure that the audit complies with the objective.
- Performance: Data-gathering, covers all activities of the inspection including the on-site audit.
- Reporting: End report which includes the results and statement of compliance.
- Follow-up/Closure: All audit items have been carried out and if necessary, a verification of follow-up actions is part of a subsequent audit.

Like many companies, GE Healthcare gets inspected and audited on regular basis. Effective calibration of the equipment is in scope of all audits and is closely monitored and has to, among other aspects, be able to provide a complete calibration history of their assets. These records are saved in the form of calibration certificates covering procedure and results of the calibration procedures. This way of documentation is the means of complying with the ISO 9001 standard. Once it has been implemented and the first cer-

tificate was awarded, it generally initiates a Documentation audit and a three-year certification cycle [12]. The re-certification of this process can be broken down into five distinct steps, as Illustrated in Figure 1.

Figure 1: Certification Audit Cycle

Figure 1, shows how this process works and how Documentation, Surveillance and (Re-)Certification are linked. This system is maintained as long as the current certification stays coherent with the certification body. However, if certification bodies are changed or the version of the directive is altered, an additional a transfer audit will be needed.

3 Calibration

The main theme of this project deals with calibration. Therefore, we must specify the term “calibration”. Calibration is the measurement practice aimed to reliably reproduce, detect and document the deviations of a measurement device from a reference device. The outcome of this comparison determines, if the error is significant enough to initiate an adjustment procedure. The calibration of the measurement devices is therefore a comparison where the accuracy of the device is determined by using a precision instrument known to be accurate and calibrated.

Periodical calibrations and maintenance of the measurement device performance are controlled, including their inaccuracies. The reliability of the entire measurement operation is based on calibration, so it must be carefully structured, monitored and documented. However, the term calibration strictly speaking only refers to the act of comparison and does not include any corrective or preventive actions.

Generally, all measurement devices are calibrated in some way at the manufacturing stage, in order to confirm that the device meets the specification and accuracy given by the manufacturer and thus transfers them in an "appropriate state". As measurement devices wear and change during their life-cycle, the calibration must be repeated at regular intervals to confirm that the device still meets its accuracy requirement. Constant

calibrations can be used to ensure that the measuring instrument operates continuously within the approved precision, thus ensuring high quality and reliable results.

An essential element which cannot be ignored is traceability. Traceability means that the measurement results or the deviation from a standard from the measured reference to the reported device can be traced back to guidelines based on good practice procedures. These are usually founded in national or international standards. Traceability can be assured at different times and in different places. In order to maintain traceability throughout a products life cycle the necessary calibrations have to be performed by using a metrological quality standard.

The concept of making a calibration traceable to a national standard can be summarised in a few key elements. The foundation of traceability in calibration is established via an unbroken chain of comparisons between its own measurements and relevant international or national standards. This link between calibrations and standards can be achieved by formally addressing the laboratories reference standards. The measurement uncertainty must be calculated for each step using appropriate means and as result the overall uncertainty of the chain can be stated. In many fields, reference materials replace physical reference standards which follow the same traceability structure as previously described. Certification of reference materials and devices are often used to demonstrate the traceability to relevant standards. This process follows calibration hierarchy which can visualized as seen in Fig. 2.

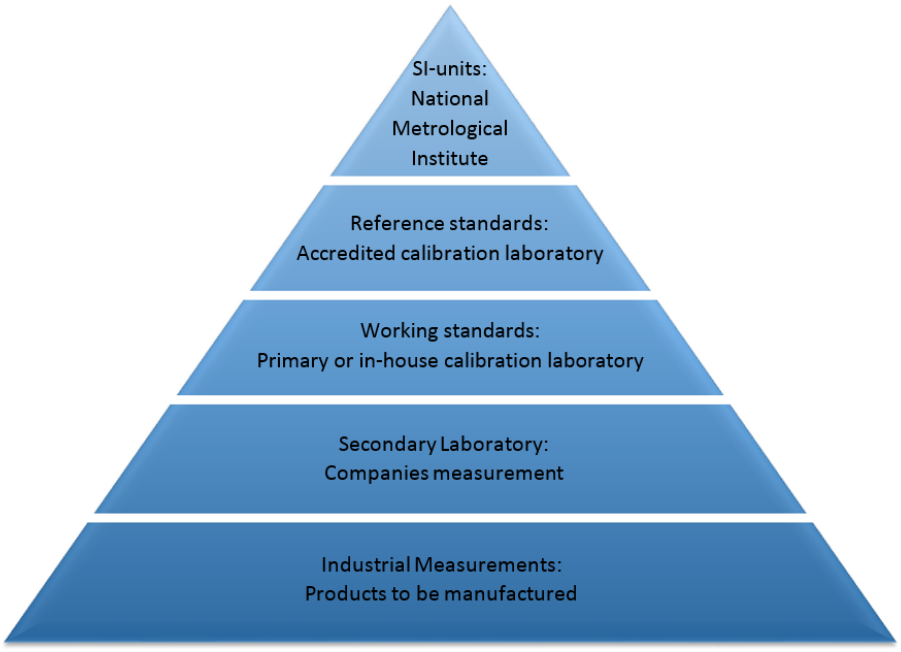

Figure 2: Calibration Hierachy

3.1 Internal and External Calibration

In order to ensure that all these guidelines are held up, a company can make the choice between establishing and maintaining an on-site laboratory or shipping their devices to external laboratories for calibration. Generally, an on-site laboratory saves money in terms of costs of the external-calibration and the resulting transportation but most of all it saves time. This can be a major factor to consider. Additionally, Table 1 summarizes the general steps that have to be taken in both internal and external calibrations. However, maintaining and managing a calibration laboratory also results in costs that must not be underestimated.

Table 1: Internal and External Calibration at GEHC

If…	Then…
The device is calibrated in its own calibration laboratory	• Calibrate and Approve the device according to GE Healthcare guidelines
The device is calibrated in an approved external calibration laboratory	• Check that the supplier that is used is in the approved supplier list • Calibration Personnel approves that the requirements have been met • Calibration Personnel performs visual inspection of the device and reports possible damage

Of course, it doesn't mean a manufacturer must choose between either. They can make use of external, as well as internal calibrations. The question is, to what extend external calibrations are necessary. So, in order for a laboratory to be allowed to perform calibrations it requires reference devices of sufficient accuracy. Additionally, special tools may be needed to be able to perform calibrations and adjustments.

The outcome must be the same however, so, for the consumer there is no difference if the calibration was conducted internally or externally. The result will be in both cases documented with certificates of calibration. The purpose of the calibration certificate is to inform the customer of the calibration result. Such a certificate is the most important document proving that, for example, the company's quality system is based on traceable measurements. Uncertainty, traceability and reference standards as well as the selected calibration method must be reported to clarify the result. The calibration date must of course also be part of this document in order to determine the calibration period. In ad-

dition, conditions such as air pressure and temperature must be described. The calibration certificate is verified by the signature of the person performing the work and of the person in charge of the laboratory.

3.2 General Procedure of Calibrations at GEHC Finland

The calibration procedure describes the general requirements for calibration, the measurement of new measurement devices, the production of measurement devices, the selection of the calibration range, the calibration of measurement devices, and the procedure for delayed or lost measurement devices or when calibration devices have not met their requirements [13]. Since the contents of the guidance is confidential to a major degree they cannot be described in exceeding detail in this thesis.

GE Healthcare Finland separates Measurement- and Test Devices into three categories:

- Calibrated Measurement devices tagged “ML”
- Product development´s Maintenance (Test) devices tagged “HL”
- Product development´s Auxiliary devices tagged “AL”

All calibrations must be conducted by qualified personnel that is trained in the procedures and have attained the necessary professional knowledge to understand and conduct both the procedure and the device under test. Appropriately, these are called either Calibration Technicians or Calibration Engineers, depending on their expertise. Although both are qualified to perform a calibration procedure, only a Calibration Engineer may formulate calibration manuals.

3.2.1 Instructions

Manuals and instructions for the specific procedure can be found in part in files at the calibration laboratory or in a validated virtual storage system for documents. In the preparation of the calibration manual, the measurement equipment supplier, designer or installer (Engineering Representative) is required to provide the necessary information and

to assist in the preparation of the instructions on measuring instrument operation, measurement methods and connections, accuracy and reproducibility. Calibration personnel is responsible for maintaining calibration instructions. The calibration instructions are stored and maintained in a virtual database.

3.2.2 Measurement Device

Calibrated Measurement Devices, or ML´s, are all those measurement, test and control devices used to verify specific end-user product's characteristics, to verify the characteristics of specified processes, or to verify R&D lab verification tests. The calibration personnel maintain the records of the measurement device and schedules calibrations for ML-devices and calibrated devices in their asset management system. During the Calibration, the personnel keeps record of:

- Compared Values between the calibrated and reference device
- Their Measurement variables and range
- Determined accuracy and repeatability of the measurement device
- Precision of the measurement device in accordance with the calibration manual´s specifications

3.2.3 Maintenance Devices

The Maintenance Test Equipment, labelled "HL", is a device that is needed to feed data and signals to the Unit Under Test (UUT) and is used in product development lab verification tests and needs maintenance on regular bases. These devices include, for example, patient monitors and modules. Maintenance test equipment may also be other product development test equipment that is without measurement and thus calibration characteristics, but must be maintained at regular intervals to guarantee its expected and correct function. R&D labs maintain test record and service schedules in the HL Asset Management System and supply them to maintenance according to device-specific service instructions.

3.2.4 Auxiliary Device

Auxiliary devices, also known as AL´s, are other test equipment used in product development lab verification tests that are not a UUT and are not subject to maintenance. The purpose of these auxiliary devices is to test connectivity and compatibility. The R&D laboratories maintain a sub-list of the AL instrument panel.

3.2.5 Reference Device

Referential measurement devices are all GE Healthcare Finland Helsinki internal references to verify the accuracy of the measuring devices performing according to metric standards. If possible, measurement variables for the measuring instruments are defined to determine the internal reference or the standard deviation.

If there is no internal reference or metric, the device is calibrated at a national measuring site or accredited laboratory. Referential measuring devices should, as a rule, be calibrated at national measurement sites or accredited calibration laboratories. This ensures that the measurement uncertainty remains within the desired limits and achieves an unbroken, documented calibration chain that ensures traceability of measurement results to national and international standards and, thus, SI units.

If no measurements of a reference measurement instrument´s calibration can be traced back to a national or international measurement standard, the calibration criteria need to be documented. This also includes the documentation of natural constant or derived quantities used or acquired during the calibration. Since all overrides are subject to OOT-reporting a measurement instrument designated as a reference measurement device should be at least four times more accurate than a standard measurement device. For some quantities, it may be justified that the accuracy of the reference device is less than four times the accuracy requirement. In the latter case, however, it would be advisable to conduct a calibration-related measurement uncertainty study.

3.3 Calibration Provider (Trescal)

Trescal is one of the calibration service providers for GE Healthcare Helsinki and conducts part of the externally performed calibrations. Commonly a manufacturer has more

than one calibration provider on top of their in-house laboratories. This is due to the various requirements of the directives and the accreditations of the calibration laboratories. Trescal´s laboratories have the necessary accreditations and laboratory environment to be allowed to perform special calibrations.

Trescal is an international group specializing in calibration services, calibration, inspections, repairs and vehicle control systems. Trescal has over 2,000 employees worldwide. Trescal is represented in 17 countries across Europe, the United States, Asia and North Africa. Their headquarter is located in France, Paris. GE Healthcare's calibration services are provided by Danish Trescal A/S. Trescal laboratories are ISO/IEC 17025-accredited and / or certified. This means that the laboratories have a quality system in accordance with ISO/IEC 17025 for their calibration and maintenance.

Evaluating the technical competence of a potential calibration supplier is important, but it can be difficult to determine. ISO/IEC 17025 is an internationally recognized standard that ensures that the measurement equipment is properly calibrated by an independent and qualified calibration laboratory.

After an order confirmation, has been received the staff prepares the equipment for shipping, Figure 3.

Figure 3: Shipment for external calibration

3.3.1 Accreditation

Accreditation refers to the recognition of a formal qualification of a laboratory by an outside official body. An accredited calibration laboratory meets the ISO / IEC 17025 Laboratory Standard requirements and is accredited by a national accreditation body, for instance FINAS in Finland. An accreditation body operates within in the guidelines of defined standards and carries out the calibrations indicated in the scope of accreditation. The accreditation process evaluates laboratory management and quality systems as well as technical qualifications in assigned tasks. Accreditation is an external evaluation that increases confidence in the supplier's calibration services. Accredited calibration laboratories are usually required whenever a formal recognition of the third party is required. For example, when the device is used as a reference device in standard calibrations.

Criteria include personnel qualifications, equipment and methods, calibration and traceability, measurement conditions and documentation. The measurement results of the accredited laboratory are therefore verified and traced and meet the requirements of generally accepted quality management systems. Certification, on the other hand, is a written certificate issued by a third party that the product, management system or personnel meets certain requirements.

3.4 Process

The requirements for medical devices in the global market are complex. However, in every case, the manufacturer must act conscientiously and comply with them, and fill them up to the last paragraph. For example, the environmental conditions in which the calibrations are conducted must be regulated. Meaning, the temperature, pressure and humidity of the laboratory are monitored and reported for each calibration. Additionally, appropriate safety measures must be taken and calibrated devices must be implemented to ensure repeatable as well as reliable measurements.

The most important conditions for the various quality standards in calibration of measurement instruments are broadly consistent and clear. The main content of the requirements is described in the "Development and Improvement of Operations" in the ISO 9001 standard which, summarized, states that the Supplier shall establish and maintain documented control, calibration and maintenance procedures for inspection, measurement and testing tools, including testing software, used by the Supplier demonstrating that the

specified requirements are met. Inspection, measurement and testing equipment shall be used in a manner that ensures that the measurement uncertainty is known and meets the required measurement capability. [4.]

The global calibration procedure guidelines implemented in the GE Healthcare Quality Management System are also based on several international standards, as well as laws or regulations. GE Healthcare's Global Quality Procedure dictates that all measurement instruments used for inspection, measurement and testing must meet calibration requirements. The Global Policy Guidelines are based on the following standards:

- ISO 9001: Quality Management System Requirements
- ISO 13485: Quality Management System for Medical Devices
- American National Standard for Calibration: Calibration and Measurement Equipment
- GAMP Good Practice Guide (Calibration management)

Including also following regulation:

- U.S. Code of Federal Regulations 21 CFR (§820.72; §211; § Part 58)

3.4.1 Troubleshooting

Working only with ideal values is not only inefficient but virtually impossible. This is the reason why each directive and process has tolerances in which it is allowed to operate. Thus, tolerance is the maximum permissible error meaning it is the value that limits the largest permissible error or deviation of the actual value of the measured quantity. The fact that the measurement device does not meet the requirements set for the calibration measurements means that the unit is in OOT mode. Out of Tolerance mode may increase the risk of deviations on all devices or systems for which measurements are performed. OOT situation always leads to an investigation where the potential effects must be evaluated, and if necessary, corrected. In the worst case this may lead to a product recall. A person using a measurement device may have numerous but specific measures to troubleshoot problems. Results of calibration may indicate that a device shows already

signs of drifting into out of tolerance territory. Depending on the situation, how close the next calibration is and how close it is to actually be out of tolerance this may be reason for special measures to ensure the device continues to be safe to use until the next inspection.

Compliance in calibration is expressed as shown in Figure 4:

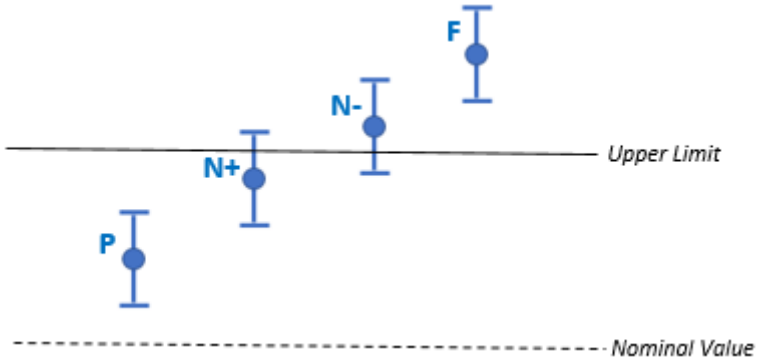

Figure 4: Model of Compliance of Calibration

- P: Passed, thus compliant
- N+: Unspecified, compliance cannot be stated with 95% probability. Although, measured value may be compliant the margin is below the uncertainty of the measurement.
- N-: Unspecified, compliance cannot be stated with 95% probability. The margin of the measured value is below the uncertainty of the measurement.
- F: Failed, thus not compliant

In the uncertainty calculations, estimates are determined for the error sources of the measurement and related corrected results. The uncertainties of these corrections are quadrupled together when interdependent uncertainty components are summed up squarely, they cancel each other because aggregates are always positive figures. As a result, a confidence interval is created, whereby the measured value is at a certain statistical probability but cannot exceed 95%.

The calibration intervals for the measuring instruments used by GEHC's services are defined per device. When determining the calibration intervals, for example, the device

should be taken into account in terms of stability, usage, manufacturer recommendation, structure, calibration history and age. Defining the calibration range may be subject to change if deemed necessary by the experienced staff after gaining a level of specialized expertise to specific device type over a long term of calibration results. If the device is stable, the calibration interval may be extended and shortened, if the device results differ significantly from the previous calibration. A typical calibration interval is a year. A too short interval makes calibration a heavy and resource demanding routine, but too long a calibration interval does not provide reliable enough information on the device measurement function.

4 Enterprise Asset Management

In order to keep track of state, location and status of the numerous devices, a well-structured and efficient management system needs to be in place. Enterprise Asset Management, or short EAM, generally covers the entire lifecycle management of the physical assets in an organization, such as installations, real estate assets and of course equipment. EAM Software helps the staff to oversee where their calibrated devices are currently located, in which state they are and when the next calibration is due.

4.1 Calibration Data Management

An underlying factor of managing measurement instruments at GE Healthcare Finland is to manually track and upgrade Excel file-based process. During this work, the plan was not to abandon this but rather to establish a substitution option, namely the Infor EAM system. The proportion of measurement instruments that have passed the calibration deadline can this way be monitored at an international quality management level.

However, bottlenecks in Excel-based calibration management lack automated monitoring and innovative distribution of information. In practice, the file is saved on a local hard drive and a back-up is maintained in a cloud services. This restricts the data of course to be only accessed through one person since there is currently no uniform database for calibration data management. In addition to this, maintaining the versions of the calibration data and the management software itself has to be locally updated. Thus, the cali-

bration data bookkeeping becomes tedious if inadmissible and for instance the calibration data that needs to be updated is saved for an earlier version that lacks part of the calibration data.

Infor EAM potentially improves both the data storage and the tracking challenges. During the transition preserving the latest calibration documents for audits and other calibration database needs to be verified. However, it was already agreed that a few of the measurement device records will need eliminated because they have become obsolete. There were also certain measurement devices that were no longer needed due to various types of flaws and therefore are no longer needed to be monitored and can be erased from the system.

4.2 GAGEtrak

Cybermetrics´s solution to managing calibration tasks is called GAGEtrak. It is one of many software solutions handling calibrations management out on the market. Cybermetrics was founded in 1992 and is located in Phoenix in the United States. They focus on developing Quality Assurance software solutions, like GAGEtrak, which are scalable and tailored to meet the demands of the company they have been deployed to.

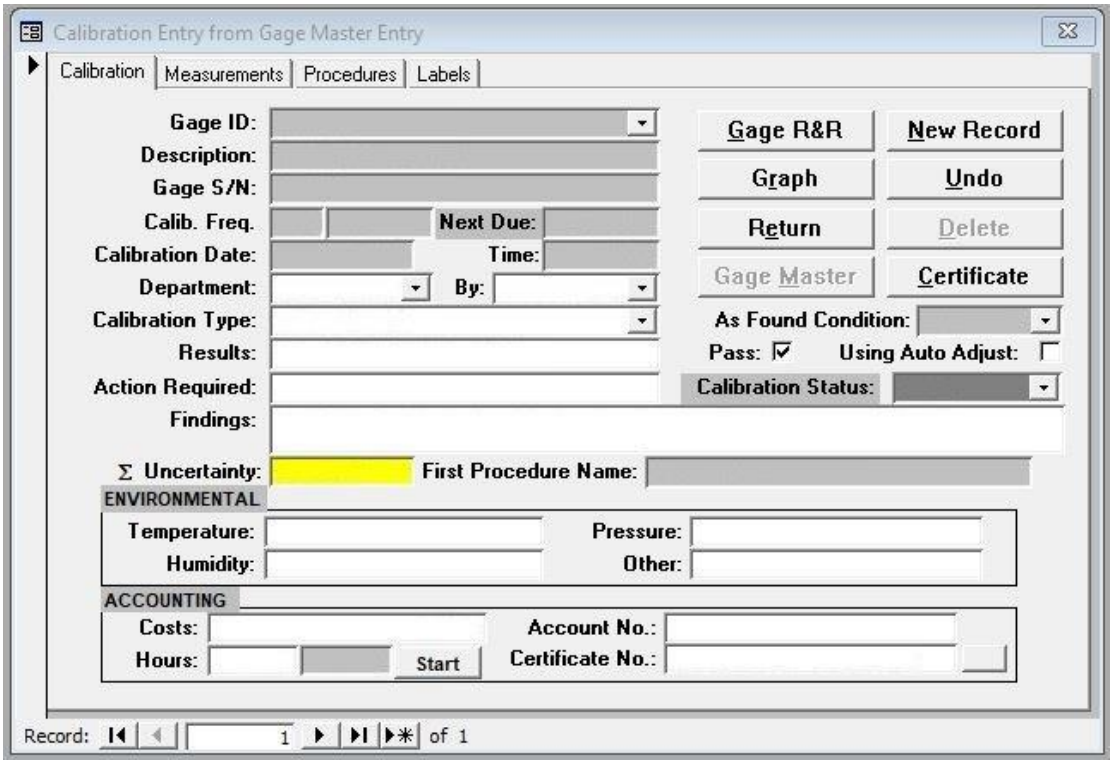

Figure 5: Example for GAGEtrak in Calibration

In Figure 5 a basic template of GAGEtrak for Calibration can be seen after a calibration has been conducted. It allows the user to enter all acquired results and saves them either in GAGEtrak original or custom-made template. The filled in results get then turned into Calibration Certificate, which is essential for the eventual audit.

GAGEtrak has a multitude of tools available to cover the many needs a customer might have. Although, some of GAGEtrak´s tools might actually never be used by some of their customers, their aim is to be as versatile as possible. This includes being compatible with several formats, most of all, but not limited to, Microsoft Excel. These so-called output or export formats allow the user to transmit reports, for instance to Rich Text Format, Portable Document Format or also Microsoft Excel. If you output to an Excel Spreadsheet and PDF, like it is common practice at General Electric Healthcare, it ensures that the report is widely accessible. One of the drawbacks of GAGEtrak, however, is that it needs to be installed on the user's computer which is not only an outdated method but also can lead to version and compatibility problems for operating systems and thus the users.

4.2.1 Risk Assessment

GAGEtrak has been a reliable resource for many years and helped the calibration team to manage their assets. Improving workload management, minimizing costs over time, maintaining schedules and assure standards compliance and has been a good software solution meeting the needs of GEHC. However, technology is a very fast paced environment, more so for software solutions which have constant updates and competitors.

These developments consequently lead to GEHC revaluating GAGEtrak´s efficiency, since it became apparent that GAGEtrak was no longer satisfying in its tasks. Although, it operates successfully at GEHC Helsinki, the staff noticed certain short-comings as of recently. Thus, it poses a potential risk not only for the work practise of the calibration team but also for GE Healthcare as a whole. Using an outdated software can lead to numerous failures but the most fatal would be lost or corrupted data which would be a serious Quality hazard. Although Cybermetrics still releases new version of GAGEtrak, its tool-set is not as compatible to GEHC Finland's needs as compared to other provider´s solutions.

This assessment of the current situation and potential development led to the decision of replacing GAGEtrak with another enterprise asset management system.

4.3 Infor EAM

The Infor Enterprise Asset Management system, true to its name can oversee and maintain the records of a multitude of assets and facilities. However, its main usage is to manage manufacturing equipment, facility maintenance, spare parts, indirect material stockroom and instrument calibration. Their aim to simplify compliance is achieved by improving workflow and featuring functions like compliant eRecords with signatures, reporting and up to date Tableau Dashboard, visualizing significant information for the user.

4.3.1 Architecture

Infor EAM is a web based, integrated asset management system and thus operates via the browser on your computer and does not require the installation of a separate client to run it. The basic principle of Infor EAM´s architecture can be simplified like Figure 6, shows.

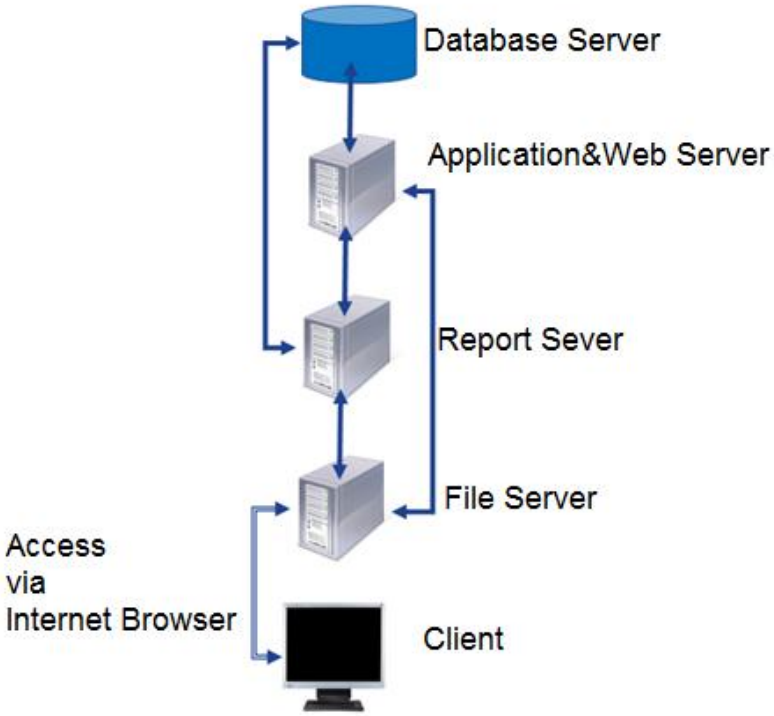

Figure 6: Infor EAM Architecture Model [15]

This setup is not only an advantage for the customer but also for the supplier. It eliminates any client installation which reduces costs and deployment delays. [15.] The latter is a major time saver for all parties involved because it means initializations and version updates can be easier deployed. However, deploying it to a new organization has a different set of obstacles than local based management system would have.

4.3.2 Key Functions

Infor EAM has fundamentally the basic set of what is needed of an Enterprise Management System. It is used to manage all maintenance related activities, such as keeping record of all the assets data like equipment, tools, calibrated items and linked documents. Through assigning current state, work orders and monitoring asset history, workflow can be effectively utilized in order to manage the workflow of all repairs, preventive maintenance and calibration effectively. The dashboard can be used to easily identify key performance indicators such as calibration volume, proactive versus reactive work orders and asset performance.

These functions have a significant impact on the business by managing a substantial amount of work orders and assets that a less modern system might not be able to handle. Infor EAM International Standard and FDA audit compliance makes it a valuable addition to any company. Infor EAM also supports numerous languages in its system, which is a strong move towards customer satisfaction since being able to work with it in one's mother-tongue, as opposed to expecting an English working environment, can be a strong decision factor for some.

4.3.3 Workflow (Calibrations)

The Asset List View enables the user to search and identify specific calibrated items. These assets are defined and then associated with preventive maintenance procedures, ad-hoc or "repair" work order and calibrations while simultaneously enabling the users to track the costs of the items and procedures. Work orders can be generated in two ways: the first is automatically from Preventive Maintenance schedules and the other via creating an ad-hoc for repairs.

Work orders also provide workflow. Calibration Work orders have a different workflow compared to maintenance work orders. Calibrations orders are usually labelled by their following related status turned in, out to vendor and closed. However, either will conclude with an electronic signature. The method of how Infor EAM implements work orders can be visualized as seen in Figure 7.

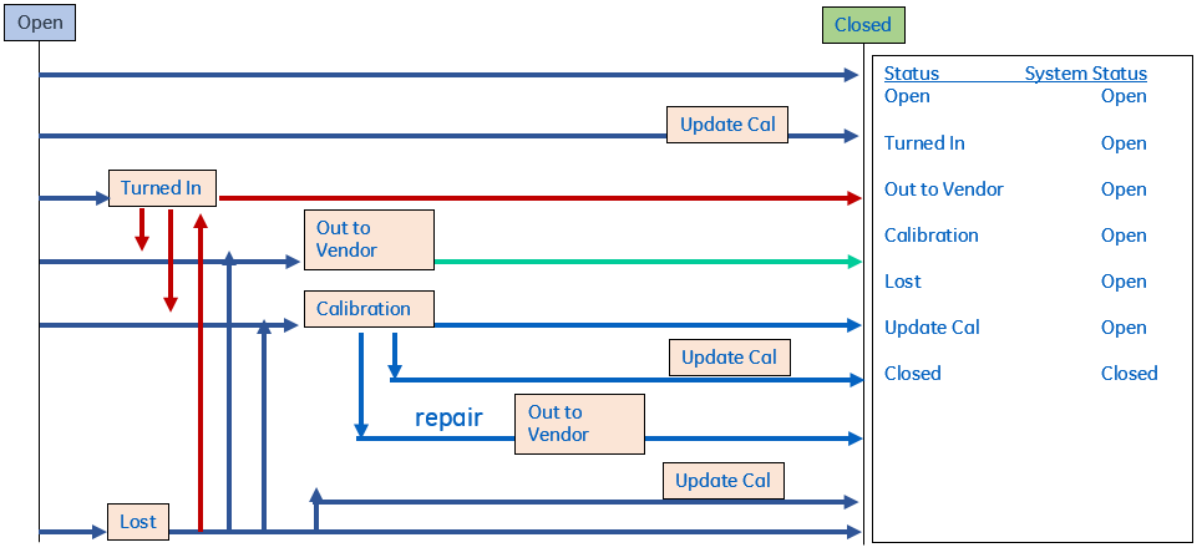

Figure 7: Infor EAM Calibration Work Flow Status

5 Calibration of Gas Mass Flow Meter

Gas flow meters can be divided into two major categories namely Volume Flow meters and Mass Flow meters. These two can be broken down into further subcategories. Volume Flow meters include area flow, positive displacement flow and differently pressure flow meters. Mass Flow meters on the other hand include Coriolis flow, vortex flow and thermal flow meters [17]. These differences in operation give a small indication on the purpose and the environment in which they can be effectively used.

In Volume Flow like the name suggests, the movement of a gas relative to its volume over time is quantified and measured. Since only volume is measured, a volumetric flow measurement can be successful without any knowledge of the gas composition. However, the major disadvantage of it is that volumetric flow is very sensitive to changes in temperature and pressure and either will alter the results significantly.

$$Q = \frac{dV}{dt} \quad (1)$$

Q: Volume Flow

V: Volume

t: Time

Since in our case we are dealing with a Mass Flow measurement we will focus a little more on this. However, it is important to know the basics of both to understand their strengths and drawbacks.

Mass Flow measurements deal with quantifying the movement of a gas relative to its mass over time. Here, we need to know what gas or gas composition is measured. This brings the inherent advantage of that the mass of the fixed gas composition stays constant regardless of changing environmental conditions. Mass flow is useful for controlling chemical reactions where the number of molecules present is of importance. For instance, during processes similar to chemical vapor deposition, during which gas is frequently heated, depend on this characteristic.

$$\dot{m} = \frac{dm}{dt} \quad (2)$$

ṁ: Gas Mass Flow

m: Mass

t: Time

However, knowing the exact gas composition is not always possible, which is the fundamental drawback of Mass Flow measurements. Additionally, the measurement device needs to be configured and in case of multiple measurements with a range of gas compositions completely emptied of any residuals of the previous gas and appropriately reconfigured. This makes mass flow meters impractical for any unknown or custom mixed gas compositions.

5.1 Mass Flow Meters by Sierra

Here we will describe the calibration steps for the Mass Flow Meter TopTrak 820, as seen in Figure 8, manufactured by Sierra. The basic working principle of the device is based on a thermal flow sensor. The transducer in the TopTrak is based on heat transfer and the first law of thermodynamics which states that the change in the internal energy of a closed system is equal to the amount of heat supplied to the system, subtracting the work done by the system in its environment.

Generally, the Top-Trak Mass Flow Meters require a 12 to 15 VDC external power source. The transducer´s 0 to 5 VDC is required to enable the system to record the flow, log the acquired data and in other types of Top-Trak even flow control. In- and Output connections are established via a 9-pin D-Connector on the side of the measuring device. [14.]

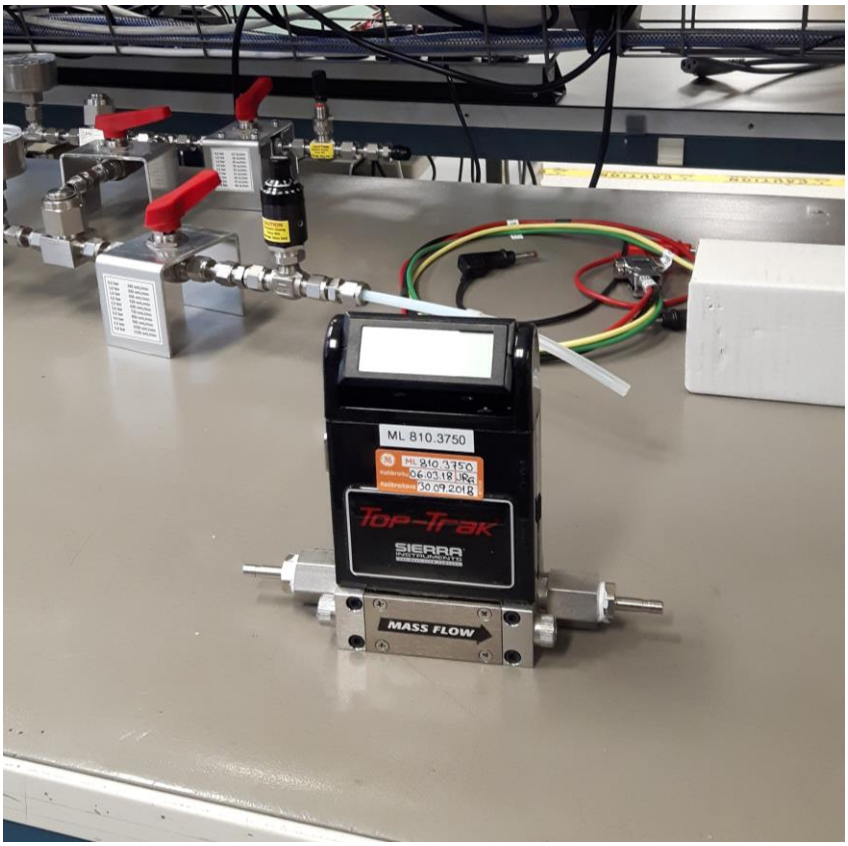

Figure 8: Sierra Mass Flow Meter

5.1.1 Working Principle

During the operation process, gas enters the device flow section where it is divided into two flow paths, one passing through the sensor tube, the other through the laminar flow bypass-element. This bypass generates a pressure drop, forcing a small fraction of the total flow to pass through the sensor tube, see Figure 9.

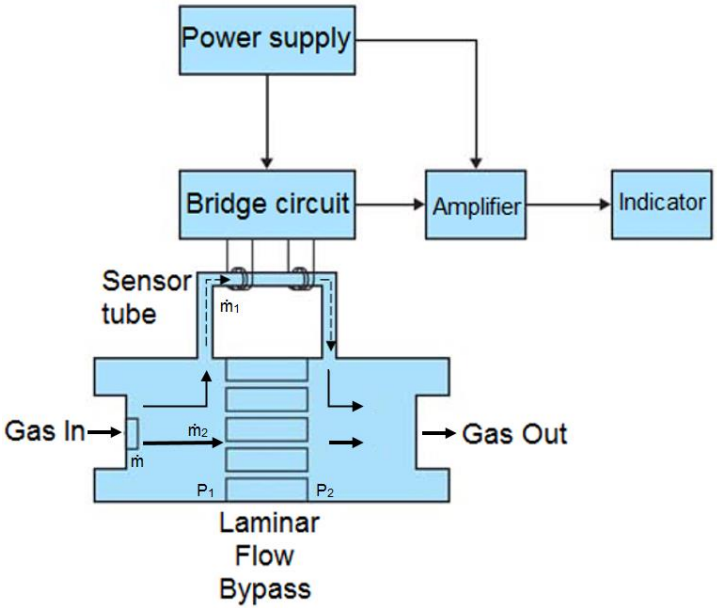

Figure 9: Operational Model of Mass Flow Meter

The two resistance temperature detector coils wound around the sensor tube, possess a large temperature coefficient. Thus, when electric current flows through these elements direct a constant amount heat into the gas stream. During this the gas mass flow carries heat from the upstream side to the downstream side, this results in a temperature difference that is detectable by the resistance detector coils and gives the output signal accordingly. The Flow Measuring Principle is based on the fact that the molecules of the gas carry away the heat, the output signal is linearly proportional to gas mass flow as represented in Equation 3 and 4.

$$\dot{m} = \dot{m}_1 + \dot{m}_2 \tag{3}$$

$$H = \dot{m}_1 * C_p * (T_2 - T_1) + H_0 \tag{4}$$

$$\dot{m} = \frac{H - H_0}{C_p * \Delta T} \tag{5}$$

$\dot{m}$: Gas Mass Flow

$\dot{m}1$: Sensor Tube Gas Mass Flow

$\dot{m}2$: Laminar Bypass Gas Mass Flow

H_0: Initial Entropy

H: Directed Entropy

C_P: Gas Specific Entropy

T_1: Measured Temperature of Upstream

T_2: Measured Temperature of Downstream

5.2 Functional Testing

As part of quality assurance, functional tests are conducted for every device prior to its calibration. Here, basic specifications of the device are inspected disregarding their accuracy and only verifying the system is operational. In the case of the Mass Flow Meter, the overall condition of the device is inspected, checking for any visible damage. Subsequently, the Mass Flow meter is tested for leakage to determine if the device is functional. Here, the meter was approved operational with no apparent damage and a leakage result of -0,57 mbar/2min.

5.3 Calibration

The Calibration of a Mass Flow Meter is rather straight forward. The guidelines for a proper calibration are often set by the manufacturers themselves but to ensure compliance with international standards, the owners may have additions to the manufacturer's instructions. GE Healthcare´s instruction manual on Mass Flow Meter Calibration states general requirements and environmental conditions which need to be ensured for the calibration. Additionally, the Document has sections for manufacturer specific cases. This is also the case for Mass Flow Meters manufactured by Sierra.

The Calibration interval for mass flow meters is only six months which is half of normal calibration interval. Mass Flow meters and controllers are fairly sensitive instruments. This makes them more susceptible to drifting due to environmental factor or simply han-

dling. Initially, the laboratories' necessary environmental conditions, meaning Temperature and Air-pressure, are established and recorded. These are in many cases very similar to ordinary conditions and rarely need to be artificially generated. Additionally, to power the device itself it needs a system connected where the gas and its flow rate can be controlled. Purging the mass flow meter of any remaining gas prior to the calibration is an essential step and is one of the first things conducted after the proper calibration set up has been established, as seen in Figure 10.

Figure 10: Mass Flow Meter Calibration Set-up

For this calibration, a gas composition has to be used that has the same gas coefficient as air. Here, GE Healthcare used nitrogen which matches the air coefficient of 1. During the calibration, the measurement devices flow rate is inspected on six Flow Set points, beginning at 30 ml/min. The measured value of Sierra´s Mass Flow Meter is compared at each point to the result of the reference device. Additionally, the Analog Output of the measurement device is monitored which ranges from 0 to 5 VDC.

5.4 Documentation

While the calibration is on-going, its results are recorded by hand on printed-out template form. Following, the recorded data, see Appendix 1, is entered in an excel sheet that is custom made by GE Healthcare. However, it is generated to be compatible with GAGEtrak so as the final step the calibration the Calibration Certificate can be printed

and signed by the person who conducted the calibration and approved by a second qualified technician or engineer. The resulting calibration is analysed in Table 2 and can visualized as seen in Figure 11.

Table 2: Mass Flow Calibration Results

Flow Set-point	Reference Flow	Flow Reading	Analog Output	Analog Output	Flow Reading Error	Analog Output Error	Error Limit	Calibr. Uncert. (k=2)
mL/min	mL/min	mL/min	VDC	mL/min	mL/min	mL/min	mL/min	mL/min
30	31,18	31,0	0,510	30,60	-0,18	-0,58	± 4,50	± 1,17
60	59,49	59,0	0,978	58,70	-0,49	-0,79	± 4,50	± 1,21
120	119,10	119,3	1,974	118,44	0,23	-0,66	± 4,50	± 1,77
180	178,87	179,0	2,969	178,16	0,13	-0,71	± 4,50	± 1,84
240	239,40	238,7	3,968	238,10	-0,73	-1,30	± 4,50	± 1,95
300	297,37	299,3	4,970	298,22	1,97	0,85	± 4,50	± 2,44

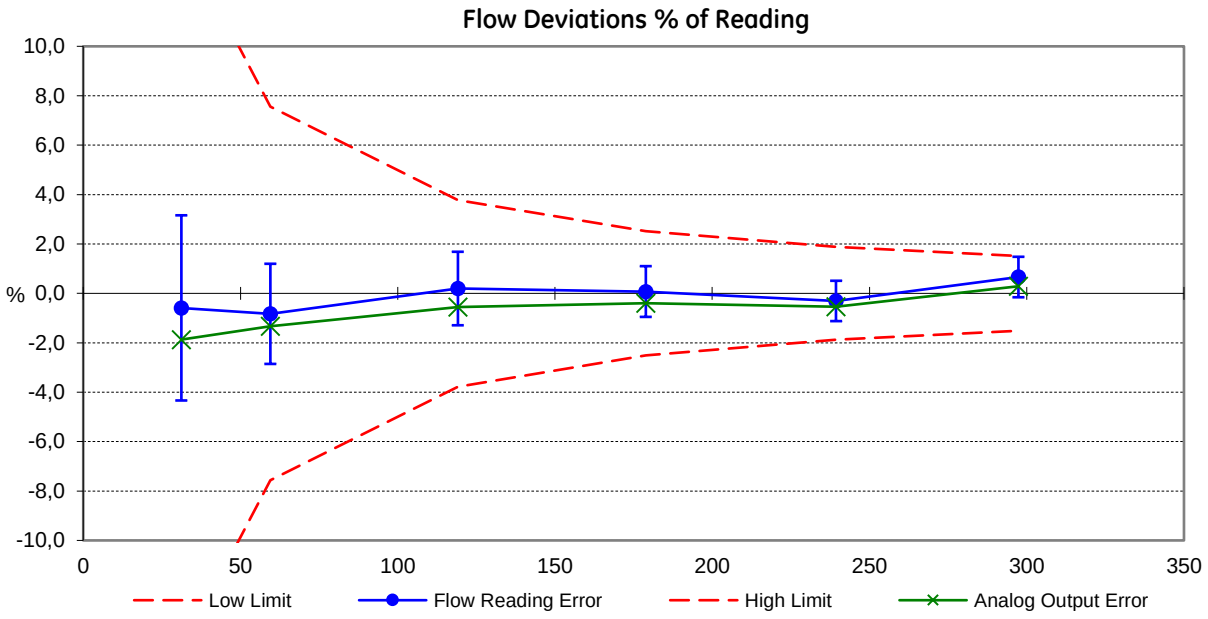

Figure 11: Flow Deviation of Measurement and Reference Device

The results of the calibration show that although the mass flow meter passes the requirements, it drifts towards the out of tolerance region. However, counteractive measures were not deemed necessary and the standard calibration interval will be applied to this mass flow meter. Thus, it was approved by completing the calibration with a certificate

and attaching a new label to the device, maintaining retractability of the device and its next calibration due date.

6 Preparing for Infor EAM

The purpose of this project work was to investigate the calibration process as a whole at GE Healthcare in Helsinki, as well as in general for manufacturers of medical devices. This was all part to gain the necessary understanding of the calibration work flow in General Electric Healthcare, in order to start moving from GAGEtrak to Infor EAM. In contrast to the previous pages of this thesis where the general requirements and process were investigated, the following section will have a more direct view on the General Electric Healthcare perspective and its calibration workflow at their Helsinki site.

6.1 Assessing Current Situation

Currently the work flow of the calibration itself is working well but the staff noticed shortcomings of the tools available to them. Especially looking at the asset management software called “GAGEtrak” is becoming impractical and thus damages the efficiency of the calibration team´s work. The most noticeable flaw of GAGEtrak seems to be its incompatibility with certain Operating Systems and versions of operating system. This poses a potential risk because with every update or change of computers, it is uncertain if GAGEtrak will be operational. The calibration team would be forced to ship measurement devices, they would otherwise be able to perform in internal calibrations. Increasing the costs due to delayed work and payments to the calibration providers.

6.1.1 Work Flow

The current calibration work can be divided into three sections which eventually merge into the same step, given the device is generally operational. The aim is being able to compose a certificate, attach the appropriate label and calibration information to the measurement device and into the asset management system. The initial steps are recognizing if the device is new to the calibration program or is already existing in the system. Additionally, we need to establish mechanisms which handle late or previously lost and now turned in measurement devices.

If the measurement device is new to the calibration program at GE Healthcare it needs to be registered first at the Helsinki site. After the risk assessment, it might be either established that the device doesn't require calibration, in which case the reason gets recorded and the device gets labelled accordingly, or the measurement device gets send to the calibration team located in the in-house calibration laboratory. At this stage, proper calibration procedures will be established, if at all possible, and performed accordingly. Following this, a calibration manual and a calibration certificate are composed, which, hold a distinct identification number for the said device.

However, the routine work for the calibration team is calibrating already existing measurement devices. In this case the device is supposed to be handed to the calibration at the latest on its due date. Otherwise, a notice will be send out determining if the device is late or lost. Following this, the calibration team will either initiate the calibration procedures or ship the device to an accredited calibration provider that has the appropriate laboratory environment and equipment to perform all necessary calibrations. The calibration results may indicate that although the device can still be formally approved, the measurement results are already drifting too close to the out of tolerance range to grant the device a routine life-cycle. In this situation the calibration personnel determine that the calibration interval shall be changed.

Late devices are evaluated according to location and usage. For instance, if the measurement device has been in use past its due date on the manufacturing floor, corrective and preventive actions must be taken before it can be approved to moved towards the calibration team.

6.1.2 Impact

GAGEtrak comes short compered to Infor EAM, even though the two applications essentially fulfil the same purpose and provide similar methods of completing these tasks. The technical differences have been discussed in the previous sections respectively. However, we will summarize it briefly here as well, in order to provide a better understanding of why this upgrade is necessary.

All the calibration work eventually passes through the Asset Management system, so it is a major part of the calibration work flow. Thus, both GAGEtrak´s shortcomings, as well as improvements by changing the system will have a major impact on the calibration

teams work. GAGEtrak in its current state works fairly locally and needs to be installed separately on every machine, although the databases can be shared via an internal network. Infor EAM relieves this by being a web based application. The advantages are of course being more accessible to newer operating systems and increasing the speed of implementation for new users to its system. Additionally, GAGEtrak is currently only used by the calibration team due to its functional limitations. Infor Enterprise Asset Management, true to its name, is able to connect multiple departments, moving Calibration, Engineering and Manufacturing departments closer together. This is a definitive advantage, potentially having all in one system instead of being separated by applications and nurturing collaboration.

One of the major factors why Infor EAM was chosen was because it runs on an enterprise server Hardware and is overall already a validated and proven system for GE Healthcare The user friendliness provided by Infor EAM´s solution may not be of the biggest concern for many; still, it cannot be disregarded. Infor provides not only more modern technologies but also better visuals backing up the information and displaying it so that also a wider range of users are able to understand the data in front of them, this is very well illustrated in Figure 12. This provides a better work environment, potentially enabling the calibration to an even greater efficiency.

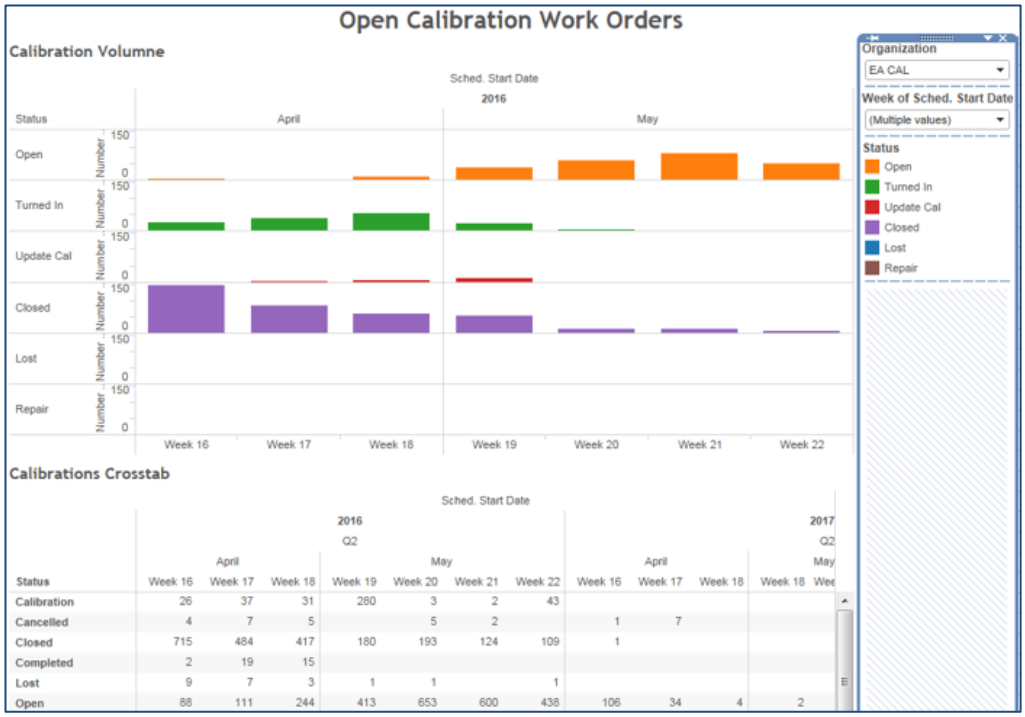

Figure 12: Infor EAM Calibration Dashboard [15]

6.2 Implementation and Deployment planning

The integration of any system into an enterprise, such as GE Healthcare, requires careful planning. This project required a collaboration with GE Healthcare Global IT from GE Digital. This was not only necessary to have proper guidance throughout the process of implementing Infor EAM here in Helsinki, but also to ensure that all requirements and regulations are upheld. They immediately helped with establishing the necessary channels for the cost centres and channels to Infor.

Together we defined the exact parameters and requirements necessary to meet the work orders. A schedule and scope for the overall project was developed after mapping out the details of how many organizations are involved and thus, the volume of assets operating in GE Healthcare. Although the schedule was always to be rather tight and fast paced, the original time of completion was to be estimated during March 2018.

A 16-step plan was result of these preparation meetings, where the first steps have been already completed by the discussion meetings. During those we walked through the upload template in order to understand the organization´s assets, certificate templates, queries and responses. The Global Team provided us with a development instance of Infor EAM, in which we could insert a compilation of 25 test-assets. The plan was to acquire hands on experience with Infor EAM with own assets. This would be followed by increasing the test assets number, improving feedback on the assets location, structure, asset IDs and crucial dates. This process would go over several weeks of test migrations and validating data.

The final phases of implementation could be started once the tests concluded that the transferring methods ensured that all data is correct and complete. However, the documentation, not only the test themselves, need to be checked, approved and released so that it can be archived and provided for future audits. These documents include detailed information on the implementation procedure and training material for the Helsinki users. This would initiate the Go-live date of Infor EAM at Helsinki Calibration, marking the start when it could officially be used by GE Healthcare Helsinki employees.

6.2.1 Obstacles

The project did not go as smoothly as planned. Communication between parties involved caused major delays in the overall work. Such, that the first implementation schedule was impossible to meet, and the date of completion was moved to early April. Unfortunately, those were not the only obstacles due to the work load of this implementation on our side and for the Global team it was necessary to split the scope into two phases focusing the implementation on the more crucial sector here in Helsinki. This means that the phase one was to be completed in April and phase two during June. Consequentially this moves the complete implementation of Infor EAM is to a time after this study has been completed.

7 Conclusion

The nature of this project made a fascinating topic to pick because it promised new challenges and potential to improve a wide variety of skills. This was well established by initially possessing a fundamental understanding of calibration, communication skills and data management. However, it was a pity that due to time limitations and complications that occurred during the project, the whole project could not be included in this thesis. Nonetheless, a lot of ground could be covered during the duration of the project and foundations and experience was gathered needed to continue and finish the work.

The two main goals of this thesis were to research how calibrations are performed on medical devices and implementing Infor EAM in General Electric Healthcare at their Helsinki site. Secondarily, the calibration workflow was analysed in order to give suggestions to improve the performance of the overall calibration and aid the calibration personnel in their daily tasks. I gathered my own experiences in the field by studying GE Healthcare´s calibration guidelines and working with the calibration personnel. Based on this knowledge a few points could be raised and will be brought GE Healthcare´s attention.

Simultaneously, the initial steps for the implementation of Infor EAM were taken. The process was started by contacting the responsible team within GE Digital and agreeing with them on important matters like implementation window, organizations involved,

amount of assets and estimating the costs. From then on, we scheduled regular meetings during which we dealt with problems and worked as best as we could in accordance with the schedule created during one of the initial meetings.

Although, this project is not yet completed already a lot of valuable lessons have been learned. For instance, communication problems need to be immediately addressed and in some cases transparency of the processes needs to be demanded. In this project various individual interests had been confronted with each other which caused friction in an international environment. Thus, by discussing, planning and defending GE Healthcare´s interest's negotiation skills were continuously developed even up to now.

Overall, although the thesis covers this project in an incomplete state it can be said a lot of tasks were covered successfully. Especially, establishing the ground work and setting GE Healthcare towards the path of improved asset management has been a big step. Undoubtedly, Infor EAM will improve the work of the calibration team and everyone is looking for presently Go-Live day for the system at GE Healthcare Calibration.

References

1 General Electric. GE Healthcare in Finland – Company Information.
URL: http://www.gehealthcare.fi/fi-fi/tietoa_meista
Accessed: 07.12.2017

2 Organization for Standardization. ISO – Fact Sheet.
URL: https://www.iso.org/about-us.html
Accessed: 07.12.2017

3 International Electrotechnical Commission. IEC – Commission Background.
URL: http://www.iec.ch/about/
Accessed: 21.12.2017

4 E. Hiltunen, L. Linko, S. Hemminki, M. Hägg, E. Järvenpää, P. Saarinen, S. Simonen, P. Kärhä. 2011. MIKES: Laadukkaan mittaamisen perusteet.

5 TÜV Süd: International Organization for Standardization (ISO). ISO 9001:2015 - Qualitätssicherung durch Prozessoptimierung.
URL: https://www.tuev-sued.de/management-systeme/iso-9001
Accessed: 15.01.2017

6 Regulation (EU) No 1025/2012 of the European parliament and Council on European standardisation. 2012.

7 European Commission for European Harmonised Standards on Medical devices. Council Directive 93/42/EEC. 1993.

8 Regulation (EU) 2017/745 of the European parliament and Council of 2017 on medical devices.

9 EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes. 2003.

10 TÜV Süd: Medical Devices Directive 93/42/EEC
URL: https://www.tuv-sud.com/industries/medical-devices-healthcare/market-approval-amp-certification/eu-market-access/medical-devices-directive-93-42-eec
Accessed: 15.01.2017

11 U.S. Food & Drug. CFR - Code of Federal Regulations. FDA QSR 21 CFR. 2017.

12 ISO 9001 Audit. Audit General Definition and Life Cycles.
URL: https://advisera.com/9001academy/blog/2016/10/18/what-is-an-iso-9001-surveillance-audit/
Accessed: 06.02.2018

13 GE Healthcare Internal Document. Helsinki Control of inspection measuring and test equipment.

14 Sierra 820 Series Top-Trak™ Mass Flow Meters. Instruction Manual.

15 GE Healthcare Internal Document. Infor EAM Overview 2016.

16 International Electrotechnical Commission. IEC 60601.
URL: https://www.tuv-sud.com/industries/medical-devices-healthcare/testing-amp-assessment/testing-of-active-medical-devices/iec-60601-1
Accessed: 21.04.2018

17 Mass Flow. Mass Flow versus Volume Flow Principles.
URL: http://www.kofloc.co.jp/kofloc_e/support/index.php?type=2&category_id=50
Accessed: 21.03.2018

Calibration Record **ID No.: ML XXX.XXXX** **Calibration Date: 06.03.2018**

Appendix A: Flow Measurements

Flow Measurements

Flow Setpoint	REF Std Temp	ML Resolution	1.				2.				3.				Std Deviation of Mean
			ML	Analog Output	REF	Temp and Gas Corrected REF Flow	ML	Analog Output	REF	Temp and Gas Corrected REF Flow	ML	Analog Output	REF	Temp and Gas Corrected REF Flow	
mL/min	°C	mL/min	mL/min	Vdc	mL/min	mL/min	mL/min	Vdc	mL/min	mL/min	mL/min	Vdc	mL/min	mL/min	mL/min
30	21,1	1	31	0,509	31,19	31,19	31	0,510	31,18	31,18	31	0,511	31,18	31,18	0,006
60	21,1	1	59	0,980	59,52	59,52	59	0,978	59,48	59,48	59	0,977	59,48	59,48	0,023
120	21,1	1	120	1,984	119,1	119,10	119	1,971	119,1	119,10	119	1,967	119,1	119,10	0,577
180	21,1	1	179	2,970	178,3	178,30	178	2,958	178,2	178,20	180	2,980	180,1	180,10	0,493
240	21,1	1	238	3,956	238,3	238,30	239	3,975	240,0	240,00	239	3,974	239,9	239,90	0,379
300	21,1	1	300	4,983	297,3	297,30	299	4,968	297,3	297,30	299	4,960	297,5	297,50	0,643

Flowchart of Current Calibration Workflow