Development of a Generic Tool Condition Monitoring Validation Methodology

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"A phenomenon will be said to be controlled when, through the use of past experience, we can predict, at least within limits, how the phenomenon may be expected to vary in the future"

Walter Andrew Shewhart (1931)

Economic Control of Quality of Manufactured Product

Abstract

This research brings GMP validation techniques to bear on a system that monitors the tool wear aspect of CNC machining, known as Tool Condition Monitoring (TCM), with a view to improving the overall performance of the process. The work was carried out in tandem with an EU FP7 funded project which installed force, acoustic and vibration sensors on CNC machines in Ireland, Poland, Italy and Norway.

The validation techniques are focused on the medical devices sector, primarily because the medical devices sector is bound by Good Manufacturing Practices (GMP's), which are mandatory regulatory requirements. GMPs are enforced in different parts of world by different regulatory bodies; some of the more recognizable bodies would be the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO) and the European Union (EU). Validation is an essential part of good manufacturing practices and the approach of bringing GMP validation techniques to TCM has not yet been implemented in this industry, which otherwise relies heavily on validation.

The validation process consists of identifying and testing all aspects of a process that could affect the final product. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required quality specifications throughout the product lifecycle.

One of the unique elements of this research was the incorporation of a Case-Based Reasoning (CaBR) control system into the TCM, and the application of the validation model to CaBR, an area which has received little attention in literature. The system must be trained by a machine operator, during the setup process, to identify when a tool is at end of life and based on this data makes its own decisions around the degree of tool wear present on the tooling. Validation of the CaBR system was completed by establishing whether an individual test case had been solved correctly, through benchmarking against learned information and operator expectation.

The REALISM TCM system was tested in accordance with regulatory requirements and has passed testing for the turning operation, boring operation and detection of catastrophic tool failure (CTF), the drilling operations however, failed validation testing.

Declaration

I hereby declare that all work produced in this document is entirely my own work, except where otherwise stated, and has not been submitted in whole or in part to any other University.

Signature: _____

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Date:

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1.0 Introduction

1.1 Research Project Overview

1.1.1 Background

In precision engineering, cutting tool condition has a large effect on the accuracy and surface finish of machined parts. Currently, errors associated with tool wear are usually only detected at the end of the machine cycle, by which time the product is only of scrap value.

Scrap at the Schivo Ltd. facility, between 2012 and 2015 has on average accounted for 2.95 % of all parts produced, and cost the company over €1.25 million euros at standard cost (figure 1-1 and figure 1-2).

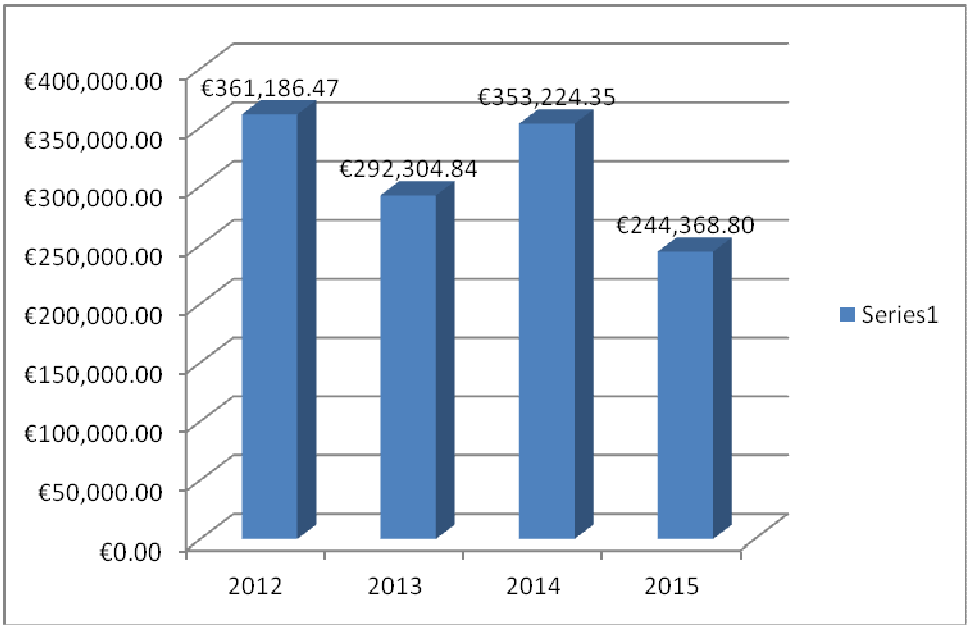

Figure 1-1: Scrap Value 2012 - 2015

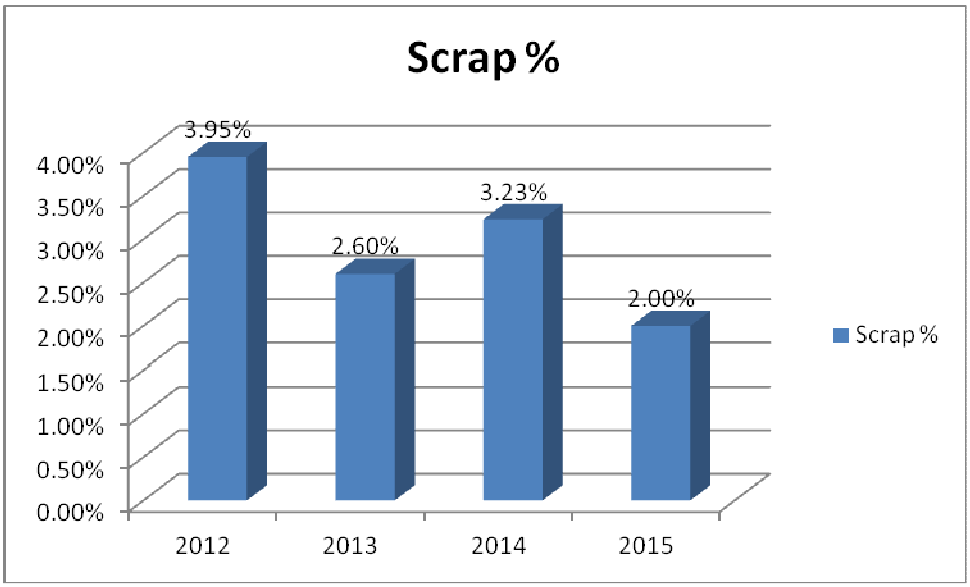

Figure 1-2: Scrap Percentage 2012 - 2015

Machining of parts is primarily performed by Computer Numerical Control (CNC) machines. If CNC machines were equipped with real-time monitoring, machining parameters could be adjusted, in real-time, to compensate for tool wear and the tools could be replaced at appropriate intervals before they reach end of tool life. This would result in both better control over the machining process and would also lead to a significant reduction in scrap rates.

This project proposes to bring GMP validation techniques to bear on the tool wear aspect of machining, known as Tool Condition Monitoring (TCM), with a view to improving the overall performance. The work will be carried out in tandem with an EU FP7 funded project that will install force, acoustic and vibration sensors on selected machines in Schivo Ltd. This approach of bringing validation techniques to TCM has not yet been implemented in an industry that otherwise relies heavily on validation.

The REALISM project has participants across a number of EU member states. The consortium partners are listed in Table 1-1: The REALISM Consortium.

Table 1-1: The REALISM Consortium

Name	Country	Participant Type
Schivo Ltd.	Ireland	SME

Name	Country	Participant Type
Waterford IT (WIT)	Ireland	RTD
IDT Solutions	Norway	SME
Warsaw University of Technology (WUT)	Poland	RTD
Tulino CTM	Italy	SME
University of Naples	Italy	RTD
Gjovic University (GUC)	Norway	RTD

The REALISM project consortium work packages are broken down, as detailed in Figure 1-3: REALISM Project Work Package Overview. While the focus of this paper is WP7 – Validation and Evaluation, the success of this work package requires both process and component information and understanding of all the other work packages.

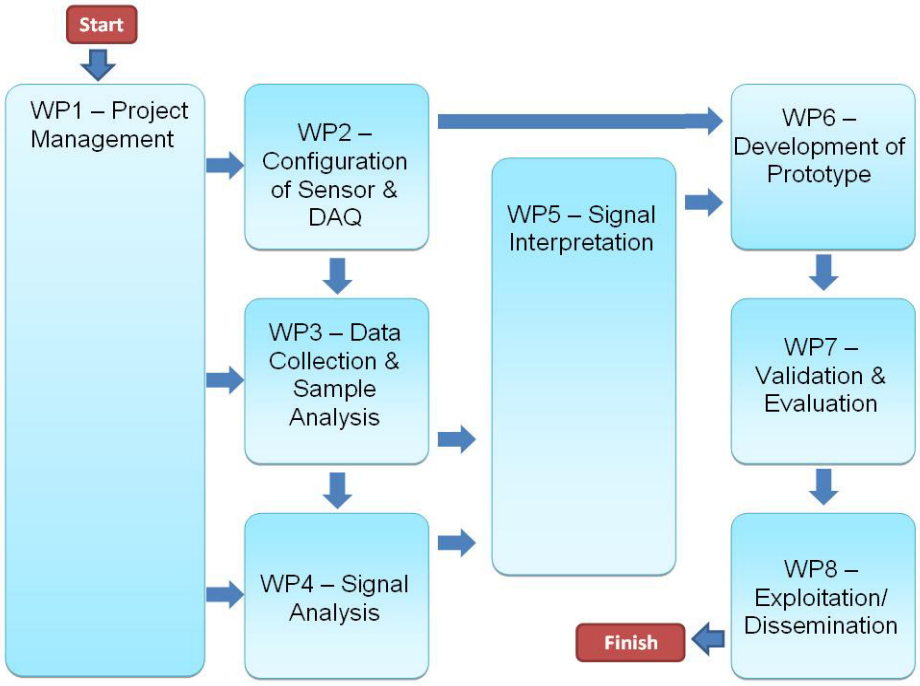

Figure 1-3: REALISM Project Work Package Overview

1.1.2 Aim/Objective

The aim of this project is to develop a validation model for a real-time TCM system, which incorporates a Case-Based Reasoning (CaBR) control system, which will be implemented on a fully functional factory floor demonstrator/prototype. The application of a GMP style of validation to a TCM, or a system which incorporates a CaBR, is an area which has received little attention in literature. The CaBR portion of the system must initially be trained by a machine operator, three times during the setup process, to identify when a tool is at end of life, and based on this learned data makes its own decisions around the degree of tool wear present on the tooling during subsequent machining operations. Validation of the CaBR system will be completed by establishing whether an individual test case had been solved correctly, through benchmarking against learned information and operator expectation.

For the purposes of this research, the author poses the research question:

Is it possible to develop a generic tool condition monitoring validation methodology?

The objective of this research project is to establish:

- Should a TCM, incorporated with a CaBR, in a medical devices manufacturing environment, be validated or verified?
- Can a GMP style of validation be applied to a TCM, which incorporates a CaBR?
- What are the barriers pertaining to the validation of a system which incorporates a CaBR system, and what is the impact from external variables on the training process?
- Is a TCM, incorporated with a CaBR capable of adaption to a wide range of machining scenarios, such as turning, boring and drilling?

Through a review of the literature in Chapter 2.0, the author identifies three key regulatory bodies, and their validation guidelines, and based on those guidelines, the following individual research questions are asked:

- What exactly are qualification, validation and verification?
- What is the ideal validation approach for a tool condition monitoring system?

- Why validate the TCM system?
- What are the barriers pertaining to the validation of a system which incorporates a CaBR system?
- What is the impact to system training from outside influencing variables, such as the mechanical properties of the tooling, and operator opinion?

The author anticipates that by answering the research questions listed, the findings will benefit future SMEs looking to install a TCM system in a GMP environment, and could also form the basis for future research, discussed in Section 0. In addition, the study may reveal barriers and factors effecting implementation of the validation model that have not been identified through the review of literature.

1.1.3 Research Methodology

A quantitative research method is deemed by the author to be most suited for the research study, and will be completed by running trials, taking objective measurements and completing statistical analysis of the data collected.

1.2 History of Validation

Prior to 1963 the only method available to the FDA to prove that a process had/had not done what it was designed to do, was to take samples from the process and analyse them against a specification. According to Helle et al. (2003) things began to change during the late 1960s and the early 1970s when new types of incidents, such as poorly mixed, highly potent tablets and insufficient sterilization procedures for large volume parenterals caused serious patient disorders. In 1963, following the publication of the cGMP regulations for pharmaceuticals, the law changed and now stated that pharmaceutical manufacturers now had to follow cGMP regulations and that the FDA was now authorised to perform inspections on these manufacturing facilities. The concept of validation was first proposed by two FDA officials, Ted Byers and Bud Loftus, in the mid 1970's, to improve the quality of pharmaceuticals. According to Chapman et al. (1991) the U.S.F.D.A. was the pioneer in advocating the concept of process validation, but until 29th September 1978 the definition of process validation did not appear in any part of their literature and no cGMP regulations

mentioned process validation.

These changes to how processes were regulated came as a direct result of a number of serious accidents in which people were injured, and even killed. As a result the need for process validation was elevated by US authorities and the term "validated manufacturing process" was defined in the Drug Process Inspections Compliance Program in 1978 and in 1987 the Guideline on General Principles of Process Validation was published which defined the requirements around process validation.

In the EU similar advances in how processes were controlled was taking place. In 1968 new guidelines were introduced governing the sale and distribution of medicinal products, and in 1971 the first edition of the Orange Guide was published by the Pharmaceutical Inspection Convention (PIC). In 1989, the first edition of the European Guide to GMP superseded all national guidelines within the European Union (EU). This guide was put together by the European Commission and the EMEA and has served as a model for all European countries regardless of whether or not they belong to the EU. In 2001, Annex 15 to the EU Guide to GMP came into operation titled “Qualification and Validation”.

The concept of validation has expanded through the years covering a wide range of activities including but not limited to:

- Manufacturing Process
- Manufacturing Equipment
- Cleanroom Environment Validation
- Cleaning Validation
- Product Validation
- Software Validation
- Sterilization Validation
- Laboratory Equipment
- Laboratory Methods

Validation is founded on regulatory requirements, and is an integral part of cGMP, ref Figure 1-4 for details on the evolution of process validation.

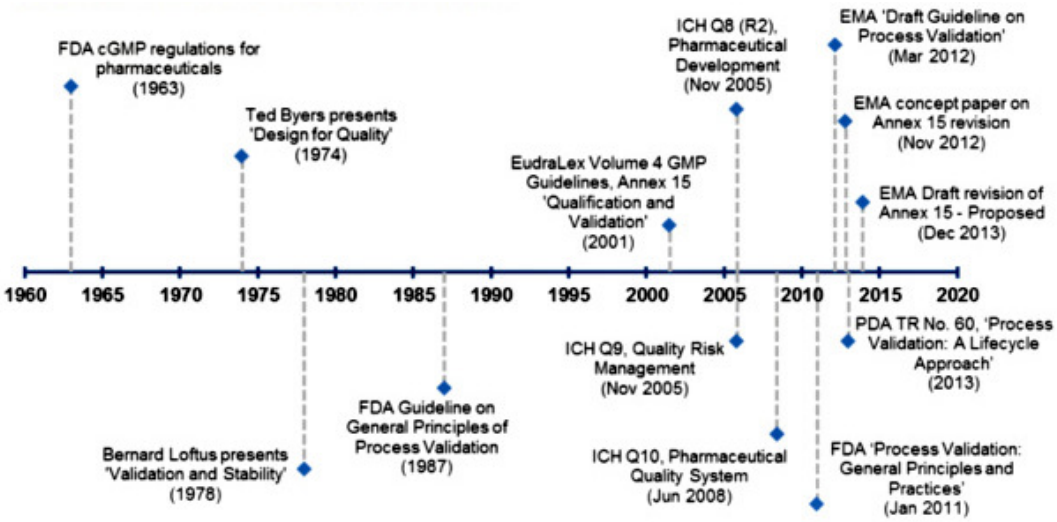

Figure 1-4: Evolution of Process Validation - Greene et al. (2013)

2.0 Synthesis of the Literature

2.1 Introduction

The scope of this literature review was determined by the primary research area: "Development of a generic tool condition monitoring system". There is no existing research that investigates the application of GMP validation to a tool condition monitoring system and in addition, validation of a CaBR based system is an area which has received very little attention in literature.

Therefore, in the following literature review the author will look at existing regulatory guidelines around GMP validation, along with any previous research done in the field of validation, with a particular focus on a GMP style of validation, to establish what the collective literature claim to be the most valid approach to validating a tool condition monitoring system, which incorporates a case based reasoning system.

2.2 Selection of Regulatory Standards

In precision engineering, tool wear has a large effect on the accuracy and surface finish of machined parts and according to Teti et al. (2010) is the single greatest contributor to scrap in the industry. In the surgical products' market, cosmetic finish requirements placed on parts continues to be raised to new levels. Similarly, in the aerospace industry parts need to be increasingly accurate. Through the development of CNC (Computer Numerical Control) technology, tolerances of 1µm are now possible. However, SMEs involved in this project still see significant failures in the current technology, particularly in the area of tool wear monitoring.

CNC (Computer Numerical Control) Machining is a subtractive manufacturing process which involves the use of computers to control lathes, milling machines, grinders, routers or various other machine tools. CNC machines are automated pieces of equipment that can manufacture components from various different materials including, but not limited to, plastics, metals and waxes. The code used to program CNC units is called G-code. It contains information about the required tooling and machine movements required to manufacture specific components. Some newer additive manufacturing technologies such as 3D metal and plastic printers now use CNC; however additive manufacturing is outside the scope of this research.

CNC machines are used to manufacture product for various industries, including but not limited to Aerospace, Medical Devices, Oil & Gas and Automotive. CNC machine shops will commonly seek voluntary certification, when they determine that the certification is beneficial to their operations, some examples of voluntary certifications are ISO 9001 Quality Management System, ISO 13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes and AS 9100 Quality Management Systems – Requirements for Aviation, Space and Defence Organisations.

The ISO 9001, ISO13485 and AS9100 standards all required that "the organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records and

e) revalidation."

While the certification bodes above refer to validation within their standard, it is within the medical devices and pharmaceutical sectors that validation is most prevalent, this is because companies who are manufacturing for the medical devices and pharmaceutical sectors are bound by GMP's or Good Manufacturing Practices. GMPs are a mandated regulatory requirement and if you are manufacturing medical devices for distribution you must be in compliance with these regulations. GMPs are enforced in different parts of world by different regulatory bodies; some of the more recognizable bodies would be U.S. Food and Drug Administration (FDA), the World Health Organization (WHO) and the European Union (EU).

While the guidelines outlined by each regulatory body vary from country to country, all the

guidelines cover the same basic principles including, but not limited to, hygiene, controlling environmental conditions, controlling processes, controlling change, standardization through instructions and procedures, training, maintaining records and managing complaints and recalls. GMP guidelines are not a prescriptive set of instructions on how to manufacture products, they contain a series of general principles that must be observed during manufacturing. There are numerous ways that a company can fulfil the requirements of the GMP guidelines and the method of fulfilment will vary from company to company. It is the company's responsibility to determine the most effective and efficient method to implement the guidelines.

Within the aerospace and oil and gas industries, where GMP guidelines are not prevalent, 100% inspection is more common place, and sampling inspection is less frequently used. Guidelines stipulate that an organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. 100% inspection is one of the common forms of verification within the CNC industry, and it is based on this verification activity that aerospace and oil and gas industries for example are able to bypass the requirement for formal validation activities. Verification is discussed in more detail later in this text however because of the prevalence of verification activities within the aerospace and oil and gas industries the author has decided to narrow the focus of this research to the medical devices industry.

The European Commission in its guidelines Annex 15: Qualification and validation (2014), the US FDA in its Guidance for Industry Process Validation: General Principles and Practices (2011) and the WHO Annex 4 Supplementary guidelines on good manufacturing practices: validation (2006) respectively define process validation as follows:

“Documented evidence that the process, operated within established Parameters, can perform effectively and reproducibly to produce a Medicinal product meeting its predetermined specifications and quality attributes”.

“Process validation is establishing documented evidence which provides a high degree of assurance that a specified process will consistently produce a product meeting its pre-determined specifications and quality characteristics.”

“Documented evidence which provides a high degree of assurance that a specific process will consistently result in a product that meets its predetermined specifications and quality

characteristics".

As expected there are commonalities between the definitions outlined by the regulatory bodies, summarized in Table 2-1: Validation. A comparison of definitions from GMP regulatory bodies.

Table 2-1: Validation. A comparison of definitions from GMP regulatory bodies

Agency	Objective/ Documented Evidence	Established Parameters	Repeatedly/ Consistently	Predetermined Specifications
European Commission	√	√	√	√
Food and Drug Administration	√	√	√	√
International Conference on Harmonisation	√	√	√	√
World Health Organisation	√	√	√	√

Through comparison we can summarize validation as **documented evidence,** showing that if we have a process with specific **predetermined parameters** and we constantly input the same parameters to the process, we will **consistently** achieve an output from that process that meets our **pre-determined specifications**. Our predetermined inputs and outputs are most commonly derived from process development studies.

It's important to note, that the US FDA guidance document Guidance for Industry - Process Validation General Principles and Practices explicitly states that the "guidance does not cover medical devices and that guidance on process validation for medical devices is provided in a separate document, Quality Management Systems – Process Validation, edition 2. The Global Harmonisation Task Force (GHTF), now referred to as the

International Medical Device Regulators Forum (IMDRF), was a voluntary group of representatives from national medical device regulatory authorities and the members of the medical device industry whose goal was the standardization of medical device regulation across the world. The representatives from its five founding members (the European Union, the United States, Canada, Japan and Australia) were divided into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own unique regulatory framework. Founded in 1992, the GHTF was created in "an effort to respond to the growing need for international harmonization in the regulation of medical devices." The GHTF disbanded late in 2012 however its mission has been taken over by the International Medical Device Regulators Forum (IMDRF), a successor organization composed of officials from regulatory agencies— not industry — around the world. It must be noted that GHTF produce a guideline, not a "Regulation".

2.3 Qualification, Verification and Validation - What's the difference?

The terms Qualification, Verification and Validation are often not very well understood, and are often incorrectly interchanged. So, what's the difference?

2.3.1 Qualification

The voluntary guidelines outlined in ISO 9000 (2005), section 3.8.6, defines a qualification process as the process used to demonstrate the ability to fulfil specified requirements. The regulatory guidelines are more prescriptive, with the WHO stating that qualification is the "action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results " they further suggest that "validation and qualification are essentially components of the same concept. The term qualification is normally used for equipment, utilities and systems, and validation for processes. In this sense, qualification is part of validation." The US FDA guidance, while it doesn't explicitly define qualification, it does specify that during the process qualification (PQ) stage of the validation lifecycle "the process design is evaluated to determine if it is capable of reproducible commercial manufacture. This stage has two elements: (1) design of the facility and qualification of the equipment and utilities and (2) process performance qualification (PPQ)".

Qualifications should be thought of as tests that are completed on equipment, utilities, facilities and analytical equipment. They are physical tests that are completed to ensure that they are installed, operating and performing and they should be prior to completing a validation. This is perhaps best illustrated by the funnel diagram in Figure 2-1 below. All the qualification (xQ) activities are inputs into the funnel with the output being a validated process.

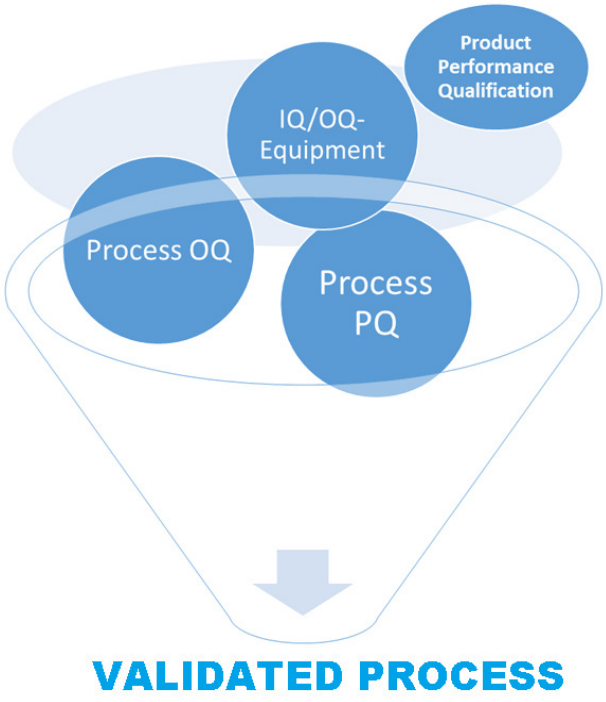

Figure 2-1: Qualification – Funnel Diagram

Within industry the commonly accepted method of validating equipment or processes is through the use of qualification protocols, IQ (Installation Qualification) is typically used to test the installation, OQ (Operation Qualification) to test the operation and PQ (Performance Qualification) to test the performance, against specification. This is reinforced by the GHTF (2004) guidelines which state that the "validation of a process is the mechanism or system used by the manufacturer to plan, obtain data, record data, and interpret data and that these activities fall into three phases: 1) an initial qualification of the equipment used and provision of necessary services – also known as installation qualification (IQ); 2) a demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters – also known as operational qualification (OQ); and 3) and establishment of long term process stability – also known as

performance qualification (PQ)".

Process Validation (PV) is generally completed on live product manufactured from a qualified process. Qualification should be completed on physicals such as equipment, utilities and facilities, whereas validation is completed on manufacturing processes and procedures. Importantly, it must be noted that Validations cannot be completed without qualifications. This is reinforced by the WHO, who specify that "In this sense, qualification is part of validation."

2.3.2 Verification & Validation

ISO 9000 (2005) in sections 3.8.4 and 3.8.5 define verification is the "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled" and validation is the "confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled". Part 820.75 (a) of the US FDA Quality Systems Regulation (2014) simply states that "where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures." There is no clear guidance from the US FDA on verification, so what exactly does "fully verified" mean?

The most commonly accepted method of verification within industry is 100% inspection, however none of the guidelines explicitly say that 100% inspection is required. US FDA (2014) Part 820.70 specifies that "Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications." Where process controls are needed, they shall include, among other things, "monitoring and control of device parameters and component and device characteristics during production." It can therefore be concluded, from the US FDA guideline, that whatever the method of verification chosen there must be a sound rationale behind the decision to choose the method, and this must be documented in your plan or protocol. This therefore allows for alternative methods of verification; however the documented justification for the choice of method must be robust. Helle et al. (2003) suggest that the three most often referred to definitions of pharmaceutical process validation are those presented by the European Agency for the Evaluation of Medicinal

Products (EU), the US Food and Drug Administration (US FDA) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). While the three definitions are very similar; it is suggested that “the only difference is that FDA expresses a minor uncertainty of the concept by stating that process validation only provides a high degree of assurance, not absolute assurance, that the process will produce the intended result.

Within industry, verification and validation are commonly thought in the following context:

Verification = "Are we building the product right?"

Validation = "Are we building the right product?"

One distinct advantage of validation is that it is based on objective evidence. This evidence is generally collected through process development activities, or process experience, over a period of time and generally presents itself in in the form of a statistical analysis, of the process and its performance. Verification on the other hand is completed at a point in time i.e.: Part A gets inspected followed by Part B, Part C etc..., and no knowledge of the process is gathered, other than the fact that each individual part passed or failed inspection. Without statistical knowledge of the process it can be difficult to justify lower level sampling plans and therefore the cost of 100% verification needs to be absorbed into the cost of the manufacturing process. It’s important to mention that 100% verification is also never 100% effective. Juran (1935) estimated that 100% verification was only 80% effective, however by 1979 Sinclair (1979) demonstrated that not only was Juran correct in his estimations that 100% verification was not 100% effective, but also that he was optimistic with his figure of 80%. Sinclair (1979) concluded that the human species is unlikely to develop into an error proofed condition any time soon. The efficacy of an inspection process depends on a number of critical factors including, but not limited to inspector training and qualifications, the number of features and components to be inspected, the lighting in the inspection area, operator fatigue levels, time constraints on the inspection process, tools and equipment and there sensitivity and accuracy level and environmental conditions which may induce a slight expansion or contraction. Some of the influencing factors are illustrated in Figure 2-2: Effectiveness of 100% Inspection.

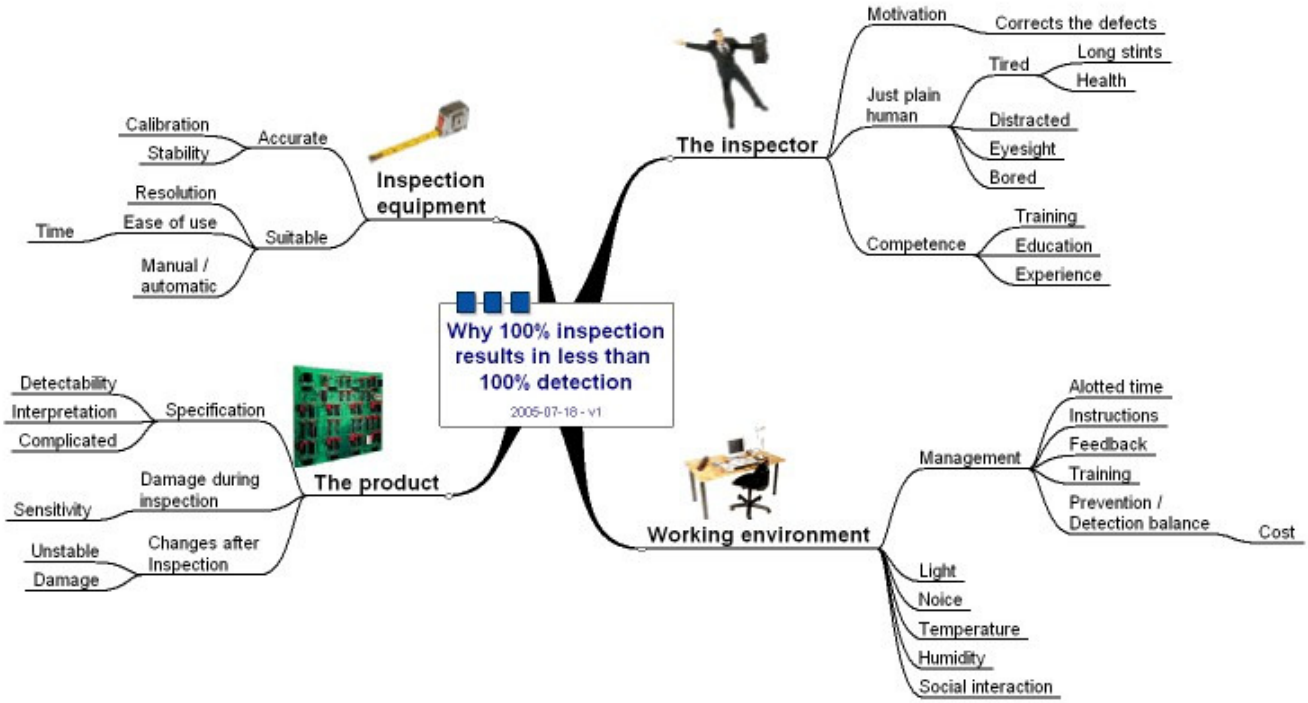

Figure 2-2: Effectiveness of 100% Inspection – Gefvenberg (2005)

There may some circumstances where verification is preferable to validation or vice versa, for example if the method of verification requires destructive testing, or the cost of verification too going to be too high, then validation is preferable, or if on the other hand the product is a short term product, or a small batch quantity, the cost of validation may be too high and therefore verification may be a more preferable option. The GHTF (2004) guidance document illustrates a decision tree, Figure 2-3: GHTF Process Validation Decision Tree, which helps in the determination of whether a process should be validated or not. Is a very simple illustration but provides an effective roadmap to help with the decision as to whether to verify or validate a process. It asks 2 questions, is the process output verifiable? And is verification sufficient and cost effective? The cost effectiveness verification is an extremely important consideration. Snow et al. (2012) suggest that "in many cases it may be more cost effective to validate the process upfront to understand and control variation, this in turn would help with improving process capabilities, increase process yields and lower scrap. They do also however stipulate that this is a business decision that needs to be taken early in the process development phase of the project.

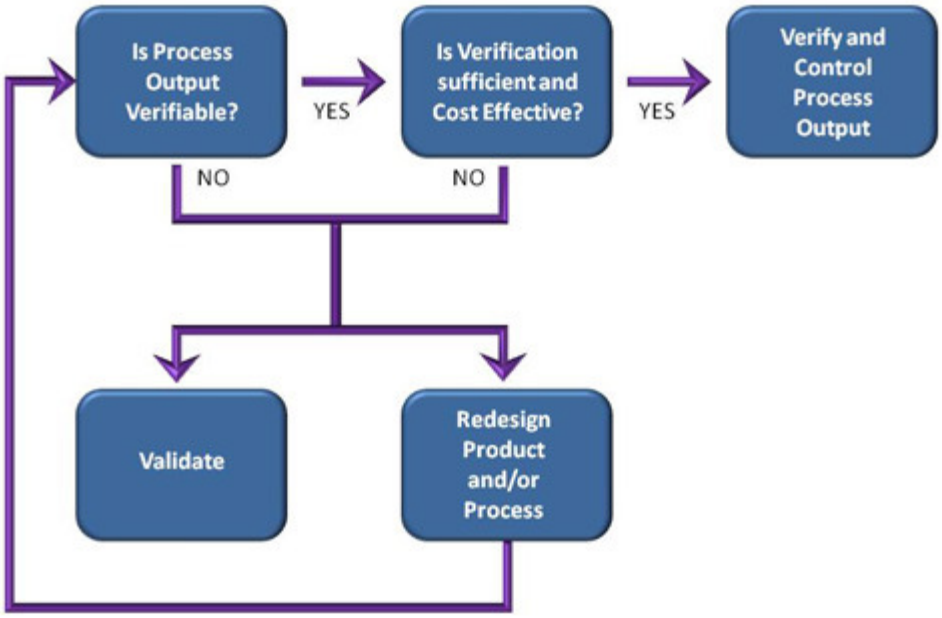

Figure 2-3: GHTF Process Validation Decision Tree – Snow et al. (2012)

The GHTF (2004) suggest that each process should have a specification describing both the process parameters and the output desired. The business should then consider whether the output can be verified by subsequent monitoring or measurement. If the answer is yes, then the consideration should move to whether or not verification alone is sufficient to eliminate unacceptable risk, and is it a cost effective solution. If yes, the output should be verified and the process should be appropriately controlled, if not validation, or product redesign, is required to get the product to a point where verification is sufficient and cost effective.

The GHTF (2004) gives guidance, through examples, of processes that should be considered for validation, processes that should be considered for verification and processes that are suitable for either validation or verification. While it's not an exhaustive list, it does give a good top level overview. Processes which should be validated are details as follows:

- Sterilization processes
- Clean room ambient conditions
- Aseptic filling processes
- Sterile packaging sealing processes

- Lyophilization process
- Heat treating processes
- Plating processes
- Plastic injection moulding processes

Processes which may be satisfactorily covered by verification are detailed as follows:

- Manual cutting processes
- Testing for colour, turbidity, total pH for solutions
- Visual inspection of printed circuit boards
- Manufacturing and testing of wiring harnesses

And processes which may be verifiable, but for business purposes, validation can be chosen are detailed as follows:

- Certain cleaning processes
- Certain human assembly processes
- Numerical control cutting processes
- Certain filling processes

It's important to note however, that although the guidance specifies which process "should be" validated or verified, it is the manufacturer who will ultimately decide whether to validate or verify the process as they are the one who fully understands their own processes. The US FDA however will be expecting processes that are specified as requiring consideration for validation, in the GHTF guidance, are validated, so if you determine that verification is sufficient, your rationale needs to documented in your validation plan or validation protocol.

Although verification and validation are seen independent entities within the guidance documents, they can, and are, within industry, often used in parallel with each other. Examples of such situations are complex processes in which there are a number of sub processes, the answer to the suite of questions detailed in Figure 2-3: GHTF Process Validation Decision Tree may lean towards verification or validation depending on the sub

process being scrutinised, another situation may be where process capability targets cannot be achieved for a particular part of a process, then this particular sub process may then then subjected to 100% verification, and this verification is built into the overall validated process.

The voluntary standards ISO13485, AS9100 and ISO 9001 in their guidelines specify that:

"The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records and

e) revalidation."

The important statement within this part of the requirement is "where the resulting output cannot be verified by subsequent monitoring or measurement". According to Brecken (2009), processes where the resulting output cannot be verified by subsequent monitoring or measurement are frequently referred to as "special processes". The superseded standard, ISO 9001:1994 included the term "special process". In 2000 the term special process was removed and ISO 9001 now refers to special processes as "processes requiring validation." Similarly AS9100 and ISO13485 changed their terminology in line with the base standard ISO 9001. Brecken (2009) concludes that special processes refer to processes that produce outputs whose output cannot be verified, before being released to the customer and that these type of products and services require special attention during production to ensure that they're free from defects.

To comply with regulatory requirements all special processes must be validated. Validation of special processes provides confidence that the process is fully understood and the output

will achieve consistent results against the required specifications.

In summary, verification can be thought of as a method of testing that provides assurance at a point in time that a product will do what it is intended to do without causing another problem. Validation on the hand provides measurable evidence that over time the product will work properly. In the medical devices industry process validation is generally seen as the endpoint of all validation activities because product quality and safety for patients are the main purpose of all GMP activities.

2.4 Types of Validation

GMP validation activities, within industry, will typically fall into one of 3 categories, prospective validation, which is validation of a process before manufacture of commercial product, concurrent validation, which is validation carried out where the product being manufactured is intended for commercial release and product is held until validation passes or retrospective validation, which is validation when the system has already been in operation for commercial purposes and is not recommended. This concurs with regulatory requirements, with the EU (2014) specifying that process validation should normally be completed prior to the distribution and sale of the medicinal product (prospective validation). In exceptional circumstances, where this is not possible, it may be necessary to validate processes during routine production (concurrent validation). Processes in use for some time should also be validated (retrospective validation) and the WHO (2006) stating that there are two basic approaches to validation — one based on evidence obtained through testing (prospective and concurrent validation), and one based on the analysis of accumulated (historical) data (retrospective validation) and that prospective validation is preferred, and retrospective validation is no longer encouraged. The US FDA in their 2011 guidance document has however moved away from the specific use of the terms prospective validation, retrospective validation and concurrent validation and instead the guidance document aligns process validation activities with the product lifecycle model. Oechslein (2011) in her review of the 2011 FDA guidance document Guidance for Industry Process Validation: General Principles and Practices, suggests that retrospective validation will presumably be a thing of the past and will no longer be mentioned by the FDA and that’s the term concurrent validation has been replaced by "con-current release of PPQ

batches", she further suggests that this makes it clear that there are no longer different approaches to validation, but just a single one: the life cycle model. Lifecycle models are reviewed in Section 2.5, however at this point is important to note that the lifecycle approach is now also being adopted by the EU and WHO and draft guidelines featuring the lifecycle approach are currently out for approval.

Prospective validation is the preferred method of validation within industry as it poses the least risk from a patient, business and compliance standpoint.

2.5 Validation Lifecycles

The introduction of the US FDA's 2011 Guidance document has seen the definition of validation move on significantly from the traditional definition, in 1987 Guidelines, which defines process validation as "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics" with the newer definition now defining process validation as the "collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product". Katz et al. (2012) suggest that by aligning process validation activities with a lifecycle approach, the 2011 Guidance communicates that process validation is an ongoing program rather than a discrete and isolated activity and that prior to the issuance of the 2011 Guidance it was widely accepted throughout industry, and, indeed implied or stated in some FDA guidance documents, that process validation was a static, three-batch demonstration.

The US FDA (2011) guidance document describes process validation activities in three stages:

Stage 1 – Process Design: The commercial process is defined during this stage based on knowledge gained through development and scale-up activities.

Stage 2 – Process Qualification: During this stage, the process design is confirmed as being capable of reproducible commercial manufacturing.

Stage 3 – Continued Process Verification: Ongoing assurance is gained during routine production that the process remains in a state of control.

An additional item to note in the 2011 Guidance is its strong emphasis on the use of statistics to aid validation activities, ref Figure 2-4.

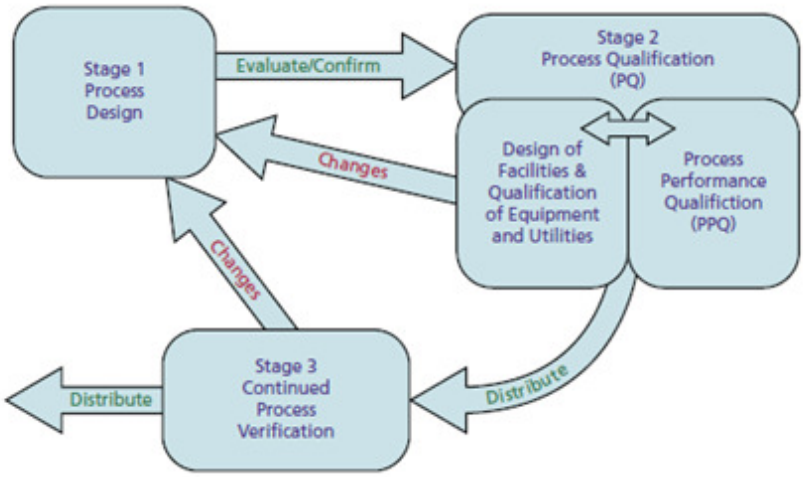

Figure 2-4: FDA Lifecycle Approach – Katz et al. (2012)

Following the release of the US FDA guidance in 2011, the EU, in March 2012, released an initial draft version of its new guideline on Process Validation. The EU document is not as comprehensive or prescriptive as the US FDA guidance however as with the US FDA, the EU 2012 draft guideline is formalising the concept of the validation life cycle, as part of the product life cycle. PharmOut (2013) in their white paper EMA Draft Guidance: Process Validation suggest that the lifecycle approach is a much more robust method of validation and that key shortcoming of traditional process validation has been the idea that a manufacturer can perform a minimum of three validation batches at product commercialisation and, if successful, make the product routinely in the future without further consideration to process validation. They also suggest that in such cases, the validation effort 'dies' when the product is successfully launched, and there may be no ongoing life cycle considerations. Unlike the US FDA's 2011 guidance, the EU's 2012 guidance document does not formally break down the validation life cycle into a defined group of stages, however, PharmOut (2013) in their White Paper - EMA Draft Process Validation Guidance suggests that parallels can be drawn between the two approaches and broadly; the three stages described by the US FDA can be applied to the EMA guidance as follows:

US FDA Stage 1 – Product Development

Although the EMA guideline does not specify what kinds of documentation or testing activities should be conducted during product development, it does encourage leveraging of development phase activities, such as Design Space and pilot scale production to assist with product understanding and development of validation strategies, including continued process verification (CPV).

US FDA Stage 2 – Process Qualification

This stage is the key focus of traditional validation, where the process validation batches are executed and approved, leading to routine commercial manufacture. The draft EMA guideline still permits this traditional approach, but offers alternatives (CPV and a hybrid approach), as well as providing some additional clarity around expectations for the traditional approach.

US FDA Stage 3 – Continued Process Verification

As difficult as it may be to avoid, 'continued process verification' should not be confused with CPV, or 'Continuous Process Verification'. Continued process verification is the ongoing monitoring of the validated state of a process, usually through tools such as statistical analysis of batch data, non-conformances, customer complaints and similar product quality feedback mechanisms. It is a cumulative process across multiple batches.

In April 2014 the WHO published their draft Proposal for Revision of the Supplementary Guidelines on Good Manufacturing Practices: Validation, Appendix 7:Non-Sterile Process Validation. Again as with the US FDA and EU guidelines, in the new guidance document, the WHO (2014) encourages manufacturers to plan towards implementing the new approach in process validation that covers process design, process qualification and continued process verification, in the product life-cycle, and states that thorough knowledge of product and process development studies; previous manufacturing experience; and quality risk management (QRM) principles are essential in all approaches to process validation as the focus is now on the life-cycle approach. The WHO (2014) product lifecycle is illustrated in Table 2-2: WHO Lifecycle Approach – WHO (2013).

Table 2-2: WHO Lifecycle Approach – WHO (2013)

Product life-cycle		
Process validation		
Process design	Process qualification	Continued process verification
-Pilot scale (and scale-up batches where appropriate) -Risk assessment to identify critical quality attributes and process control parameters -Protocols and reports -Validate process -Define CQA and CPPs to be monitored in Phase II	-Premises -Utilities -Equipment -Commercial-scale batches -In-line, online and/or at-line monitoring -Defined number of batches	-Periodic review of trends -May include sampling and testing -In-line, online and/or at-line monitoring
Change control		
GMP		

With the advent of the lifecycle approach, however it may be illustrated by regulatory bodies, the key message is the same:

- Process validation is an ongoing program rather than a discrete isolated activity
- Regular review and analysis of product quality and process performance data is required to monitor trends
- The lifecycle approach has been aligned with the product lifecycle, Figure 2-5, which includes design and development phases' right through to decline.

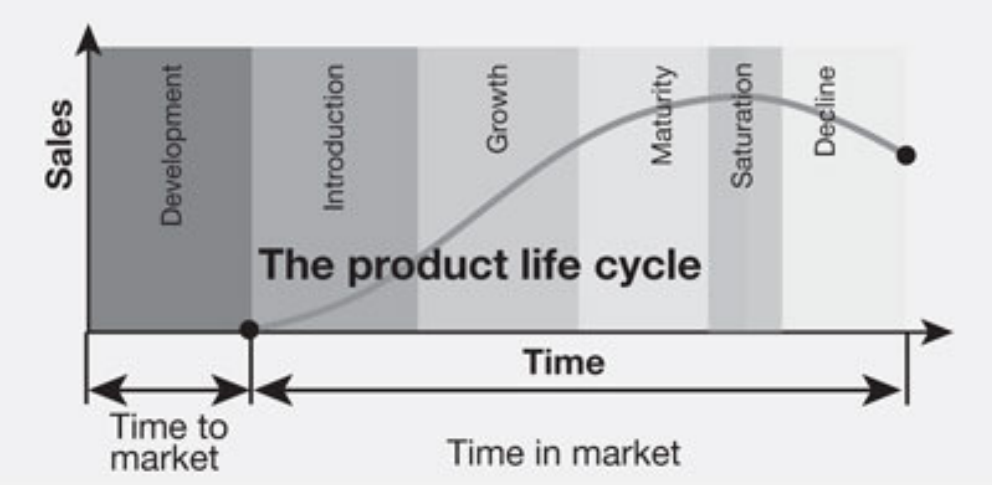

Figure 2-5: Product Lifecycle (Ref: Business Case Studies (2016))

2.6 Why Validate?

At the highest level, Validation is a Government Regulation and is considered to be an integral part of Good Manufacturing Practices (GMP) which are a mandated requirement for the manufacture of medical devices. Khushboo DS et al. (2014) suggest that validation is also an integral part of quality assurance and it involves the systematic study of systems, facilities and processes aimed at determining whether they perform their intended functions adequately and consistently as specified. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. And that validation in itself does not improve processes but confirms that the processes have been properly developed and are under control. The GHTF (2004) suggest that "while the completion of process validation is a regulatory requirement, a manufacturer may decide to validate a process to improve overall quality, eliminate scrap, reduce costs, improve customer satisfaction, or other reason and that a validated process may well result in a reduced time to market for new products.

Mohammed (2012) cited in Khushboo DS et al. (2014) suggest that there are a number of key benefits to process validation including:

- Consistent output
- Reduction in rejections and reworks
- Reduction in utility cost

- Avoidance of capital expenditures
- Fewer complaints about process related failure
- Reduced testing of in process and finished goods
- More rapid and accurate investigations into process deviation
- More rapid and reliable start-up of new equipment
- Easier scale-up from development work
- Easier maintenance of equipment
- Improve employee awareness of processes
- More rapid automation

And proposed that since each and every step in validation is monitored constantly there are less rejects and reworks, which would lead to an effective cost reduction and that's there are four major advantages of validation, namely:

- Assurance of Quality
- Process Optimization
- Reduction of Quality Costs
- Safety

While we validate to prove that our product, processes and supporting systems perform over time as we have initially specified, and there are also various benefits associated with process validation, detailed above, within industry there are essentially 3 areas of focus from a validation perspective:

- Compliance Focus - Validation provides us with documented evidence that all our systems operate as specified and comply with relevant national and international regulations.
- Business Focus - Validation gives us systems and product that we fully understand and which perform predictably.
- Patient Focus - Validation and maintaining processes in a validated state are key activities which contribute to safe, functional and effective devices

2.7 Validation Approach

Currently the US FDA lifecycle approach is "gold brick standard" for process validation, with the EU and WHO following closely behind with their 2012 and 2014 draft guidance documents, however, both the US FDA (2011) and EU (2012) both clearly stipulate that the new guidance documents, while they may be useful, are not applicable to the medical devices industry. The US FDA (2011) guidance explicitly states that "guidance on process validation for medical devices is provided in the GHTF guidance document, Quality Management Systems – Process Validation, edition 2. This document has not been revised since 2004 or been republished by the International Medical Device Regulators Forum (IMDRF) since the GHTF disbanded in 2012.

In the US FDA 2011 guidance there are 3 stages to process validation:

- Stage 1 — Process Design
    - Building and Capturing Process Knowledge and Understanding
    - Establishing a Strategy for Process Control
- Stage 2 — Process Qualification
    - Design of a Facility and Qualification of Utilities and Equipment
    - Process Performance Qualification
    - PPQ Protocol
    - PPQ Protocol Execution and Report
- Stage 3 — Continued Process Verification

The GHTF 2004 guidance document sticks with the traditional validation approach, and suggests that the validation of a process is the mechanism or system used by the manufacturer to plan, obtain data, record data and interpret data and that these activities may also fall into three phases:

- Phase 1 - An initial qualification of the equipment used and provision of necessary services – also known as installation qualification (IQ)
- Phase 2 - A demonstration that the process will produce acceptable results and

establishment of limits (worst case) of the process parameters – also known as operational qualification (OQ)

- Phase 3 - Establishment of long term process stability – also known as performance qualification (PQ)

While the GHTF guidance does not, within its phase breakdown, mention maintaining the validated state or continued process verification, there is a full section dedicated to maintaining a state of validation, later in the body of the guidance document, which details how to monitor and control the process, dealing with changes in processes and/or product, maintaining a continued state of control, and also gives examples of reasons for revalidation. It can therefore be inferred that maintaining the validated state or continued process verification is also an integral part of the process validation guidance detailed by the GHTF.

One of the unique elements of this research is the incorporation of a Case-Based Reasoning (CaBR) control system into the TCM, and the application of the validation model to the CaBR, an area which has received little attention in literature. According to engineering.purdue.edu (2017), case-based reasoning is the act of developing solutions to unsolved problems by basing the solution on pre-existing solutions of a similar nature. Standard rule based systems are designed to move and manipulate numbers, `number crunchers', on the other hand, the case based reasoning system has the ability to mimic and can implement the general mechanisms underlying human intelligence. Gupta (1991), cited in O'Leary (1993) proposes that virtually all research in verification and validation has been focused on rule-based systems rather than other knowledge representations, such as case-based systems. Gonzalez et al. (1998) further suggest that "Validation of knowledge-based system has received great attention from researchers in the last several years, however, the majority of the reported validation work to date has centred around rule-based systems and that "published literature that deals with validation of Case-Based Reasoning (CaBR) systems is indeed scarce. The CaBR system developed as part of the TCM system shall be trained by machine operator, during the setup process, to identify when a tool is at end of life, and based on this training shall make its own decisions around the degree of tool wear present based on the sensor information received. Validation of the CaBR system will establish whether an individual test case has been solved correctly through

benchmarking the results against learned information, and operator expectation.

The US FDA (2002) in their General Principles of Software Validation - Guidance for Industry and FDA Staff, similar to their process validation guidelines recommend that software validation is aligned to a lifecycle model however, they do not explicitly recommend the use of any specific software life cycle model, and specify that the software developers should establish a software life cycle model that is appropriate for their product and organization. They further suggest that that the software life cycle model that is selected should cover the software from its birth to its retirement and activities in a typical software life cycle model include the following:

- Quality Planning
- System Requirements Definition
- Detailed Software Requirements Specification
- Software Design Specification
- Construction or Coding
- Testing
- Installation
- Operation and Support
- Maintenance
- Retirement

Dr. Ludwig Huber, a leading expert for FDA and equivalent international, at the at the IVT Computer System Validation Conference (2009), described the PIC/S Good Practices Guide on Using Computers in GxP Environments as the most detailed and most specific official document that has ever been developed on using computers in regulated areas.

The PIC/S (2007) at various stages refer to the most recognised industry standard for validating software based systems the Good Automated Manufacturing Practice (GAMP) guidelines, which were developed by the Pharmaceutical Industry Systems Validation Forum in the UK. The PIC/S (2007) details how the GAMP Guide has evolved and defines the best practices in specifying, designing, building, testing, qualifying and documenting

software systems to a rigorous validation management scheme. More than 50 healthcare professionals, from the Americas and Europe, participated in the creation of the most up to date version of the GAMP guidelines, GAMP 5. The GAMP 5 software development lifecycle is illustrated in Figure 2-6: Software Validation activities against the SDLC. There are clear similarities between both the software validation and process validation requirements with the planning & design, Testing (IQ, OQ, PQ) and maintenance of the validated state evident in both disciplines.

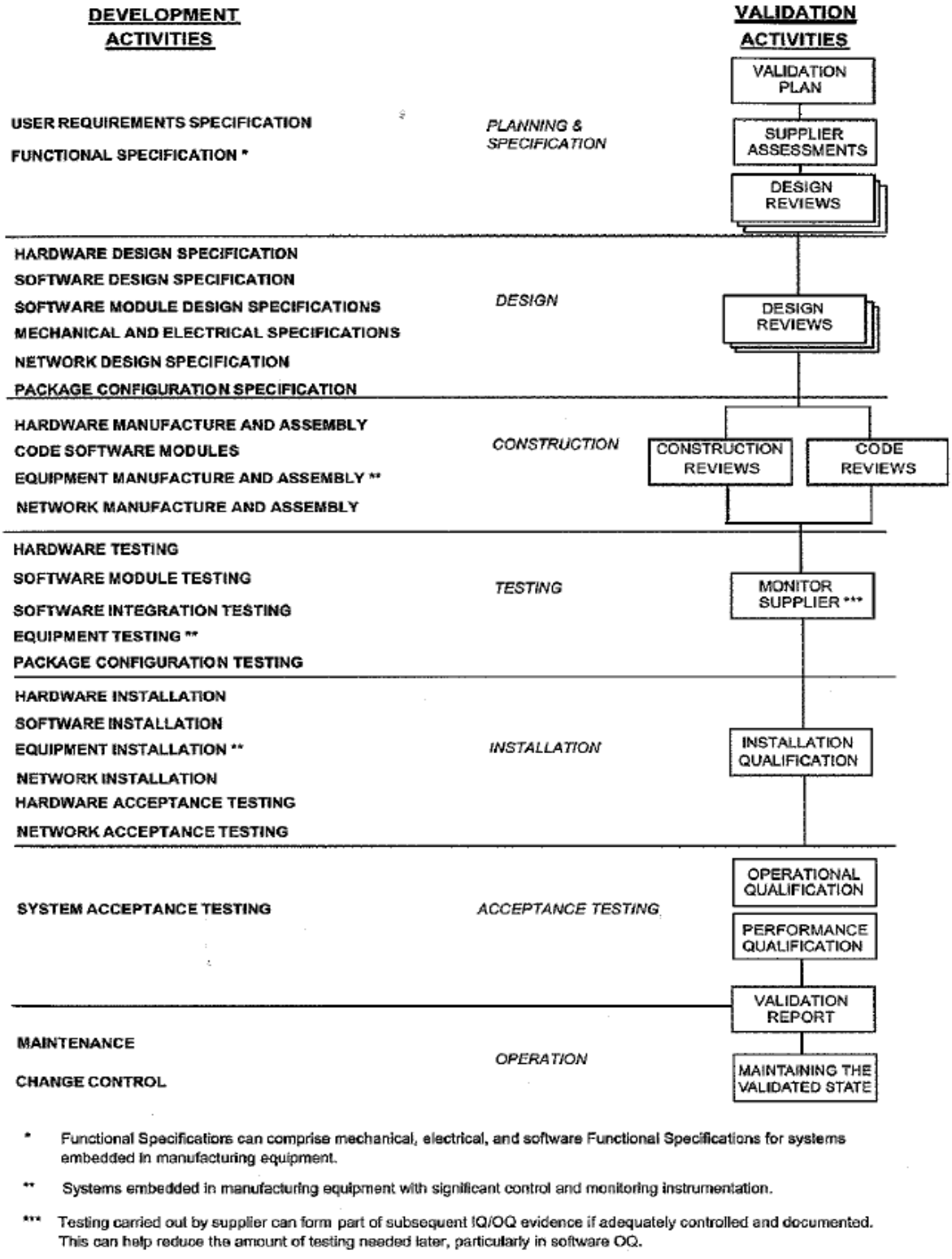

Figure 2-6: Software Validation activities against the SDLC – GAMP 4 (2001)

By comparison of guidelines, validation can be illustrated as shown in Figure 2-7: . This life cycle is representative of the required validation activities, no matter what discipline,

starting with the specifications phase, and ending with ongoing monitoring or change control phase. Each stage of the proposed TCM lifecycle, Figure 2-7: TCM Validation Lifecycle, is reviewed against regulatory requirements, in the preceding sections.

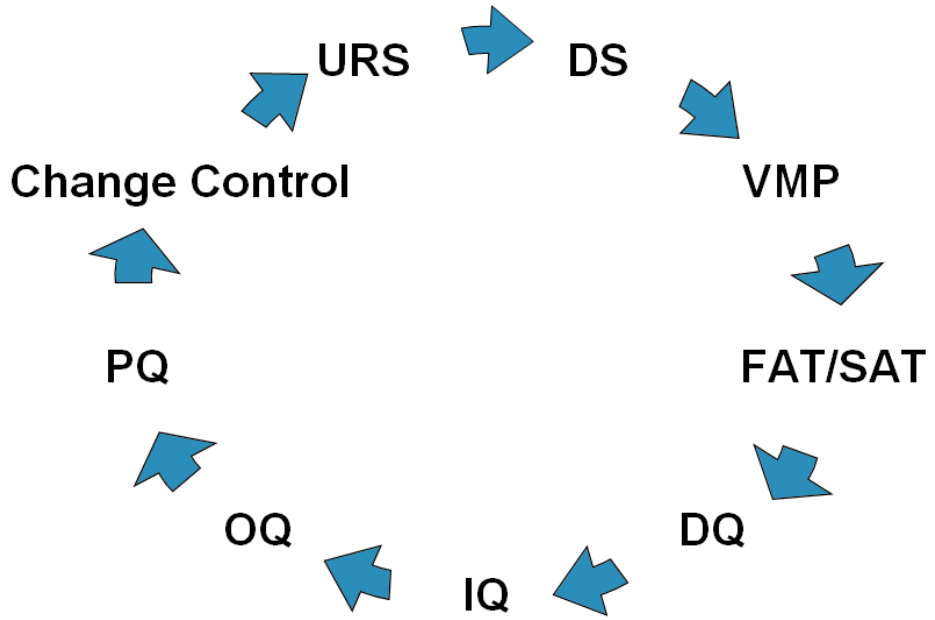

Figure 2-7: TCM Validation Lifecycle

2.7.1 Requirements / Specifications

Specification documents, while not mandated, are integral to any validation process. These documents form the foundation for validation, by establishing the baseline standards from which the system is validated. A brief overview of the most common specification documents is detailed below:

- User Requirements Specification (URS): A detailed outline of all system quality requirements as defined by the system user. Each requirement in the URS will be verified or tested as part of validation (IQ/OQ/PQ/PV).
- Functional Specification (FS): A document describing the detailed functions of a system (i.e. what a system will do). The FS links to the system OQ, which tests all the functions specified and verifies that the system operates as specified.
- Design Specification (DS): A document describing in detail how a system is built.

The DS links to both the IQ, which checks that the correct equipment or system is supplied and that it is installed correctly.

The V-Model, as it is commonly referred to in validation literature, detailed in Figure 2-8: V Model, illustrates the interactions between the specifications and the test protocols and highlights the importance of the specifications to the qualification process. The URS is used when constructing the testing in the PQ, FS to construct the testing in the OQ and DS to construct the testing in the IQ.

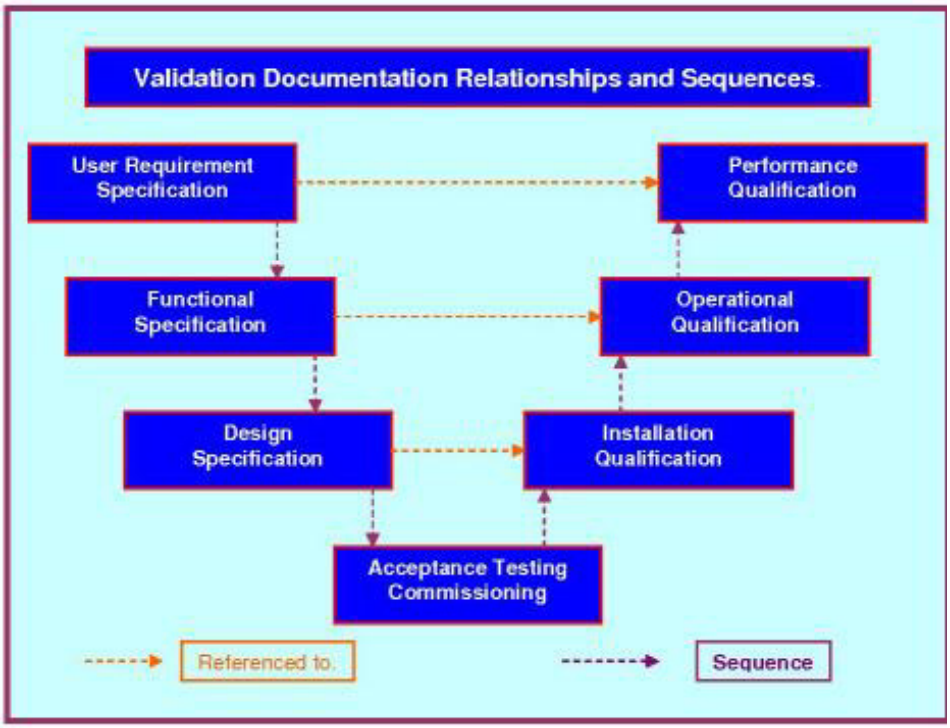

Figure 2-8: V Model (Ref - Validation-Online.net)

2.7.2 Validation Master Plan (VMP)

The Validation Master Plan (VMP) is a document that has never been mandatory, but is always one of the first documents a regulator asks to view. The GHTF (2004) suggest that once a validation team had been developed manufacturers develop what is referred to as a master validation plan which identifies the processes to be validated, the schedule for validations, interrelationships between processes requiring validation and timing for revalidations. The EU (2014), in their guidance documents Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice Title: Qualification and validation, dedicate a full section to planning for validation. While there is no explicit requirement for the use

of a VMP they do suggest that all validation activities should be planned and the key elements of a validation programme should be clearly defined and documented in either a validation master plan (VMP) or an equivalent document. They then go on to suggest that the VMP should be a summary document which is brief, concise and clear and "should contain data on at least the following information:

- Validation policy.
- The organisational structure for validation activities.
- Summary of the facilities, systems, equipment, processes on site and the current validation status.
- Template formats to be used for protocols and reports.
- Planning and scheduling.
- Change control and deviation management for validation.
- Handling of acceptance criteria
- References to existing documents.
- An assessment of the resources required.
- The ongoing validation strategy, including revalidation and / requalification, where applicable.
- Confirmation that the materials used for validation are of the required quality and suppliers are qualified to the appropriate level.

The WHO (2006) in their guidelines Annex 4 Supplementary guidelines on good manufacturing practices: validation, contradicts the GHTF and EU standards, through direct reference to a validation master plan. In their guidance around validation documentation requirements they stipulate that documentation associated with validations should include standard operating procedures (SOPs), specifications, a validation master plan (VMP), qualification protocols and reports and validation protocols and reports. They further recommend that the contents of the validation master plan should reflect the key elements of the validation programme and that it should be clear and concise and contain at least the following:

- a validation policy
- organizational structure of validation activities
- summary of facilities, systems, equipment and processes validated and to be validated
- documentation format (e.g. protocol and report format)
- planning and scheduling
- change control
- references to existing documents.

The FDA (2011) in their guidance for Industry Process Validation: General Principles and Practices guidance again does not make specific reference to a validation master plan however like the GHTF recommend an integrated team approach to process validation and states that project plans are essential elements for success. They go onto specify that qualification of utilities and equipment can be covered under individual plans or as part of an overall project plan and that the plan should consider the requirements of use and can incorporate risk management to prioritize certain activities and to identify a level of effort in both the performance and documentation of qualification activities. The plan, they specify, should identify the following items:

- the studies or tests to use,
- the criteria appropriate to assess outcomes,
- the timing of qualification activities,
- the responsibilities of relevant departments and the quality unit, and
- the procedures for documenting and approving the qualification.

The VMP, or whatever planning method selected, should be thought of as the top level plan which documents the equipment, facilities, processes and systems that will be validated within the scope of the validation activities. The VMP should be a living document that is periodically updated when significant changes are made to the plan or when validation milestones are reached. VMP's are not mandatory, however what is mandatory is the planning of the validation activities. It's not uncommon within industry to

place the planning activities within the body of the qualification/validation protocols for smaller qualifications/validations, however for larger projects formal planning documents, normally in the form of VMP's are commonly used.

2.7.3 FAT, SAT, IQ, OQ & PQ

The FDA (2011) Guidance for Industry Process Validation: General Principles and Practices guidance no longer makes reference to the terms installation qualification, operational qualification and performance qualification. PharmOut (2011) in their white paper FDA Guidance for Industry Update - Process Validation, suggest that while there is no reference to the terms there is still a clear expectation that equipment will be qualified, and that the qualification will include all the aspects that have traditionally fallen into the IQ/OQ/PQ categorization. The new guidance shifts the focus from completing a specific named suite of qualification documents, to ensuring that equipment and utility qualification activities are appropriate and fit for purpose. The EU (2014) in their guidance documents Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice Title: Qualification and validation stick with the traditional qualification and validation approach and have clear references to the distinct qualification stages of:

- Design qualification (DQ)
    - The first element of the validation of new facilities, systems or equipment could be design qualification.
    - The compliance of the design with GMP should be demonstrated and documented.
- Installation qualification (IQ)
    - Installation qualification (IQ) should be performed on new or modified facilities, systems and equipment.
    - IQ should include, but not be limited to the following:
        - installation of equipment, piping, services and instrumentation checked to current engineering drawings and specifications;
        - collection and collation of supplier operating and working

instructions and maintenance requirements;

- calibration requirements;
- verification of materials of construction.

- Operational qualification (OQ)
  - Operational qualification (OQ) should follow Installation qualification.
  - OQ should include, but not be limited to the following:
    - tests that have been developed from knowledge of processes, systems and equipment;
    - tests to include a condition or a set of conditions encompassing upper and lower operating limits, sometimes referred to as “worst case” conditions.
  - The completion of a successful Operational qualification should allow the finalisation of calibration, operating and cleaning procedures, operator training and preventative maintenance requirements. It should permit a formal "release" of the facilities, systems and equipment.
- Performance qualification (PQ)
  - Performance qualification (PQ) should follow successful completion of Installation qualification and Operational qualification.
  - PQ should include, but not be limited to the following:
    - tests, using production materials, qualified substitutes or simulated product, that have been developed from knowledge of the process and the facilities, systems or equipment;
    - tests to include a condition or set of conditions encompassing upper and lower operating limits.
- Process Validation
  - Process validation should normally be completed prior to the distribution and sale of the medicinal product (prospective validation). In exceptional circumstances, where this is not possible, it may be necessary to validate

processes during routine production (concurrent validation). Processes in use for some time should also be validated (retrospective validation).

The WHO (2006) in their Annex 4 Supplementary guidelines on good manufacturing practices: validation also suggests that there are four stages of qualification:

- design qualification (DQ)
- installation qualification (IQ)
- operational qualification (OQ)
- performance qualification (PQ)

Although less prescriptive than the EU guidance, the WHO do specify the following considerations for each of the qualification stages

- Design qualification
    - Design qualification should provide documented evidence that the design specifications were met.
- Installation qualification
    - Installation qualification should provide documented evidence that the installation was complete and satisfactory.
    - The purchase specifications, drawings, manuals, spare parts lists and vendor details should be verified during installation qualification.
    - Control and measuring devices should be calibrated.
- Operational qualification
    - Operational qualification should provide documented evidence that utilities, systems or equipment and all its components operate in accordance with operational specifications.
    - Tests should be designed to demonstrate satisfactory operation over the normal operating range as well as at the limits of its operating conditions (including worst case conditions).
    - Operation controls, alarms, switches, displays and other operational

components should be tested.

- Measurements made in accordance with a statistical approach should be fully described.

- Performance qualification
  - Performance qualification should provide documented evidence that utilities, systems or equipment and all its components can consistently perform in accordance with the specifications under routine use.
  - Test results should be collected over a suitable period of time to prove consistency.

The GHTF (2004) similarly describes qualification activities as falling into three phases:

- an initial qualification of the equipment used and provision of necessary services – also known as installation qualification (IQ);
- a demonstration that the process will produce acceptable results and establishment of limits (worst case) of the process parameters – also known as operational qualification (OQ)
- establishment of long term process stability – also known as performance qualification (PQ)

Again, as with the EU and WHO, the GHTF provide guidelines specifying what should be tested at each stage of qualification:

- Installation qualification (IQ)
  - Equipment design features (i.e. materials of construction cleanability, etc.)
  - Installation conditions (wiring, utilities, functionality, etc.)
  - Calibration, preventative maintenance, cleaning schedules
  - Safety features
  - Supplier documentation, prints, drawings and manuals
  - Software documentation

- Spare parts list
- Environmental conditions (such as clean room requirements, temperature, humidity)

The GHTF (2004) propose that sometimes IQ activities are conducted at the equipment supplier's site, prior to equipment shipment to determine if the equipment is ready for shipment. Within industry, this is referred to as FAT or Factory Acceptance Testing. Factory acceptance testing is not a mandatory requirement however it is frequently utilised on larger projects, and engineers from the customer site will generally travel to the supplier's facility for testing. Any faults or failing tests can then be rectified at the supplier's facility prior to dispatch. The GHTF (2004) suggest that copies of the FAT should be used to supplement installation qualification. Usually however you would not rely solely upon the FAT results. Within industry, witnessed testing which has passed at the suppliers facility, that does not have a direct quality or safety impact is frequently leveraged into the qualification protocols when the equipment arrives at the customer site. It's important to note, that while IQ means is it installed correctly and IQ activities may be conducted at the equipment supplier's site location prior to equipment shipment, it is impossible to fully assess the installation without connection to the desired utilities at the customer's site.

SAT or Site Acceptance Testing is a commissioning activity that follows FAT. SAT is also not a mandatory requirement however, within industry, is frequently completed prior to formal qualification testing. Site acceptance testing is completed by the supplier after the equipment has been installed, at the customer facility. Again SAT can be leveraged into the qualification reports, if witnessed by the customer, and is generally a repeat of the testing completed at the customer facility during FAT testing.

At the OQ phase, the GHTF suggest that process parameters should be challenged to assure that they will result in a product that meets all defined requirements under all anticipated conditions of manufacturing, for example through the use of worst case testing. OQ considerations should include:

- Process control limits (time, temperature, pressure, line speed, setup conditions, etc.)

- Software parameters
- Raw material specifications
- Process operating procedures
- Material handling requirements
- Process change control
- Training
- Short term stability and capability of the process, (latitude studies or control charts)
- Potential failure modes, action levels and worst-case conditions (Failure Mode and Effects Analysis, Fault Tree Analysis)
- The use of statistically valid techniques such as screening experiments to establish key process parameters and statistically designed experiments to optimize the process can be used during this phase.

At the PQ phase the key objective is to demonstrate the process will consistently produce acceptable product under normal operating conditions." PQ considerations should include:

- Actual product and process parameters and procedures established in OQ
- Acceptability of the product
- Assurance of process capability as established in OQ
- Process repeatability, long term process stability

2.7.4 Change Control

The final part of the lifecycle is change control. The GHTF (2004) suggest that "any changes in the process and /or product including changes in procedures, equipment, personnel, etc. should be evaluated to determine the effect of those changes on the validated process, and the effect should be documented and rationalised, or formal revalidation may be required. Important to note, the GHTF (2004) also mention that revalidation may not be as extensive as the initial validation and all aspects of the original validation may not needs to be repeated. The EU (2014) propose that written procedures

should be in place to describe the actions to be taken if a change is proposed to a starting material, product component, process equipment, process environment (or site), method of production or testing or any other change that may affect product quality or reproducibility of the process and the need for, and the extent of, requalification and re-validation should be determined. The WHO (2016) propose that changes should be controlled in accordance with a SOP, as changes may have an impact on a qualified utility, system or piece of equipment, and a validated process and/or procedure.

Khushboo DS et al (2014) suggests that validation should not be thought of as a standalone function and it is an integral part of quality assurance. Change control is a mandatory part of any QMS and the existing company's change control procedures should incorporate details on re-validation and re-qualification, as required. It's important to note that while change control is mandatory, all regulatory bodies reviewed as part of this research clearly state that the extent of the re-qualification/re-validation can be assessed by the individual who is responsible for assessing the change control. The important thing is that the rationale for full, partial or no re-qualification/re-validation is thoroughly documented as part of the change control process.

2.8 Risk

Within industry the term risk based validation is commonly discussed. In the US FDA (2011) Guidance for Industry Process Validation: General Principles and Practices the FDA define validation as establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes. The FDA allow companies can make their own determination as to how much validation testing is necessary, and the amount of testing should be proportionate to the amount of risk that can be attributed to the process. The US FDA (2011) guidance document aligns itself with the lifecycle approach to process validation, and employs risk based decision making throughout that lifecycle. It is suggested that all attributes and parameters should be evaluated in terms of their roles in the process and their impact on the product or in-process material, and this information should be re-evaluated as new information becomes available. They also specify that the degree of control over those attributes or parameters should be commensurate with their

risk to the process and process output. Similarly, the EU (2014) in their Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice Title: Qualification and validation and The WHO (2006) in their Annex 4 Supplementary guidelines on good manufacturing practices: validation, retrospectively suggests that a risk assessment approach should be used to determine the scope and extent of the validation activities required and they define risk analysis as a method to assess and characterise the critical parameters in the functionality of an equipment or process. In the 2014 draft of the WHO (2014) Proposal for Revision of the Supplementary Guidelines on Good Manufacturing Practices : Validation, Appendix &: Non-Sterile Process Validation the guidelines, around risk, have now been aligned to the US FDA requirements, due to the incorporation of lifecycle model. The draft now suggests that quality risk management (QRM) principles are essential in all approaches to process validation, as the focus is now on the life-cycle approach and that a risk assessment approach should be followed to determine the scope and extent to which process(es) and starting material variability may affect product quality.

The US FDA guidance on General Principles of Software Validation states: "The selection of validation activities, tasks, and work items should be commensurate with the complexity of the software design and the risk associated with the use of the software for the specified intended use." Stroud (2010) in his blog on considerations for risk based validation also mentions that the US FDA's Part 11 Scope and Application guidance document states: "We recommend that you base your approach (to implement Part 11 controls, e.g., validation) on a justified and documented Risk Assessment and a determination of the potential of the system to affect product quality and safety, and record integrity."

The heart of validating any process is ensuring that it is installed to specification, and capable of consistently meeting those specifications. By taking a risk based approach to validation the areas of a system, process or piece of equipment, that pose the greatest product quality and/or safety risks, can be more rigorously tested, than those that don't. Stroud (2010) proposes that if there is one area of focus that is worthy of the time spent, it is in conducting the risk assessment and that an effective and efficient risk based validation process will result in less validation work, faster system deployment and a reduction in overall validation costs. The US FDA, EU and WHO guidelines have been developed in line with the principles outlined in the International Conference on Harmonisation (ICH) guidelines Q8, Q9, Q10 and Q11. The ICH Q9 guideline on quality risk management

provides data on the principles, and examples of tools, for quality risk management, that can be applied to different aspects of pharmaceutical quality and in Annex 1 provides a detailed overview of the most commonly used risk management methods & tools, including:

- Failure Mode Effects Analysis (FMEA)
- Failure Mode, Effects and Criticality Analysis (FMECA)
- Fault Tree Analysis (FTA)
- Hazard Analysis and Critical Control Points (HACCP)
- Hazard Operability Analysis (HAZOP)
- Preliminary Hazard Analysis (PHA)
- Risk Ranking and Filtering

According to Silvianita et al. (2011) risk assessments are used for estimating the likelihood and the outcome of risks to human health, safety and the environment and for unearthing decisions about how to deal with those risks. It's proposed that each risk analysis method has its limitations, a number of which are detailed in the Table 2-3: Limitations of Hazard Risk Analysis Methods.

Table 2-3: Limitations of Hazard Risk Analysis Methods Silvianita et al. (2011)

No.	Hazard Risk Analysis Methods	Limitations	Tendency to Type of Decision Analysis
1.	Failure Modes and Effects Analysis (FMEA)	- Examination of human error is limited - Focus is on single event initiators of problems - Examination of external influences is limited - Results are dependent on the mode of operation	- Highly structured assessment relying on evaluation of component failure modes and team experience - Uses frequently as the basis for optimizing planned
2.	Hazard and Operability (HAZOP) Analysis	- Requires a well defined system or activity - Time consuming - Focuses on one event causes of deviations	Used to review procedures and sequential operations
3.	Fault Tree Analysis (FTA)	- Narrow focus - Art as well as science - Quantification requires significant expertise	Assessments generates relative importance of various failure and contributing events
4.	Event Tree Analysis (ETA)	- Limited to one initiating event - Can overlook subtle system dependencies	Analysis technique generates failure sequences and contributing events

In the GHTF (2004) guideline, the most commonly accepted guideline for the validation of medical devices, there is specific reference to both the Failure Modes and Effects Analysis (FMEA) and Fault Tree Analysis (FTA). It mentions that an FMEA is systematic analysis

of the potential failure modes. It includes the identification of possible failure modes, determination of the potential causes and consequences and an analysis of the associated risk. It also includes a record of corrective actions or controls implemented resulting in a detailed control plan and that FMEAs can be performed on both the product and the process. Typically an FMEA is performed at the component level, starting with potential failures and then tracing up to the consequences. This is a bottom up approach. A variation to the FMEA is a Fault Tree Analysis, which starts with possible consequences and traces down to the potential causes. This is the top down approach. An FMEA tends to be more detailed and better at identifying potential problems. However, a fault tree analysis can be performed earlier in the design process before the design has been resolved down to individual components. Within industry there are various method of assessing risk, including those mentioned in this text, and companies may often develop their own in-house risk assessment tools.

2.9 Worst Case Testing

The concept of worst-case conditions was a key theme in the1987 FDA guidance on process validation. The 1987 guidance defined worst-case as: A set of conditions encompassing upper and lower limits and circumstances, including those within standard operating procedures, which pose the greatest chance of process or product failure when compared to ideal condition, because of this attempts to cover worst-case conditions would often mean that parameters applied to validation batches would bear little or no resemblance to the standard operating conditions of the process. PharmOut (2011) in their white paper on the FDA Guidance for Industry Update - Process Validation say that the 2011 FDA guidance has not only removed the concept of worst-case conditions, but has redefined the expectation by saying that commercial manufacturing process and routine procedures must be followed. The new guidance moves the responsibility for addressing processing variability to the Process Design stage of validation activities and the intention is that the variability is captured earlier, during the process development phase of the project.

The WHO (2014), in Annex 15, defines worst case as a condition or set of conditions encompassing the upper and lower processing limits for operating parameters and

circumstances, within SOPs, which pose the greatest chance of product or process failure when compared to ideal conditions. Such conditions do not necessarily include product or process failure and are moving in a similar direction to the US FDA by suggesting that traditionally three batches have been considered the minimum number for process validation; however, the number of batches should be based on risk assessment.

The EU suggest that the OQ should include, but not be limited to, tests that have been developed from knowledge of processes, systems and equipment and tests to include a condition or a set of conditions encompassing upper and lower operating limits, sometimes referred to as "worst case" conditions. They do however stick with the traditional approach and suggest that a minimum of three consecutive batches is required for a successful validation.

2.10 Tool Wear

In order to understand tool wear it is important to have some knowledge of the different wear mechanisms to which Cutting tools may be subjected. Tool wear can fall into a number of different categories, detailed in the following sections.

2.10.1 Flank wear

Figure 2-9: Flank Wear – Sandvik

Flank wear is the most common type of wear, and is the preferred wear type, as it offers predictable and stable tool life. Flank wear occurs due to abrasion with the work piece.

2.10.2 Crater wear

Figure 2-10: Crater wear – Sandvik

Crater wear is localized to the rake side of the insert and is due to a chemical reaction between the work piece material and the cutting tool, it is amplified by cutting speed. Excessive crater wear weakens the cutting edge and may lead to fracture.

2.10.3 Built-up edge (BUE)

Figure 2-11: Built-up edge – Sandvik

This wear type is caused by pressure welding of the chip to the insert. It is most common when machining sticky materials, such as low carbon steel, stainless steel and aluminium. Low cutting speed increases the formation of built-up edge.

2.10.4 Notch wear

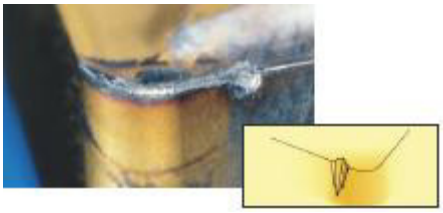

Figure 2-12: Notch wear – Sandvik

Insert wear characterized by excessive localized damage on both the rake face and flank of the insert at the depth of cut line. Caused by adhesion (pressure welding of chips) and a deformation hardened surface. A common wear type when machining stainless steels and high resistant super alloys (HRSA).

2.10.5 Plastic deformation

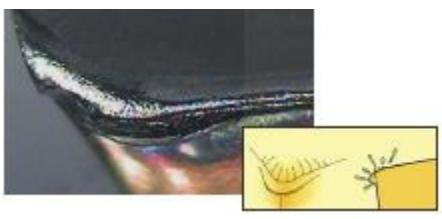

Figure 2-13: Plastic deformation – Sandvik

Plastic deformation takes place when the tool material is softened. This occurs when the cutting temperature is too high for a certain grade. In general, harder grades and thicker coatings improve resistance to plastic deformation wear.

2.10.6 Thermal cracks

Figure 2-14: Thermal cracks – Sandvik

When the temperature at the cutting edge changes rapidly from hot to cold, multiple cracks may appear perpendicular to the cutting edge. Thermal cracks are related to interrupted cuts, common in milling operations, and are aggravated by the use of coolant.

2.10.7 Edge chipping/breakage

Figure 2-15: Edge chipping/breakage – Sandvik

Chipping or breakage is the result of an overload of mechanical tensile stresses. These stresses can be due to a number of reasons, such as chip hammering, a depth of cut or feed that is too high, sand inclusions in the work piece material, built-up edge, vibrations or excessive wear on the insert.

Within industry, tool life is thought of as the amount of time that a tool produces an acceptable output before it requires changing. Because the tooling is not visible during machining, tool condition is generally, according to Kalpakjian et al. (2013), measured through one or more of the following conditions and changed once one or more of the conditions are reached:

- High current or power consumption on the machine

- Vibration and/or chatter
- Catastrophic tool failure
- Deviations in work piece tolerances
- Poor surface finish on work piece
- Adverse chip formation

Within a laboratory/research and development (R&D) environment the tooling is instead be measured through one or more of the following conditions:

- Total breakage of the tool or tool tip(s)
- Massive fracture at the cutting edge(s)
- Excessive increase in cutting forces and/or vibration
- Average wear (flank or crater) reaches its specified limit(s)

In addition it is possible, within laboratory/research and development (R&D) environment, to physically measure the tools against pre-determined limits. According to Kharagpur (2009) this is generally when the flank wear reaches 0.3 mm or crater wear reaches 0.15 mm. There are various different methods that can be used to take the physical measurements, some of which are detailed below:

- Scales, for volume or weight
- Optical microscope
- Scanning electron microscope (SEM)
- Surface roughness measurement equipment

The Machinery's Handbook (2012) proposes that the best measure of tool wear is flank wear because flank wear always takes place and cannot be avoided. Flank wear is the distance between the top of the cutting edge and the bottom of the flank wear land. Although there are many exceptions, as a rough estimate, high-speed steel tools should be replaced when the width of the flank wear land reaches 0.005 to 0.010 inch for finish turning and 0.030 to 0.060 inch for rough turning; and for cemented carbides 0.005 to 0.010 inch for finish turning and 0.020 to 0.040 inch for rough turning. When a new tool is

used, the initial flank wear is often quite large in relation to the subsequent wear. Under normal operating conditions, the width of the flank wear land will increase at a uniform rate until the tool reaches catastrophic failure.

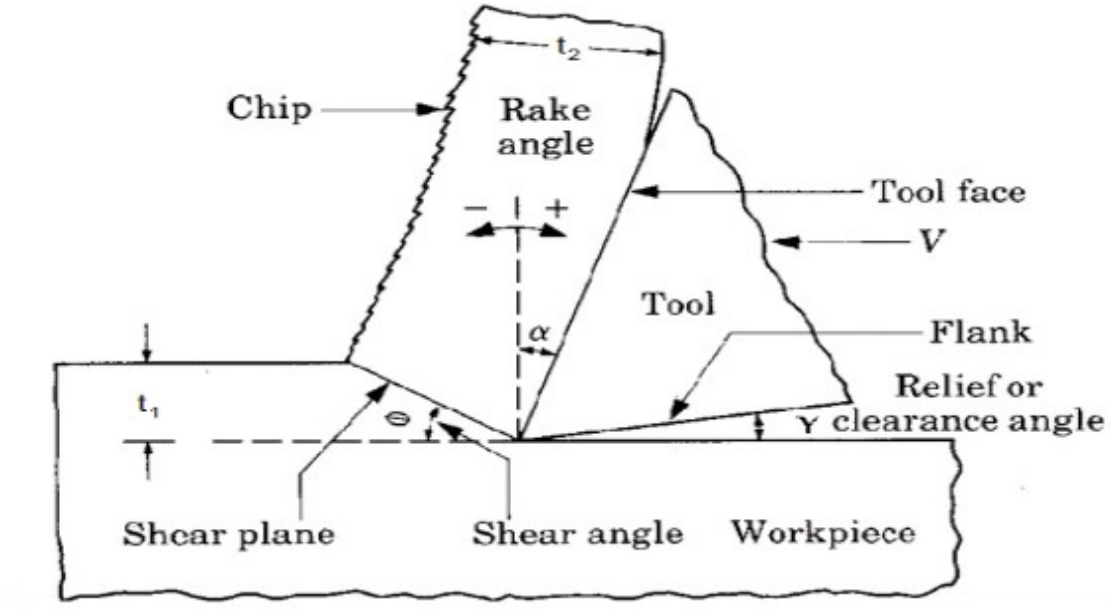

Figure 2-16: Cutting terminology – Palamivendhan (2014)

2.11 Chapter Summary

The review of literature in this section looks specifically at GMP validation, the existing guidelines, validation terminology, types of validation, validation lifecycles, the validation decision making process, validation approaches, risk, worst case testing and tool wear. Through review of the literature three key regulatory bodies were identified, namely, the US FDA, the EU and the WHO. After careful review of the guidelines, it was established that there was minimal differences between the suggested approaches, with the USFDA currently being more advanced in their guidelines, however, the EU and WHO had already drafted new revisions of the guidelines which again aligned their proposed methods. Unusually, in the US FDA guidance document there was a note explicitly stating that the "guidance does not cover medical devices and that guidance on process validation for medical devices is provided in a separate document, Quality Management Systems – Process Validation, edition 2". For this reason, the Global Harmonisation Task Force (GHTF) guidelines, while not a regulatory guideline, were also considered as part of the

literature review.

The literature review identified that there was a commonly accepted approach to GMP style validation and that a validation lifecycle approach was essential. Validation should not be viewed as a static or standalone occurrence. All literature reviewed stressed the importance of change control, and revalidation where required. For this reason it is essential that validation should form part of a company's change control process.

The GHTF proposed quite a simple, but effective decision tree, which suggests that prior to commencing GMP validation you should ask a number of questions, namely, can the output be verified by subsequent monitoring or measurement. If the answer is yes, then the consideration should move to whether or not verification alone is sufficient to eliminate unacceptable risk, and is it a cost effective solution. If yes, the output should be verified and the process should be appropriately controlled, if not validation, or product redesign is required to get the product to a point where verification is sufficient and cost effective.

This then brought the review to one of the most commonly misunderstood, and most often incorrectly interchanged terms, Qualification, Verification and Validation. It was established, through review of literature, that qualifications should be thought of as tests that are completed on equipment, utilities, facilities and analytical equipment. They are physical tests that are completed to ensure that they are installed, operating and performing and they should be prior to completing a validation, and that verification can be thought of as a method of testing that provides assurance at a point in time that a product will do what it is intended to do without causing another problem. Validation on the hand provides measurable evidence that over time the product will work properly.

It was established that within industry the term risk based validation is a statement that is commonly used. The author discovered that by taking a risk based approach to validation the areas of a system, process, or piece of equipment, that pose the greatest product quality and/or safety risks, can be more rigorously tested, than those that don't, and that if there was one area of focus that is worthy of the time spent, it was conducting the risk assessment, and that an effective and efficient risk based validation process will result in less validation work.

The review of literature also highlighted one of the more significant challenges of the validation activities. The proposed TCM system incorporates a Case-Based Reasoning

(CaBR) control system. The system must trained by machine operator, during the setup process, to identify when a tool is at end of life, and based on this training shall make its own decisions around the degree of tool wear present based on the sensor information received. It was established that one of the biggest challenges to system training is that, within industry, tool life is thought of as the amount of time that a tool produces an acceptable output before it requires changing. The tooling is not physically measured, as it would be within a laboratory/research and development (R&D) environment. The operator training would be solely based on evaluation of, and the operator's opinion in the areas of:

- High current or power consumption on the machine
- Vibration and/or chatter
- Catastrophic tool failure
- Deviations in work piece tolerances
- Poor surface finish on work piece
- Adverse chip formation

To overcome this challenge it will be necessary to physically measure tool wear, as you would in a laboratory/research and development (R&D) environment. After measuring an analytical comparison of the measured data, against the operator's opinion, shall be completed. This will establish whether an individual test case has been solved correctly through benchmarking the measured results against the learned information and the operator expectation.

The method chosen to capture the physical tool wear, is the measurement of flank wear, because according to the Machinery's Handbook (2012), flank wear always takes place, and cannot be avoided during machining operations.

3.0 Methodology

3.1 Introduction

It is hypothesised that machining processes can be accurately monitored and that appropriate adjustments can be made during the CNC machining process, to maintain the quality of process output, extend tool life-time and increase machine productivity.

The general structure of a Tool and Process Condition Monitoring System is presented in Figure 3-1: System Overview. In the cutting zone there are many process variables (cutting forces, vibration, Acoustic Emission, noise, temperature, surface finish, etc.) influenced by tool and process condition. Those which are potentially useful for Tool condition monitoring (TCM) can be measured by appropriate sensors. Signals acquired from these sensors are then subject to signal processing, the aim of which is the generation of useful signal features, correlated with tool or process condition. Signal features are then integrated into final diagnosis, which can be presented to the operator and/or sent to the Numerical controller (NC), executing the appropriate action.

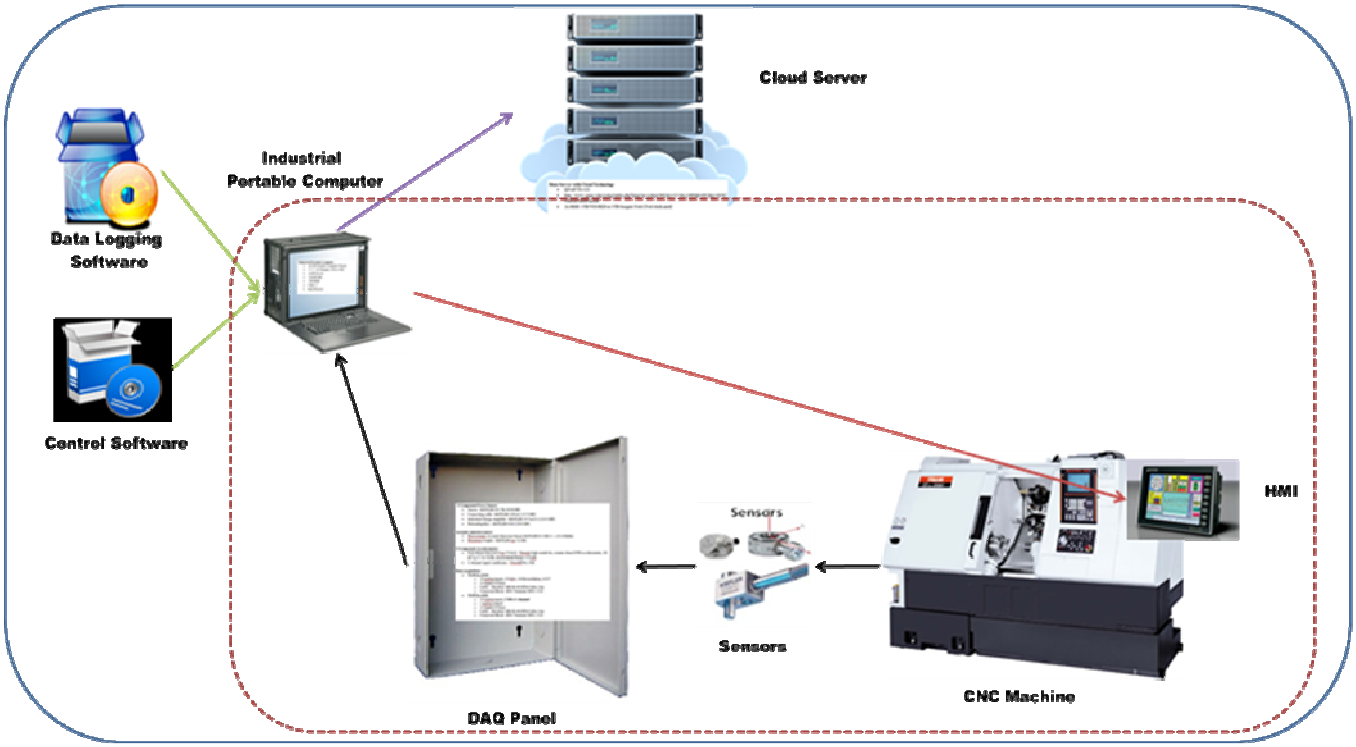

Figure 3-1: System Overview

According to Hutton (1991), there are several phenomena, which can be used for extracting indications around the state of a machining process.

- Acoustic emission.
- Cutting forces and torque
- Temperature
- Motor power and current.
- Vibrations
- Machine vision

The REALISM project is based on a sensor fusion system, whereby multiple process parameters are sensed and combined to provide accurate feedback on the operation performance. The ability to monitor the performance of the operation will allow the user to prevent wasteful manufacturing operations, by allowing intervention to correct the situation, such as by making offsets to allow for tool wear or adjusting spindle speeds to correct cutting conditions, thus giving predictable surface finishes and product dimensions.

The underlying concept of REALISM is that a machining process can be controlled through the use of sensors from the cutting interface. This concept is not new and studies have shown that accurately monitoring a process of this nature is possible, Fang et al. (2011) and in fact, some academic members of the project consortium have been at the forefront of this research. However, what is novel here is the integration of a case based reasoning system (CaBR), based on a neural network.

3.2 TCM System Overview

The TCM consists of a 3-axis force sensor, an acoustic emission sensor, 3-axis accelerometer, a data acquisition card, an industrial portable computer, custom Data Logging Software and custom Control Software, linked back to a Human Machine Interface (HMI). The sensors have initially been deployed on a Mazak Quickturn Nexus 200II machine at Schivo Ltd. based in Waterford, Ireland, with future deployments planned at IDT Solutions, Norway and Tulino CTM, Italy.

The full suite of components contained within the TCM system is detailed as follows:

- 3-Component Force Sensor:

- Sensor - KISTLER 9017B (4930CHF)
- Connecting cable - KISTLER 1694A5 (527 CHF)
- Industrial Charge Amplifier - KISTLER 5073A311 (1235 CHF)
- Preloading Key – KISTLER 9463 (309 CHF)

- Acoustic emission sensor:
  - Piezoceramic Acoustic Emission Sensor KISTLER 8152B111 – (50-400kHz)
  - Piezotron Coupler - KISTLER type 5125B1
- 3-Component Accelerometer
  - PCB PIEZOTRONICS typ 356A16 - Triaxial, high sensitivity, ceramic shear ICP® accelerometer, 100 mV/g, 0.5 to 5k Hz, measurement Range ±50 g pk
  - 3-channel signal conditioner - VibAMP PA-3000
- Data acquisition:
  - NI PCIe-6320
  - 16 analogue inputs, 250 kS/s, 16-bit resolution, ±10 V
  - 24 digital I/O lines
  - Cable – Shielded: SHC68-68-EPM Cable (2m)
  - Connector Block - BNC Terminal: BNC-2110
  - NI PCIe-6361
  - 16 analog inputs, 2 MS/s 1-channel
  - 2 analog outputs
  - 24 digital I/O lines
  - Cable – Shielded: SHC68-68-EPM Cable (2m)
  - Connector Block - BNC Terminal: BNC-2110

- Industrial Portable Computer
    - ACME Portable Computer Chassis
    - 17.3", 16:9 Display 1920 x 1080
    - 2x PCI-E x16
    - 128GB SSD
    - 2TB HDD
    - USB 3.0
    - 1Gb Ethernet
- Data Server with Cloud Technology
    - QNAP TS-420
    - 2x HDD: 3TB WD RED or 3TB Seagate NAS (NAS dedicated)
- HMI
    - 19" SXGA TFT LCD with Touchscreen

A top level system overview schematic is detailed in Figure 3-1: System Overview along with the panel drawings for the DAQ panel in Figure 3-2.

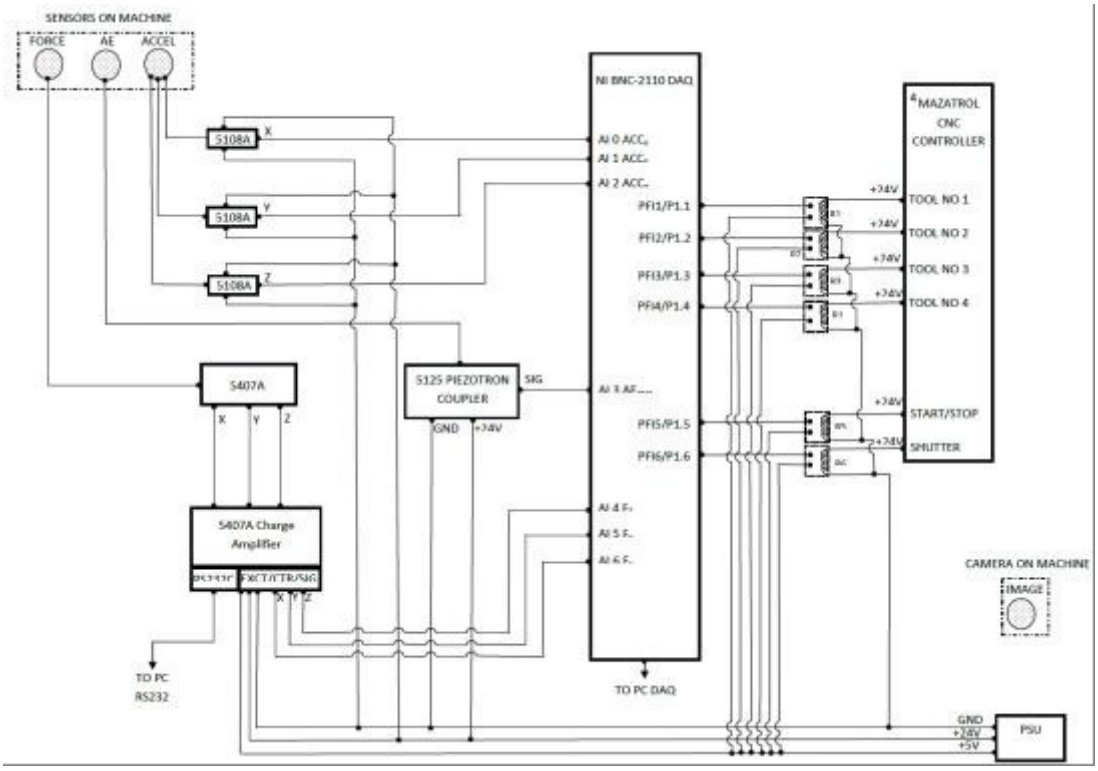

Figure 3-2: DAQ Panel Wiring Diagram

3.3 Validation Materials

In order to reduce external variability, during the validation trials, and improve result accuracy, the following tooling and workpiece material have been selected for use during all validation trials:

- DMNG-150604-QM2025 Sandvik (Turning Tip)
- CCMT-060204 EN PF26 Iscar (Boring Tip)
- 7mm HSS Tin Tip-Coated Jobber Drill Hartner (Drilling)
- Workpiece material; SS316l

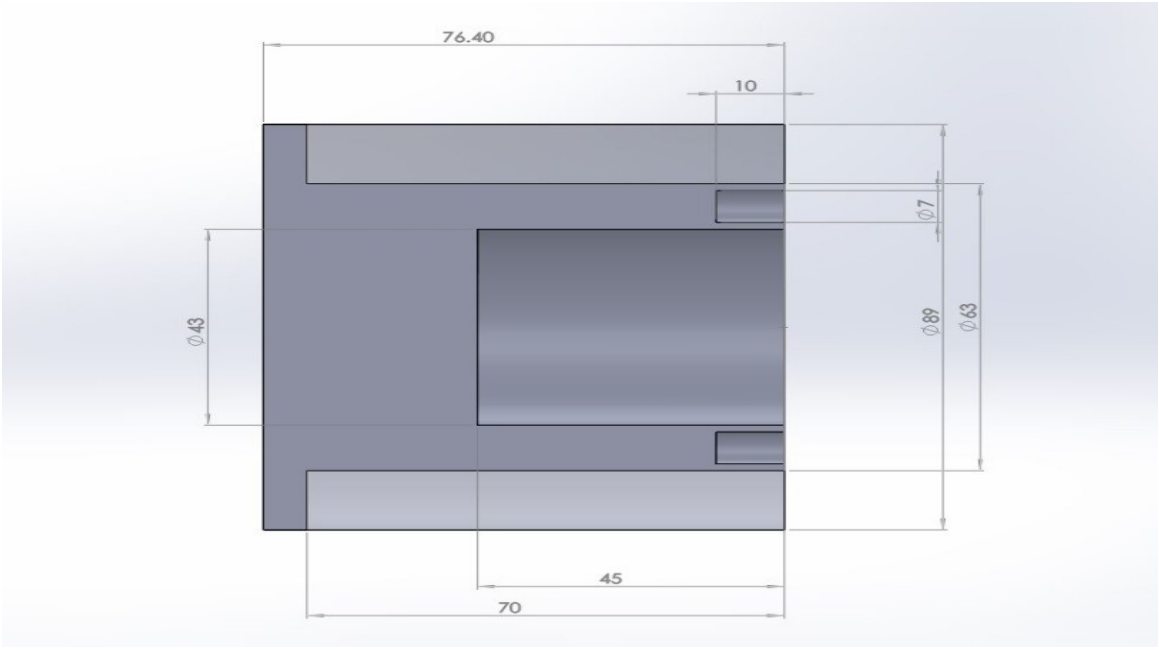

Figure 3-3: Work Piece

3.4 Validation Approach

3.4.1 Installation Qualification

In order to comply with European, U.S. and other GMP requirements, the following tests/verifications have been considered for inclusion in the IQ protocol:

- Risk assessment\C&E matrix\FMEA
- Documentation verification
- Process map
- SOP's
- Utilities
- Purchase orders
- Equipment
- Components
- Critical measuring instrumentation
- Drawings

- Spare parts
- Maintenance
- Environmental requirements
- Safety
- Warranty
- Integration/Interconnections
- Installation instructions
- Training
- Materials of construction
- Product contact listing
- Lubrication/Fluids

3.4.1.1. Risk Assessment

The risk assessment can be used to identify the components of the equipment or system which require validation and those that do not. Thus, it serves as a focusing tool to narrow the validation to the GMP critical items. The C&E matrix emphasizes the importance of understanding of critical to quality outputs or customer requirements. This document relates the Key Process Input Variables to the Key Process Output Variables (customer requirements or process/equipment outputs) using the process map as a primary source. The C&E matrix may not be required for a previously well-defined process where the key inputs and outputs have been previously defined using other methods.

In well-defined processes key factors may be known and highlighted in the process map which may be rationalized as a substitute for FMEA and C&E matrix deliverables. In cases where development work has been done by personnel outside the plant, the variables can be transferred from the development report submitted by that party.

The FMEA identifies and captures the way in which a system or process can fail. The FMEA quantifies the risks associated with the specific causes and prioritizes actions that should be taken to minimize the risk. Some key findings from this document may be the

identification of potential variables to be investigated further during a qualification to minimize risk. A FMEA may not be required for a previously well-defined process where the key inputs, outputs, controls, and risk mitigation have been previously defined using other methods.

3.4.1.2. Documentation Verification

Equipment documentation must be verified as adequately representing the installed system. Modifications made to the system require subsequent modification of the SOPs, work instructions (if applicable), and equipment documentation to keep them up to date.

The following documents should be considered for their applicability:

- Equipment Manuals and/or data sheets
- Electronic copies of manuals, drawing, and design documentation
- Vendor commissioning documents
- Specifications - The documents to be considered may include:
    - User Requirement Specifications
    - Functional Specifications
    - Design Specifications
- Miscellaneous Documentation including but not limited to:
    - Component datasheets
    - Test Reports
    - Cleaning/Flushing Reports
    - Pump/Motor Performance Curves
    - Certifications
    - Dye Penetrant Test
    - Filter Integrity Test Reports
    - Weld documentation
    - Passivation and electro polish documentation

- Hydrostatic test reports
- Pressurisation test reports
- Filter Media Certifications
- For plants which produce product for European markets, CE certification to show equipment complies with European community laws may be applicable.
- Logbooks - Various regulatory agencies require logbooks for critical pieces of equipment. These regulations require a chronological written record of cleaning, maintenance, validation, calibration, use and repair.

3.4.1.3. Process Map

For each process, one must determine the critical process steps, and associated risks, through either the development of a process map and/or a C&E Matrix or FMEA. Critical steps should be defined and described showing the flow from one stage to another. Critical to Quality System boundaries should also be clearly established, providing defined validation scopes. Well defined boundaries are key aspects in determining the degree of impact a system or components of that system have on product quality.

3.4.1.4. SOPs (or Work Instructions where applicable)

In order to operate a system or piece of equipment in a validated manner, the same procedure must be used each time it is put in service. The procedures should be uniquely identified and controlled within the company's quality system. SOPs or work instructions must be at an approved status in order to proceed with OQ testing and qualification of SOP's is more often part of the OQ protocol.

3.4.1.5. Utilities

Utilities that are required for the continuous operation of equipment are considered support utilities. Without them the system would not operate properly; therefore support utilities must be verified to ensure their proper installation, connection and identification. Each utility must be checked for proper connections and supply rates confirmed to meet requirements. Examples of utility supply installations to be verified include nitrogen, liquid carbon dioxide, natural gas, non-process air, steam, vacuum, electrical power, drainage,

heating/cooling water, glycol etc... Electrical requirements shall be clearly defined in specifications with acceptable ranges indicated.

3.4.1.6. Purchase orders

The purchase order verification is performed in order to ensure that all items listed on the purchase order have been delivered and received.

3.4.1.7. Equipment

An equipment list should be created to ensure that all individual pieces of equipment are properly identified, physically documented, match expected model and manufacturer specifications, and are entered into site systems as applicable. The listing should be include all of the individual pieces of equipment which comprise the system and should be created from the PO and equipment specifications. During execution you should verify the internal equipment number is generated and the equipment is labelled and document the actual manufacturer, model number, serial number, and tag name of each piece of equipment.

3.4.1.8. Component schedule

Critical components are those which a failure could result in a process or quality related failure. The critical components of the system should be physically verified against available documentation after installation. Critical components are those components that are integral to the equipment's suitability for its intended use. A listing of all system components should include manufacturer, model, and serial numbers. This list is verified in the field for correctness and completeness to ensure system documentation is accurate and complete.

If acceptable substitutes are listed they must be verified to confirm that they conform to the original specifications of the installed components.

Cut sheets or manuals must be provided for each critical component.

3.4.1.9. Critical measuring instrumentation

Measuring instruments that are used to make operational decisions for the equipment which affect product quality or which provide data that is recorded as part of production or GMP maintenance records are considered to be critical measuring instruments. Critical instruments will be verified in accordance with available calibration documentation (i.e.,

appropriate range, precision, accuracy) before or as they are installed. Verification of entry into the site calibration system will occur at this time. Critical instrumentation for equipment may include pressure/vacuum gauges, temperature sensors, timers, transmitters, display systems, process analytical technology (PAT), data loggers or recorders.

A listing of instruments deemed critical should be included which itemizes the instruments, their precision and accuracy, operational range, and engineering units. Manufacturers and model numbers are also required in the component schedule. Cut sheets or manuals must be provided for each critical instrument.

The component list and critical instrument listing may be combined as appropriate as long as there is a differentiation between critical (impact) and non-critical (non-impact) items and critical measuring devices are identified.

3.4.1.10. Drawings

Various types of drawings including but not limited to Process and Instrumentation Drawings (P&IDs), Electrical, Schematics, Structural, Mechanical, Pneumatic, Hydraulic are used to graphically represent systems. Typically, drawings are created during the design phase of a project and once approved, serve as a portion of the specification used to build or create the system. Drawings provide details, specifications and troubleshooting information for the critical equipment or systems. Once built, the approved or as-built drawings serve as one of the most important means of documenting on paper what the system is and what it consists of. Modifications to the system often require subsequent updating of the drawings to keep them up-to-date. Because of their importance to the documentation of the system, the drawings should be verified to ensure that they adequately represent the installed system. Tag names, component placement, and key specifications and interconnections must be physically verified against the official drawings and the review documented. Electrical schedules (lists of the electrical components of the system including manufacturer and model number) and schematics should be provided if not already included in the component schedules.

3.4.1.11. Spare Parts

A recommended spare parts list should be obtained from the manufacturers, any quality critical parts should be ordered or are in stock, and any acceptable substitutes have been

identified.

3.4.1.12. Maintenance

The purpose of maintenance is to assure equipment is maintained and operates in optimal condition. A preventative maintenance (PM) program ensures maintenance materials (e.g., parts list, spare parts, lubricants, manuals, maintenance SOPs or work instructions, service contracts in case PM) are in place before equipment goes into operation. Preventative Maintenance will be established according to manufacturer's recommendations or a documented rationale for the deviation should be provided and filed with the IQ.

Documentation should be provided to supply objective evidence that items have been added to the Preventative Maintenance program. This may include screen prints or reports from a computerized system or copies of initiation documents for paper based systems. The supporting documents should include equipment number, description, PM procedure reference or steps, frequency, start or last performed date, next due date, and a link to any materials required.

3.4.1.13. Safety

Safety verification is performed to ensure the system or equipment being installed meets all required safety features. The safety specifications may be standard for a piece of equipment but should generally be based on site safety requirements. Typically, things like guards being in place over moving parts, safety interlocks, emergency stops, pinch point identification, and no sharp or protruding corners are safety features to be checked. In general this can be a checklist. Exceptions to this would be emergency stop buttons or safety interlocks which should be challenged using GMP level documentation (expected results and acceptance criteria given for each). Judgment shall be used in determining which features may be verified (checklist) or validated (GMP level documentation). Any 3rd party verifying safety conditions should provide a written report of the verification. Such report should describe the equipment and standards or acceptance criteria used in measurements and the equipment used shall be traceable to NIST standard or equivalent. The report shall be attached to the completed protocol.

3.4.1.14. Environmental Requirements

If there are any specific environmental requirements or restrictions they should be clearly

spelled out within the test protocol. Equipment may for example require a specific temperature or humidity range in order to operate correctly. In addition, an air quality controlled environment or negative pressure condition may be required.

3.4.1.15. Warranty

Equipment warranties for services or equipment replacement can be critical in cases of mechanical failure. Conditions of the warranty agreement may be in the form of required PMs. This test provides a place to file the warranty and ensure all conditions of the warranty are met and integrated into site PMs or procedures.

3.4.1.16. Integration/Interconnections

Any interconnections/integration instructions should be fully documented and included with the required verification details (if provided). Integration to existing systems may be required. Specific instructions for making an operational integration may be included. Such integration should be performed in a controlled manner in order to keep any previously performed testing valid.

3.4.1.17. Installation

Installation instructions detail the steps to be taken to assure proper setup and initial start-up of the equipment. Verification of the installation instructions assure that proper steps have been followed. Design a test to check the equipment and its components for proper electrical installation. This may include wiring additions or power connections.

3.4.1.18. Training

Key personnel (those expected to execute or assist with execution) should be trained before equipment goes into operational qualification. Personnel should also be trained on procedures specific to their function relating to the equipment. This specifically relates to training provided by the vendor of the equipment or system. Verification of this training should be included in the IQ.

3.4.1.19. Materials of Construction

This test is performed to clearly outline the requirements for product contact materials, for example:

- Compatible with product, cleaning and sanitizing agents

- Smooth and easy to clean
- Resistant to temperature extremes, if applicable
- Particle release must be avoided (low or non-fibre shedding)
- Will not contribute foreign substances to the product

3.4.2 Operational Qualification

Operational Qualification Protocols are a collection of tests used to support the functionality of equipment or systems. Their goals are to confirm that the system can sequence through its operating steps and those key process parameters or functions are checked to ensure they are in compliance with the operating specifications. OQ also should ensure that the system does not operate in ways that are undesirable, and also that the system responds appropriately under fault or failure conditions. Tests contained in the OQ document are derived from appropriate specifications and will vary depending on the system under validation.

A prerequisite to the OQ activity is a completed and approved IQ protocol and report. In the event that an item remains open in the IQ that has no impact on the performance of the OQ (for example, redlined drawings which have been verified but need to be updated or other documentation found to be in error which must be corrected) a protocol deviation to the OQ may be opened. The protocol deviation must include the rationale for the “no impact” and decision to proceed to OQ. All elements to the IQ and OQ (protocol, report, deviations, etc.) must be closed prior to PQ, or a documented rationale for the deviation should be provided and filed with the OQ.

Completed and approved specifications are utilized in writing OQ tests and should, where available, to generate the OQ tests and design operational challenges. The specifications should address operational characteristics such as permanent recording, visual indication, design/specification range, normal operating range, alert and action limits, and functional interrelationship of each component within the system. Proper operation of controllers, indicators, recording devices, alarms, interlocks, as well as their operation within specified parameters, for example, temperature, pressure, flow, speed, etc., should be challenged. All these aspects of the requirements should be verified during OQ testing.

If a Factory Acceptance Test (FAT) or Site Acceptance Test (SAT) has been performed,

some or all of these tests may be leveraged in the OQ protocol. Consideration must be however given as to how the system may be disassembled and challenges made upon reassembly in the plant, in order to use the testing performed "off location". Any tests whose results may be invalidated by moving or disassembling the equipment should be delayed until the equipment is placed in situ, or reproduced when the equipment is in situ.

Equipment must meet all operational challenge tests performed on the system over the full operating range as defined by the specifications, or in other words, at the worst case conditions. The test should clearly list all critical operating parameters and their corresponding test function. Test data sheets or test tables allowing sufficient space to document all actual results and the overall PASS/FAIL status of the executed test must be created. These test scripts can be incorporated into the body of the protocol, or included as attachments.

The FDA has defined worst case testing as "a set of conditions including those within standard operating procedures which pose a greater chance for process or product failure than ideal conditions". It is not an expectation that all process specifications are challenged, but the critical or output of the process step must be examined and validated. It is an expectation that you operationally challenge a system under conditions which would be deemed "worst case". This could involve high speed for a belt driven operation or high and low temperature for an oven for example. For the intent and purpose of an OQ, the "worst case" condition should provide the most challenging situation for the equipment to physically function. Worst case parameters for the process and performance will be tested in the PQ or PV challenges. Careful consideration and rationale should be stated for the "worst case" condition.

In order to meet Corporate, European, U.S. and other cGMP requirements, the following items must be considered for inclusion in the OQ protocol when applicable to the system:

- Verification of Start-up Procedures, Operational and Cleaning SOPs (or work instructions)
- Calibrations
- Individual Device Operation
- Operator Interface Testing

- Alarms
- Interlocks
- Safety Devices
- Operational Testing
    - Sequence Testing
    - Functional Challenges, Normal Operation
    - Worst Case Testing
    - Capacity Testing
    - Loss of Utilities Testing
    - Integrated Testing

3.4.2.1. SOP or Work Instruction Verification

This test is required in order to assure the availability of written operating procedures that can be verified for completeness and accuracy, or which can be redlined to make them so, during normal function and/or cycle testing and which can be updated and approved prior to PQ/PV execution. The SOP (or work instruction) shall be initially approved and controlled in such a manner that any alterations and updates may be tracked. Therefore, the SOP (or work instruction) shall be officially signed and issued an initial version number, indicating it is intended for OQ execution. If no changes are required, this version can remain effective. If changes are required, the reasons for revision should be updated for the next version to indicate changes were made as a result of the OQ testing. This test serves to ensure that the outcomes of the individual OQ tests are not altered or biased by operating the system in a manner that differs significantly from the intended methodology for operation during normal use.

3.4.2.2. Calibration

All critical instruments used during testing for measuring, monitoring or recording must be calibrated. This test assures all test instruments used during the qualification, whether they are part of the equipment itself or external instruments used to record data, are calibrated. Verification and identification of measurement system to be used in measuring quality of

product may include calibration or measurement system analysis tools. If a Gauge Repeatability and Reproducibility (Gauge R&R) is not to be performed, a rationale must be included as to why it is not necessary.

3.4.2.3. Individual Device Operation

This test is required in order to assure that selected switches, push buttons, indicators, controllers, recorders, etc., function in accordance with the specifications. Test all functions one by one for their proper operation, starting with the power on/off switch and recording the outcome for each function. The test design shall include specific instructions for operating each device and the specific reaction expected. The list of devices shall be developed from the component list in the corresponding IQ protocol.

3.4.2.4. Operator Interface Testing

If the system has an operator interface panel (HMI-human machine interface), screen, soft keys or LED screen, documentation shall be provided which displays the exact appearance of the screens or panel the operator will see, as well as an explanation of the various functions of any keys or buttons that exist. The operating controls located on the Control Panel(s) of the equipment should be tested. This test is required in order to assure that the operator keys or interface panel functions are in accordance with the specifications.

3.4.2.5. Alarm Testing

Process quality, equipment and operator safety are ensured through the proper operation of alarms. Alarm triggers and their clearance shall be included. The test should verify and document that abnormal events and/or alarm conditions are detected, and the system responds to each abnormal event and/or alarm condition as described in the requirements and specifications documents.

3.4.2.6. Interlock Testing and Safety Devices

Process quality, equipment and operator safety are ensured through the proper operation of interlocks. This assures that conditions that may cause problems with safety, product or equipment are mechanically or electronically blocked from occurring. You must verify and document proper operation of specified interlocks and that the system responds to activation/deactivation of the interlock.

3.4.2.7. Operational Testing

Operational testing involves test runs to challenge critical. Test challenges shall be designed against process variables and operational ranges. Various components can make up operational testing such as verification of proper sequencing, verification of normal operations and SOP (or work instruction) verification, worst case testing and capacity testing.

3.4.2.8. Sequence Testing

The purpose of sequence testing is to verify that individual pieces of equipment are able to perform the series of sequential functions that define the equipment operation. This may involve start-up, shut down and loss of power sequencing.

3.4.2.9. Functional/Cycle Testing

In order to produce a quality product, the system must reliably execute the cycles that will be used. This test should confirm that all cycles would operate as desired. Adequate functional testing may require a sufficient number of repetitions to assure reliable and meaningful results.

3.4.2.10. Worst Case (stress) and/or Edge of Failure Testing

The system should be challenged under conditions which mimic a worst case situation (outside or at limits of production settings). Extra assurance and working range is established through testing of extreme conditions. The equipment should be tested at (or near) the upper/lower limits of its design specification and outside (or at the edge of) the process operating range. This assures that the equipment is qualified to handle conditions even during times of extreme process upset conditions. Examples include, but are not limited to:

Pump rating is 0-100 GPM (or L/min); process operating range is 30-70 GPM. Therefore, a worst case test might test the pump operation at 20 and 80 GPM.

Tank mixer is rated 0-400 RPM; process operating range is 50-250 RPM. Therefore, a worst case test might test the mixer at 30 and 300 RPM.

3.4.2.11. Capacity Testing

Capacity testing is performed in cases where a system produces an amount of a commodity. Utility systems require this kind of testing. Equipment and systems would

qualify for this type of testing in the sense that mass consumption and output would be challenged. The system should be operated at the maximum consumption or production rate for a period of time and testing should verify that the system is capable of producing the amount of commodity specified, or verify that the input required is achievable.

3.4.2.12. Loss of Utility Testing

Process quality, equipment and operator safety are ensured through proper fail-safe operations. If there is a loss of utility, it should be verified how the system is expected to respond. Testing should create (or simulate when conditions may be dangerous to personnel or equipment) a loss of utility condition for each specified utility, observe the system response and compare to the expected response.

3.4.2.13. Integrated Testing

Within a system there can be many components. It is critical to show that the components operate as a total system. This is the same as in functional testing, except that multiple integrated components of the system are tested together. It is necessary to test that systems that are connected to each other also operate as expected. This integration testing may be completed as part of PQ, but can be done in the OQ protocol also, especially if these systems are permanently assembled together. When there is risk involved with product use, the integration testing initially involves testing with test batch runs. Testing with actual product is performed during the PQ.

3.4.3 Performance Qualification

The goal of performance qualification is to demonstrate ruggedness and to assure that a system performs as specified when operating in its normal environment under the conditions required by a specific process. Performance qualification should be conducted in a manufacturing or equivalent environment. Performance qualification is verification that the components of a system or a group of systems (process unit) meet requirements and specifications when operated as an integrated process over the intended operating ranges.

In operation qualification, individual components or subsystems are tested for suitable operation over their entire specified operating range. In performance qualification, the

operation of the combined components within the expected operating range for the specific process is performed. Another term for this is “integration testing”.

Table 3-1: Relationship between OQ, PQ & PV provides a high level overview of the relationship between OQ, PQ and PV.

Table 3-1: Relationship between OQ, PQ & PV

Protocol	OQ	PQ	PV
Purpose	(Sub-) System's functionality	Process behaviour (all sub-systems combined)	Product behaviour
Environment	Testing environment	Manufacturing environment or equivalent	Manufacturing environment
Critical parameters	System related	Process related	Product related
Acceptance criteria	System specific	Process specific	Product specific
Testing Range	System Operating Range	Process Normal Operating Range (part of system's range)+	Product Operating Target (part of process' range)+

PQ is typically performed for, but may not be limited to:

- Processing equipment unit operations
- Manufacturing support processes including cleaning, sanitization, sterilization, aseptic processing
- Utility generation, storage and distribution

- Environmentally controlled storage and distribution
- Classified environments (e.g., clean rooms and isolators)
- Packaging and labelling processes at least through the operation of placing the primary (the package in contact with the product) package into the carton. This testing can be conducted with product.
- Any computerized business process specifically required by cGMP (e.g., document and record storage, laboratory information management, tracking calibration or preventive maintenance).

Representative numbers of equipment and test replicates should be performed to qualify all identical equipment. The representative numbers of equipment and test replicates are dependent on the complexity and criticality of the equipment and test. For example, a representative mixer can be tested, and the test results are applicable for all other identical mixers. However, for equipment as critical as an autoclave for sterility, each identical autoclave should have at least an abbreviated PQ performed demonstrating critical functions are verified.

Equipment is deemed identical when they carry identical specifications, and are qualified with identical IQ and OQ protocols. The manner in which reproducibility is demonstrated will depend on the process and ranges being qualified. This rationale should be detailed and approved prior to testing.

For units of batch processes, reproducibility is demonstrated by performing a number of replicate trials. These trials are conducted with operating parameters at different values within their ranges to support the operation across its range. This is required unless data is available from other sources such as development lab scale studies, technology transfer reports or appropriate engineering studies. Continuous processes are normally assessed in terms of consistency. The process must be assessed over a sufficient period of time to ensure it consistently produces the required outcome. The length of this will depend on the process being considered, for example, a cold storage area within a temperature-controlled warehouse, three (3) days may be sufficient, if this covers use (loading and unloading) of the area and defrost cycles for the system. For Purified and WFI generation systems, it may need to have a form of evolution over a year to take into account seasonal variations.

Completed and approved IQ and OQ protocol reports are required before PQ can begin on any given “Direct Impact” system. All elements to the IQ and OQ protocols must be closed prior to PQ performance, including all deviations. Completed, current and approved specifications are utilized in writing PQ tests and should be available, where applicable, prior to PQ creation. All SOPs, specifications (final product specifications), and work instructions must be in an approved form prior to execution of the PQ. It is key that the system is operated using approved SOPs during PQ testing. This will ensure the same performance is achieved during routine operation as during validation. For the same reason, actual users should be trained and used for execution. When designing performance challenges specifications should be carefully utilized. The specifications should address the quality of the output of the equipment or system.

Performance Qualification runs are either performed at nominal (production range) settings or are performed at “worst case” challenge settings. This determination should be made, and justified, in the rationale section of the individual protocol. Three (3) consecutive, successful runs are typically required for Performance Qualifications. If three (3) runs are not required, the justification must be discussed in the rationale section of the protocol.

General tests performed in the PQ include:

- Verification of Start-up Procedures (SOP’s, WI, etc.)
- Calibration
- User Requirement Challenges - The testing is individualized based upon the equipment/system to be validated. Testing in this section is typically derived from specifications or performance descriptions. These tests are designed to test the performance of the equipment to demonstrate its ability to produce output which meets requirements and specifications.

3.4.3.1. SOP Verification

This test is required in order to assure the availability of written operating procedures and or work instructions that can be verified for completeness and accuracy during PQ/PV execution. The documents must be approved prior to the start of PQ testing. This test also serves to ensure that the outcomes of the individual PQ tests are not altered or biased by

operating the system in a manner that differs significantly from the intended methodology for operation during normal use.

3.4.3.2. Calibration

All critical instruments used during testing for measuring, monitoring or recording must be calibrated. This test assures all test instruments used during the qualification, whether they are part of the equipment itself or external instruments used to record data, are calibrated. Verification and identification of measurement system to be used in measuring quality of product must be made. This may include calibration or measurement system analysis tools.

3.4.3.3. Performance Testing

Performance testing involves test runs to ensure the system produces outputs of a predetermined quality when operated in the normal operating range. Key process inputs and outputs shall be monitored (as developed in the process map, FMEA, and C&E matrix documents). Specific performance verification tests are determined from the specifications and output expected. Testing may include industry expected testing as well as in-house generated system specific testing (based on specifications). The rationale for the tests created and used should be documented in the PQ protocol.

3.5 Validation Methodology

Validation is documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance specifications and quality attributes.

Validation testing on the REALISM TCM consisted of 3 key stages, detailed as follows:

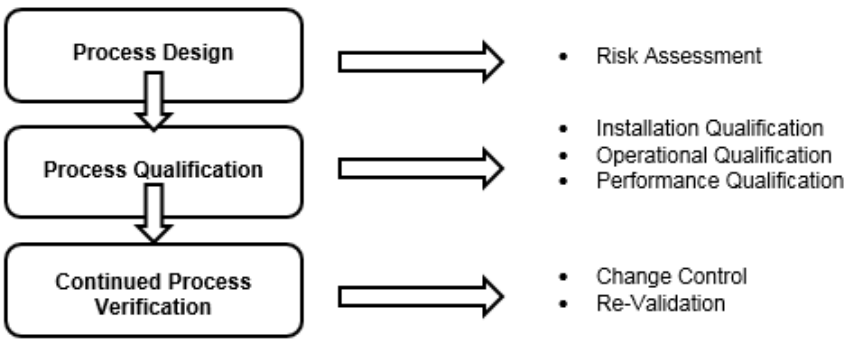

Figure 3-4: Validation Methodology

3.5.1 Process Design

3.5.1.1. Risk Assessment

In Validation Risk Management, the objective is simple, to thoroughly consider what could go wrong and develop a test strategy to assess whether the validated state is maintained.

There are two ways to use risk management:

- Identification of low risk areas to reduce testing / resources.
- Rigorous assessment of scenarios to identify risks to quality, safety and regulatory compliance.

Figure 3-5: Basic Principle of Risk Management

Many valid methods exist for risk management including Impact Assessments, FMEAs, HACCPs, HAZOPs, and FMECAs, along with various other less formal methods, regulators expect that the risk management effort is matched to the risk. For the REALISM TCM Failure Mode and Effects Analysis was chosen as the Risk Management tool because FMEAs primarily deal with the risk of the equipment to the product and to production. The focus is generally to mitigate risks through controls.

The process was analysed under the following headings:

- Process Function
    - What are we doing?
- Process Requirement
    - What are we supposed to do?
- Potential Failure Mode (How)
    - How can this fail?
- Potential Effect of Failure (What)
    - What is the effect of this failure? And is it internal to the company, or does it have an effect externally?

- Severity
    - Ref Table 3-2: Rating Scales
- Potential Cause(s)/Mechanism of Failure
    - What can cause the failure?
- Current Process Control Prevention
    - How do we currently prevent this from happening?
- Probability of Occurrence
    - Ref Table 3-2: Rating Scales
- Current process Control Detection
    - How do we currently detect these failures?
- Likelihood of Detection
    - Ref Table 3-2: Rating Scales

After the failure has been graded based on Severity, Probability of Occurrence and Likelihood of Detection the risk priority number (RPN) was calculated. The Risk Priority Number (RPN) is a quantified value expressing the overall risk and is calculated as follows (Severity) x (Probability) x (Detection) = RPN. Once the RPN was calculated we categorised the failures into 4 categories, detailed below. Intolerable failures must be counter measured and eliminated:

- Intolerable
- As low as reasonably practicable/Safety
- As low as reasonably practicable/Efficacy
- Acceptable

Table 3-2: Rating Scales

Severity Rating Scale		
Rating	**Category**	**Description**
4	Serious/ Severe	Very high severity ranking when a potential failure mode affects safe system operation **without warning**.
3	Moderate	Very high severity ranking when a potential failure mode affects safe system operation **with warning**.
2	Minimal	System inoperable with equipment damage.
1R	Reliability	System inoperable without equipment damage.
1	Negligible	No effect

Probability Rating Scale			
Rating	**Category**	**Description**	**Failure Probability**
5	High	Very High: Failure is almost inevitable.	> 1 in 50
4	Moderate	Occurrence likely	1 in 50 > x > 1 in 500
3	Low	Occurrence possible	1 in 500 > x > 1 in 5,000
2	Remote	Occurrence unlikely	1 in 5,000 > x > 1 in 50,000
1	Negligible	Product contained	≤ 1 in 50,000

Detection Rating Scale			
Rating	**Category**	**Description**	**Use**
5	High	Design control **cannot** detect potential cause/mechanism and subsequent filure mode	> 1 in 50
4	Moderate	Remote chance that the design control will detect potential cause/mechanism and subsequent failure mode	1 in 50 > x > 1 in 500
3	Low	Low chance that the design control will detect potential cause/mechanism and subsequent failure mode	1 in 500 > x > 1 in 5,000
2	Remote	Moderate chance that the design control will detect potential cause/mechanism and subsequent failure mode	1 in 5,000 > x > 1 in 50,000
1	Negligible	Design control **will** detect potential cause/mechanism and subsequent filure mode	≤ 1 in 50,000

A cross functional team was gathered, and each of the components, and sub components, listed in Section 3.2, were risk assessed. During the risk assessment process each of the failure modes was graded for severity, probability and detection and a RPN number calculated, ref Section 8.2 for the completed FMEA. Two intolerable failure modes were detected as part of the FMEA activities, both relating to the CaBR portion of the system, namely:

- Variability within the mechanical properties of the tooling, and its impact on system training
- Poor system training, due to variation in the operator's expectation around the degree of tool wear present. Due mainly to the fact that the operator is training based on an opinion rather than factual measurements.

In order to mitigate the risks, Various tool life's were tested under laboratory style conditions at Schivo Ltd., by running roughing, boring and drilling tools from new condition, through to catastrophic tool failure. Work pieces were faced, rough turned, bored and drilled. The tools were removed and measured at intervals on an optical microscope however, prior to removal of the tooling operator opinion was captured; this opinion was based solely on how the process was performing, through consideration of the following:

- High current or power consumption on the machine
- Vibration and/or chatter
- Catastrophic tool failure
- Deviations in work piece tolerances
- Poor surface finish on work piece
- Adverse chip formation

Machining parameters remained constant throughout each of the trials and through statistical analysis of the collected data, detailed in Sections 4.2 and 4.3 it was possible to regrade both of the intolerable failure modes. Intolerable failures were eliminated, using the statistical analysis, and the intolerable failures were subsequently re-graded as "As low as reasonably practicable/Safety".

FAILURE MODE AND EFFECTS ANALYSIS

PROB = LIKELIHOOD THAT A PARTICULAR CAUSE WILL OCCUR THAT WILL LEAD TO THE FAILURE, TIED TO THE END EFFECT AND THE CAUSE, AND PREVENTION PROCESS CONTROLS
SEV = SEVERITY OF FAILURE EFFECT
DET = LIKELIHOOD OF FAILURE NOT BEING DETECTED BY CURRENT PROCESS CONTROLS
RISK PRIORITY NUMBER (RPN) = SEV x PROB x DET PROBABILITY*SEVERITY # = PROB*SEV

FMEA No. : Issue Date :
Attendees :

ITEM	PROCESS FUNCTION	PROCESS REQUIREMENT	POTENTIAL FAILURE MODE (HOW)	POTENTIAL EFFECT OF FAILURE (WHAT)	EV	POTENTIAL CAUSE(S)/ MECHANISM OF FAILURE	CURRENT PROCESS CONTROL PREVENTION	ROB	CURRENT PROCESS CONTROL DETECTION	DET	RPN	RISK	RECOMME
	6 Omron MY4IN Relays	Provide logic high signals from machine M-Code block back to DAQ	Open circuit	No Signal	1R	Component Failure	None	2	Loss of signal	1	2R	AC	
			Short circuit	Continuous Signal	1R	Overload	None	2	None	5	10R	AL-R	
	21 Pheonix Contact Cable Blocks	Connect cables between components	Open circuit	No Signal		Component Failure	None		Loss of signal		4	AL-S	
			Short circuit	Continuous Signal		Overload	None		None		4	AL-S	
	Schneider C4 IC60	Protection of mains power	Open circuit	No Power	1	Component Failure	None	2	Loss of Power	1	2	AC	
			Short circuit	Continuous Power	2	Overload	None	2	None	5	20	AL-S	
			Faulty unit supplied	No Power/Continuous Power	2	Faulty product	None	2	None	5	20	AL-S	
5	**Industrial Portable Computer**	Platform for running custom software	Internal component failure	Incorrect/No Analysis of Signal Data	1R	Faulty component	None	2	None	5	10R	AL-R	
			Faulty unit supplied	Incorrect/No Analysis of Signal Data	1R	Faulty product	None	2	None	5	10R	AL-R	
			Lightening/Power Surge	Destruction of Equipment	4	Act of God	Surge Protection & Transformer	1	None	5	20	AL-S	
8	**Custom Control Software**	Taking inputs from DAQ and interpreting to provide feedback to user on degree of tool wear	Poor Programming	Program Error	2	Poor Poramming	Labview Program Software Operating Sytdem Error	2	Erro Message	2	8	AC	
			Corrupted Program	Program Error	2	Acto of God	Labview Program Software Operating Sytdem Error	2	Erro Message	2	8	AC	
			Invalid Data										
			Damaged Componets upstream	Output Data Invalid	4	Damaged Upstream Components	Captured Individually Above	1	none	1	4	AL-S	
			Digital Signals Incorrect	Output Data Invalid	4	Damaged Upstream Components	Captured Individually Above	1	none	1	4	AL-S	
			mechanical propoerties	Output Data Invalid	4	Poor Quality Tooling	None	3	None	4	48	IN	
			Operator Error	Inaccurate output	4	Poor Operator Training	User Manual/SOP - Use of Senior Setter for training of system	1	none	4	16	AL-S	
			Poor System Output										
			Poor System Training	Output Data Invalid	4	Inconsistant training received by system	None	3	None	4	48	IN	
			Incorrect Treshold Paramaters	incorrect output readings	4	Force tresholds set incorrectly	User Manual/SOP - Use of Senior Setter for training of system	1	None	4	16	AL-S	
9	**HMI - 19" SXGA TFT LCD with Touchscreen**	Interface for operator and trainer interaction	Damage during installation	User Unable to interact with system	2	Poor installation	Follow installation instruction	2	System not operable	1	4	AC	
			Internal component failure	User Unable to interact with	1R	Faulty component	None	2	System not operable	1	2R	AC	

Figure 3-6: Extract from FMEA

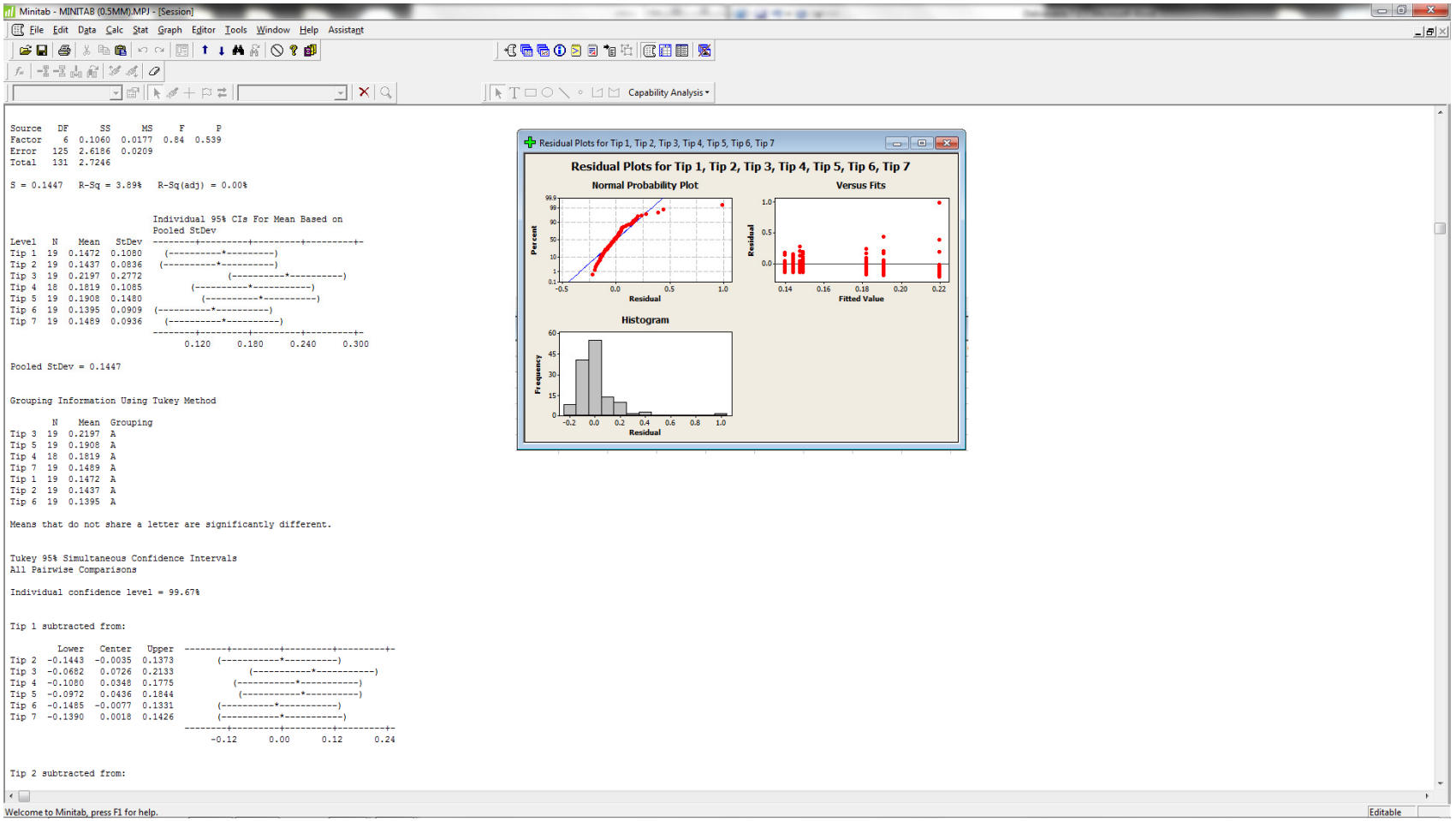

Figure 3-7: Extract of Statistical Analysis through Minitab®

3.5.2 Process Qualification

3.5.2.1. IQ – Installation Qualification

An installation qualification is documented verification that equipment or systems, as installed or modified, comply with approved design, the manufacturer's recommendations, and/or user requirements. This is where the Installation of equipment, or software, is recorded and checked against the requirements. The installation environment and connections with other systems is usually verified.

The REALISM TCM was reviewed against regulatory requirements and in order to comply with European, U.S. and other cGMP requirements, the following tests, applicable to the system, were executed as part of the IQ testing of the REALISM TCM:

3.5.2.1.1. Personnel Identification (Signature Log)

All personnel involved in the execution and review of the test protocol shall enter their name and signature on the Signature Log.

3.5.2.1.2. Validation Test Equipment Verification

All equipment/instrumentation used during the execution of the protocol must be calibrated and be in current calibration when the testing is conducted. A copy of all calibration certificates will be attached to the IOQ protocol.

3.5.2.1.3. Validation Materials Verification

All test materials used during the execution of the protocol must be recorded on the validation tests material test sheet. Each entry will be signed and dated.

3.5.2.1.4. Software Disaster Recovery

Testing shall verify that the correct software is installed, and that a disc image of the software can be loaded on to the machine.

3.5.2.1.5. Software Verification

The control system type and software version for the REALISM TCM shall be verified.

3.5.2.1.6. Equipment Installation Verification

Testing shall verify that a documented walk down of the Mechanical and Electrical system has been completed.

3.5.2.1.7. Documentation Verification

Testing shall verify that all the relevant documentation is available and reviewed. In some cases this documentation will be attached to the relevant datasheet and will form a permanent part of this protocol, alternatively its permanent stored location will be recorded on the Documentation Verification Checklist for future reference.

3.5.2.1.8. Drawing Verification

The drawings shall be inspected, to ensure that they accurately reflect the actual equipment layout. Any drawings, which have been redlined to accurately reflect the installed equipment, will be signed, dated and the original red-lined, marked-up drawings will be attached to the protocol.

3.5.2.1.9. SOP Verification

Testing will identify whether a revision is required as a result of validation, and also if the latest revision of SOP's are available at the time of execution.

3.5.2.1.10. Verification of Utility Supply and Installation

Utilities that are required for the continuous operation of equipment are considered support utilities. Without them the system would not operate properly. This test verifies that required support utilities are correctly installed.

3.5.2.1.11. Safety Features Verification

Process quality, equipment and operator safety are ensured through the proper operation of alarms and interlocks. Alarm triggers, interlocks shall be tested here.

3.5.2.2. OQ – Operation Qualification

An operational qualification is documented evidence that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges. This is where the system is checked right across its operating ranges, all functionality is verified, and alarm / failure conditions are checked.

In order to comply with European, U.S. and other cGMP requirements, the following tests, applicable to the system, were executed as part of the OQ testing of the REALISM TCM:

3.5.2.2.1. Start-up / Shutdown / Loss of Power

Testing shall verify that the REALISM TCM starts up and shuts down as per design intent and there are no adverse side effects during a power loss.

3.5.2.2.2. Graphics Screen Test

To verify that the graphics associated with REALISM TCM are in accordance with the project specifications.

3.5.2.2.3. User Adjustable Set Point Verification

To verify that the set points described as user adjustable are available for the user to adjust from the GUI.

3.5.2.2.4. Data Logging Test

To verify that the data logging associated with the REALISM TCM operates in accordance with the project specifications.

3.5.2.2.5. PLC Input / Output Testing

Testing shall verify that the PLC controller software, in the DAQ panel, is operating per design intent.

3.5.2.2.6. Integrated Software Testing

Testing shall verify that the integrated REALISM TCM software package is operating per design intent.

3.5.2.3. PQ – Performance Qualification

A performance qualification is documented evidence that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications. This is the final testing, run under normal operating conditions before the system is released for full use.

3.5.2.3.1. Personnel Identification (Signature Log)

All personnel involved in the execution and review of the test protocol shall enter their name and signature on the Signature Log.

3.5.2.3.2. Validation Test Equipment Verification

All equipment/instrumentation used during the execution of the protocol must be calibrated and be in current calibration when the testing is conducted. A copy of all calibration certificates will be attached to the PQ protocol.

3.5.2.3.3. Validation Materials Verification

All test materials used during the execution of the protocol must be recorded on the validation tests material test sheet. Each entry will be signed and dated.

3.5.2.3.4. Performance Testing

Performance testing involves test runs to ensure the system produces outputs of a predetermined quality when operated under normal operating conditions.

3.5.2.4. Continued Process Verification

3.5.2.4.1. Change Control/Revalidation

Revalidation is the re-execution of all or part of the protocol to maintain the validated state.

Where no significant changes have been made to the system or process, and a quality review confirms that the system or process is consistently producing material meeting its specifications, there is normally no need for revalidation

Revalidation is required following:

- Introduction of a new Equipment / Process / Software
- Change to Equipment / Process / Software that impacts the original validation
- Change to a procedure that impacts the Validated State

3.6 Chapter Summary

In this chapter it was established that the TCM system is a sensor, software and hardware fusion, that consists of a 3-axis force sensor, an acoustic emission sensor, 3-axis accelerometer, a data acquisition card, an industrial portable computer, custom Data Logging Software and custom Control Software (CaBR), linked back to a Human Machine

Interface (HMI), and that the equipment has initially been deployed on a Mazak Quickturn Nexus 200II machine at Schivo Ltd. based in Waterford, Ireland.

After a review of the literature and regulatory requirements in Section 2.0 the author was in a position to establish a number of areas which should be included for consideration when completing a validation. This was not an exhaustive list, and has been created based on the equipment and the surrounding environment at Schivo Ltd. As with every validation, anything that can have a direct impact on the quality of the finished product or the safety of employees must be considered for validation. Validations are generally unique to the equipment, process, software etc. under validation however, the author feels that a good solid overview of the key areas which should be considered, within a typical GMP environment, have been outlined in Section 3.4.

In Section 3.5 the author applied the validation guidance to the TCM system, and has generated the IOPQ test scripts, specific to the TCM system, which are believed to meet with Corporate, European, U.S. and other cGMP requirements. The scripts are detailed in Section 3.5.2, and the completed IOPQ test protocol is attached in Appendix 1, Section 8.1.

It was established during the literature review, in Section 2.0, that a risk based approach, and a lifecycle, was extremely important to the validation activities. The author applied a variant of the US FDA lifecycle, which is now being adopted by the EU and WHO, to the validation process on the TCM system, Figure 3-8: Validation Methodology.

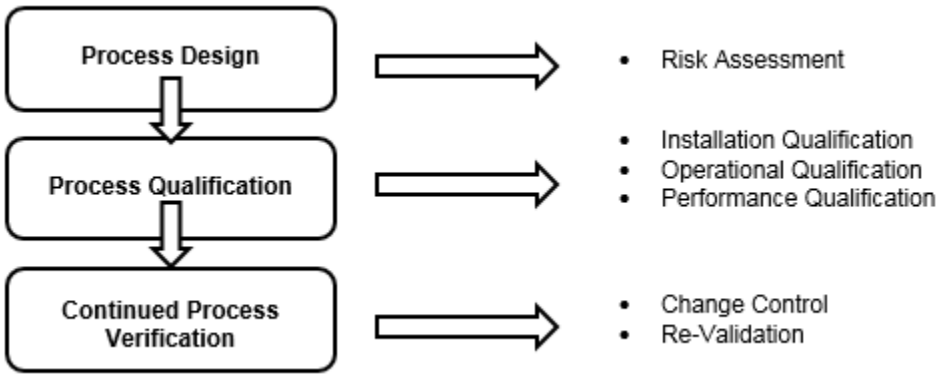

Figure 3-8: Validation Methodology

The lifecycle starting point, was completion of a Risk Assessment. Through the use of a FMEA, the author was able to identify two intolerable failure modes, both relating to the CaBR portion of the system.

Because case-based reasoning is the act of developing solutions to unsolved problems by basing the solution on pre-existing solutions of a similar nature, the CaBR system, developed as part of the TCM system, must initially be trained by machine operators, to identify when a tool is at end of life. This human intervention was one of the key variables identified as part of the FMEA activities, or more specifically:

- Poor system training, due to variation in the operator's expectation around the degree of tool wear present. Due mainly to the fact that the operator is training based on an opinion rather than factual measurements.

The second key variable identified was the mechanical properties of the tooling used. There is an assumption that the tooling being used is consistent and that there is no impact on system training from premature failure tooling due to its mechanical properties.

Through statistical analysis, Section 4.0, the author was able to reduce the risks and progress to the IOPQ testing of the system.

As this was the initial validation of the system there was no necessity to consider the change control and re-validation portion, however it was recommended that the TCM system be included within Schivo Ltd. change control process.

4.0 Results/Analysis

4.1 Introduction

When the TCM system was risk assessed, two intolerable failure modes were detected both relating to the CaBR portion of the system, namely:

- Variability within the mechanical properties of the tooling, and its impact on system training
- Poor system training, due to variation in the operator's expectation around the degree of tool wear present. Due mainly to the fact that the operator is training based on an opinion rather than factual measurements.

In order to mitigate the risks, various tool life's were tested under laboratory style conditions at Schivo Ltd., by running roughing, boring and drilling tools from new condition, through to catastrophic tool failure. Work pieces were faced, rough turned, bored and drilled. The tools were removed and measured at intervals on an optical microscope. However, prior to removal of the tooling operator opinion was captured; this opinion was based solely on how the process was performing.

Machining parameters remained constant throughout each of the trials and through statistical analysis of the collected data, detailed in Sections 4.2 and 4.3 it was possible to regrade both of the intolerable failure modes. Intolerable failures were eliminated, using the statistical analysis, and the intolerable failures were subsequently re-graded as "As low as reasonably practicable/Safety".

Once the risk assessment criteria was satisfied, a full Installation Qualification, Operational Qualification and Performance Qualification was completed on the system. A copy of the test protocol is available for reference in Appendix 8.1, and the results of the IOPQ testing is detailed in Sections 4.4 and 4.5.

4.2 Variability within the mechanical properties of the tooling

Trial 1 consisted of running seven DNMG-150604-QM Sandvik 2025 turning tips, , under laboratory style conditions at Schivo Ltd., from new condition through to catastrophic tool failure. Thirteen SS316l work pieces were faced and rough turned, and the tip was removed

and measured at intervals on an optical microscope. Machining parameters, as outlined in Table 4-1: Trial 1 Machining parameters, remained constant throughout the experiment.

Table 4-1: Trial 1 Machining parameters

Feed rate (mm/rev)	Surface speed (Vc) (m/min)	Depth of Cut (mm)	Cut length (mm)
0.25	225	4	73

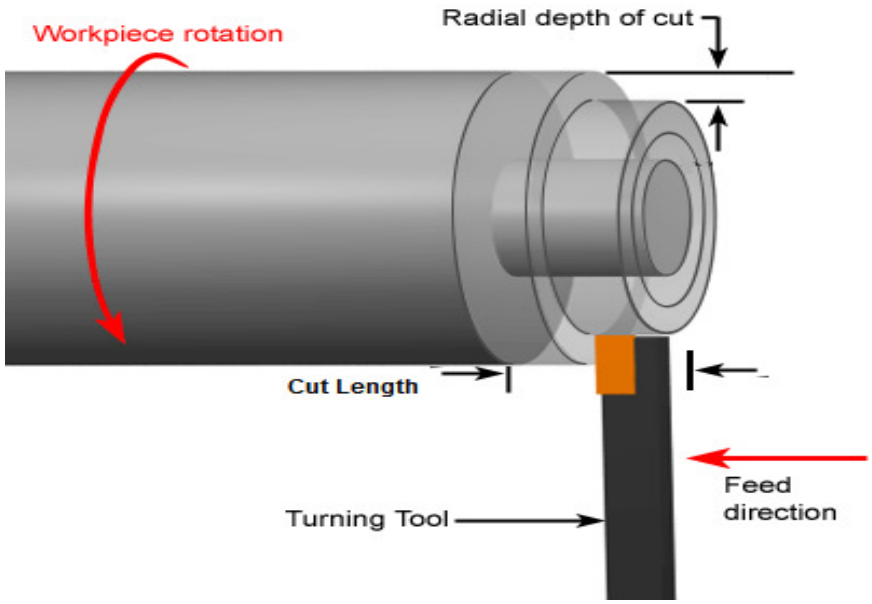

Figure 4-1: Machining Parameters

The flank wear on the 7 tips was measured at 5 distinct intervals, 0mm, 0.25mm, 0.5mm, 0.75mm and 1mm, over a distance of 1mm from the tip of the cutting insert towards the centre, using ImageJ 1.51J software. The results of the tool wear was documented and it was noted that the number of passes before and after the last recorded value of CTF was consistent and the total average of the tool wear value recorded on the tips before CTF was 0.27mm. This was in line with Kharagpur (2009) expectation of 0.3mm, however, when compared to the expectations outlined in the Machineries handbook of 0.020 to 0.040 inch (0.508mm to 1.016mm), for rough turning, the tips fell significantly short of expectation.

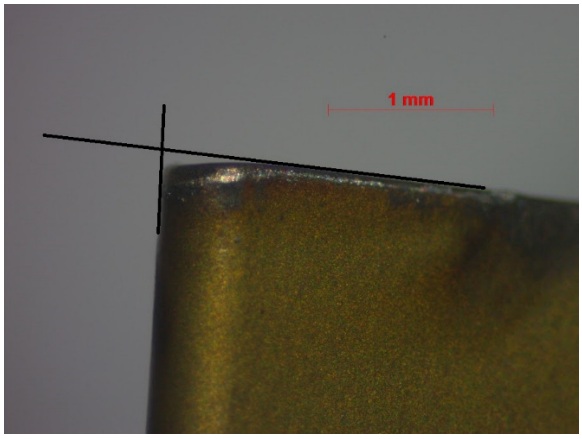

Figure 4-2: Flank Wear

Table 4-2: Last worn value recorded before CTF

Last Worn Value before CTF		No of Passes Before	No of Passes After
Trial	Value		
1	N/A[1]	N/A	N/A
2	0.22	18	4
3	0.30	16	3
4	0.29	17	3
5	0.29	17	3
6	0.27	18	3
7	0.25	18	4
Average	0.27		

In investigating the premature tip failure, it was noted that the Sandvik data sheets recommend the cutting settings listed in Table 4-3: Recommended Cutting Settings DNMG-150604-QM for a 0.4 radius DNMG-150604-QM carbide insert. While the feed rate and depth of cut are in line with manufacturer's recommendations the cutting speed was far in excess of the recommended maximum speed, of 195m/min, at 225m/min. The higher cutting speed was used to accelerate CTF, which had a direct impact on the last recoded lower than expectation flank wear measurement prior to CTF. The decision to

[1] Tip 1 was excluded as there was insufficient information collected during the trial, due to a system error.

accelerate CTF was taken because the Mazak Quickturn Nexus 200II is a fully operational production machine in the Schivo Ltd. Facility, and there was limited windows of opportunity available to complete the R&D work as part of the REALISM Project. The acceleration of CTF has no impact on the final results as the rete of wear is not a key part of the system, the key part of the system is the accurate measurement of tool wear percentage.

Table 4-3: Recommended Cutting Settings DNMG-150604-QM

Recommended Depth of			Recommended Cutting			Recommended Cutting		
ap =	Min	Max	fn =	Min	Max	vc =	Min	Max
3.00	1.00	7.50	0.25	0.18	0.30	175	165	195

Trial 2 consisted of running a further seven tool life's, this time on 3 different types of tools, turning tools, boring tools and drilling tools, under laboratory style conditions at Schivo Ltd., from new condition through to catastrophic tool failure. Again the tooling was removed and measured at intervals on an optical microscope. Machining parameters, as outlined in Table 4-1: Trial 1 Machining parameters, remained constant throughout the experiment. This time Turning, Boring and Drilling operations were statistically analysed using an ANOVA Analysis to determine whether there was any statistically significant differences between the means of each of the independent tool lives.

Table 4-4: Trial 2 Machining parameters

Tool Type	Operation Type	Feed rate (mm/rev)	Surface speed (Vc) (m/min)	Speed (rev/min)	Depth of Cut (mm)	Cut length (mm)
DMNG-150604-QM2025 Sandvik	Turning	0.25	175	N/A	2.5	70
CCMT-060204	Boring	0.25	N/A	2250	2	45

Tool Type	Operation Type	Feed rate (mm/rev)	Surface speed (Vc) (m/min)	Speed (rev/min)	Depth of Cut (mm)	Cut length (mm)
7mm HSS jobber	Drilling	0.275	N/A	1250	7	10

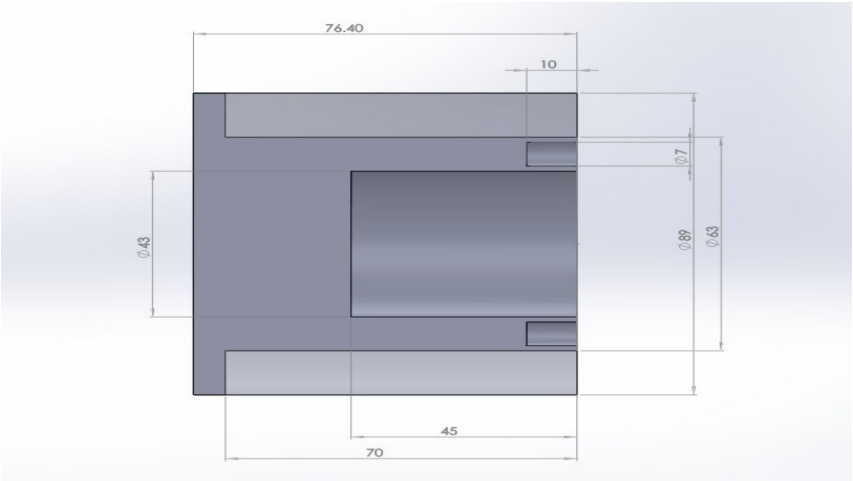

Figure 4-3: Trial 2 Work Piece

The wear on the tools was measured at 3 distinct intervals, Figure 4-4: Flank Wear Turning & Boring, over a smaller distance, to maintain greater accuracy, from the tip of the cutting insert towards the centre. The results of the tool wear were documented and it was noted that the total average of the tool wear value recorded on the tips before CTF was 0.39mm for the Turning Operations, 0.20mm for the Boring Operations and 0.33mm for the drilling operations. Flank wear for drilling was measure on one cutting edge of the drill only, an assumption of equal wear on both cutting edges was taken.

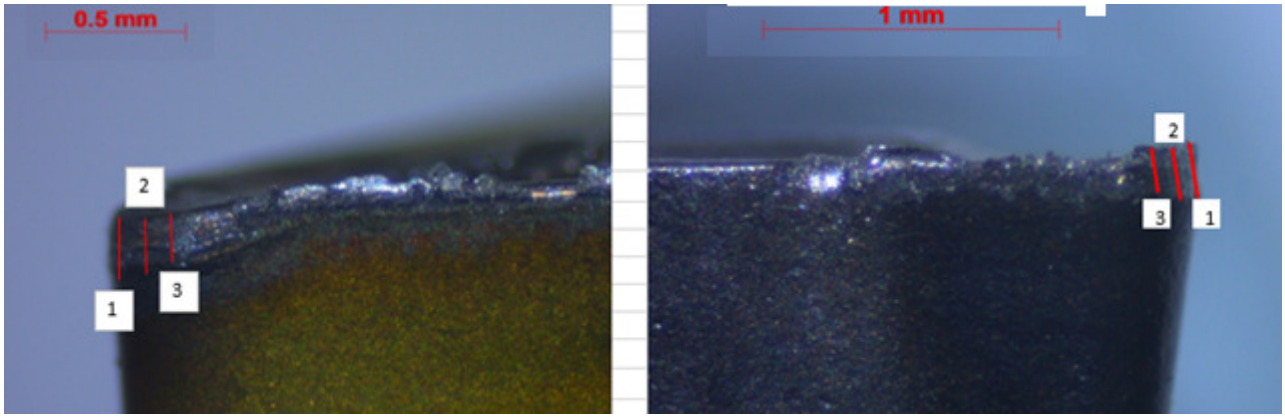

Figure 4-4: Flank Wear Turning & Boring

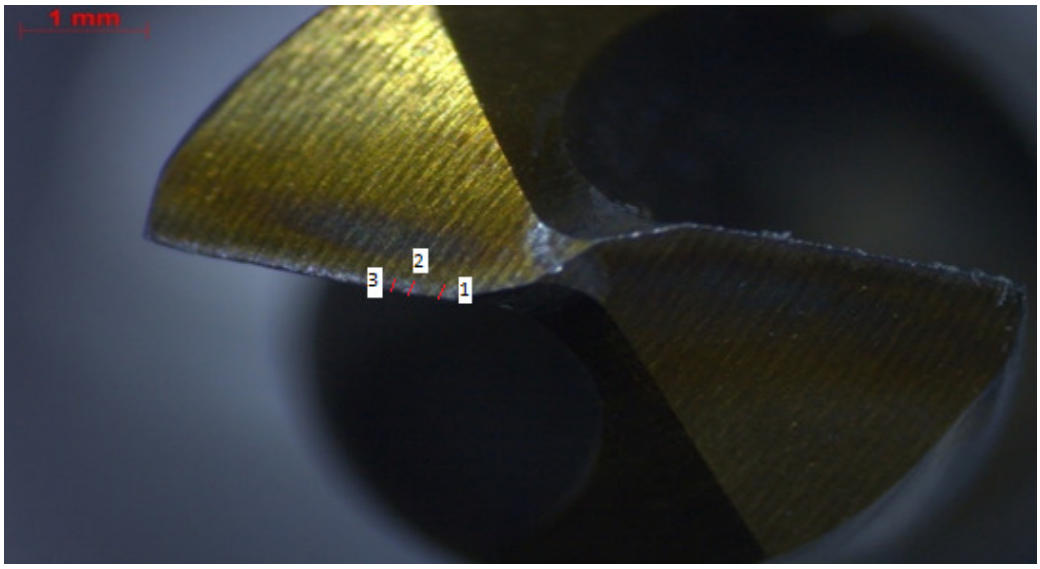

Figure 4-5: Flank Wear Drilling

Table 4-5: Trial 2 Last worn value recorded before CTF [Turning]

Last Worn Value before CTF	
Trial	Value
1	0.36
2	0.38
3	0.38
4	0.39
5	0.38

Last Worn Value before CTF	
Trial	Value
6	0.39
7	0.39
Average	0.38

Table 4-6: Trial 2 Last worn value recorded before CTF [Boring]

Last Worn Value before CTF	
Trial	Value
1	0.21
2	0.22
3	0.23
4	N/A
5	0.14
6	0.24
7	0.16
Average	0.20

Table 4-7: Trial 2 Last worn value recorded before CTF [Drilling]

Last Worn Value before CTF	
Trial	Value
1	0.32
2	0.31
3	0.33
4	0.34
5	0.35
6	CTF
Average	0.33

A one-way ANOVA was used to compare the means between the groups determines whether any of those means are statistically significantly different from each other.

Testing of the turning data,

Table 4-9: Analysis of Means - Turning Trial, concluded that there were no unusual data points and there is no significant difference between the mean of the wear values on the seven turning tools. The P value was significantly greater than 0.05 at 0.850 indicating no statistical significance. In addition, Figure 4-7: Interval Plot - Turning Tool clearly shows that all confidence intervals, across all 7 tips analysed, include the mid-point of the confidence interval for each of the individual tips, which, again, confirms the assumption of no statistical significance.

Analysis of Figure 4-6: Residual Plots - Turning Tool shows that the data is a good fit for normality and, in addition, the residuals, although clustered across the fits, are appropriately spread out. Because of the assumption of normality, for the post hoc testing, Tukeys honest significance test was selected. Tukeys honest significance test individually compares all the possible pairs of means for statistical significance. At the individual confidence level all pairs of means include zero, Figure 4-8: Tukey Simultaneous 95% CI's - Turning Tool, which confirms no statistical difference in the means and with a confidence level of 99.64% we can be confident that each individual interval contains the true

difference between any pair of group means. Additionally, in

Table 4-9: Analysis of Means - Turning Trial, Tukey pairwise comparisons, all means share the same grouping value, only means that do not share a letter are seen as being significantly different.

Table 4-8: Trial 2 Turning Data

	Tip 1	Tip 2	Tip 3	Tip 4	Tip 5	Tip 6	Tip 7
20.00%	0.05	0.05	0.06	0.05	0.06	0.05	0.05
40.00%	0.15	0.12	0.22	0.19	0.2	0.12	0.13
60.00%	0.24	0.17	0.29	0.29	0.28	0.26	0.33
80.00%	0.33	0.3	0.31		0.3	0.29	0.36
95.00%	0.36	0.38	0.38		0.38		
100.00%	0.39	0.43	0.42		0.45		

Table 4-9: Analysis of Means - Turning Trial

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor  Levels  Values
Factor       7  Tip 1, Tip 2, Tip 3, Tip 4, Tip 5, Tip 6, Tip 7

Analysis of Variance
Source  DF   Adj SS    Adj MS  F-Value  P-Value
Factor   6  0.04791  0.007985     0.43    0.850
Error   28  0.51624  0.018437
Total   34  0.56415

Model Summary
       S   R-sq  R-sq(adj)  R-sq(pred)
0.135784  8.49%      0.00%       0.00%

Means
Factor  N    Mean   StDev       95% CI
Tip 1   6  0.2533  0.1328  (0.1398, 0.3669)
Tip 2   6  0.2417  0.1514  (0.1281, 0.3552)
Tip 3   6  0.2800  0.1285  (0.1664, 0.3936)
```

```
Tip 4   3  0.1767  0.1206  (0.0161, 0.3373)
Tip 5   6  0.2783  0.1372  (0.1648, 0.3919)
Tip 6   4  0.1800  0.1140  (0.0409, 0.3191)
Tip 7   4  0.2175  0.1513  (0.0784, 0.3566)

Pooled StDev = 0.135784
```

Tukey Pairwise Comparisons

Grouping Information Using the Tukey Method and 95% Confidence

Factor	N	Mean	Grouping
Tip 3	6	0.2800	A
Tip 5	6	0.2783	A
Tip 1	6	0.2533	A
Tip 2	6	0.2417	A
Tip 7	4	0.2175	A
Tip 6	4	0.1800	A
Tip 4	3	0.1767	A

Means that do not share a letter are significantly different.

Tukey Simultaneous Tests for Differences of Means

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Tip 2 - Tip 1	-0.0117	0.0784	(-0.2606, 0.2372)	-0.15	1.000
Tip 3 - Tip 1	0.0267	0.0784	(-0.2222, 0.2756)	0.34	1.000
Tip 4 - Tip 1	-0.0767	0.0960	(-0.3815, 0.2282)	-0.80	0.983
Tip 5 - Tip 1	0.0250	0.0784	(-0.2239, 0.2739)	0.32	1.000
Tip 6 - Tip 1	-0.0733	0.0876	(-0.3516, 0.2049)	-0.84	0.979
Tip 7 - Tip 1	-0.0358	0.0876	(-0.3141, 0.2424)	-0.41	1.000
Tip 3 - Tip 2	0.0383	0.0784	(-0.2106, 0.2872)	0.49	0.999
Tip 4 - Tip 2	-0.0650	0.0960	(-0.3698, 0.2398)	-0.68	0.993
Tip 5 - Tip 2	0.0367	0.0784	(-0.2122, 0.2856)	0.47	0.999
Tip 6 - Tip 2	-0.0617	0.0876	(-0.3399, 0.2166)	-0.70	0.991
Tip 7 - Tip 2	-0.0242	0.0876	(-0.3024, 0.2541)	-0.28	1.000
Tip 4 - Tip 3	-0.1033	0.0960	(-0.4082, 0.2015)	-1.08	0.930
Tip 5 - Tip 3	-0.0017	0.0784	(-0.2506, 0.2472)	-0.02	1.000
Tip 6 - Tip 3	-0.1000	0.0876	(-0.3783, 0.1783)	-1.14	0.910
Tip 7 - Tip 3	-0.0625	0.0876	(-0.3408, 0.2158)	-0.71	0.991
Tip 5 - Tip 4	0.1017	0.0960	(-0.2032, 0.4065)	1.06	0.935
Tip 6 - Tip 4	0.003	0.104	(-0.326, 0.333)	0.03	1.000
Tip 7 - Tip 4	0.041	0.104	(-0.288, 0.370)	0.39	1.000
Tip 6 - Tip 5	-0.0983	0.0876	(-0.3766, 0.1799)	-1.12	0.916
Tip 7 - Tip 5	-0.0608	0.0876	(-0.3391, 0.2174)	-0.69	0.992
Tip 7 - Tip 6	0.0375	0.0960	(-0.2673, 0.3423)	0.39	1.000

Individual confidence level = 99.64%

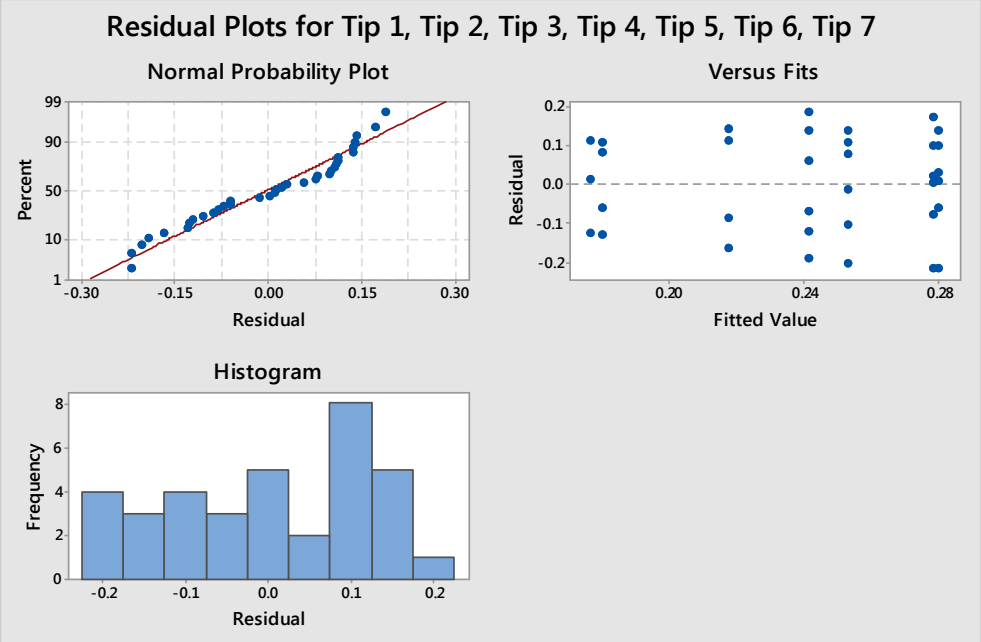

Figure 4-6: Residual Plots - Turning Tool

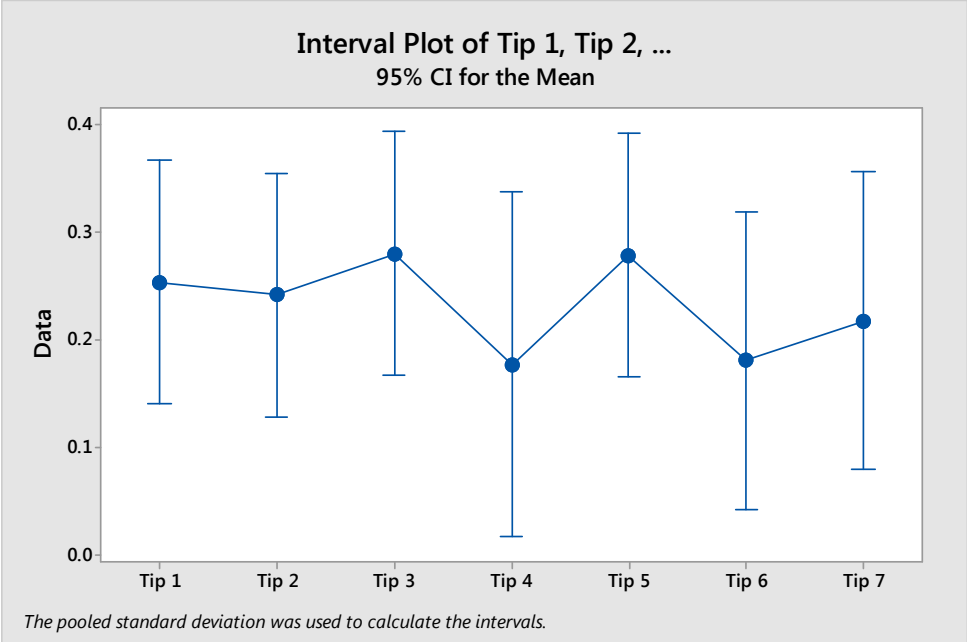

Figure 4-7: Interval Plot - Turning Tool

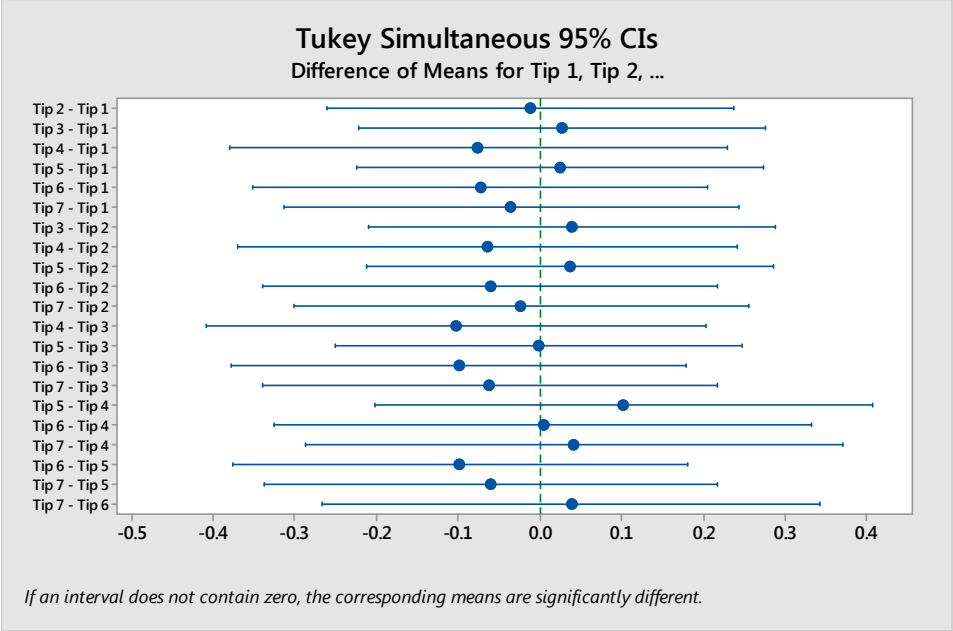

Figure 4-8: Tukey Simultaneous 95% CI's - Turning Tool

Testing of the boring data, Table 4-11: Analysis of Means - Boring Trial, concluded that there were no unusual data points and there is no significant difference between the mean of the wear values on the seven turning tools. The P value was significantly greater than 0.05 at 0.846 indicating no statistical significance in the means and all tips shared the same grouping factor. At the individual confidence level all pairs of means include zero which confirms no statistical difference in the means and with a confidence level of 99.64% we can be confident that each individual interval contains the true difference between any pair of group means.

Table 4-10: Trial 2 Boring Data

	Tip 1	Tip 2	Tip 3	Tip 4	Tip 5	Tip 6	Tip 7
15.00%	0.05	0.06	0.05	0.05	0.04	0.05	0.04
30.00%	0.07	0.07	0.08		0.12	0.07	0.06
50.00%	0.13	0.16	0.13	0.1	0.14	0.12	0.13
60.00%	0.16	0.2	0.19	0.15	0.16		0.15
90.00%	0.21	0.23	0.23		0.23	0.2	0.18

	Tip 1	Tip 2	Tip 3	Tip 4	Tip 5	Tip 6	Tip 7
100.00%	0.3	0.3	0.3		0.26	0.26	

Table 4-11: Analysis of Means - Boring Trial

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05
Rows unused             2

Equal variances were assumed for the analysis.

Factor Information

Factor  Levels  Values
Factor       7  Tip 1, Tip 2, Tip 3, Tip 4, Tip 5, Tip 6, Tip 7

Analysis of Variance
Source  DF   Adj SS    Adj MS  F-Value  P-Value
Factor   6  0.01878  0.003130     0.44    0.846
Error   30  0.21323  0.007108
Total   36  0.23201

Model Summary
        S   R-sq  R-sq(adj)  R-sq(pred)
0.0843070  8.09%      0.00%       0.00%

Means
Factor  N    Mean   StDev       95% CI
Tip 1   6  0.1533  0.0927  (0.0830, 0.2236)
Tip 2   6  0.1700  0.0934  (0.0997, 0.2403)
Tip 3   6  0.1633  0.0946  (0.0930, 0.2336)
Tip 4   3  0.1000  0.0500  (0.0006, 0.1994)
Tip 5   6  0.1583  0.0791  (0.0880, 0.2286)
Tip 6   5  0.1400  0.0886  (0.0630, 0.2170)
Tip 7   5  0.1120  0.0597  (0.0350, 0.1890)

Pooled StDev = 0.0843070
```

Tukey Pairwise Comparisons

```
Grouping Information Using the Tukey Method and 95% Confidence

Factor  N    Mean  Grouping
Tip 2   6  0.1700  A
Tip 3   6  0.1633  A
Tip 5   6  0.1583  A
Tip 1   6  0.1533  A
Tip 6   5  0.1400  A
Tip 7   5  0.1120  A
Tip 4   3  0.1000  A
Means that do not share a letter are significantly different.

Tukey Simultaneous Tests for Differences of Means

Difference of  Difference       SE of                              Adjusted
```

Levels	of Means	Difference	95% CI	T-Value	P-Value
Tip 2 - Tip 1	0.0167	0.0487	(-0.1368, 0.1702)	0.34	1.000
Tip 3 - Tip 1	0.0100	0.0487	(-0.1435, 0.1635)	0.21	1.000
Tip 4 - Tip 1	-0.0533	0.0596	(-0.2413, 0.1347)	-0.89	0.971
Tip 5 - Tip 1	0.0050	0.0487	(-0.1485, 0.1585)	0.10	1.000
Tip 6 - Tip 1	-0.0133	0.0511	(-0.1743, 0.1477)	-0.26	1.000
Tip 7 - Tip 1	-0.0413	0.0511	(-0.2023, 0.1197)	-0.81	0.982
Tip 3 - Tip 2	-0.0067	0.0487	(-0.1602, 0.1468)	-0.14	1.000
Tip 4 - Tip 2	-0.0700	0.0596	(-0.2580, 0.1180)	-1.17	0.898
Tip 5 - Tip 2	-0.0117	0.0487	(-0.1652, 0.1418)	-0.24	1.000
Tip 6 - Tip 2	-0.0300	0.0511	(-0.1910, 0.1310)	-0.59	0.997
Tip 7 - Tip 2	-0.0580	0.0511	(-0.2190, 0.1030)	-1.14	0.912
Tip 4 - Tip 3	-0.0633	0.0596	(-0.2513, 0.1247)	-1.06	0.934
Tip 5 - Tip 3	-0.0050	0.0487	(-0.1585, 0.1485)	-0.10	1.000
Tip 6 - Tip 3	-0.0233	0.0511	(-0.1843, 0.1377)	-0.46	0.999
Tip 7 - Tip 3	-0.0513	0.0511	(-0.2123, 0.1097)	-1.01	0.949
Tip 5 - Tip 4	0.0583	0.0596	(-0.1297, 0.2463)	0.98	0.955
Tip 6 - Tip 4	0.0400	0.0616	(-0.1542, 0.2342)	0.65	0.994
Tip 7 - Tip 4	0.0120	0.0616	(-0.1822, 0.2062)	0.19	1.000
Tip 6 - Tip 5	-0.0183	0.0511	(-0.1793, 0.1427)	-0.36	1.000
Tip 7 - Tip 5	-0.0463	0.0511	(-0.2073, 0.1147)	-0.91	0.968
Tip 7 - Tip 6	-0.0280	0.0533	(-0.1962, 0.1402)	-0.53	0.998

Individual confidence level = 99.64%

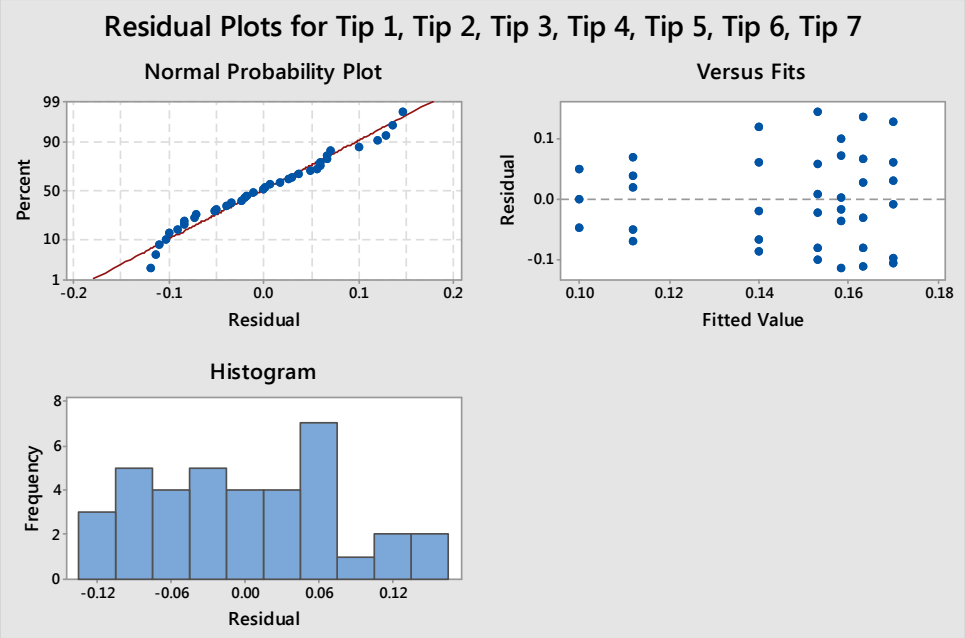

Figure 4-9: Residual Plots - Boring Tool

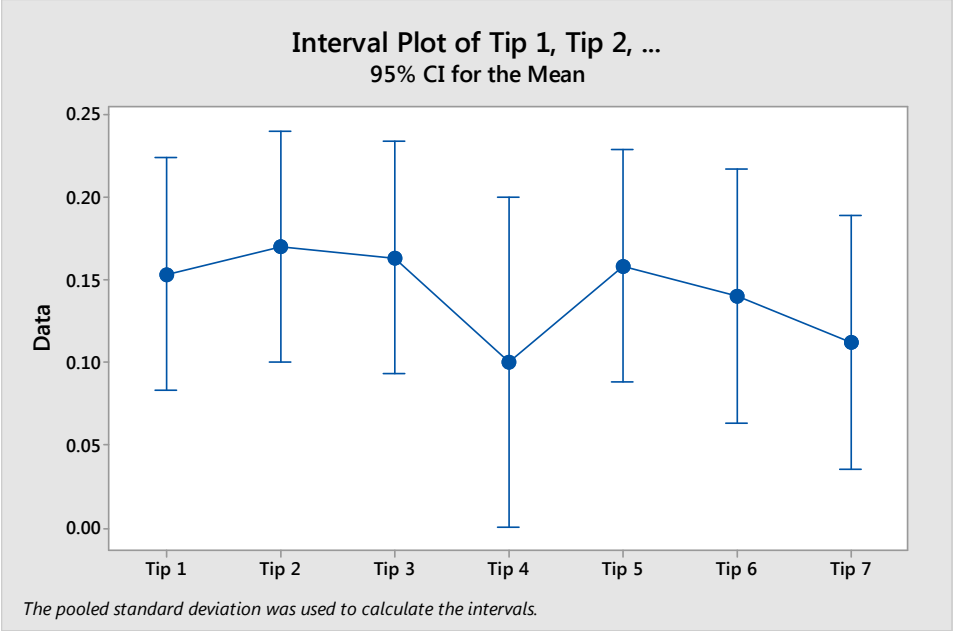

Figure 4-10: Interval Plot - Boring Tool

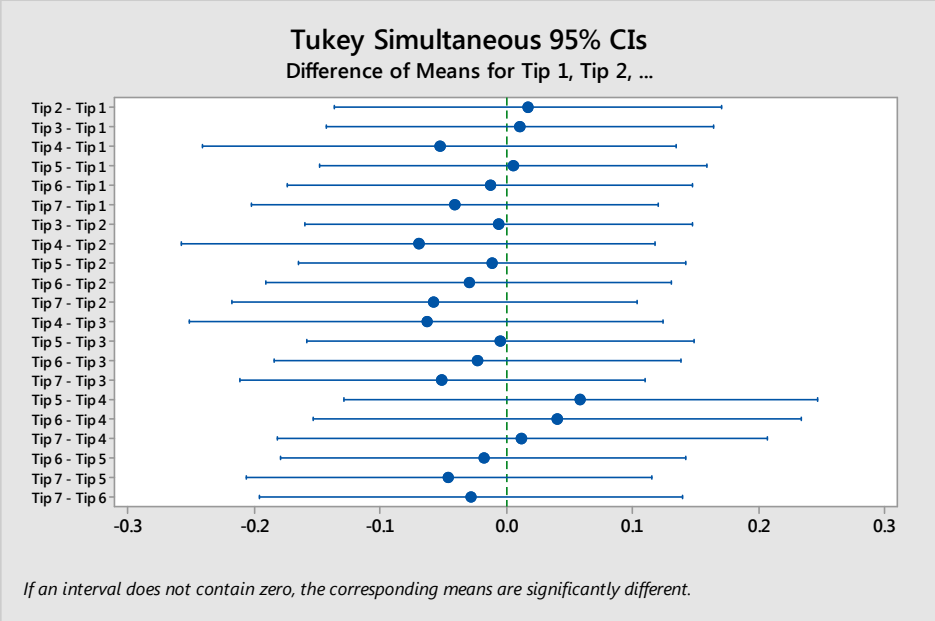

Figure 4-11: Tukey Simultaneous 95% CI's - Boring Tool

Testing of the Drilling data, Table 4-13: Analysis of Means - Drilling Trial, concluded that there were no unusual data points and there is no significant difference between the mean of the wear values on the six drilling tools. The P value was significantly greater than 0.05 at 0.855 indicating no statistical significance in the means and all tips shared the same

grouping factor. At the individual confidence level all pairs of means include zero which confirms no statistical difference in the means and with a confidence level of 99.51% we can be confident that each individual interval contains the true difference between any pair of group means.

Table 4-12: Trial 2 Drilling Data

	Drill 1	Drill 2	Drill 3	Drill 4	Drill 5	Drill 6
15.00%	0.05	0.06	0.05	0.05	0.04	
25.00%	0.07	0.07	0.08	0.07	0.06	0.06
50.00%	0.13	0.16	0.13	0.08	0.13	0.12
60.00%	0.16	0.2	0.19	0.12	0.15	0.15
85.00%	0.23	0.23	0.2	0.2	0.18	
95.00%	0.27	0.26	0.23	0.25	0.23	
100.00%	0.3	0.3	0.3	0.26	0.26	

Table 4-13: Analysis of Means - Drilling Trial

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05
Rows unused             1

Equal variances were assumed for the analysis.

Factor Information

Factor  Levels  Values
Factor       6  Drill 1, Drill 2, Drill 3, Drill 4, Drill 5, Drill 6

Analysis of Variance
Source  DF   Adj SS    Adj MS  F-Value  P-Value
Factor   5  0.01469  0.002937     0.39    0.855
Error   32  0.24391  0.007622
Total   37  0.25860

Model Summary
        S   R-sq  R-sq(adj)  R-sq(pred)
0.0873059  5.68%      0.00%       0.00%

Means
```

```
Factor   N    Mean   StDev       95% CI
Drill 1  7  0.1729  0.0971  (0.1056, 0.2401)
Drill 2  7  0.1829  0.0918  (0.1156, 0.2501)
Drill 3  7  0.1686  0.0875  (0.1014, 0.2358)
Drill 4  7  0.1471  0.0883  (0.0799, 0.2144)
Drill 5  7  0.1500  0.0816  (0.0828, 0.2172)
Drill 6  3  0.1100  0.0458  (0.0073, 0.2127)

Pooled StDev = 0.0873059
```

Tukey Pairwise Comparisons

```
Grouping Information Using the Tukey Method and 95% Confidence

Factor   N    Mean  Grouping
Drill 2  7  0.1829  A
Drill 1  7  0.1729  A
Drill 3  7  0.1686  A
Drill 5  7  0.1500  A
Drill 4  7  0.1471  A
Drill 6  3  0.1100  A
Means that do not share a letter are significantly different.

Tukey Simultaneous Tests for Differences of Means
                     Difference       SE of
Adjusted
Difference of Levels    of Means  Difference        95% CI    T-Value   P-
Value
Drill 2 - Drill 1         0.0100   0.0467  (-0.1312, 0.1512)     0.21
1.000
Drill 3 - Drill 1        -0.0043   0.0467  (-0.1455, 0.1369)    -0.09
1.000
Drill 4 - Drill 1        -0.0257   0.0467  (-0.1669, 0.1155)    -0.55
0.993
Drill 5 - Drill 1        -0.0229   0.0467  (-0.1641, 0.1184)    -0.49
0.996
Drill 6 - Drill 1        -0.0629   0.0602  (-0.2452, 0.1195)    -1.04
0.900
Drill 3 - Drill 2        -0.0143   0.0467  (-0.1555, 0.1269)    -0.31
1.000
Drill 4 - Drill 2        -0.0357   0.0467  (-0.1769, 0.1055)    -0.77
0.971
Drill 5 - Drill 2        -0.0329   0.0467  (-0.1741, 0.1084)    -0.70
0.980
Drill 6 - Drill 2        -0.0729   0.0602  (-0.2552, 0.1095)    -1.21
0.829
Drill 4 - Drill 3        -0.0214   0.0467  (-0.1627, 0.1198)    -0.46
0.997
Drill 5 - Drill 3        -0.0186   0.0467  (-0.1598, 0.1227)    -0.40
0.999
Drill 6 - Drill 3        -0.0586   0.0602  (-0.2409, 0.1238)    -0.97
0.923
Drill 5 - Drill 4         0.0029   0.0467  (-0.1384, 0.1441)     0.06
1.000
Drill 6 - Drill 4        -0.0371   0.0602  (-0.2195, 0.1452)    -0.62
0.989
Drill 6 - Drill 5        -0.0400   0.0602  (-0.2223, 0.1423)    -0.66
0.985

Individual confidence level = 99.51%
```

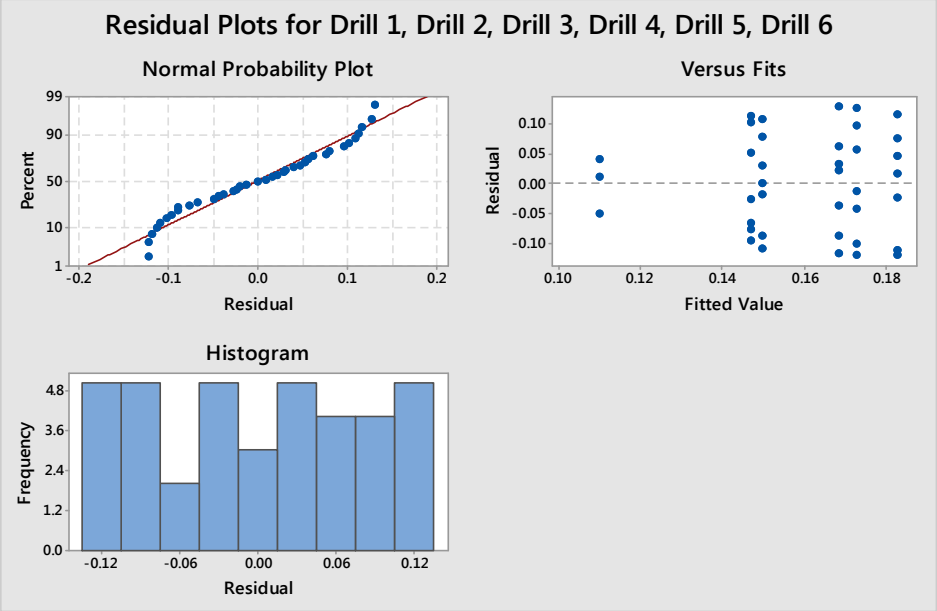

Figure 4-12: Residual Plots - Drilling Tool

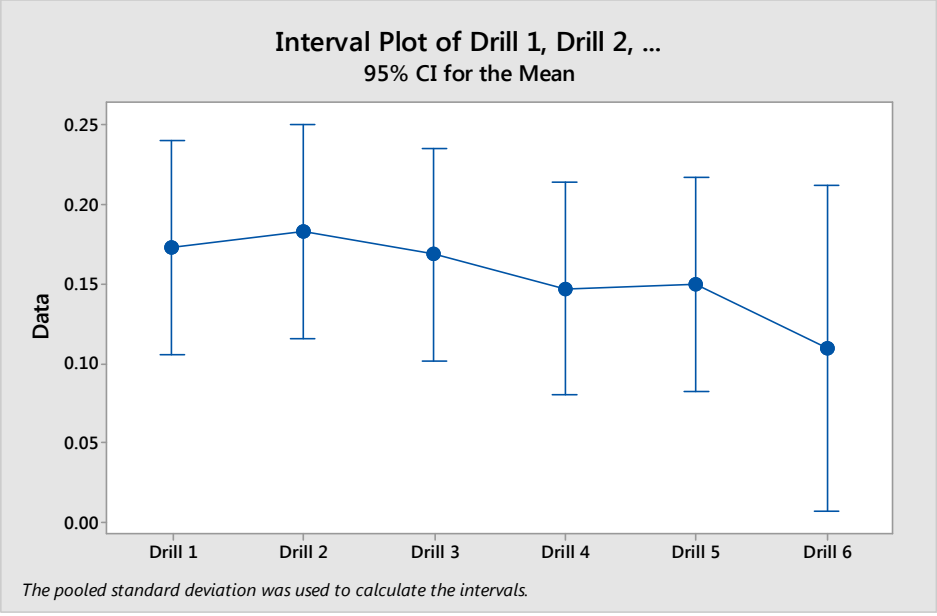

Figure 4-13: Interval Plot - Drilling Tool

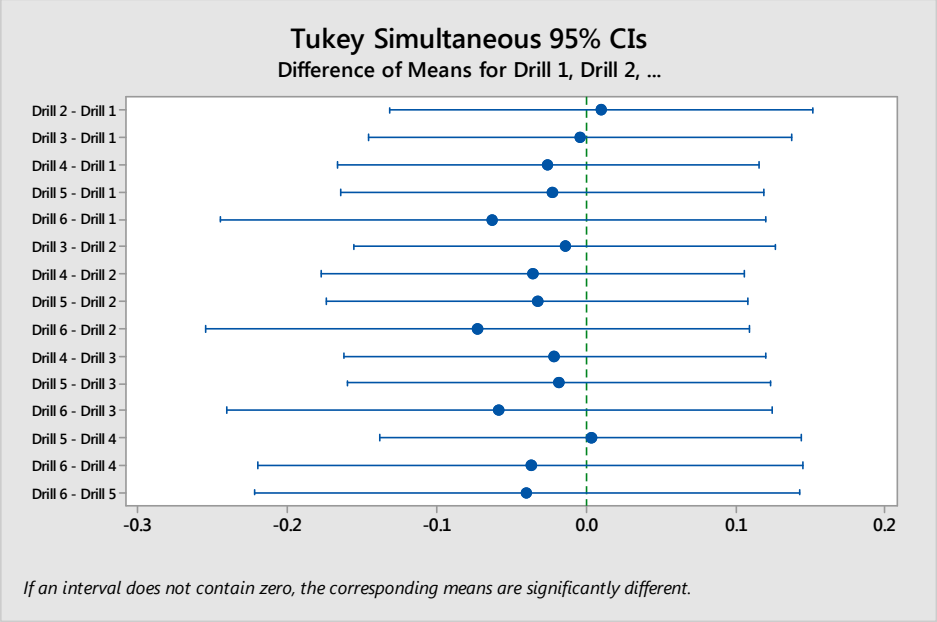

Figure 4-14: Tukey Simultaneous 95% CI's - Drilling Tool

Through the use of statistical analysis, variability within the mechanical properties of the tooling was eliminated as being a variable.

4.3 Variability due to the System Training Process

The control software within the REALISM TCM incorporates a neural network Case-Based Reasoning (CaBR) system, which requires the operator to initially teach the TCM by identifying when a pre-determined number of tools are worn. From this teaching, the TCM will compare the learned results against process conditions, gathered from the sensors, allowing the system to make decisions around the degree of tool wear present on the cutting tool. Because of this, satisfactory system training is extremely important. In order to reduce system input variability only senior machine setters are to train the TCM, access levels have been included in the prototype which restrict users from the training function. For the variability trials around system training the senior machine setter within the Mazak cell was used for data collection purposes, Various tool life's were tested under laboratory style conditions at Schivo Ltd., by running roughing, boring and drilling tools from new condition through to catastrophic tool failure. Work pieces were faced, rough turned, bored and drilled. The tools were removed and measured at intervals on an optical microscope

however, prior to removal of the tooling operator opinion was captured; this opinion was based solely on how the process was performing, taking the following conditions into account:

- High current or power consumption on the machine
- Vibration and/or chatter
- Catastrophic tool failure
- Deviations in work piece tolerances
- Poor surface finish on work piece
- Adverse chip formation
- Smell

During Trial 2 the turning, boring and drilling tools were removed and measured at intervals, on an optical microscope[2].However, prior to removal of the tooling the operator's opinion, as to the degree of tool wear present based on the conditions outlined above, was captured. The data was statistically analysed using Paired T-Test to determine whether there was any statistically significant differences between the actual tool wear and the operator's opinion. The paired t-test determines whether there is a statistically significant difference in the mean of a dependent variable between two related groups.

Table 4-14: Operator opinion Turning Test Data

Trial #	Actual Measurement	Operator Opinion
Turning 1	11.90%	20.00%
Turning 1	35.71%	40.00%
Turning 1	57.14%	60.00%
Turning 1	78.57%	80.00%

[2] Drilling operations were not measured using an optical microscope due to difficulties measuring the flank. Numerous alternative methods were investigated including higher powered microscopes, vision systems and touch probe CMM's however none of which yielded a satisfactory result. Drilling wear was calculated using the $\Delta T = t/T$ method proposed by Jemielniak et al. (2005)

Trial #	Actual Measurement	Operator Opinion
Turning 1	85.71%	95.00%
Turning 1	92.86%	100.00%
Turning 2	11.90%	20.00%
Turning 2	28.57%	35.00%
Turning 2	40.48%	50.00%
Turning 2	71.43%	80.00%
Turning 2	90.48%	90.00%
Turning 2	102.38%	100.00%
Turning 3	14.29%	20.00%
Turning 3	52.38%	40.00%
Turning 3	69.05%	60.00%
Turning 3	73.81%	80.00%
Turning 3	90.48%	95.00%
Turning 3	100.00%	100.00%
Turning 4	11.90%	20.00%
Turning 4	45.24%	40.00%
Turning 4	69.05%	60.00%
Turning 5	14.29%	20.00%
Turning 5	47.62%	50.00%
Turning 5	66.67%	65.00%
Turning 5	71.43%	80.00%
Turning 5	90.48%	90.00%
Turning 5	107.14%	100.00%
Turning 6	11.90%	20.00%
Turning 6	28.57%	35.00%

Trial #	Actual Measurement	Operator Opinion
Turning 6	45.24%	50.00%
Turning 6	61.90%	60.00%
Turning 6	69.05%	75.00%
Turning 7	11.90%	15.00%
Turning 7	30.95%	40.00%
Turning 7	54.76%	50.00%
Turning 7	78.57%	70.00%
Turning 7	85.71%	80.00%

Table 4-15: Operator opinion Boring Test Data

Trial #	Actual Measurement	Operator Opinion
Boring 1	17.86%	15.00%
Boring 1	25.00%	30.00%
Boring 1	46.43%	50.00%
Boring 1	57.14%	60.00%
Boring 1	82.14%	90.00%
Boring 1	107.14%	100.00%
Boring 2	21.43%	15.00%
Boring 2	25.00%	25.00%
Boring 2	57.14%	50.00%
Boring 2	71.43%	75.00%
Boring 2	82.14%	90.00%
Boring 2	107.14%	100.00%
Boring 3	17.86%	15.00%

Trial #	Actual Measurement	Operator Opinion
Boring 3	28.57%	25.00%
Boring 3	46.43%	40.00%
Boring 3	67.86%	60.00%
Boring 3	82.14%	90.00%
Boring 3	107.14%	100.00%
Boring 4	17.86%	20.00%
Boring 4	35.71%	40.00%
Boring 4	53.57%	60.00%
Boring 5	14.29%	15.00%
Boring 5	42.86%	40.00%
Boring 5	50.00%	50.00%
Boring 5	57.14%	60.00%
Boring 5	71.43%	80.00%
Boring 5	82.14%	90.00%
Boring 5	92.86%	100.00%
Boring 6	17.86%	15.00%
Boring 6	25.00%	30.00%
Boring 6	28.57%	35.00%
Boring 6	42.86%	50.00%
Boring 6	71.43%	80.00%
Boring 6	92.86%	100.00%
Boring 7	14.29%	15.00%
Boring 7	21.43%	20.00%
Boring 7	46.43%	50.00%
Boring 7	53.57%	60.00%

Trial #	Actual Measurement	Operator Opinion
Boring 7	64.29%	70.00%

Table 4-16: Operator opinion Drilling Test Data

Trial #	Actual Measurement	Operator Opinion
Drilling 1	17.86%	15%
Drilling 1	25.00%	25%
Drilling 1	46.43%	50%
Drilling 1	57.14%	60%
Drilling 1	82.14%	85%
Drilling 1	97.62%	95%
Drilling 1	107.14%	100%
Drilling 2	21.43%	15%
Drilling 2	25.00%	25%
Drilling 2	57.14%	50%
Drilling 2	71.43%	70%
Drilling 2	82.14%	85%
Drilling 2	95.24%	95%
Drilling 2	107.14%	100%
Drilling 3	17.86%	15%
Drilling 3	28.57%	30%
Drilling 3	46.43%	50%
Drilling 3	67.86%	60%
Drilling 3	71.43%	70%
Drilling 3	82.14%	80%

Trial #	Actual Measurement	Operator Opinion
Drilling 3	107.14%	100%
Drilling 4	17.86%	15%
Drilling 4	25.00%	25%
Drilling 4	28.57%	35%
Drilling 4	42.86%	50%
Drilling 4	71.43%	75%
Drilling 4	90.48%	85%
Drilling 4	92.86%	100%
Drilling 5	14.29%	15%
Drilling 5	21.43%	25%
Drilling 5	46.43%	40%
Drilling 5	53.57%	55%
Drilling 5	64.29%	60%
Drilling 5	82.14%	85%
Drilling 5	92.86%	100%
Drilling 6	24.36%	25%
Drilling 6	42.86%	50%
Drilling 6	53.57%	55%

Testing of the turning data concluded that there were no unusual data points, and there is no statistically significant difference between the means of the measured and predicted tool wear measurements. With a P Value of 0.055, ref Table 4-17: Results Paired T-Test Operator Opinion [Turing Trial], it was concluded that the means differ at the 0.055 level of significance and we can, with 95% confidence, say that the true mean difference is between -0.00047014 and 0.041268. If the true means differed by 0.034282 you would have a 90% chance of detecting the change.

Table 4-17: Results Paired T-Test Operator Opinion [Turing Trial]

```
Paired T for Operator Opinion - Actual Measurment

                     N    Mean   StDev  SE Mean
Operator Opinion    37  0.5905  0.2781   0.0457
Actual Measurment   37  0.5701  0.2988   0.0491
Difference          37  0.0204  0.0626   0.0103


95% CI for mean difference: (-0.0005, 0.0413)
T-Test of mean difference = 0 (vs ≠ 0): T-Value = 1.98  P-Value = 0.055
```

Testing of the boring data concluded that there were no unusual data points, and there is no statistically significant difference between the means of the measured and predicted tool wear measurements. With a P Value of 0.069, ref Table 4-18: Results Paired T-Test Operator Opinion [Boring Trial], it was concluded that the means differ at the 0.069 level of significance and we can, with 95% confidence, say that the true mean difference is between -0.0013331 and 0.033934. If the true means differed by 0.028977 you would have a 90% chance of detecting the change.

Table 4-18: Results Paired T-Test Operator Opinion [Boring Trial]

```
Paired T for Operator Opinion - Actual Measurement

                      N     Mean    StDev  SE Mean
Operator Opinion     39   0.5410   0.2960   0.0474
Actual Measurement   39   0.5247   0.2851   0.0457
Difference           39  0.01630  0.05440  0.00871


95% CI for mean difference: (-0.00133, 0.03393)
T-Test of mean difference = 0 (vs ≠ 0): T-Value = 1.87  P-Value = 0.069
```

Testing of the drilling data concluded that there were no unusual data points, and there is no statistically significant difference between the means of the measured and predicted tool wear measurements. With a P Value of 0.748, Table 4-19: Results Paired T-Test Operator Opinion [Drilling Trial], it was concluded that the means differ at the 0.748 level of significance and we can, with 95% confidence, say that the true mean difference is between –0.017403 and 0.012602. If the true means differed by 0.024650 you would have a 90% chance of detecting the change.

Table 4-19: Results Paired T-Test Operator Opinion [Drilling Trial]

```
Paired T for Operator Opinion - Actual Measurement

                      N      Mean    StDev  SE Mean
Operator Opinion     38    0.5711   0.2949   0.0478
Actual Measurement   38    0.5735   0.2992   0.0485
Difference           38  -0.00240  0.04564  0.00740


95% CI for mean difference: (-0.01740, 0.01260)
T-Test of mean difference = 0 (vs ≠ 0): T-Value = -0.32  P-Value = 0.748
```

Through the statistical analysis of the data, variability due to operator opinion was eliminated as a variable in the training process.

4.4 Installation & Operational Testing

The full IOQ test criteria is outlined in Appendix 1, Section 8.1. The IOQ testing took place in Schivo Ltd.'s manufacturing facility in Waterford. A summary of the IOQ testing is outlined in Table 4-20: IOQ Test Results.

Table 4-20: IOQ Test Results

Test Description	Test Result	DRF's Generated	Comments
Personnel Identification (Signature Log)	Pass	None	None
Validation Test Equipment Verification	Pass	None	None
Validation Materials Verification	Pass	None	None
Software Disaster Recovery	Pass	None	None
Software Verification	Pass	None	None
Equipment Installation Verification	Pass	None	None
Documentation Verification	Pass	None	None
Drawing Verification	Pass	None	None

Test Description	Test Result	DRF's Generated	Comments
SOP Verification	Pass	None	None
Verification of Utility Supply and Installation	Pass	None	None
Safety Features Verification	Pass	None	None
Start-up / Shutdown / Loss of Power	Pass	None	None
Graphics Screen Test	Pass	None	None
User Adjustable Set Point Verification	Pass	None	None
Data Logging Test	Pass	None	None
PLC Input / Output Testing	Pass	None	None

4.5 Performance Qualification Testing

The PQ test criteria is outlined in Appendix 1, Section 8.1. The PQ testing took place in Schivo Ltd.'s manufacturing facility in Waterford. Performance testing involved running trials to ensure that the system produces outputs of a predetermined quality when operated under normal operating conditions. The test involved running pre-recorded banks of test data and statistically comparing the results from the system against the measured tool wear values. Two versions of the TCM software were tested as part of the initial PQ testing with version 2 of the software yielding significantly better results than version 1 for the turning and boring operations.

Testing of the TCM results was completed using a regression analysis, linear regression was used to calculate an equation that minimizes the distance between the fitted line, measured data, and all of the version 1 and 2 TCM results. With linear regression testing, generally a model fits the data well if the differences between the observed values and the model's predicted values are small and unbiased. For example, if the model's R-squared is

70%, the variance of its errors is 70% less than the variance of the dependent variable and the standard deviation of its errors is ~50% less than the standard deviation of the dependent variable. According to Moore et al. (2013), if R-squared value < 0.3 this value is generally considered a None or Very weak effect size, if R-squared value 0.3 < r < 0.5 this value is generally considered a weak or low effect size, if R-squared value 0.5 < r < 0.7 this value is generally considered a Moderate effect size and if R-squared value r > 0.7 this value is generally considered strong effect size. Similarly Henseler et al. (2009) proposed a rule of thumb for acceptable R2 with 0.75, 0.50, and 0.25 are described as substantial, moderate and weak respectively.

For the TCM analysis an R-squared value of 70% and a P value of <0.05 was set as the pass/fail limit. At 70% the standard deviation of the errors is approximately one-half of the standard deviation of the dependent variable and the size effect is considered to be strong.

Table 4-21: Percent of Variance vs Percent of Standard Deviation Explained

Percent of variance explained (R-squared)	Percent of standard deviation explained (1 minus square root of 1-minus-R-squared)
99.9%	97%
99.5%	93%
99%	90%
98%	86%
95%	78%
90%	68%
80%	55%
75%	50%
50%	29%
25%	13%
20%	11%
15%	7.8%
10%	5.1%
5%	2.5%
2%	1.0%

A summary of the IOQ testing is outlined in Table 4-22: PQ Test Results.

Table 4-22: PQ Test Results

Test Description	Test Result	DRF's Generated	Comments
Personnel Identification (Signature Log)	Pass	None	None
Validation Test Equipment Verification	Pass	None	None
Validation Materials Verification	Pass	None	None
Performance Testing	Pass	DRF-001	Passed under Deviation

The performance testing involved training the system three times, before running test runs using pre-recorded banks of sensor data. The system, based on the training, calculated the level of tool wear present, and the data collected from the TCM system was statistically analysed against the measured tool wear. In addition, the data was used to Simulate Catastrophic Tool Failure (CTF) and the results of the CTF testing was documented. Two separate versions of the CaBR software were tested as part of the validation activities.

For the turning operations the results for Tool 2 against version 2 of software fell marginally below the 70% R-sq target, at 69.91%, however after running a correlation analysis it was noted that there was an 83.6% correlation between the 2 sets of data and a probability of 0.038 so the test was passed, under deviation. Version 2 of the CaBR software yielded a better result across all 3 tool life's and was recommended as acceptable for use within the TCM system, for turning operations.

Pearson correlation of Tool 2 - Turning and Tool 2 - Ver 2 = 0.836

P-Value = 0.038

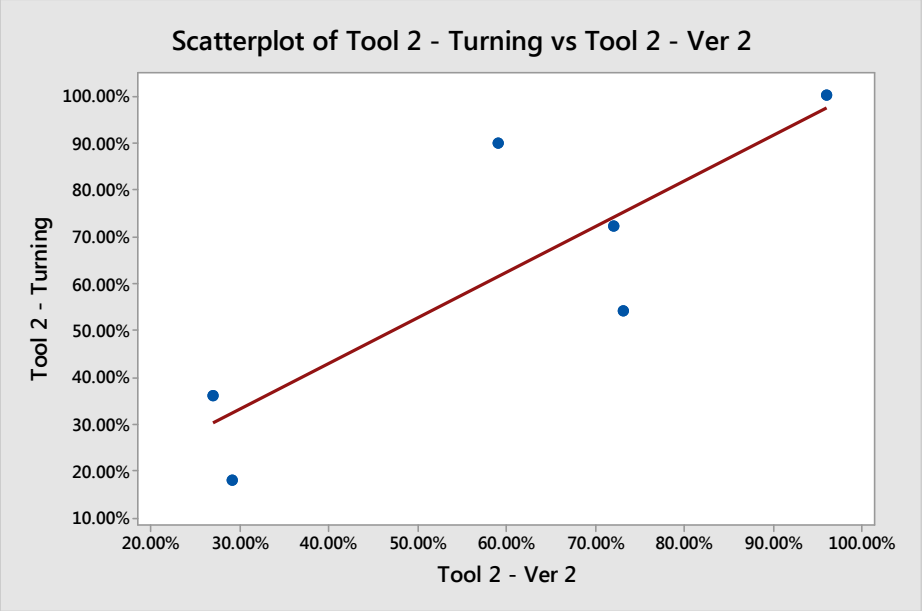

Figure 4-15: Pearson Correlation Test – Turning

Table 4-23: Turing Results (Residuals Analysis)

Turning	Version 1			Version 2		
Tool #	R-sq	P-Value	Result	R-sq	P-Value	Result
Tool 1	91.83%	0.003	Pass	85.43%	0.008	Pass
Tool 2	64.79%	0.053	Fail	69.91%	0.038	Pass
Tool 3	62.54%	0.061	Fail	89.81%	0.004	Pass
		Average		81.72%		

Again for the boring operations Version 2 of the CaBR software yielded a better result across all 3 tool life's and was recommended as acceptable for use within the TCM system, for boring operations.

Table 4-24: Boring Results (Residuals Analysis)

Boring	Version 1			Version 2		
Tool #	R-sq	P-Value	Result	R-sq	P-Value	Result
Tool 1	71.51%	0.017	Pass	98.99%	0.000	Pass

Tool 2	57.82%	0.079	Fail	98.58%	0.000	Pass
Tool 3	70.14%	0.077	Pass	99.33%	0.000	Pass
		Average		98.97%		

The results of the drilling results fell significantly lower than expectation across both Version 1 and Version 2 of the CaBR software and it was necessary to raise a deviation, DRF-001, during the testing process. The deviation states that the drilling operations should be re-tested after the CaBR software, for drilling, has been adjusted by the consortium.

Table 4-25: Drilling Results (Residuals Analysis)

Drilling	Version 1			Version 2		
Tool #	R-sq	P-Value	Result	R-sq	P-Value	Result
Tool 1	1.73%	0.779	Fail	19.64%	0.319	Fail
Tool 2	35.40%	0.159	Fail	0.30%	0.908	Fail
Tool 3	34.56%	0.412	Fail	4.73%	0.782	Fail
		Average		8.23%		

Version 3 of the CaBR software, for drilling, was subsequently created by the consortium, and tested for drilling operations, however, again fell short of target, ref Table 4-26: Drilling Results - Version 3 (Residuals Analysis) . This time however, for tool life 1, there was a pass result at 92.84% and a significantly improved result for tool life 2 at 56.34%.

One key variable was identified, namely the method of collecting the drilling benchmark measurements, $\Delta T = t/T$ method as opposed to a physical measurement, however after statistical analysis of the data, the author is confident in concluding that the anomaly in the drilling results lay within the CaBR software, and not in the method used to obtain the benchmark measurements. Details of the analysis and testing are outlined in Section 4.6.

Funding and timeline restrictions didn't allow for further manipulation of the CaBR software, or allow a successful outcome to the testing of the drilling data, and the performance qualification testing was passed, under the deviation that the prototype

system, while suitable for used in Turning, Boring and detection of CTF, is currently not suitable for use in drilling operations.

Table 4-26: Drilling Results - Version 3 (Residuals Analysis)

Drilling	Version 3		
Tool #	R-sq	P-Value	Result
Tool 1	92.84%	0.000	Pass
Tool 2	56.34%	0.052	Fail
Tool 3	10.52%	0.676	Fail

Catastrophic Tool Failure (CTF) was simulated using the pre-recorded banks of test data, and system reaction to the CTF was monitored to ensure that the outputs from the simulated conditions meet with acceptance criteria. CTF validation was again completed on two versions of the CaBR software and the results are presented in Table 4-27: CTF Test Results. Validation was completed across 39 machining operations. Version 1 of the CaBR software was found to have an 80% accuracy while version 2 was found to have a 100% accuracy. Given the accuracy of version 2, it was concluded that no further development, or statistical analysis, was necessary and version 2 of the CaBR software was recommended as acceptable for use within the TCM system, for CTF detection.

False detection of CTF was found at boring #6 and drilling #32, in version 1 (highlighted in yellow). Only points marked as CTF in the table below are true CTF. All true CTF's were detected correctly for version 2. Points at which the system detected CTF are marked with a tick(☑)

Table 4-27: CTF Test Results

Op no.	Turning (T) Boring (B) Drilling (D)	Consumed tool life (ΔT)	CTF		Op no.	T / B / D	Consumed tool life (ΔT)	CTF		Op no.	T / B / D	Consumed tool life (ΔT)	CTF		Op no.	T / B / D	Consumed tool life (ΔT)	CTF	
			Ver 1	Ver 2				Ver 1	Ver 2				Ver 1	Ver 2				Ver 1	Ver 2
1	T	17%	0	0	11	T	90%	0	0	21	T	51%	0	0	31	T	17%	0	0
	B	14%	0	0		B	68%	0	0		B	51%	0	0		B	17%	0	0
	D	14%	0	0		D	56%	0	0		D	42%	0	0		D	84%	0	0
2	T	34%	0	0	12	T	CTF	☑	☑	22	T	68%	0	0	32	T	34%	0	0
	B	29%	0	0		B	85%	0	0		B	68%	0	0		B	34%	0	0
	D	28%	0	0		D	70%	0	0		D	56%	0	0		D	98%	☑	0
3	T	51%	0	0	13	T	18%	0	0	23	T	85%	0	0	33	T	51%	0	0
	B	43%	0	0		B	CTF	☑	☑		B	85%	0	0		B	51%	0	0
	D	42%	0	0		D	84%	0	0		D	70%	0	0		D	14%	0	0
4	T	68%	0	0	14	T	36%	0	0	24	T	102%	0	0	34	T	68%	0	0
	B	57%	0	0		B	17%	0	0		B	102%	0	0		B	68%	0	0
	D	56%	0	0		D	98%	0	0		D	84%	0	0		D	28%	0	0
5	T	85%	0	0	15	T	54%	0	0	25	T	17%	0	0	35	T	85%	0	0
	B	71%	☑	0		B	34%	0	0		B	17%	0	0		B	85%	0	0
	D	70%	0	0		D	33%	0	0		D	98%	0	0		D	42%	0	0
6	T	102%	0	0	16	T	72%	0	0	26	T	34%	0	0	36	T	102%	0	0
	B	86%	0	0		B	51%	0	0		B	34%	0	0		B	102%	0	0
	D	84%	0	0		D	66%	0	0		D	14%	0	0		D	56%	0	0
7	T	18%	0	0	17	T	90%	0	0	27	T	51%	0	0	37	T	17%	0	0
	B	100%	0	0		B	68%	0	0		B	51%	0	0		B	17%	0	0
	D	98%	0	0		D	99%	0	0		D	28%	0	0		D	70%	0	0
8	T	36%	0	0	18	T	CTF	☑	☑	28	T	68%	0	0	38	T	34%	0	0
	B	17%	0	0		B	85%	0	0		B	68%	0	0		B	34%	0	0
	D	14%	0	0		D	CTF	☑	☑		D	42%	0	0		D	84%	0	0
9	T	54%	0	0	19	T	17%	0	0	29	T	85%	0	0	39	T	51%	0	0
	B	34%	0	0		B	17%	0	0		B	85%	0	0		B	51%	0	0
	D	28%	0	0		D	14%	0	0		D	56%	0	0		D	98%	0	0
10	T	72%	0	0	20	T	34%	0	0	30	T	102%	0	0					
	B	51%	0	0		B	34%	0	0		B	102%	0	0					
	D	42%	0	0		D	28%	0	0		D	70%	0	0					

T – Turning

B – Boring

D – Drilling

4.6 Analysis of Benchmark Measurements for Drilling Operations

Drilling results fell lower than expectation, across all 3 version of the CaBR software tested. One key difference between the testing completed on the drilling operations compared with the Turing and Boring was the use of an alternate method of measuring the actual tool wear. Drilling operations were not measured using an optical microscope due to difficulties measuring the flank. Numerous alternative methods were investigated including higher powered microscopes, vision systems and touch probe CMM's however none of which yielded a satisfactory result. Drilling wear was calculated using the $\Delta T = t/T$ method proposed by Jemielniak et al. (2005). Jemielniak et al. (2005) proposed that the used-up portion of the tool life (ΔT), defined as the ratio of the cutting time as performed so far (t) to the overall tool life span (T) can be used to measure the degree of tool wear present.

To investigate if this different measurement technique was impacting on the poor drilling results the author completed some additional testing on the $\Delta T = t/T$ method. The $\Delta T = t/T$ method was statistically analysed against both the actual tool wear measurements and the operator opinion for both the Turing and Boring operations. Again, a one-way ANOVA was used to compare the means between the groups determines whether any of those means are statistically significantly different from each other.

Testing of both the turning and boring data concluded that there were no unusual data points and there is no significant difference between the mean of the wear values using either of the three methods of measurement, Optical Microscope, Operator opinion or $\Delta T = t/T$, for either the Turing or the Boring operations. The P values were significantly greater than 0.05 at 0.893 and 0.863 for turning and boring respectively, indicating no statistical significance in the means, and all tips shared the same grouping factor. At the individual confidence level all pairs of means included zero which confirms no statistical difference in the means, and with a confidence level of 98.07% and 98.08% respectively for Turning and Boring we can be confident that each individual interval contains the true difference between any pair of group means, ref Table 4-31: One Way ANOVA Turning (Measured vs Operator vs t/T) and Table 4-32: One Way ANOVA Boring (Measured vs Operator vs t/T) for details of the ANOVA analysis, and Figure 4-16 to Figure 4-21 for the supporting graphical representations.

The author was therefore confident in concluding that the anomaly within the drilling results lay within the CaBR software and not in the method used to obtain the benchmark measurements.

Table 4-28: ΔT = tc/T Turning Data

	t	Tc = t + t +	$T = \Sigma t_c$	$\Delta T = t_c/T$
Operation	min	min	min	%
Turning 1	1.96	1.96	11.76	0.17
	1.96	3.92		0.34
	1.96	5.88		0.51
	1.96	7.84		0.68
	1.96	9.80		0.85
	1.96	11.76		1.02
Turning 2	1.96	1.96	11.76	0.17
	1.96	3.92		0.34
	1.96	5.88		0.51
	1.96	7.84		0.68
	1.96	9.80		0.85
	1.96	11.76		1.02
Turning 3	1.96	1.96	11.76	0.17
	1.96	3.92		0.34
	1.96	5.88		0.51
	1.96	7.84		0.68
	1.96	9.80		0.85
	1.96	11.76		1.02
Turning 4	1.96	1.96	5.88	0.17
	1.96	3.92		0.34

	t	Tc = t + t +	T = Σt_c	$\Delta T = t_c/T$
Operation	min	min	min	%
	1.96	5.88		0.51
Turning 5	1.96	1.96	11.76	0.17
	1.96	3.92		0.34
	1.96	5.88		0.51
	1.96	7.84		0.68
	1.96	9.80		0.85
	1.96	11.76		1.02
Turning 6	1.96	1.96	10.90	0.18
	1.96	3.92		0.36
	1.96	5.88		0.54
	1.96	7.84		0.72
	1.96	9.80		0.90
	1.10	10.90		1.00
Turning 7	1.96	1.96	11.00	0.18
	1.96	3.92		0.36
	1.96	5.88		0.54
	1.96	7.84		0.72
	1.96	9.80		0.90
	1.20	11.00		1.01

Table 4-29: ΔT = tc/T Boring Data

	t	Tc = t + t + t……	T = Σt_c	ΔT = t_c/T
Operation	min	min	min	%
Boring 1	1.09	1.09	6.54	0.17
	1.09	2.18		0.34
	1.09	3.27		0.51
	1.09	4.36		0.68
	1.09	5.45		0.85
	1.09	6.54		1.02
Boring 2	1.09	1.09	6.54	0.17
	1.09	2.18		0.34
	1.09	3.27		0.51
	1.09	4.36		0.68
	1.09	5.45		0.85
	1.09	6.54		1.02
Boring 3	1.09	1.09	6.54	0.17
	1.09	2.18		0.34
	1.09	3.27		0.51
	1.09	4.36		0.68
	1.09	5.45		0.85
	1.09	6.54		1.02
Boring 4	1.09	1.09	3.27	0.17
	1.09	2.18		0.34
	1.09	3.27		0.51
Boring 5	1.09	1.09	7.63	0.14
	1.09	2.18		0.29

	t	Tc = t + t + t……	T = Σtc	ΔT = tc/T
Operation	min	min	min	%
	1.09	3.27		0.43
	1.09	4.36		0.57
	1.09	5.45		0.71
	1.09	6.54		0.86
	1.09	7.63		1.00
	1.09	1.09		0.17
	1.09	2.18		0.34
	1.09	3.27		0.51
	1.09	4.36		0.68
	1.09	5.45		0.85
Boring 6	1.09	6.54	6.54	1.02
	1.09	1.09		0.17
	1.09	2.18		0.34
	1.09	3.27		0.51
	1.09	4.36		0.68
Boring 7	1.09	5.45	5.45	0.85

Table 4-30: ΔT = tc/T Drilling Data

	t	Tc = t + t + t……	T = Σtc	ΔT = tc/T
Operation	min	min	min	%
	0.48	0.48		0.14
	0.48	0.96		0.28
Drilling 1	0.48	1.44	3.36	0.42

	t	Tc = t + t + t……	T = Σt_c	ΔT = t_c/T
Operation	min	min	min	%
	0.48	1.92		0.56
	0.48	2.4		0.7
	0.48	2.88		0.84
	0.48	3.36		0.98
	0.48	0.48		0.14
	0.48	0.96		0.28
	0.48	1.44		0.42
	0.48	1.92		0.56
	0.48	2.4		0.7
	0.48	2.88		0.84
Drilling 2	0.48	3.36	3.36	0.98
	0.48	0.48		0.14
	0.48	0.96		0.28
	0.48	1.44		0.42
	0.48	1.92		0.56
	0.48	2.4		0.7
	0.48	2.88		0.84
Drilling 3	0.48	3.36	3.36	0.98
	0.48	0.48		0.14
	0.48	0.96		0.43
	0.48	1.44		0.86
	0.48	1.92		1.43
	0.48	2.4		2.14
Drilling 4	0.48	2.88	3.36	3.00

	t	Tc = t + t + t……	T = Σtc	ΔT = tc/T
Operation	min	min	min	%
	0.48	3.36		4.00
Drilling 5	0.48	0.48	3.36	0.14
	0.48	0.96		0.28
	0.48	1.44		0.42
	0.48	1.92		0.56
	0.48	2.4		0.7
	0.48	2.88		0.84
	0.48	3.36		0.98
Drilling 6	0.48	0.48	1.47	0.33
	0.48	0.96		0.98
	0.48	1.44		1.96
	0.03	1.47		2.96

Table 4-31: One Way ANOVA Turning (Measured vs Operator vs t/T)

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor  Levels  Values
Factor       3  Measured, Operator, tc/T


Analysis of Variance
Source   DF   Adj SS    Adj MS  F-Value  P-Value
Factor    2  0.01860  0.009302     0.11    0.893
Error   108  8.90358  0.082441
Total   110  8.92219

Model Summary
       S   R-sq  R-sq(adj)  R-sq(pred)
0.287125  0.21%      0.00%       0.00%

Means
```

```
Factor     N    Mean   StDev       95% CI
Measured  37  0.5701  0.2988  (0.4766, 0.6637)
Operator  37  0.5905  0.2781  (0.4970, 0.6841)
tc/T      37  0.5593  0.2841  (0.4657, 0.6529)

Pooled StDev = 0.287125
```

Tukey Pairwise Comparisons

```
Grouping Information Using the Tukey Method and 95% Confidence

Factor     N    Mean  Grouping
Operator  37  0.5905  A
Measured  37  0.5701  A
tc/T      37  0.5593  A

Means that do not share a letter are significantly different.

Tukey Simultaneous Tests for Differences of Means

                      Difference       SE of
Adjusted
Difference of Levels    of Means  Difference        95% CI       T-Value
P-Value
Operator - Measured       0.0204      0.0668  (-0.1382, 0.1790)     0.31
0.950
tc/T - Measured          -0.0108      0.0668  (-0.1694, 0.1478)    -0.16
0.986
tc/T - Operator          -0.0312      0.0668  (-0.1898, 0.1274)    -0.47
0.887

Individual confidence level = 98.07%
```

Table 4-32: One Way ANOVA Boring (Measured vs Operator vs t/T)

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor  Levels  Values
Factor       3  Measured, Operator, tc/T

Analysis of Variance
Source   DF   Adj SS   Adj MS  F-Value  P-Value
Factor    2  0.02467  0.01234     0.15    0.863
Error   114  9.54828  0.08376
Total   116  9.57295

Model Summary

       S   R-sq  R-sq(adj)  R-sq(pred)
0.289408  0.26%      0.00%       0.00%

Means
Factor     N    Mean   StDev       95% CI
Measured  39  0.5247  0.2851  (0.4329, 0.6165)
Operator  39  0.5410  0.2960  (0.4492, 0.6328)
```

```
tc/T        39  0.5603  0.2870  (0.4685, 0.6521)

Pooled StDev = 0.289408
```

Tukey Pairwise Comparisons

```
Grouping Information Using the Tukey Method and 95% Confidence

Factor      N    Mean  Grouping
tc/T       39  0.5603  A
Operator   39  0.5410  A
Measured   39  0.5247  A

Means that do not share a letter are significantly different.

Tukey Simultaneous Tests for Differences of Means
                          Difference       SE of
Adjusted
Difference of Levels      of Means  Difference         95% CI       T-Value
P-Value
Operator - Measured         0.0163      0.0655  (-0.1394, 0.1720)      0.25
0.966
tc/T - Measured             0.0355      0.0655  (-0.1202, 0.1912)      0.54
0.851
tc/T - Operator             0.0192      0.0655  (-0.1365, 0.1749)      0.29
0.954

Individual confidence level = 98.08%
```

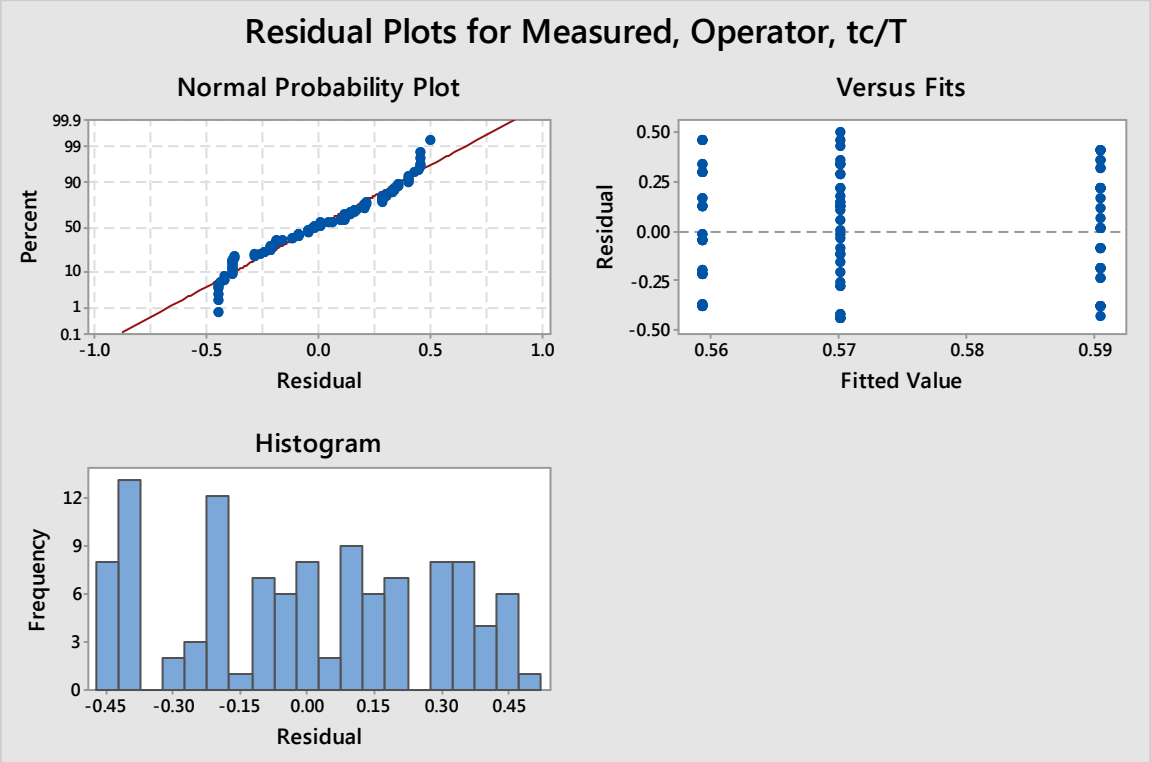

Figure 4-16: Residual Plots Turning (Measured vs Operator vs t/T)

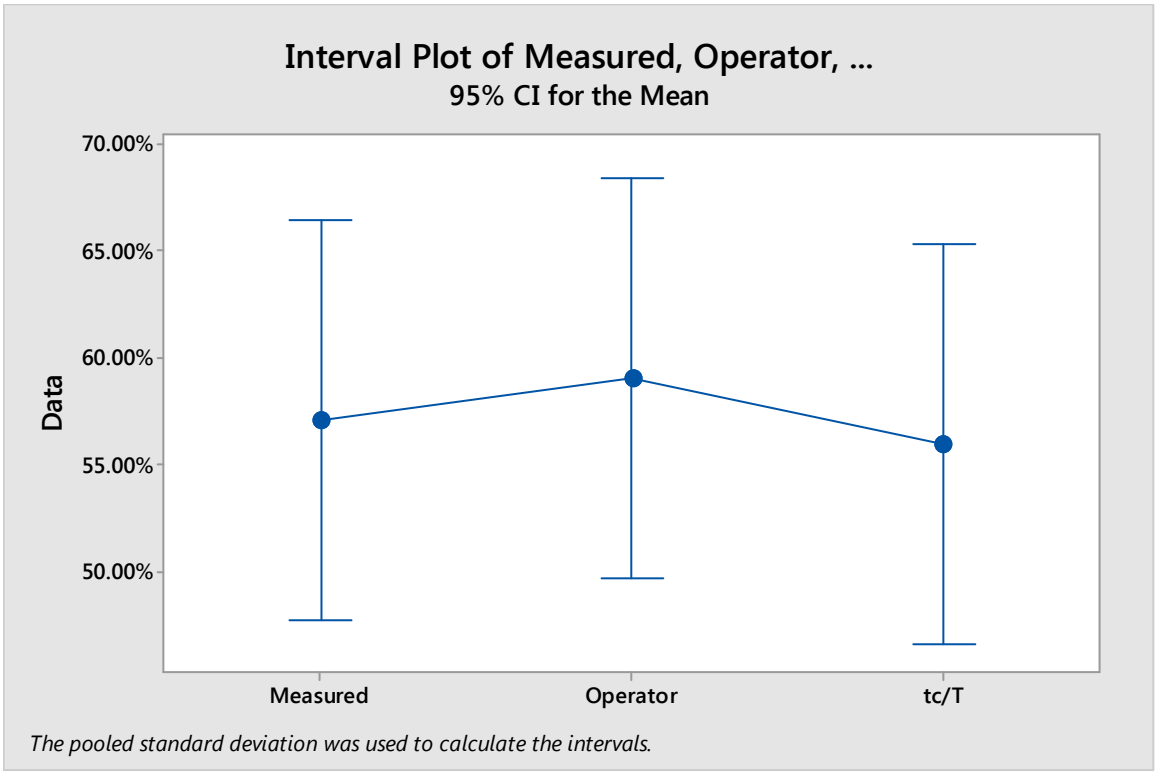

Figure 4-17: Interval Plot Turning (Measured vs Operator vs t/T)

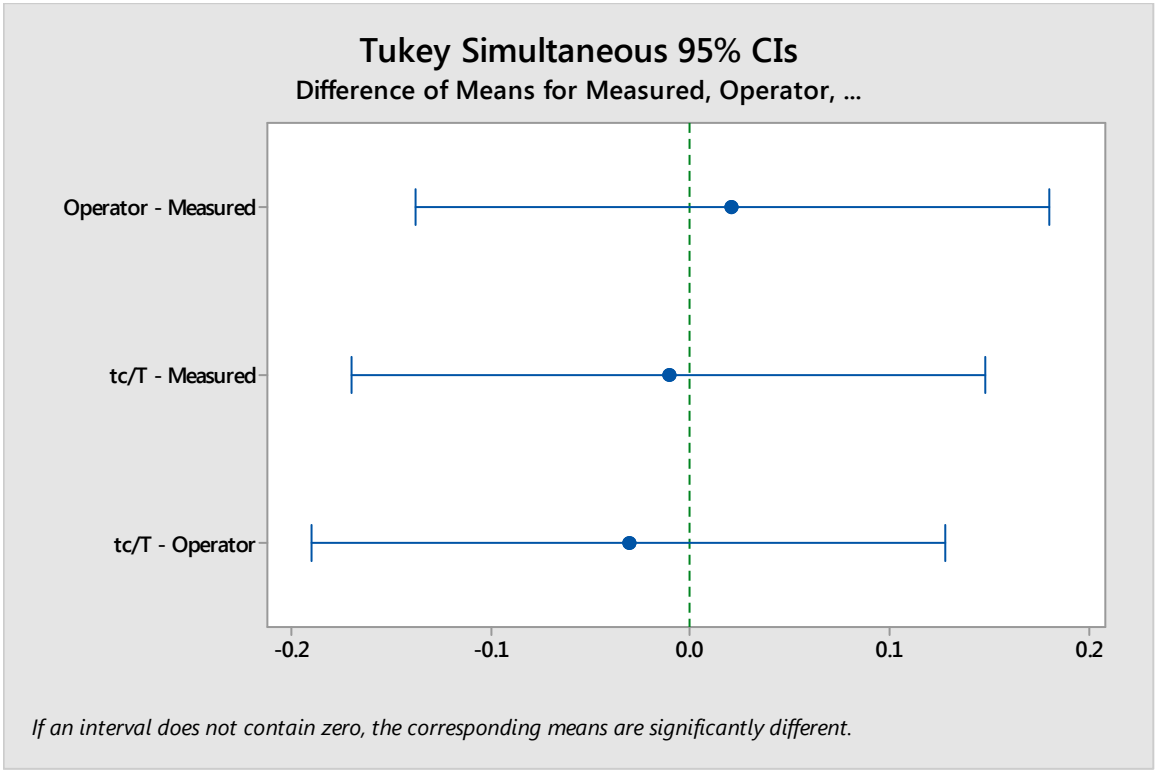

Figure 4-18: Difference of Means Turning (Measured vs Operator vs t/T)

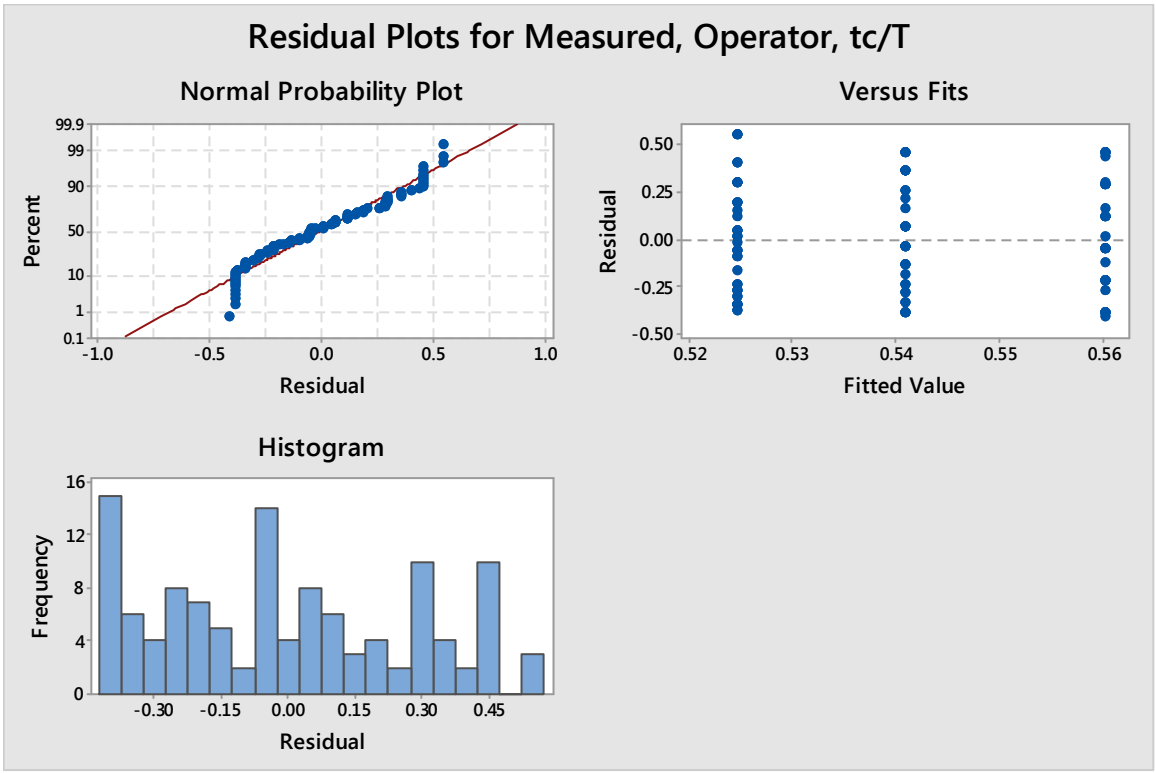

Figure 4-19: Residual Plots Boring (Measured vs Operator vs t/T)

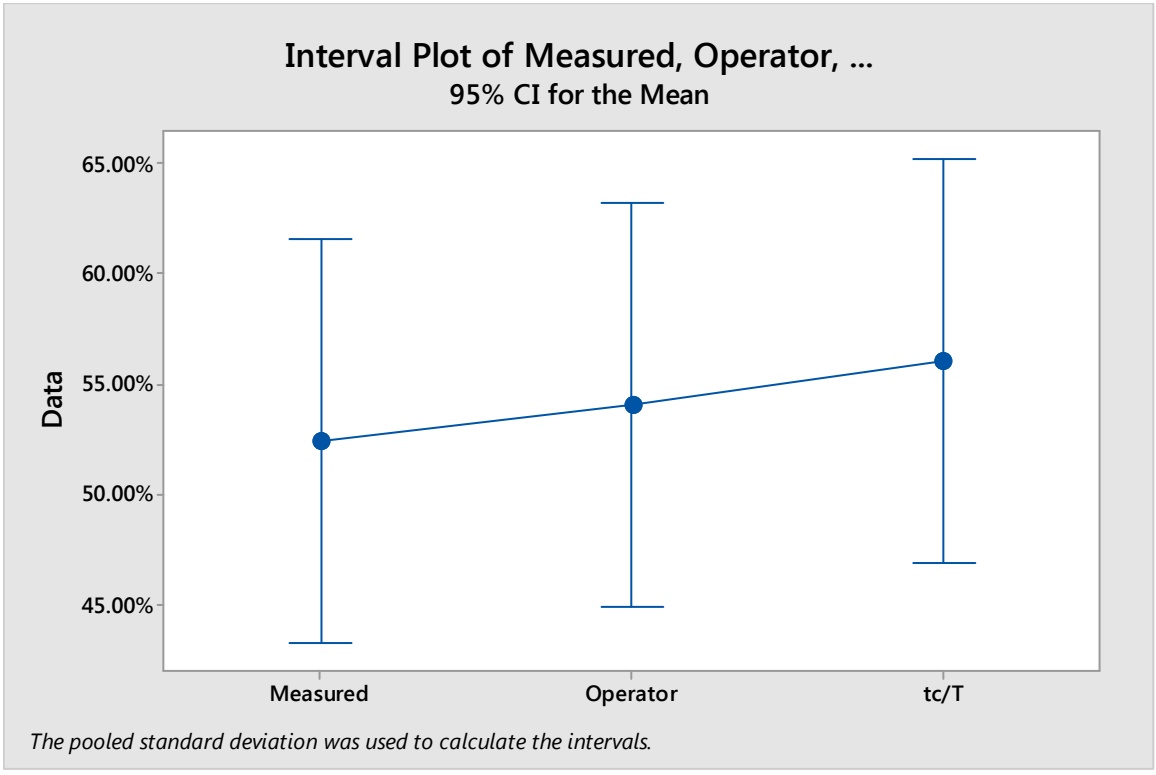

Figure 4-20: Interval Plot Boring (Measured vs Operator vs t/T)

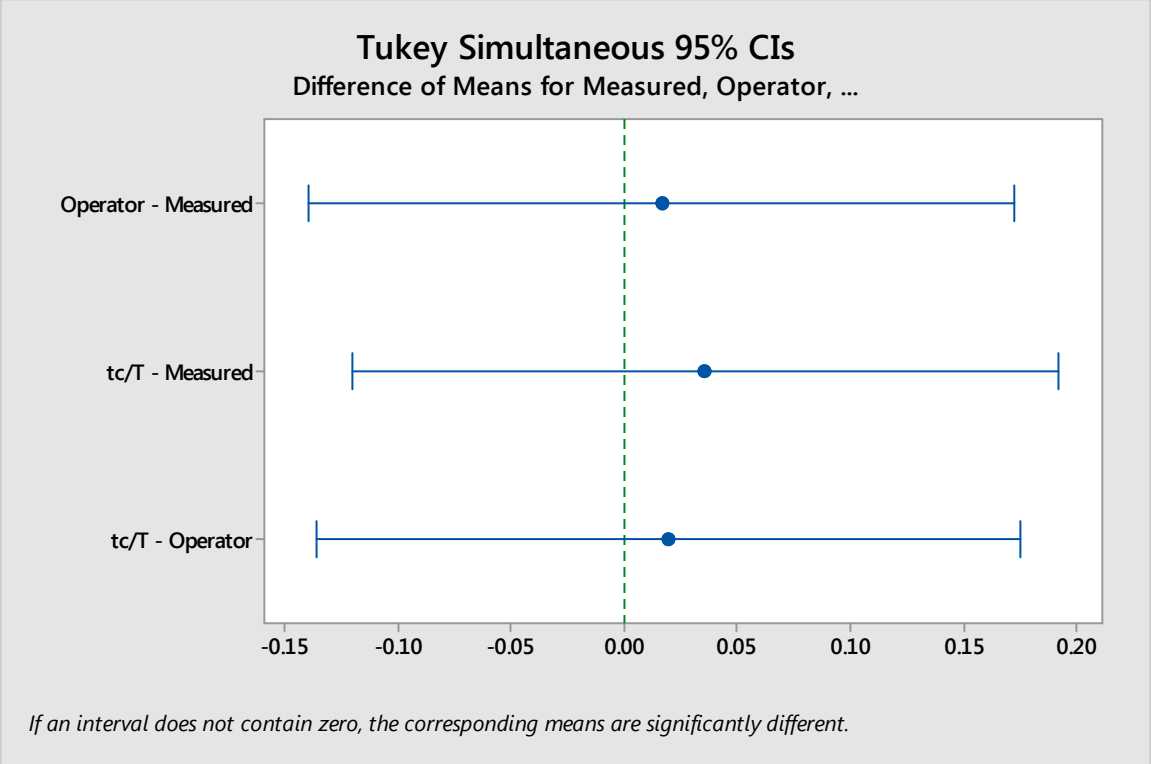

Figure 4-21: Difference of Means Boring (Measured vs Operator vs t/T)

4.7 Chapter Summary

As part of the Risk Assessment, two intolerable failure modes were detected both relating to the CaBR portion of the system, namely:

- Variability within the mechanical properties of the tooling, and its impact on system training
- Poor system training, due to variation in the operator's expectation around the degree of tool wear present. Due mainly to the fact that the operator is training based on an opinion rather than factual measurements.

In order to mitigate the risks, Various tool life's were tested under laboratory style conditions at Schivo Ltd., by running roughing, boring and drilling tools from new condition, through to catastrophic tool failure, and the data collected from these tests was statistically analysed.

After analysis of the data it was determined that neither variability within the mechanical properties of the tooling or variation in operator expectation were influencing factors on the training of the CaBR portion of the system. When statistically analysed through

Minitab, using a number of methods including ANOVA Analysis and Paired T-Testing the results were deemed to be acceptable, and formal validation of the system could commence.

The IOPQ protocol was executed, and there were no test failures in either the installation or operational qualification testing portions of the test protocol. During the PQ testing however, the author was unable to satisfactorily achieve an acceptable test result for the drilling operations. The system was deemed to have passed testing using version 2 of the CaBR software for turning operations, boring operations and for the detection of catastrophic tool failure however, funding and timeline restrictions didn't allow for further manipulation of the TCM software, to allow a successful outcome to the testing of the drilling. Prior to the formal ending of the REALISM project, one further version of the Drilling CaBR software was tested, version 3, however, while better than the previous two versions, the author was still unable to achieve an acceptable result. The PQ testing was completed by using regression testing, with a pass limit of 70%.

One key difference was noted between the data sets for turning, boring and drilling, namely, the method of collection of the data used as the benchmark measured tool wear. While the turning and boring data was physically measured using an optical microscope, the drilling data, due to difficulties physically measuring the flank, was mathematically calculated using the $\Delta T = t/T$ method, proposed by Jemielniak et al. (2005). To eliminate this fundamental difference as variable the author completed some additional statistical analysis on the data sets, and was able to, from the results of the analysis, confidently conclude that the method of obtaining the benchmark measured tool wear was not having an adverse effect on the results, and that the anomaly within the drilling results lay within the CaBR software itself.

The validation testing concluded that, while not suitable for drilling applications, the TCM system with version 2 of the CaBR software installed can suitably be used for measurement of tool wear in turning and boring operations, and for the detection of catastrophic tool failure.

5.0 Discussion

5.1 Selection of regulatory standards

After review of literature in Section 2.0, the author identified three key regulatory bodies, namely, the US FDA, the EU and the WHO.

After careful review of the guidelines from each of the three regulatory bodies, it was concluded that there was minimal differences between the approaches suggested by the different bodies, and through comparison of the standards it was established that validation was **documented evidence,** showing that if we have a process with specific **predetermined parameters** and we constantly input the same parameters to the process, we will **consistently** achieve an output from that process that meets our **pre-determined specifications**.

Within the US FDA guidance document, however, there was a note explicitly stating that the "guidance does not cover medical devices and that guidance on process validation for medical devices is provided in a separate document, Quality Management Systems – Process Validation, edition 2". For this reason, the Global Harmonisation Task Force (GHTF) guidelines, while not a regulatory guideline, were also considered as part of the literature review.

The following regulatory guidelines were considered as part of the review activities, and from these guidelines the testing in Section 8.1 IOPQ Protocol was generated:

- European Commission
    - Annex 15: Qualification and validation Brussels: Office for Medicinal Products – Quality, Safety and Efficacy
    - Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice Title: Qualification and validation
- US Food and Drug Administration
    - Guidance for Industry Process Validation: General Principles and Practices
    - General Principles of Software Validation - Guidance for Industry and FDA Staff

- World Health Organisation
    - Annex 4 Supplementary guidelines on good manufacturing practices: validation
    - Proposal for the revision of the supplementary guidelines on good manufacturing practices: Validation, Appendix 7: Non-Sterile Process Validation
    - Draft Proposal for Revision of the Supplementary Guidelines on Good Manufacturing Practices: Validation, Appendix 7:Non-Sterile Process Validation
- Global Harmonisation Task Force
    - Quality Management Systems - Process Validation Guidance

The selection of test criteria for the qualification activities was based specifically on the GMP & validation requirements of each of the selected regulatory guidelines.

GMPs are a mandated regulatory requirement and if you are manufacturing medical devices for distribution you must be in compliance with these regulations. While the guidelines outlined by each regulatory body vary from country to country, all the guidelines cover the same basic principles including, but not limited to, hygiene, controlling environmental conditions, controlling processes, controlling change, standardization through instructions and procedures, training, maintaining records and managing complaints and recalls.

GMP guidelines are not a prescriptive set of instructions on how to manufacture products, they contain a series of general principles that must be observed during manufacturing. There are numerous ways that a company can fulfil the requirements of the GMP guidelines and the method of fulfilment will vary from company to company. For the REALISM TCM the author is confident that from the suite of test scripts selected to generate the validation model, the system is in full compliance with European, U.S. and other GMP requirements.

5.2 Validation vs Verification

The GHTF (2004) proposed quite a simple, but effective decision tree, which was applied to the REALISM TCM system. Although, it was established through the review of the GHTF's Quality Management Systems - Process Validation Guidance document, validation of a numerical control cutting process is not mandatory, the REALISM TCM system was reviewed to establish if the output could be verified by subsequent monitoring or measurement, the answer being yes, the consideration then moved to whether or not verification alone was sufficient to eliminate unacceptable risk, and if it was a cost effective solution. In agreement with Snow et al. (2012), verification, or 100% inspection, was not deemed to sufficient or cost effective and after application of the decision tree to the REALISM TCM system, the author proceeded to complete full GMP validation activities on the system.

5.3 Validation Lifecycle

After review of the regulatory standards, and taking the decision to proceed with full GMP validation activities, a simple, but effective, validation lifecycle was generated for the TCM system, Section 3.5.

The REALISM TCM validation lifecycle, based on the US FDA (2011) guidelines, consisted of 3 stages:

- **Stage 1** – Process Design
    - Risk Assessment
- **Stage 2** – Process Qualification
    - Installation Qualification
    - Operational Qualification
    - Performace Qualification
- **Stage 3** – Continued Process Verification
    - Change Control & Re-Validation

Review of the regulatory guidelines detailed in Section 5.1, along with review of

applicable literature in the area of validation, concluded that the above lifecycle satisfactorily covers the system for compliance with European, U.S. and all other GMP requirements.

5.3.1 Validation Approach

As predicted, one of the key challenges of the validation activities was the incorporation of a CaBR system into the TCM system. As documented by Gupta (1991) and Gonzalez et al. (1998), the application of GMP validation to a CaBR system is an area which has received little attention in literature, and virtually all research in verification and validation has been focused on rule-based systems rather than other knowledge representations, such as case-based systems. Aside from the distinct lack of research into validation of a CaBR system, there was no research into the area of applying GMP validation to a CaBR or the area of applying validation to a TCM system.

One of the biggest challenges in validating the CaBR system, developed as part of the REALISM TCM system, was that the system requires training by a machine operator, to identify when a tool is at end of life, and only based on this training can the system make its own decisions around the degree of tool wear present, based on the sensor information received during the cutting process.

As part of the Stage 1 risk assessment activities, two intolerable failure modes were detected both relating to the CaBR portion of the system, namely:

- Variability within the mechanical properties of the tooling, and its impact on system training
- Poor system training, due to variation in the operator's expectation around the degree of tool wear present. Due mainly to the fact that the operator is training based on an opinion rather than factual measurements.

Both risks were mitigated through the use of statistical analysis, Section 4.0, and after analysis of the data it was determined that neither variability within the mechanical properties of the tooling or variation in operator expectation were influencing factors, on the training of the CaBR portion of the system and generation of the test scripts for IOPQ testing activities commenced.

An IOPQ protocol, Section 8.1, was drafted, based on the requirements outlined by the regulatory bodies. The TCM system was assessed against the regulatory requirements, and a set of test scripts were generated, which the author is confident places the system in compliance with European, U.S. and all other GMP requirements. The IOPQ protocol was executed, and there were no test failures in either the installation or operational qualification testing portions of the test protocol however, during the PQ testing, the author was unable to satisfactorily achieve an acceptable test result for the drilling operations.

Flank wear had been chosen as the preferred method of capturing the baseline tool wear data, during the IOPQ testing, because flank wear always takes place, and cannot be avoided during machining operations. There was some difficulties capturing flank wear on the optical microscope for the drilling operations and the drilling wear was instead measured using the Jemielniak et al. (2005) whereby it was proposed that the used-up portion of the tool life (ΔT), defined as the ratio of the cutting time as performed so far (t) to the overall tool life span (T) can be used to measure the degree of tool wear present. It was initially thought that the differing method of collection of the baseline target data was an influencing factor, on the drilling data, however, through additional statistical analysis, Section 4.6, the author was able to confidently conclude that the anomaly within the drilling results did not lie with the different method of collection of the target data, rather the anomaly lay within the CaBR software itself.

The REALISM Project, didn't allow for further manipulation of the TCM CaBR software, to allow a successful outcome to the testing of the drilling data and the TCM testing was passed with the deviation that the prototype system, while suitable for used in Turning, Boring and detection of CTF, is currently not suitable for use in drilling operations.

6.0 Conclusions / Recommendations

GMPs are a mandated regulatory requirement and if you are manufacturing medical devices for distribution you must be in compliance with these regulations. GMP guidelines are not a prescriptive set of instructions on how to manufacture products, they contain a series of general principles that must be observed during manufacturing. There are numerous ways that a company can fulfil the requirements of the GMP guidelines and the method of fulfilment will vary from company to company. For the REALISM TCM the validation model developed, and the selection of test criteria for the qualification activities, was based specifically on the regulatory GMP & validation guidelines from of each of the regulatory bodies selected by the author, namely the US FDA, the WHO and European Commission.

The REALISM TCM system has been tested in accordance with the regulatory requirements and has passed testing for the Turning, Boring and CTF operations. The drilling operations have however failed testing. Investigation concluded that the drilling portion of the software requires further manipulation. Funding and timeline restrictions, on the REAMISM Project, didn't allow for further manipulation of the TCM CaBR software, to allow a successful outcome to the testing of the drilling data and the TCM testing was passed with the deviation that the prototype system, while suitable for used in Turning, Boring and detection of CTF, is currently not suitable for use in drilling operations.

The author is confident that the suite of test scripts selected used to generate the validation model provides the end user with a system that is in full compliance with European, U.S. and other GMP requirements.

The objective of this research project was to establish:

- Should a TCM, incorporated with a CaBR, in a medical devices manufacturing environment, be Validated or Verified?
- Can a GMP style of validation be applied to a TCM, which incorporates a CaBR?
- What are the barriers pertaining to the validation of a system which incorporates a CaBR system, and what is the impact from external variables on the training process?

- Is a TCM, incorporated with a CaBR capable of adaption to a wide range of machining scenarios, such as turning, boring and drilling?

6.1 Validation or Verification

It was established through the review of the GHTF (2004) Quality Management Systems - Process Validation Guidance document, validation of a numerical control cutting process is not mandatory, the REALISM TCM system, while strictly not a numerical control cutting process, is a bolt on system which forms part of the cutting process. With this in mind the regulatory guidelines were reviewed and it was noted that the guidelines stipulate that "where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures." In the case of the REALISM TCM the results can be adequately verified through inspection, however verification, or 100% inspection, was not deemed to sufficient or cost effective, due to the fact that the tooling would need to be removed from the system during production, the author applied the GHTF (2004) validation decision tree to the REALISM TCM system and proceeded to complete full GMP validation activities on the system.

6.2 Validation of a TCM with CaBR & Influence of Variables

As predicted, one of the key challenges of the validation activities was the incorporation of the CaBR system into the TCM system. As documented by Gupta (1991) and Gonzalez et al. (1998), the application of GMP validation to a CaBR system is an area which has received little attention in literature, and virtually all research in verification and validation has been focused on rule-based systems rather than other knowledge representations, such as case-based systems. Aside from the distinct lack of research into validation of a CaBR system, there was no research into the area of applying GMP validation to a CaBR or the area of applying validation to a TCM system.

One of the biggest challenges in validating the CaBR system was that the system requires training by a machine operator, to identify when a tool is at end of life, and only based on this training can the system make its own decisions around the degree of tool wear present, based on the sensor information received during the cutting process. Acceptable and

consistent system training is essential as any variability in the training process will introduce variability into the CaBR software. The REALISM TCM was risk assessed, to identify any areas of the system which are more vulnerable to risk than others. As part of the risk assessment activities two intolerable failure modes were detected, both of which related to the CaBR portion of the system, namely:

- Variability within the mechanical properties of the tooling, and its impact on system training
- Poor system training, due to variation in the operator's expectation around the degree of tool wear present. Due mainly to the fact that the operator is training based on an opinion rather than factual measurements.

Because the system is so reliant on consistent information during the training process, any external variables could have a significant negative impact and may lead to overdue or premature detection of tool wear. This in turn could lead to cost implications for the end user, for example premature scrapping of cutting tools, or scrapping of machined parts due to dimensional or cosmetic failures. Both risks were mitigated through the use of statistical analysis, Section 4.0, and after analysis of the data it was determined that neither variability within the mechanical properties of the tooling or variation in operator expectation were influencing factors, however, it's important to note that the system must be trained by a suitably qualified operator, and for this reason the system has been equipped with a number of levels of security which restrict access to the training module in the system.

The author, once the variables causing the failure modes were mitigated, was successfully able to apply GMP validation to the CaBR portion of the system, through integrated software testing, and achieve an acceptable test result for the turning, boring and CTF operations, however, the drilling operations failed testing and further manipulation of the CaBR system software is required to correct the tool wear portion of the system relating to drilling.

6.3 Adaption to machining scenarios

The IOPQ protocol was executed, and there were no test failures in either the installation or

operational qualification testing portions of the test protocol. During the PQ testing however, the author was unable to satisfactorily achieve an acceptable test result for the drilling operations. The system was deemed to have passed testing using version 2 of the CaBR software for turning operations, boring operations and for the detection of catastrophic tool failure however, funding and timeline restrictions didn't allow for further manipulation of the TCM software to allow a successful outcome to the testing of the drilling. Prior to the formal ending of the REALISM project, one further version of the Drilling CaBR software was tested, version 3, however while better than the previous two versions, the author was still unable to achieve an acceptable result. One key difference was noted between the data sets for turning, boring and drilling, namely, the method of collection of the data used as the benchmark measured tool wear. While the turning and boring data was physically measured using an optical microscope, the drilling data, due to difficulties physically measuring the flank, was mathematically calculated using the $\Delta T = t/T$ method, proposed by Jemielniak et al. (2005). To eliminate this fundamental difference as variable the author completed some additional statistical analysis on the data sets, and was able to, from the results of the analysis, confidently conclude that the method of obtaining the benchmark measured tool wear was not having an adverse effect on the results, and that the anomaly within the drilling results lay within the CaBR software itself.

The validation testing concluded that, while not suitable for drilling applications, the TCM system with version 2 of the CaBR software install can suitably be used for measurement of tool wear in turning and boring operations and for the detection of catastrophic tool failure.

As part of the REALISM project sensors were to be deployed onto a milling machine in IDT Norway, however no information was gather from the milling process because the prototype system was not fully deployed to IDT, due to funding and timeline restrictions. The author is therefore unable to offer any insight into the applicability of this system to milling operations. All testing was completed for turning operations only.

The author makes recommendations for further research relating to the findings and the research topic.

- Through further research, tool wear in drilling operations, and statistical analysis of same, requires further investigation, due mainly to the inaccuracy of the data

obtained from the TCM system when benchmarked against the actual tool wear.

- Testing of the TCM system in milling operations is recommended, as the prototype system was only tested in turning operations on a CNC lathe.
- Through further research, alternative tool wear patterns should be investigated. For the purposes of this research flank wear had been chosen as the preferred method of capturing the baseline tool wear data, because flank wear always takes place, and cannot be avoided during machining operations. Flank wear however, proved extremely difficult to capture in drilling operations. There is potential that there is a more accurate method of detecting tool wear in drilling operations that could be incorporated into the REALISM TCM. This however would require a full manipulation of the software developed as part of this project.
- Through further research the adaption of the model to more advanced control methodologies, such as neural networks should be investigated. At the initial stages of this project the project intent was to incorporate a neural network, this was subsequently scaled back to the incorporation of a CaBR system.
- The REALISM TCM was a prototype system and was tested in a live production environment, however, all testing was conducted in a controlled manner, and only test pieces were used. The system was not trialled over a prolonged period, on live product, due to schedule constraints in the machine shop. Because of warranty concerns, after connection of additional sensors to the lathe, from the machine manufacturer, Mazak, the REALISM TCM had to be removed after a machine breakdown. The author recommends further collection of data, over a prolonged period of time, on live production, and statistical analysis of the data.

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8.0 Appendices

8.1 Appendix A – Realism TCM IOPQ Protocol

INSTALLATION, OPERATIONAL, PERFORMANCE QUALIFICATION FOR

REALISM TCM

Document Number: TCM-IOPQ-001-01

REVISION HISTORY

Date	Version	Revised By	Reason for Revision
08/Dec/2015	1.0	Barry Ronan	Original Version - Issued for Approval
08/Jan/2016	2.0	Barry Ronan	Updated to combine Performance Qualification

Confidential

1.0 Pre-Approval

1.1 Review Process

Review item	Review Objective
R1	Verify that this IOPQ document is correct and complete
R2	Verify that this IOPQ document is in line with the Quality Management System
R3	Verify that this IOPQ document is acceptable for use on the project

1.2 Pre-Approval Signatures

The procedure as described in this protocol is reviewed and approved by the persons listed below. If all acceptance criteria as described in the protocol are met, assurance will be provided that the REALISM TCM is suitable for use.

Prepared by:

_____ _____

Date

Signature of the Professional Responsible for preparing the document and agreement with R1.

Reviewed by:

_____ _____

Date

Signature indicates agreement with review items R3.

Approved by:

_____ _____

Date

Signature indicates agreement with review item R2& R3.

Approved by:

_____ _____

Date

Signature indicates agreement with review item R2 & R3.

-- **CONTENTS –**

2.0 Introduction

2.1 Objective

The purpose of this Installation Operational Performance Qualification (IOPQ) Protocol is to define the Installation Operational and Performace Qualification testing requirements associated with the REALISM TCM, installed at Schivo IDA Business Park, Cork Road, Waterford.

Successful completion of these IOPQ requirements will provide assurance that the installation, operation and performace of the REALISM TCM is in accordance with design specification and GMP requirements, and that the equipment performs as per it design intent throughout the anticipated operating ranges.

2.2 Scope

The scope of this IOPQ protocol is limited to the REALISM TCM, installed at Schivo, IDA Business Park, Cork Road, Waterford. This protocol will identify the test procedures, documentation and acceptance criteria to establish that the REALISM TCM is installed and operating in accordance with design specifications. The successful execution of this protocol will verify that the installation and operation of the REALISM TCM was performed successfully and that the necessary documentation is in place to support the system.

2.3 Associated Documentation

Document Number	Document Title
N/A	Deliverable 6.2 Prototype Development Report
N/A	Testing of the TCM system
N/A	Online prediction of cutting tool life in turning via cognitive decision making
N/A	Tool Wear SubVI (1 & 2)
N/A	CTF detection SubVI (1 &2)
N/A	Automatic multiple sensor data acquisition system in a real-time production environment

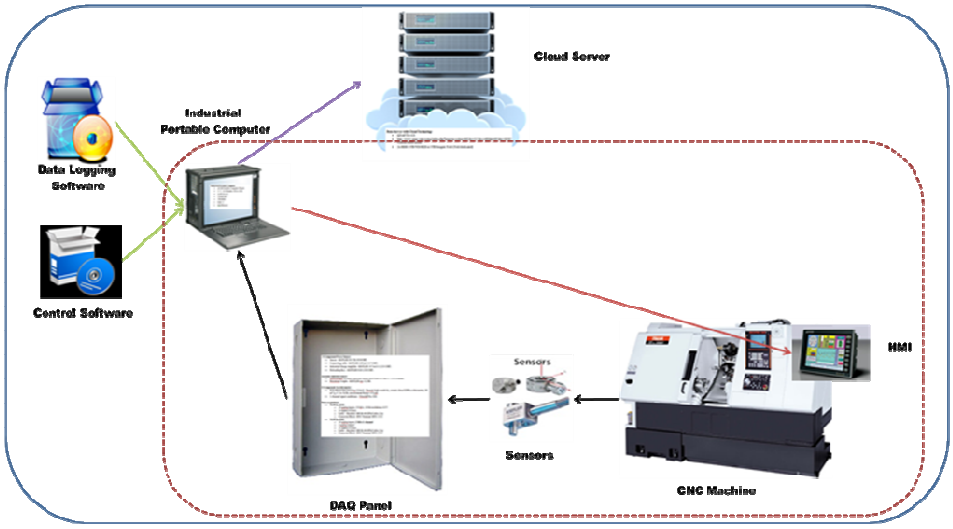
3.0 Equipment/System Description

3.1 System Overview

The REALISM TCM consists of a 3-axis force sensor, an acoustic emission (AE) sensor, a 3-axis accelerometer, data acquisition system, an industrial portable computer, custom data logging software and custom control software linked back to a human machine interface (HMI).

A schematic overview of the system is detailed in Figure 2.

The system has initially been deployed on a Mazak Quickturn Nexus 200II machine at Schivo Precision based in Waterford, Ireland.



REALISM TCM

4.0 Execution

4.1 IOPQ Summary Report

1. When all the IOPQ test datasheets have been completed and reviewed a IOPQ Summary Report will be completed.
2. The IOPQ summary report will be approved by all protocol pre-approval signatories.

4.2 Documentation

1. Document all qualification reviews, inspections and verifications at the time they are performed. Record all work and perform all qualification work required by this protocol.
2. If the inspection or verification test was not satisfactory, then the executor will document the deviation on a Deviation Report, refer to Section 13.0.
3. Upon completion of the execution of this protocol submit the completed protocol, all testing reports, and all documentation related to any Deviation for approval.

4.3 Hand Written Data

1. Must be in BLUE or BLACK ink only.
2. Sign or initial and date all data, which is hand written. (Even if no box is provided for this).

4.4 Mistakes

1. These should be crossed out by drawing a single line through the mistake.
2. All cross outs should be initialed and dated clearly with an explanation where possible.
3. WHITE OUT or TIPP-EX should never be used.

4.5 Drawing/Diagram Inspection Legend

1. Green highlighter for all items/components verified as correct (i.e. drawing/ equipment details correspond).
2. Blue highlighter for all parts where the equipment is different from the drawing (or deemed unacceptable).
3. Red highlighter to record details of drawing corrections.
4. Yellow highlighter for all parts not accessible during IOPQ
5. DO NOT highlight any parts not verified.

4.6 Comments and Deviation Reports

1. A Deviation Report is generated for any deviations, variations or statements of clarification noted during the execution of this IOPQ protocol.
2. The deviation reports will be completed as per Section 13.0 of this protocol.
3. All Deviation Reports will require an appropriate follow-up response and resolution.
4. All Deviation Reports will require sign-off and approval by a representative from the relevant department.
5. All IOPQ test sheets have a comments column where Deviation reports must be referenced by a specific DR No.
6. The Deviation Report must be correspondingly logged on the Deviation Report Log, in summary format. The Deviation Report Log is completed as per Section 14.0 of this protocol.
7. In the case of minor comments and explanations, the detail can be filled out in the comment section on the bottom of each test sheet.

4.7 Replying to Tests

1. All tests or checks which require a response of Yes / No, Pass / Fail, etc. must be responded to by writing the response, not ticking or ‘X’ing.
2. All test responses should be filled, even if non-applicable (N/A).

4.8 Acceptance Criteria

1. All required IOPQ tests have been performed and all corresponding data sheets are completed, signed off and approved.
2. All test equipment used during the qualification has been calibrated and a certificate attached to the data sheet.
3. All Deviations and comments have been adequately resolved and have been approved by a representative from the relevant department.
4. Once the IOPQ Summary Report is completed the IOPQ protocol can be signed off and post approved.

5.0 Testing Methodology

The satisfactory installation and operation of the REALISM TCM shall be verified by executing the qualification tests detailed below. The successful execution of this protocol verifies that the REALISM TCM is correctly installed, operating and performing in accordance with design specifications and Good Manufacturing Practices (GMP), and is capable of producing product according to Schivo quality requirements.

These test data sheets are broken down into the following sections for clarity:

- Purpose – This section rationalizes and briefly describes the Installation Operational qualification test being carried out in order to validate the operation of the equipment.
- Test Execution – This section provides clear step by step instruction on how the testing is to be performed.
- Acceptance Criteria – This section provides a statement(s) clearly defining what must be achieved from the Installation Operational Performance Qualification testing in order for the IOPQ to be deemed successful and for all corresponding equipment to be fit for use.
- Functional Verification – All records (i.e. results/settings/actions) from the testing performed are recorded in this section. Results (actual) are verified against the expected results and a Pass / Fail recorded against each entry as appropriate.

5.1 Test Datasheets

The following test datasheets will be executed to provide documented evidence of the system functionality:

5.1.1 Personnel Identification (Signature Log)

All personnel involved in the execution and review of this protocol shall enter their name and signature on the Signature Log.

5.1.2 Validation Test Equipment Verification

All equipment/instrumentation used during the execution of this protocol must be calibrated and be in current calibration when the testing is conducted. A copy of all calibration certificates should be attached to this IOPQ protocol.

5.1.3 Validation Materials Verification

All test materials used during the execution of this protocol must be recorded on the validation tests material test sheet. Each entry should be signed and dated.

5.1.4 Software Disaster Recovery

Testing shall verify that the correct software is installed and that a disc image of the software can be loaded on to the machine.

5.1.5 Software Verification

The control system type and software version for the REALISM TCM shall be verified.

5.1.6 Equipment Installation Verification

Testing shall verify that a documented walk down of the Mechanical and Electrical system has been completed.

5.1.7 Documentation Verification

Testing shall verify that all the relevant documentation is available and reviewed. In some cases this documentation will be attached to the relevant datasheet and will form a permanent part of this protocol, alternatively its permanent stored location will be recorded on the Documentation Verification Checklist for future reference.

5.1.8 Drawing Verification

The drawings shall be inspected, to ensure that they accurately reflect the actual equipment layout. Any drawings, which have been redlined to accurately reflect the installed equipment, should be signed, dated and the original red-lined, marked-up drawings should be attached to the protocol.

5.1.9 SOP Verification

Testing shall identify whether a revision is required as a result of validation, and also if the latest revision of SOP's are available at the time of execution.

5.1.10 Verification of Utility Supply and Installation

Utilities that are required for the continuous operation of equipment are considered support utilities. Without them the system would not operate properly. This test verifies that required support utilities are correctly installed.

5.1.11 Safety Features Verification.

Process quality, equipment and operator safety are ensured through the proper operation of alarms and interlocks. Alarm triggers, interlocks shall be tested here.

5.1.12 Startup / Shutdown / Loss of Power

Testing shall verify that the REALISM TCM starts up and shuts down as per design intent and there are no adverse side effects during a power loss.

5.1.13 Graphics Screen Test

To verify that the graphics associated with REALISM TCM are in accordance with the project specifications.

5.1.14 User Adjustable Set Point Verification

To verify that the set points described as user adjustable are available for the user to adjust from the GUI.

5.1.15 Data Logging Test

To verify that the data logging associated with the REALISM TCM operates in accordance with the project specifications.

5.1.16 PLC Input / Output Testing

Testing shall verify that the PLC controller software, in the DAQ panel, is operating per design intent.

5.1.17 Integrated Software Testing

Testing shall verify that the integrated REALISM TCM software package is operating per design intent.

5.1.18 Additional Testing

Additional testing shall be used to challenge the system, in detail, against specified functional requirements. Use the pre-formatted test sheets in section “Additional testing”, describe and record the:

- Test
- Objective
- Test Step & Description
- Expected Result & Actual Result

Attach the completed test sheets to this protocol.

6.0 Safety

Use extreme caution when opening and working inside the I/O panel. Sufficient access and working space shall be provided and maintained about all electric equipment to permit ready and safe operation and maintenance of such equipment.

Use caution when working around rotating equipment. Do not wear ties or loose fitting garment.

7.0 Glossary

Term	Definition	Term	Definition
AE	Acoustic Emissions	HMI	Human Machine Interface
CTF	Catastrophic Tool Failure	IDA	Industrial Development Authority
CAPA	Corrective & Preventative Action	I/O	Input Output
DAQ	Data Acquisition	IOPQ	Installation Operational Performace Qualification
DR	Deviation Request	PLC	Programmable Logic Controller
FMEA	Failure Mode and Effects Analysis	REALISM	Real Time In Situ Monitoring
GMP	Good Manufacturing Practices	SOP	Standard Operating Procedures
GUI	Graphical User Interface	TCM	Tool Condition Monitoring
Hz	Hertz	V	Voltage

8.0 Installation Qualification

The Installation Operational Performance Qualification is the documentation process that verifies that the equipment has been properly installed and is operating according to design and manufacturer's specification. The critical attributes are tested via the following IOPQ test sheets.

8.1 Signature Log

The following is a record of each individual who signs or initials any page of this document in the process of system qualification. Anyone who signs or initials any column in this Protocol (other than the approvals page) shall fill in the data requested below. The purpose of this table is to trace initials and signatures back to an individual.

Name	Title	Signed Name / Initials	Date

8.2 Test Equipment / Instruments

Identify and record the details of all items of test equipment/instruments used during this site acceptance testing exercise.
Review calibration records and confirm that any instrumentation used is calibrated.
Attach a copy of the calibration certificate(s) to this IOPQ protocol.

SHEET _____ OF_____

(Photocopy as required)

Description of Test Equipment / Instrument	Identification Number of Test Equipment / Instrument	Calibrated Yes / No

Comments:

Completed by:		Date:	

8.3 Test Materials

Record the details of the test materials used throughout the execution of this site acceptance testing.

SHEET _____ OF_____

(Photocopy as required)

Item number	Description	Sign & Date

Comments:

Completed by:		Date:	

	TEST NAME:
	8.4 **Software Disaster Recovery**

Purpose:

The purpose of this test is to verify that a disc image of the software can be loaded on to the machine. The validation will be completed using the reloaded software.

Test execution:

1) Load the software onto the machine using the backup disc.

Acceptance criteria:

Disc image of the software can be loaded onto the machine.

SOFTWARE DISASTER RECOVERY				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**

SOFTWARE DISASTER RECOVERY				
Load the software onto the machine using the backup disc	Software is loaded on the REALISM TCM. The REALISM TCM performs as per	Yes/No: _____		

Actual result meets acceptance criteria:

Yes / No:_____

Comments:

Completed By:		**Date:**	

	TEST NAME:
	8.5 **Software Version**

Purpose:

To document the software version currently operating on the REALISM TCM.

Test execution:

1) Record the control system software version/date for the REALISM TCM.

Acceptance criteria:

The software version(s)/date has been documented and recorded.

SOFTWARE VERSION				
List	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
REALISM TCM Control	!Realism TCM-AT V006-4	Yes/No: _____		

SOFTWARE VERSION				
Software				
DAQ PLC Program	PLC-001-01	Yes/No: _____		
GUI	Integrated_TCM_GUI_V4	Yes/No: _____		
Operating System	Windows 7 Pro SP1 00371-OEM-9046234-43104	Yes/No: _____		
Lab View	2013 SP1 13.0.1f2 32Bit	Yes/No: _____		
A backup of the REALISM TCM Control Software has been supplied? Yes ☐ No ☐ Verified By / Date:				
Actual result meets acceptance criteria: Yes / No:_____				

SOFTWARE VERSION			
Comments:			
Completed By:		**Date:**	

	Test Name:
	8.6 **Equipment Installation Verification**

Purpose:

To confirm components listed below match the installed components in the REALISM TCM.

Test execution:

1) Inspect and document the equipment components listed below against the installed equipment. Determine if the installed equipment matches the specified requirement; document the verification method; initial and date the entry.
2) Documents used for verification are to be attached.

Acceptance criteria:

A documented walk down of the mechanical and electrical systems has been completed.

EQUIPMENT INSTALLATION VERIFICATION

Description	Expected / Acceptance Criteria	Acceptance Criteria Met Yes/No If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	Pass / Fail	Verified by / Date
3 Component Force Sensor	KISTLER 9017B (4930CHF)	Yes/No: _____		
Force Sensor Connecting cable	KISTLER 1694A5 (527 CHF)	Yes/No: _____		
Force Sensor Breakout Box	KISTLER 5407A	Yes/No: _____		
Force Sensor Industrial Charge Amplifier	KISTLER 5073A311 (1235 CHF)	Yes/No: _____		
Force Sensor · Preloading Key	KISTLER 9463 (309 CHF)	Yes/No: _____		
Acoustic Emission Sensor	Piezoceramic Acoustic Emission Sensor KISTLER 8152B111 – (50-400kHz)	Yes/No: _____		
Acoustic Emission Sensor Connecting Cable	KISTLER 1601V	Yes/No: _____		

EQUIPMENT INSTALLATION VERIFICATION				
Description	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Acoustic Emission Sensor Piezotron Coupler	KISTLER typ 5125B1	Yes/No: _____		
3-Component Accelerometer	PCB PIEZOTRONICS typ 356A16 - Triaxial, high sensitivity, ceramic shear ICP® accelerometer, 100 mV/g, 0.5 to 5k Hz, measurement Range ±50 g pk	Yes/No: _____		
3-Component Accelerometer Connecting Cable	KISTLER 1784B3K03	Yes/No: _____		
3-Component Accelerometer Piezotron Coupler	KISTLER 5108A	Yes/No: _____		
Data Acquisition – Data Card	National Instruments BNC-2110 Data Card	Yes/No: _____		

EQUIPMENT INSTALLATION VERIFICATION				
Description	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Data Acquisition - Cable	Shielded: SHC68-68-EPM Cable	Yes/No: _____		
Data Acquisition - DAQ	National Instruments PCIe-6351 DAQ	Yes/No: _____		
Data Acquisition – Profibus Master Slave Interface	78061-01PCI Profibus	Yes/No: _____		
Data Acquisition – Programmable Logic Controller	Siemens LOGO! 12/24 RC	Yes/No: _____		
Data Acquisition – 6 No. Relays	6 Omron MY4IN Relays	Yes/No: _____		
Data Acquisition – Cable Blocks	21 Pheonix Contact Cable Blocks	Yes/No: _____		

EQUIPMENT INSTALLATION VERIFICATION				
Description	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Data Acquisition – Circuit Breaker	Schneider C4 IC60	Yes/No: _____		
Industrial Portable Computer	Elmatic Psi ACME Portable Computer Chassis 17.3", 16:9 Display 1920 x 1080 2x PCI-E x16 128GB SSD 2TB HDD USB 3.0 1Gb Ethernet Serial No – ELM00KP7711 Serial No – AEP14D0055	Yes/No: _____		
Data Server	DS414 Synolgy	Yes/No: _____		
Human Machine Interface	19" SXGA TFT LCD with Touchscreen	Yes/No: _____		

EQUIPMENT INSTALLATION VERIFICATION				
Description	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Actual result meets acceptance criteria: Yes / No:_____				
Comments:				
Completed By:		**Date:**		

	Test Name:
	8.7 Documentation Verification

Purpose:

To provide a comprehensive listing of the documentation for the REALISM TCM, and to verify that all the relevant documentation is available and reviewed.

Test execution:

1) Check the availability of the following documents. If N/A, explain the reason in the comments section.

Acceptance criteria:

The documents listed below are available, readable, in English language and reflect (or have been redlined, if necessary, to reflect) the current status of the equipment.

DOCUMENTATION VERIFICATION					
Type or Doc. #	**Title / Description**	**Satisfactory (Yes\No)**	**Location**	**Revision**	**Verified by / Date**
TCM-FMEA-001-01	FMEA – REALISM TCM				

DOCUMENTATION VERIFICATION					
Actual result meets acceptance criteria: Yes / No:_____					
Comments:					
Completed By:		**Date:**			

	TEST NAME:
	8.8 **Drawing Verification**

Purpose:

The purpose of this test is to verify that the Electrical Drawings accurately reflect the installed REALISM TCM

Test execution:

1) Obtain a copy of the current revision of the drawings listed below.
2) Record the revision of the drawing in the “Revision No.” box.
3) Verify the Drawings against the actual installation.
4) Mark up the Drawings if necessary, sign and date it and attach it to this document.

Acceptance criteria:

The Drawings accurately reflect the REALISM TCM.

Any drawings, which have been redlined to accurately reflect the installed system, are signed, dated and the original red-lined, marked-up drawings are attached to this protocol.

DRAWING VERIFICATION			
Drawing Number	**Revision Number**	**Pass / Fail**	**Verified by / Date**
DAQ Elec 001	1		
Actual result meets acceptance criteria:			

DRAWING VERIFICATION			
Yes / No:_____			
Comments:			
Completed By:		**Date:**	

	TEST NAME:
	8.9 **Standard Operating Procedures Verification**

Purpose:

To verify that all relevant SOP's been generated / updated to reflect the introduction of the REALISM TCM (Draft SOP's are **NOT** acceptable for IOPQ).

Test execution:

1) Verify that all relevant SOP's been generated / updated to reflect the introduction of the REALISM TCM.

Acceptance criteria:

All SOP's been generated / updated to reflect the introduction of the REALISM TCM.

STANDARD OPERATING PROCEDURES VERIFICATION					
SOP #	**Title**	**SOP(s) Required (Yes / No)**	**Effective SOP Available? (Yes /**	**Revision Number**	**Verified by / Date**

STANDARD OPERATING PROCEDURES VERIFICATION				
Have all relevant SOP's been generated / updated to reflect the introduction of the REALISM TCM?	**Yes/No**		**Verified by / Date**	
Actual result meets acceptance criteria: Yes / No:_____				
Comments:				
Completed By:		**Date:**		

	TEST NAME:

8.10 Verification of Utility Supply and Installation

Purpose:

Utilities that are required for the continuous operation of equipment are considered support utilities. Without them the system would not operate properly. This test verifies that required support utilities are correctly installed.

Test execution:

1) List all required utilities and their critical specifications.
2) Verify all utilities are connected properly per instructions.
3) Confirm that quantities/capacities supplied meet with user requirements.

Acceptance criteria:

All specified utility features meet specification requirements.

Component	Applicable	Not Applicable
Electrical and/or Network Connection	☒	☐
Compressed Air	☐	☒
Potable Water	☐	☒
Deionised Water	☐	☒

STANDARD OPERATING PROCEDURES VERIFICATION

STANDARD OPERATING PROCEDURES VERIFICATION						
IOPQ Ref #	**Service**	**Characteristics**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
1.	Electrical Supply	Voltage :	24V ±5% Result: _____V	Yes/No: _____		
		Phase:	1	Yes/No: _____		
		Amperage:	29A (Full Load) Result: _____A	Yes/No: _____		

STANDARD OPERATING PROCEDURES VERIFICATION						
2.	Network Connections	No. of LAN Drops Installed:	1	Yes/No: _____		
Actual result meets acceptance criteria: Yes / No:_____						
Comments:						
Completed By:				**Date:**		
	TEST NAME:					
	8.11 **Safety Feature Verification**					
Purpose:						

STANDARD OPERATING PROCEDURES VERIFICATION
The purpose of this test is to verify that the EHS requirements associated with the REALISM TCM are operating correctly.
Test execution: 1) Verify that the system responds to abnormal events and the associated safety features are activated following the abnormal event.
Acceptance criteria: System satisfactorily responds to abnormal event.

SAFETY FEATURE VERIFICATION				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Ensure the REALISM TCM is running as per normal operation.	REALISM TCM is running	Yes/No: _____		

SAFETY FEATURE VERIFICATION				
Simulate a Catastrophic Tool Failure (CTF) condition.	The REALISM TCM sends a signal to the CNC machine and stops the machining operation.	Yes/No: _____		
Reset the REALISM TCM CTF fault and restart the machining operation.	REALISM TCM and the CNC machine are running.	Yes/No: _____		
Allow 5 minutes to pass.	System running for 5 minutes	Yes/No: _____		
Actual result meets acceptance criteria: Yes / No:_____				
Comments:				
Completed By:		**Date:**		

9.0 Operational Qualification

The purpose of this Operational Qualification is to establish, by field-testing, that the REALISM TCM is functioning according to acceptable operating parameters. The Operational Qualification is a testing procedure that allows for the evaluation of the specific system. Standard tests are conducted to verify proper operation. Controls are adjusted during this phase of testing to verify operation in accordance with design specifications. This testing is documented using the following test sheets.

	Test Name:
	9.1 **Startup / Shutdown / Loss of Power**

Purpose:

To ensure the REALISM TCM starts up and shuts down as per design intent.

Test execution:

1) Ensure the REALISM TCM is running as per normal operation. Shut down the REALISM TCM and all associated components.
2) Allow 5 minutes to pass. Restart the REALISM TCM and all associated components.
3) Allow 5 minutes to pass. Record Pass or fail in the relevant box.
4) Simulate a power failure by isolating the electrical supply to the REALISM TCM.
5) Allow 5 minutes to pass.

Acceptance criteria:

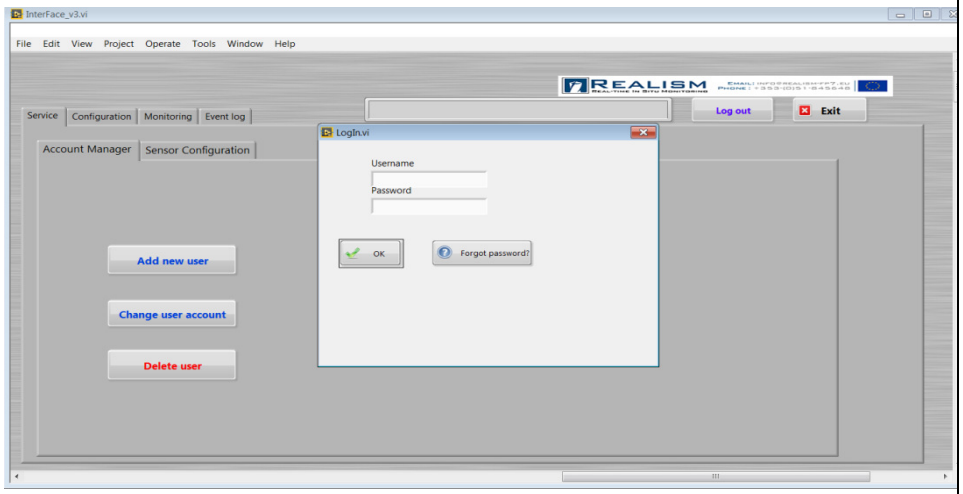
1) System Starts up and shuts down as per design intent.
2) System restarted with no adverse side effects during the power loss simulation test.

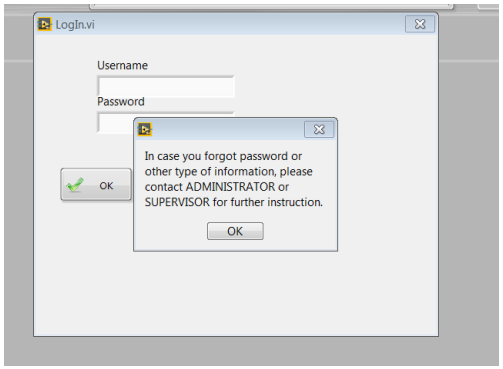
STARTUP / SHUTDOWN / LOSS OF POWER QUALIFICATION

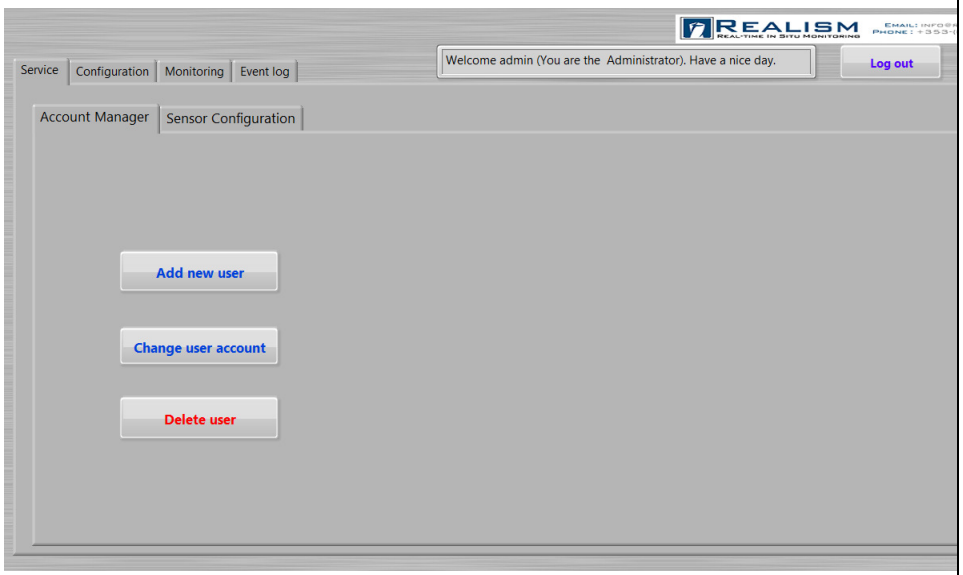
Step	Expected / Acceptance Criteria	Acceptance Criteria Met Yes/No If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	Pass / Fail	Verified by / Date
Ensure the REALISM TCM is running as per normal operation.	REALISM TCM is running	Yes/No: _____		
Shut down the REALISM TCM and all associated components.	REALISM TCM and all associated components is shutdown	Yes/No: _____		
Allow 5 minutes to pass. Restart the REALISM TCM and components.	REALISM TCM & components are restarted after 5 minutes	Yes/No: _____		
Allow 5 minutes to pass.	System running for 5 minutes	Yes/No: _____		
Simulate a power failure by isolating the electrical supply to the REALISM TCM.	REALISM TCM is shutdown	Yes/No: _____		
Allow 5 minutes to pass.	5 minutes passed.	Yes/No: _____		
Reset the power failure and allow 5 minutes to pass. Restart the REALISM TCM and components and	REALISM TCM & components are restarted after 5 minutes and	Yes/No: _____		

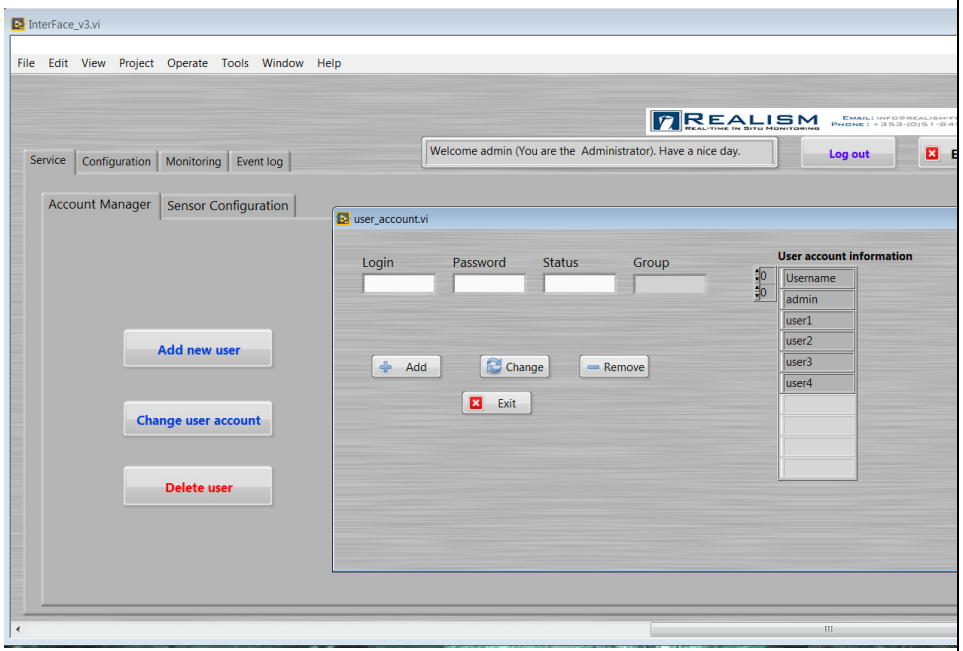
STARTUP / SHUTDOWN / LOSS OF POWER QUALIFICATION				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
allow it to run for 5 minutes.	the system runs for 5 minutes.			
Actual result meets acceptance criteria: Yes / No:_____				
Comments:				
Completed By:		**Date:**		

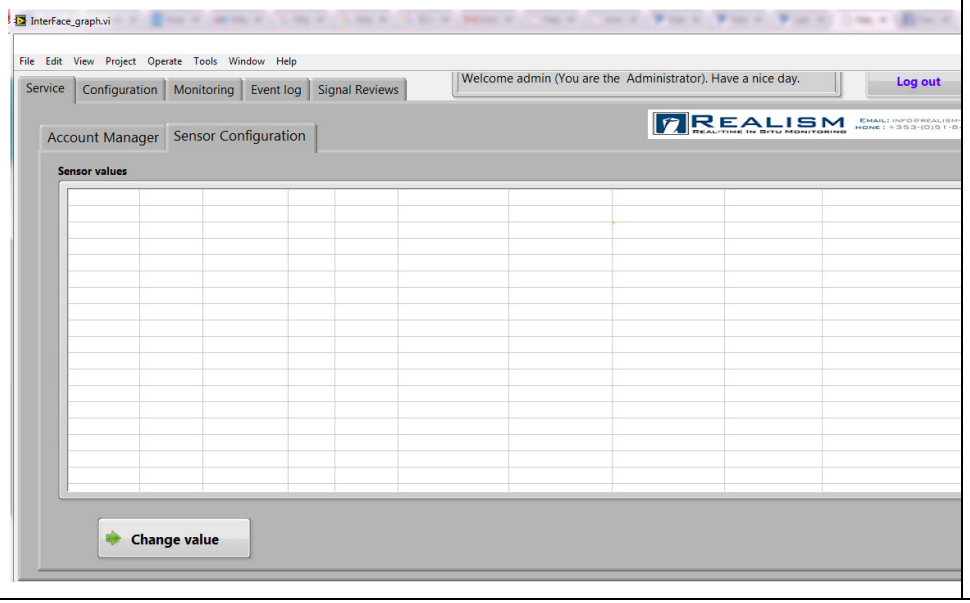
	Test Name:
	9.2 **Graphics Screen Test**
Purpose: To verify that the graphics associated with REALISM TCM are in accordance with the project specifications.	
Test execution: 1) All graphics associated with the REALISM TCM shall be walked down and verified against the installed system. 2) Verify that each jump button operates as expected.	
Acceptance criteria: 1) The graphics associated with REALISM TCM are in accordance with the project specifications.	

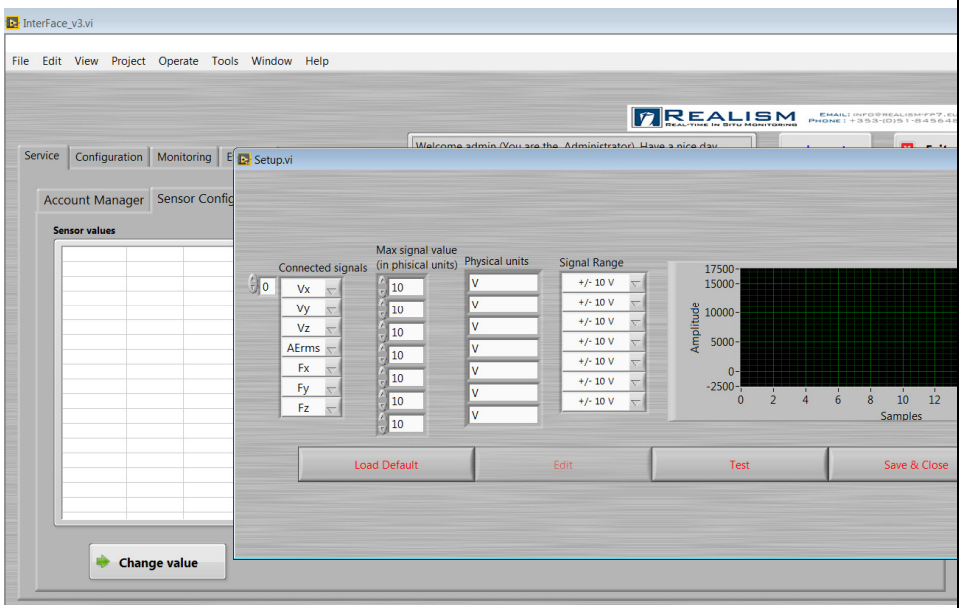
GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Login In		Yes/No: _____		

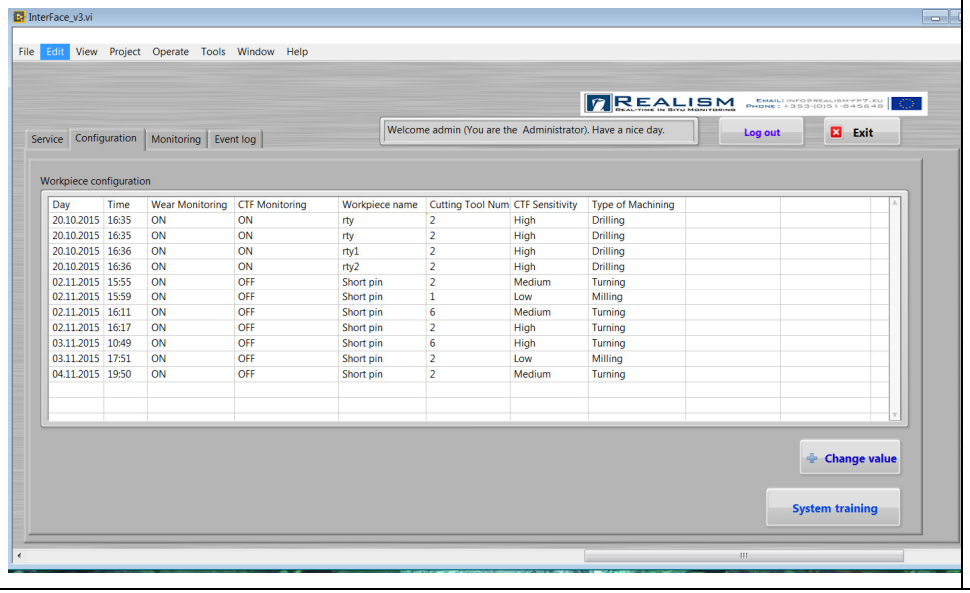
GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Forgot Password		Yes/No: _____		

GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Account Management		Yes/No: _____		

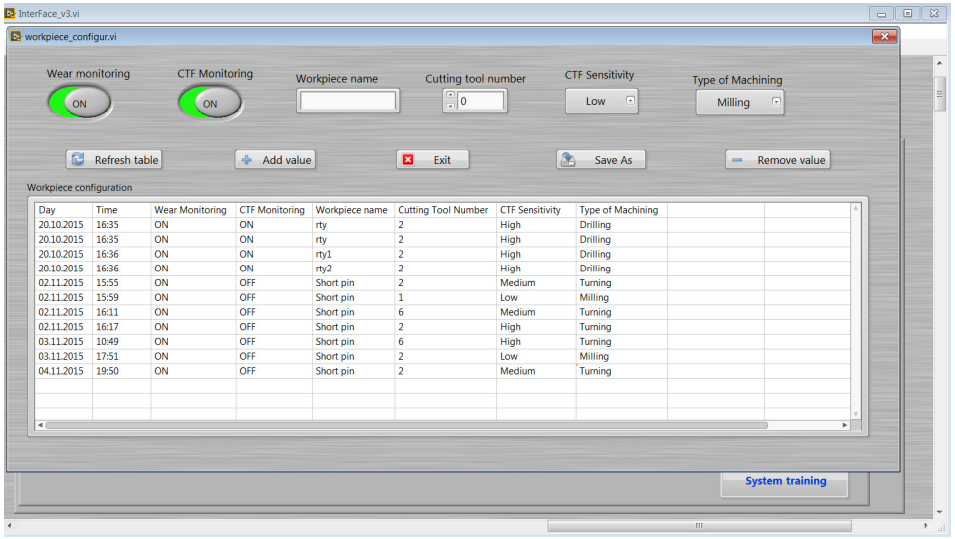
GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Account Manager		Yes/No: _____		

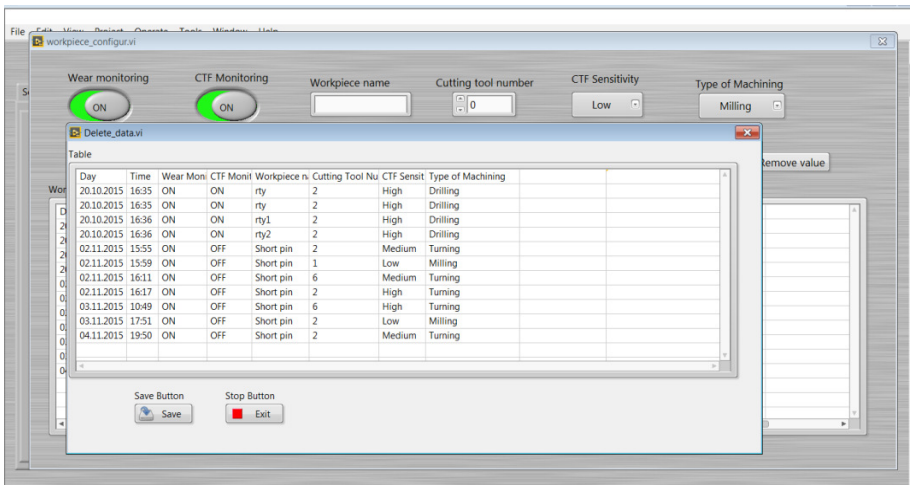
GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Sensor Configuration		Yes/No: _____		

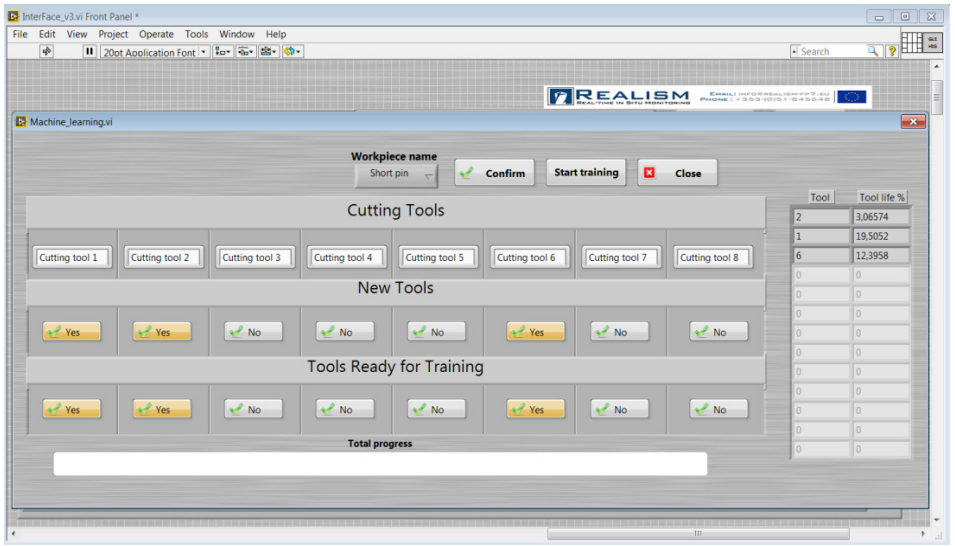
GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Change Sensor Configuration		Yes/No: _____		

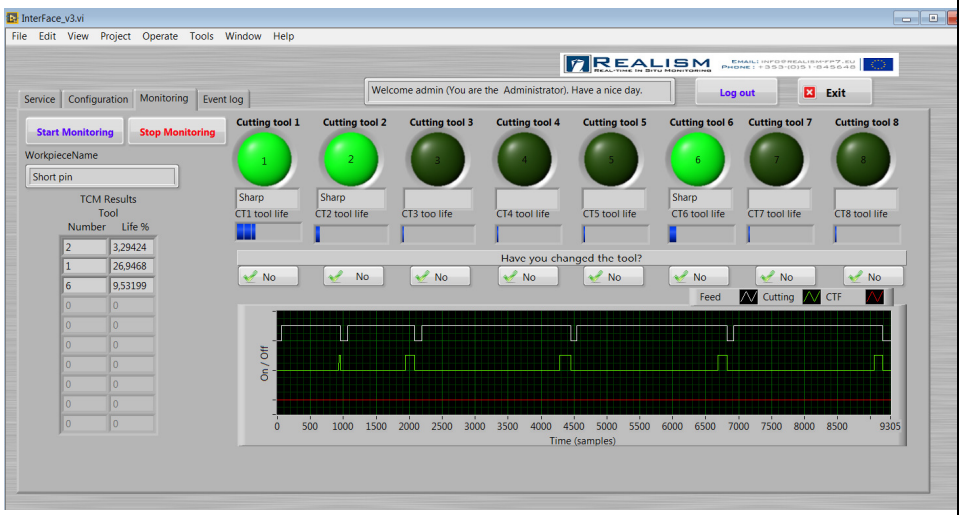
GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Work Piece Configuration & System Training		Yes/No: _____		

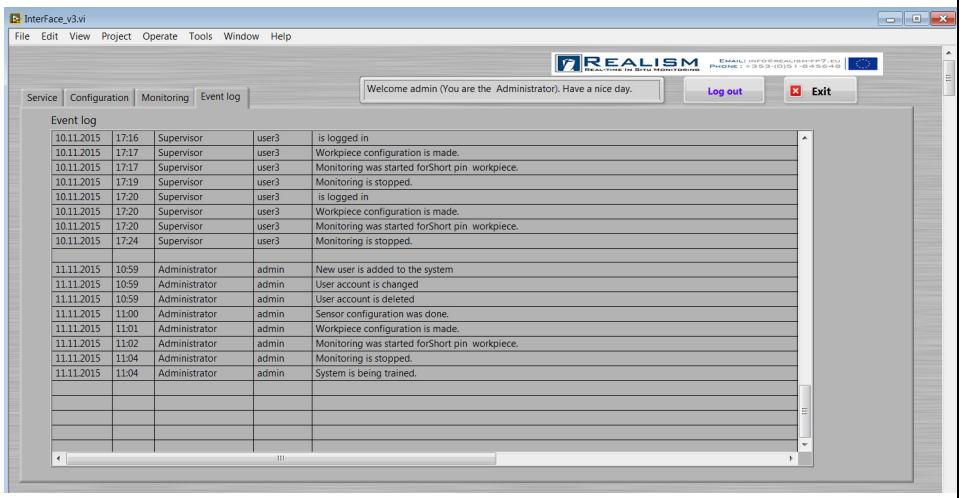
Day	Time	Wear Monitoring	CTF Monitoring	Workpiece name	Cutting Tool Num	CTF Sensitivity	Type of Machining
20.10.2015	16:35	ON	ON	rty	2	High	Drilling
20.10.2015	16:35	ON	ON	rty	2	High	Drilling
20.10.2015	16:36	ON	ON	rty1	2	High	Drilling
20.10.2015	16:36	ON	ON	rty2	2	High	Drilling
02.11.2015	15:55	ON	OFF	Short pin	2	Medium	Turning
02.11.2015	15:59	ON	OFF	Short pin	1	Low	Milling
02.11.2015	16:11	ON	OFF	Short pin	6	Medium	Turning
02.11.2015	16:17	ON	OFF	Short pin	2	High	Turning
03.11.2015	10:49	ON	OFF	Short pin	6	High	Turning
03.11.2015	17:51	ON	OFF	Short pin	2	Low	Milling
04.11.2015	19:50	ON	OFF	Short pin	2	Medium	Turning

GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Change Work Piece Configuration		Yes/No: _____		

GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Delete Work Piece Configuration		Yes/No: _____		

GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
System Training		Yes/No: _____		

GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
System Monitoring		Yes/No: _____		

GRAPHICS SCREEN TEST				
Step	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 4.6 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Event Log		Yes/No: _____		

GRAPHICS SCREEN TEST			
Actual result meets acceptance criteria: Yes / No:_____			
Comments:			
Completed By:		**Date:**	

	Test Name:
	9.3 **User Adjustable Set Point Verification**

Purpose:

To verify that the set points described as user adjustable are available for the user to adjust from the GUI.

Test execution:

1) Verify that each set point can be adjusted from the GUI.

Acceptance criteria:

1) All set points described as user adjustable are available for the user to adjust from the GUI.

USER ADJUSTABLE SET POINT VERIFICATION					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
1	Using the GUI screen shots from test 9.2, verify that all user adjustable set points are available for the user to adjust from the GUI.	All set points described as user adjustable are available for the user to adjust from the GUI.	Yes/No: _____		
Actual result meets acceptance criteria: Yes / No:_____					

USER ADJUSTABLE SET POINT VERIFICATION			
Comments:			
Completed By:		**Date:**	

	Test Name:
	9.4 **Data Logging Test**

Purpose:

To verify that the data logging associated with the REALISM TCM operates in accordance with the project specifications.

Test execution:

1) Verify that each event is being logged in the REALISM TCM log file.

Acceptance criteria:

1) All data logging associated with the REALISM TCM operates in accordance with the project specifications.

DATA LOGGING TEST					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
1	Open the event log window.	Event Log window is open	Yes/No: _____		
2	Browse to the following directory and confirm the event log file exists C:\Realism Data\ Eventlog	Event Log file exists	Yes/No: _____		
3	Compare the content of the Event Log File against the Event Log	Contents are the same	Yes/No: _____		
	Trigger additional events by logging in and out of the system and confirm that the additional events are captured	Additional events are captured and contents of the event log and event log file are the same.	Yes/No: _____		

DATA LOGGING TEST			
Actual result meets acceptance criteria: Yes / No:_____			
Comments:			
Completed By:		**Date:**	

	Test Name:
	9.5 **PLC Input / Output Testing**

Purpose:

To verify that the PLC controller software, in the DAQ panel, is operating per design intent.

Test execution:

2) Simulate the conditions outlined in the test steps below.
3) Verify that the outputs from the simulated conditions meet with acceptance criteria.

Acceptance criteria:

2) Outputs from the simulated conditions meet with acceptance criteria.

PLC INPUT / OUTPUT TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
1	Ensure the REALISM TCM is running as per normal operation.	REALISM TCM is running	Yes/No: _____		
2	Apply 24V to the coolant pump relay.	The relay switches closed and P0.1 turns ON (green) on the GUI	Yes/No: _____		
3	Apply 24V to the M402 relay.	The relay switches closed and immediately open again. P0.6 turns ON (green) on the GUI	Yes/No: _____		
4	Apply 24V to the M400 Cut Start relay.	The relay switches closed and immediately open again. P0.0 turns ON (green) on the GUI	Yes/No: _____		
5	Apply 24V to the M401 Cut Feed End relay.	The relay switches closed and immediately open again. P0.0 turns OFF on the GUI	Yes/No: _____		

PLC INPUT / OUTPUT TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
6	Apply 24V to the Turret Unclamp Solenoid relay.	The relay switches closed and P0.6 turns ON (green) on the GUI	Yes/No: _____		
7	Apply 24V to the M402 and M403 relays.	The relays switch closed and immediately open again. P0.6 turns OFF and P0.3 turns ON (green) on the GUI	Yes/No: _____		
8	Remove 24V to the Turret Unclamp Solenoid relay.	The relay switches open and P0.6 turns OFF on the GUI	Yes/No: _____		
9	Apply 24V to the M400 Cut Start relay.	The relay switches closed and immediately open again. P0.0 turns ON (green) on the GUI	Yes/No: _____		
10	Apply 24V to the M401 Cut Feed End relay.	The relay switches closed and immediately open again. P0.0 turns OFF on the GUI	Yes/No: _____		

PLC INPUT / OUTPUT TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
11	Apply 24V to the Turret Unclamp Solenoid relay.	The relay switches closed and P0.6 turns ON (green) on the GUI	Yes/No: _____		
12	Remove the 24V to the M402 relay.	The relay switches closed and immediately open again. P0.4 turns ON (green) and P0.3 turns OFF on the GUI	Yes/No: _____		
13	Remove 24V to the Turret Unclamp Solenoid relay.	The relay switches open and P0.6 turns OFF on the GUI	Yes/No: _____		
14	Apply 24V to the M400 Cut Start relay.	The relay switches closed and immediately open again. P0.0 turns ON (green) on the GUI	Yes/No: _____		
15	Apply 24V to the M401 Cut Feed End relay.	The relay switches closed and immediately open again. P0.0 turns OFF on the GUI	Yes/No: _____		

PLC INPUT / OUTPUT TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
16	Apply 24V to the Turret Unclamp Solenoid relay.	The relay switches closed and P0.6 turns ON (green) on the GUI	Yes/No: _____		
17	Remove the 24V to the M402 relay.	The relay switches closed and immediately open again. P0.4 turns OFF on the GUI	Yes/No: _____		
18	Remove 24V to the Turret Unclamp Solenoid relay.	The relay switches open and P0.6 turns OFF on the GUI	Yes/No: _____		
19	Remove 24V to the coolant pump relay.	The relay switches open and P0.1 turns OFF on the GUI	Yes/No: _____		
Actual result meets acceptance criteria: Yes / No:_____					

PLC INPUT / OUTPUT TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
Comments:					
Completed By:		**Date:**			

10.0 Performance Qualification

The purpose of this Performance Qualification is to establish, by field-testing, that the REALISM TCM is functioning according to acceptable operating parameters. The Performance Qualification is a testing procedure that allows for the evaluation of the specific system. Standard tests are conducted to verify proper operation. This testing is documented using the following test sheets.

	Test Name:
	10.1 **Integrated Software Testing**

Purpose:

To verify that the integrated REALISM TCM software package is operating per design intent.

Test execution:

1) The REALISM TCM will be tested offline using pre-recorded banks of test data.
2) Simulate Catastrophic Tool Failure (CTF) and Tool Wear using the test steps outlined below.
3) Verify that the outputs from the simulated conditions meet with acceptance criteria.

Acceptance criteria:

Outputs from the simulated conditions meet with acceptance criteria.

Note: System will be tested with offline data gathered from system trials (Copies of the data will be attached to this test script for use during testing). Additionally file "Tool Wear Measurements organised TCM-AT v006-4.xlsx" shall be attached for reference.

SOFTWARE INTEGRATION TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
1	Switch the REALISM TCM to Offline Mode.	The realism TCM is in offline mode.	Yes/No: _____		
2	Reset the tools ready for training and new tools buttons on the REALISM TCM GUI.	All buttons are reset.	Yes/No: _____		
3	Enter the work piece name as "Schivo Test".	Work piece name is entered as "Schivo Test".	Yes/No: _____		
4	Switch the system to training mode.	System is switched to training mode.	Yes/No: _____		
5	Using the attached file "Tool Wear Measurements_organised TCM-AT v006-4.xlsx" set up the Tools Ready for	Tools Ready for Training and New Tools toggle buttons for tools 4, 8 & 12 are configured in accordance with tool lives 1 to	Yes/No: _____		

SOFTWARE INTEGRATION TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
	Training and New Tools toggle buttons for tools 4, 8 & 12 in accordance with tool lives 1 to 3 (identified as training on "Tool Wear Measurements_organised TCM-AT v006-4.xlsx"). Simulate a Catastrophic Tool Failure (CTF) condition in the control software.	3 from "Tool Wear Measurements_organised TCM-AT v006-4.xlsx"			
6	Switch the system to monitoring mode.	System is in monitoring mode.	Yes/No: _____		
7	Run 2 trials for Turning, Boring and Drilling, at random intervals record the actual tool wear and the tool wear value predicated by the system.	2 trials have been completed. Actual results have been measured using an optical microscope and predicted values have been recorded from the TCM.	Yes/No: _____		

SOFTWARE INTEGRATION TESTING					
Item	**Test Step**	**Expected / Acceptance Criteria**	**Acceptance Criteria Met** **Yes/No** If 'No' or if actual differs from acceptance criteria a comment must be included and/or DR raised as per Section 3.2.5 of this protocol. If expected result is unknown then actual result must be documented in relevant box below.	**Pass / Fail**	**Verified by / Date**
8	Complete a R-Sq test on the data and confirm pass/fail based on the following pass criteria P-value < 0.05 and R-Sq > 70%.	Results have been recorded and analysed.	Yes/No: _____		

SOFTWARE INTEGRATION TESTING
Actual result meets acceptance criteria: Yes / No:_____

SOFTWARE INTEGRATION TESTING			
Comments:			
Completed By:		**Date:**	

	Test Name:
	10.2 **Additional Testing**
Additional testing can be used to challenge the system in detail against specified functional requirements currently outside the scope of the IOPQ.	
Purpose: **SHEET _____ OF_____** **(Photocopy as required)**	
Test execution:	
Acceptance criteria:	

ADDITIONAL TESTING				
Step	**Expected**	**Actual**	**Pass / Fail**	**Verified by / Date**

ADDITIONAL TESTING				
Actual result meets acceptance criteria: Yes / No:_____				
Comments:				
Completed By:		**Date:**		

11.0 IOPQ Summary Report

Summary Report

	INSTALLATION, OPERATIONAL PERFORMANCE QUALIFICATION FOR REALISM TCM Tool Condition Monitoring	REALISM Real-time In Situ Monitoring Version 2.0

Prepared By: _____ _____

Author Date

12.0 Post-Approval

12.1 Review Process

Review item	Review Objective
R1	Verify that this IOPQ has been completed correct and accurately
R2	Verify review of and acceptance of the findings of this IOPQ report

12.2 Post-Approval Signatures

The undersigned have reviewed and approved the IOPQ testing report, including all deviations in Section 12.

The REALISM TCM is deemed suitable for use.

Prepared by: _____ _____ Date Signature of the Professional Responsible for preparing the document and agreement with R1.
Reviewed by: _____ _____ Date Signature indicates agreement with review items R3.
Approved by: _____ _____ Date Signature indicates agreement with review item R2& R3.
Approved by: _____ _____ Date Signature indicates agreement with review item R2 & R3.

13.0 Deviation Report

13.1 Deviation Resolution Sheet

(Copy as required) Sheet _____ of _____

Deviation		**DR No.**	
Recorded by:		**Date:**	
Deviation Resolution			
Recorded by:		**Date:**	
Reviewed by:		**Date:**	

14.0 Deviation Log

(Copy as required) Sheet _____ of _____

Deviation No.	Deviation Resolution Summary		Completed By & Date
Completed by:		**Date:**	

15.0 Attachments

(Copy as required) Sheet _____ of _____

Attachment No.	Document		Sign & Date
Completed by:		**Date:**	

8.2 Appendix B – Risk Assessment (FMEA)

FAILURE MODE AND EFFECTS ANALYSIS

PROB = LIKELIHOOD THAT A PARTICULAR CAUSE WILL OCCUR THAT WILL LEAD TO THE FAILURE, TIED TO THE END EFFECT AND THE CAUSE, AND PREVENTION PROCESS CONTROLS
SEV = SEVERITY OF FAILURE EFFECT
DET = LIKELIHOOD OF FAILURE NOT BEING DETECTED BY CURRENT PROCESS CONTROLS
RISK PRIORITY NUMBER (RPN) = SEV x PROB x DET PROBABILITY*SEVERITY # = PROB*SEV

FMEA No. :	TCM-FMEA-001-01	Issue Date :	08/12/2015
Attendees :	Barry Ronan, Jonathan Downey, Denis O'Sullivan		

ITEM#	PROCESS FUNCTION	PROCESS REQUIREMENT	POTENTIAL FAILURE MODE (HOW)	POTENTIAL EFFECT OF FAILURE (WHAT)	SEV	POTENTIAL CAUSE(S)/ MECHANISM OF FAILURE	CURRENT PROCESS CONTROL PREVENTION	PROB	CURRENT PROCESS CONTROL DETECTION	DET	RPN	RISK	RECOMMENDED ACTION(S)	ASSIGNED TO	ACTION TAKEN/ ALARP JUSTIFICATION	Control Method	Open/ Closed	RESULTING CONDITION					
																		SEV	PROB	DET	RPN	RISK
1	**3-Component Force Sensor**																					
	Sensor - KISTLER 9017B (4930CHF)	Senses forces in 3 axis - XYZ	Cracked piezo element	Signal loss	2	Overloaded during pre-load	Follow installation instruction	2	Loss of signal	1	4	AC										
			Corrosion on connection pins due to collant ingress	Poor signal	1R	Coolant ingress - Poor connection	Sealed unit & Sensor Loaction	1	Poor signal	2	2R	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Damage during machining - Swarf/Workpiece	Poor/No signal	2	Swarf/Lose workpiece	Sensor location	1	Poor signal	1	2	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	2	6R	AL-R										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Connecting cable - KISTLER 1694A5 (527 CHF)	Transmit signal from sensor to Charge Amplifier	Open circuit	No Signal	2	Handling/Installation Damage	Armoured Cable	1	Loss of signal	1	2	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Armoured Cable	3	Poor signal	1	6	AC										
			Damage during machining - Swarf/Workpiece	Poor/No signal	2	Swarf/Lose workpiece	Sensor location	1	Poor signal	2	4	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	Armoured Cable	2	Poor signal	1	2R	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Kistler Breakout Box 5407A	Splits force sensor signal into 3 feeds	Open circuit	No Signal	2	Handling/Installation Damage	Armoured Cable	1	Loss of signal	1	2	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Armoured Cable	3	Poor signal	1	6	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	Armoured Cable	2	Poor signal	1	2R	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Cable Armour	Protect cable from damage	Caught in slideway of machine	Cable exposed to damage	1R	Caught in slideway of machine	Careful installation	2	No detection	5	10R	AL-R										
	Industrial Charge Amplifier - KISTLER 5073A311 (1235 CHF)	Aplifies sensor signal	Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	2	12	AL-S										
			Short circuit	No Signal	1R	Handling/Installation Damage	None	2	Poor/No Signal	2	4R	AC										
			Faulty unit supplied	Poor/No signal	2	Faulty product	Incoming test	2	Poor/No Signal	2	8	AC										
			Internal component failure	No Signal	1R	Faulty component	None	2	Poor/No Signal	2	4R	AC										
	Preloading Key – KISTLER 9463 (309 CHF)	Preloads sensor during installation to 1kN	Preloaded incorrectly	Offset signal	1R	Poor installation	Follow installation instruction & Monitor preload	2	Monitor preload on computer	1	2R	AC										
			Faulty unit supplied	Unable to function	1	Faulty product	None	3	Visual Inspection	1	3	AC										
2	**Acoustic emission sensor:**																					
	Piezoceramic Acoustic Emission Sensor KISTLER 8152B111 – (50-400kHz)	Senses acoustic emmission signals	Cracked element	Signal loss	2	Overloaded during pre-load	Follow installation instruction	2	Loss of signal	1	4	AC										
			Corrosion on connection pins due to collant ingress	Poor signal	1R	Coolant ingress - Poor connection	Follow installation instruction	1	Poor signal	2	2R	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Damage during machining - Swarf/Workpiece	Poor/No signal	2	Swarf/Lose workpiece	None	3	Poor signal	1	6	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	2	6R	AL-R										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Connecting cable	Transmit signal from sensor to Piezotron Coupler	Open circuit	No Signal	2	Handling/Installation Damage	Follow installation instruction	1	Loss of signal	1	2	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Damage during machining - Swarf/Workpiece /Coolant	Poor/No signal	2	Swarf/Lose workpiece	None	3	Poor signal	2	12	AL-S										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Braided Cable	3	Poor signal	1	3R	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	Follow installation instruction	2	Poor signal	1	2R	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Piezotron Coupler - KISTLER typ 5125B1	Suppy and Amplifies signals to DAQ unit	Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	None	3	Poor signal	1	3R	AC										
			Internal component failure	No Signal	1R	Faulty component	None	2	Poor/No Signal	2	4R	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
			Supply voltage failure	No Signal	1R	Voltage Failure	None	3	No Signal	1	3R	AC										
3	**3-Component Accelerometer**																					
	PCB PIEZOTRONICS typ 356A16 - Triaxial, high sensitivity, ceramic shear ICP® accelerometer, 100 mV/g, 0.5 to 5k Hz, measurement Range ±50 g pk	Senses vibration signals	Broken resistor	Signal loss	2	Impact Damage	Careful handling	1	Loss of signal	1	2	AC										
			Corrosion on connection pins due to collant ingress	Poor signal	1R	Coolant ingress - Poor connection	Unit sealed with sealant	4	Poor signal	2	8R	AL-R										
			Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Damage during machining - Swarf/Workpiece	Poor/No signal	2	Swarf/Lose workpiece	None	3	Poor signal	1	6	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	2	6R	AL-R										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Connecting cable	Transmit signal from sensor to 3 Channel signal conditioner	Open circuit	No Signal	2	Handling/Installation Damage	None	3	Loss of signal	1	6	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Damage during machining - Swarf/Workpiece /Coolant	Poor/No signal	2	Swarf/Lose workpiece	None	3	Poor signal	2	12	AL-S										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	None	3	Poor signal	1	3R	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Kistler 5108A Piezotron Coupler	Condition, Supply and Amplifies signals to DAQ unit	Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	None	3	Poor signal	1	3R	AC										
			Internal component failure	No Signal	1R	Faulty component	None	2	Poor/No Signal	2	4R	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
			Supply voltage failure	No Signal	1R	Voltage Failure	None	3	No Signal	1	3R	AC										
4	**Data acquisition:**																					
	NI BNC-2110 Data Card	Taking inputs from sensors and transferring to computer	Internal component failure	No Signal	2	Faulty component	None	3	Poor/No Signal	1	6	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
		Supplys output voltage to auxillary sensors and relays	Internal component failure	No Signal	2	Faulty component	None	3	Poor/No Signal	1	6	AC										
			Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
	Cable – Shielded: SHC68-68-EPM Cable (2m)	Transmit signal from DAQ to Computer	Open circuit	No Signal	2	Handling/Installation Damage	None	3	Loss of signal	1	6	AC										
			Damage during installation	Poor/No signal	2	Poor installation	Follow installation instruction	3	Poor signal	1	6	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
			Short circuit	No Signal	1R	Handling/Installation Damage	None	3	Poor signal	1	3R	AC										

ITEM#	PROCESS FUNCTION	PROCESS REQUIREMENT	POTENTIAL FAILURE MODE (HOW)	POTENTIAL EFFECT OF FAILURE (WHAT)	SEV	POTENTIAL CAUSE(S)/ MECHANISM OF FAILURE	CURRENT PROCESS CONTROL PREVENTION	PROB	CURRENT PROCESS CONTROL DETECTION	DET	RPN	RISK	RECOMMENDED ACTION(S)	ASSIGNED TO	ACTION TAKEN/ ALARP JUSTIFICATION	Control Method	Open/ Closed	RESULTING CONDITION				
																		SEV	PROB	DET	RPN	RISK
	NI PCIe-6351 DAQ		Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
		Transmit signal from DAQ to Computer and converts to logival values from voltages	Internal component failure	No Signal	2	Faulty component	None	3	Poor/No Signal	1	6	AC										
	PCI Profibus Master Slave Interface		Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
		Interfaces between DAQ and Internal computer system bus	Internal component failure	No Signal	2	Faulty component	None	3	Poor/No Signal	1	6	AC										
	Siemens LOGO! 12/24 RC		Faulty unit supplied	No Signal	2	Faulty product	Incoming test	2	Poor signal	1	4	AC										
			Electrical noise	Inaccurate signal	1R	Poor grounding	Grounding tested during installation	3	Poor signal	1	3R	AC										
		Conversion of pulse signals from machine to continuous signals for DAQ	No input signal	No Signal	2	Poor connections	Continuty test during installation	2	No signal	1	4	AC										
	6 Omron MY4IN Relays		No output signal	No Signal	2	Poor connections	Continuty test during installation	2	No signal	1	4	AC										
			Power supply failure	No Signal	2	Power supply failure	Power supply verification during installation	2	No signal	1	4	AC										
		Provide logic high signals from machine M-Code block back to DAQ	Open circuit	No Signal	1R	Component Failure	None	2	Loss of signal	1	2R	AC										
	21 Pheonix Contact Cable Blocks		Short circuit	Continuous Signal	1R	Overload	None	2	None	5	10R	AL-R										
		Connect cables between components	Open circuit	No Signal		Component Failure	None		Loss of signal		4	AL-S										
	Schneider C4 IC60		Short circuit	Continuous Signal		Overload	None		None		4	AL-S										
		Protection of mains power	Open circuit	No Power	1	Component Failure	None	2	Loss of Power	1	2	AC										
			Short circuit	Continuous Power	2	Overload	None	2	None	5	20	AL-S										
			Faulty unit supplied	No Power/Continuous Power	2	Faulty product	None	2	None	5	20	AL-S										
5	**Industrial Portable Computer**	Platform for running custom software	Internal component failure	Incorrect/No Analysis of Signal Data	1R	Faulty component	None	2	None	5	10R	AL-R										
			Faulty unit supplied	Incorrect/No Analysis of Signal Data	1R	Faulty product	None	2	None	5	10R	AL-R										
			Lightening/Power Surge	Destruction of Equipment	4	Act of God	Surge Protection & Transformer	1	None	5	20	AL-S										
8	**Custom Control Software**	Taking inputs from DAQ and interpreting to provide feedback to user on degree of tool wear	Poor Programming	Program Error	2	Poor Poramming	Labview Program Software Operating Sytdem Error	2	Erro Message	2	8	AC										
			Corrupted Program	Program Error	2	Acto of God	Labview Program Software Operating Sytdem Error	2	Erro Message	2	8	AC										
			I nvalid Data																			
			Damaged Componets upstream	Output Data Invalid	4	Damaged Upstream Components	Captured Individually Above	1	none	1	4	AL-S										
			Digital Signals Incorrect	Output Data Invalid	4	Damaged Upstream Components	Captured Individually Above	1	none	1	4	AL-S										
			Variability from tooling mechanical propoerties	Output Data Invalid	4	Poor Quality Tooling	None	3	None	4	48	IN	Statistially Analyse tooling data for significant varinace from tool to tool.	Barry Ronan	Tooling statistically analysed using Anova Method. P Values found to be within acceptable tresholds. 99% confident that there is no significant difference between tooling tested.	All tooling purchased from reputable suppliers	Closed	4	1	4	16	AL-S
			Operator Error	Inaccurate output	4	Poor Operator Training	User Manual/SOP - Use of Senior Setter for training of system	1	none	4	16	AL-S										
			Poor System Output																			
			Poor System Training	Output Data Invalid	4	Inconsistant training received by system	None	3	None	4	48	IN	Statistially Analyse operator expectation around degree of toolwear against actual toolwear present.	Barry Ronan	Operator expectation statistically analysed using Anova Method. P Values found to be within acceptable tresholds. 99% confident that there is no significant difference between operator expectation	Senior setter only will be responsible for training the TCM	Closed	4	1	4	16	AL-S
			Incorrect Treshold Paramaters	incorrect output readings	4	Force tresholds set incorrectly	User Manual/SOP - Use of Senior Setter for training of system	1	None	4	16	AL-S										
9	**HMI - 19" SXGA TFT LCD with Touchscreen**	Interface for operator and trainer interaction	Damage during installation	User Unable to interact with system	2	Poor installation	Follow installation instruction	2	System not operable	1	4	AC										
			Internal component failure	User Unable to interact with system	1R	Faulty component	None	2	System not operable	1	2R	AC										
			Faulty unit supplied	User Unable to interact with system	2	Faulty product	Incoming test	2	System not operable	1	4	AC										
			Supply voltage failure	User Unable to interact with system	1R	Voltage Failure	None	3	System not operable	1	3R	AC										
			Power supply failure	No Signal	2	Power supply failure	Power supply verification during installation	2	System not operable	1	4	AC										

8.3 Appendix C – Data Sets

Variation within the Mechanical Properties of the Tooling

Table 8-1: Mechanical Properties Turning Test Data

	Tip 1	Tip 2	Tip 3	Tip 4	Tip 5	Tip 6	Tip 7
20.00%	0.05	0.05	0.06	0.05	0.06	0.05	0.05
40.00%	0.15	0.12	0.22	0.19	0.2	0.12	0.13
60.00%	0.24	0.17	0.29	0.29	0.28	0.26	0.33
80.00%	0.33	0.3	0.31		0.3	0.29	0.36
95.00%	0.36	0.38	0.38		0.38		
100.00%	0.39	0.43	0.42		0.45		

Table 8-2: Mechanical Properties Boring Test Data

	Tip 1	Tip 2	Tip 3	Tip 4	Tip 5	Tip 6	Tip 7
15.00%	0.05	0.06	0.05	0.05	0.04	0.05	0.04
30.00%	0.07	0.07	0.08		0.12	0.07	0.06
50.00%	0.13	0.16	0.13	0.1	0.14	0.12	0.13
60.00%	0.16	0.2	0.19	0.15	0.16		0.15
90.00%	0.21	0.23	0.23		0.23	0.2	0.18
100.00%	0.3	0.3	0.3		0.26	0.26	

Table 8-3: Mechanical Properties Drilling Test Data

	Drill 1	Drill 2	Drill 3	Drill 4	Drill 5	Drill 6
15.00%	0.05	0.06	0.05	0.05	0.04	
25.00%	0.07	0.07	0.08	0.07	0.06	0.06
50.00%	0.13	0.16	0.13	0.08	0.13	0.12
60.00%	0.16	0.2	0.19	0.12	0.15	0.15
85.00%	0.23	0.23	0.2	0.2	0.18	
95.00%	0.27	0.26	0.23	0.25	0.23	
100.00%	0.3	0.3	0.3	0.26	0.26	

Variation within Operator Training

Table 8-4: Operator opinion Turning Test Data

Trial #	Actual Measurement	Operator Opinion
Turning 1	11.90%	20.00%
Turning 1	35.71%	40.00%
Turning 1	57.14%	60.00%
Turning 1	78.57%	80.00%
Turning 1	85.71%	95.00%
Turning 1	92.86%	100.00%
Turning 2	11.90%	20.00%
Turning 2	28.57%	35.00%
Turning 2	40.48%	50.00%

Trial #	Actual Measurement	Operator Opinion
Turning 2	71.43%	80.00%
Turning 2	90.48%	90.00%
Turning 2	102.38%	100.00%
Turning 3	14.29%	20.00%
Turning 3	52.38%	40.00%
Turning 3	69.05%	60.00%
Turning 3	73.81%	80.00%
Turning 3	90.48%	95.00%
Turning 3	100.00%	100.00%
Turning 4	11.90%	20.00%
Turning 4	45.24%	40.00%
Turning 4	69.05%	60.00%
Turning 5	14.29%	20.00%
Turning 5	47.62%	50.00%
Turning 5	66.67%	65.00%
Turning 5	71.43%	80.00%
Turning 5	90.48%	90.00%
Turning 5	107.14%	100.00%
Turning 6	11.90%	20.00%
Turning 6	28.57%	35.00%
Turning 6	45.24%	50.00%
Turning 6	61.90%	60.00%
Turning 6	69.05%	75.00%

Trial #	Actual Measurement	Operator Opinion
Turning 7	11.90%	15.00%
Turning 7	30.95%	40.00%
Turning 7	54.76%	50.00%
Turning 7	78.57%	70.00%
Turning 7	85.71%	80.00%

Table 8-5: Operator opinion Boring Test Data

Trial #	Actual Measurement	Operator Opinion
Boring 1	17.86%	15.00%
Boring 1	25.00%	30.00%
Boring 1	46.43%	50.00%
Boring 1	57.14%	60.00%
Boring 1	82.14%	90.00%
Boring 1	107.14%	100.00%
Boring 2	21.43%	15.00%
Boring 2	25.00%	25.00%
Boring 2	57.14%	50.00%
Boring 2	71.43%	75.00%
Boring 2	82.14%	90.00%
Boring 2	107.14%	100.00%
Boring 3	17.86%	15.00%
Boring 3	28.57%	25.00%
Boring 3	46.43%	40.00%

Trial #	Actual Measurement	Operator Opinion
Boring 3	67.86%	60.00%
Boring 3	82.14%	90.00%
Boring 3	107.14%	100.00%
Boring 4	17.86%	20.00%
Boring 4	35.71%	40.00%
Boring 4	53.57%	60.00%
Boring 5	14.29%	15.00%
Boring 5	42.86%	40.00%
Boring 5	50.00%	50.00%
Boring 5	57.14%	60.00%
Boring 5	71.43%	80.00%
Boring 5	82.14%	90.00%
Boring 5	92.86%	100.00%
Boring 6	17.86%	15.00%
Boring 6	25.00%	30.00%
Boring 6	28.57%	35.00%
Boring 6	42.86%	50.00%
Boring 6	71.43%	80.00%
Boring 6	92.86%	100.00%
Boring 7	14.29%	15.00%
Boring 7	21.43%	20.00%
Boring 7	46.43%	50.00%
Boring 7	53.57%	60.00%

Trial #	Actual Measurement	Operator Opinion
Boring 7	64.29%	70.00%

Table 8-6: Operator opinion Drilling Test Data

Trial #	Actual Measurement	Operator Opinion
Drilling 1	17.86%	15%
Drilling 1	25.00%	25%
Drilling 1	46.43%	50%
Drilling 1	57.14%	60%
Drilling 1	82.14%	85%
Drilling 1	97.62%	95%
Drilling 1	107.14%	100%
Drilling 2	21.43%	15%
Drilling 2	25.00%	25%
Drilling 2	57.14%	50%
Drilling 2	71.43%	70%
Drilling 2	82.14%	85%
Drilling 2	95.24%	95%
Drilling 2	107.14%	100%
Drilling 3	17.86%	15%
Drilling 3	28.57%	30%
Drilling 3	46.43%	50%
Drilling 3	67.86%	60%

Trial #	Actual Measurement	Operator Opinion
Drilling 3	71.43%	70%
Drilling 3	82.14%	80%
Drilling 3	107.14%	100%
Drilling 4	17.86%	15%
Drilling 4	25.00%	25%
Drilling 4	28.57%	35%
Drilling 4	42.86%	50%
Drilling 4	71.43%	75%
Drilling 4	90.48%	85%
Drilling 4	92.86%	100%
Drilling 5	14.29%	15%
Drilling 5	21.43%	25%
Drilling 5	46.43%	40%
Drilling 5	53.57%	55%
Drilling 5	64.29%	60%
Drilling 5	82.14%	85%
Drilling 5	92.86%	100%
Drilling 6	24.36%	25%
Drilling 6	42.86%	50%
Drilling 6	53.57%	55%

Process Qualification - Final Results

Table 8-7: Final Results Turning Test Data

	Tool 4	TCM Results	
	Measured tool wear	Ver 1	Ver 2
Tool 1	17%	40.00%	35.00%
	34%	51.00%	43.00%
	51%	48.00%	60.00%
	68%	86.00%	55.00%
	85%	110.00%	104.00%
	102%	122.00%	101.00%
Tool 2	18%	33.00%	29.00%
	36%	20.00%	27.00%
	54%	49.00%	73.00%
	72%	84.00%	72.00%
	90%	76.00%	59.00%
	100%	65.00%	96.00%
Tool 3	18%	42.00%	29.00%
	36%	61.00%	47.00%
	54%	64.00%	66.00%
	72%	85.00%	84.00%
	90%	62.00%	75.00%
	101%	90.00%	95.00%

Table 8-8: Final Results Boring Test Data

	Tool 8	TCM Results	
	Measured tool wear	Ver 1	Ver 2
Tool 1	14%	6.00%	12.00%
	29%	8.00%	35.00%
	43%	1.00%	41.00%
	57%	10.00%	59.00%
	71%	25.00%	77.00%
	86%	42.00%	91.00%
	100%	88.00%	102.00%
Tool 2	17%	6.00%	14.00%
	34%	4.00%	35.00%
	51%	5.00%	53.00%
	68%	6.00%	64.00%
	85%	16.00%	77.00%
	102%	53.00%	90.00%
Tool 3	17%	7.00%	18.00%
	34%	7.00%	34.00%
	51%	4.00%	46.00%
	68%	19.00%	67.00%
	85%	33.00%	84.00%

Table 8-9: Final Results Drilling Test Data

	Tool 12	TCM results		
	Measured tool wear	Ver 1	Ver 2	Ver 3
Tool 1	14%	110.00%	10.00%	2.00%
	28%	110.00%	15.00%	34.00%
	42%	110.00%	87.00%	49.00%
	56%	103.00%	31.00%	52.00%
	70%	112.00%	13.00%	55.00%
	84%	110.00%	109.00%	85.00%
	98%	111.00%	47.00%	104.00%
Tool 2	14%	16.00%	84.00%	53.00%
	28%	109.00%	24.00%	33.00%
	42%	109.00%	70.00%	42.00%
	56%	112.00%	50.00%	56.00%
	70%	111.00%	93.00%	64.00%
	84%	103.00%	7.00%	81.00%
	98%	110.00%	80.00%	65.00%
Tool 3	33%	112.00%	39.00%	35.00%
	66%	110.00%	81.00%	47.00%
	99%	106.00%	8.00%	19.00%
	101%	16.00%	121.00%	90.00%

Comparison of Measured vs Operator vs ΔT = tc/T

Table 8-10: Measured vs Operator vs ΔT = tc/T Turning Data

Trial #	Actual Measurement	Operator Opinion	tc/T
Turning 1	11.90%	20.00%	17.00%
Turning 1	35.71%	40.00%	34.00%
Turning 1	57.14%	60.00%	51.00%
Turning 1	78.57%	80.00%	68.00%
Turning 1	85.71%	95.00%	85.00%
Turning 1	92.86%	100.00%	102.00%
Turning 2	11.90%	20.00%	17.00%
Turning 2	28.57%	35.00%	34.00%
Turning 2	40.48%	50.00%	51.00%
Turning 2	71.43%	80.00%	68.00%
Turning 2	90.48%	90.00%	85.00%
Turning 2	102.38%	100.00%	102.00%
Turning 3	14.29%	20.00%	17.00%
Turning 3	52.38%	40.00%	34.00%
Turning 3	69.05%	60.00%	51.00%
Turning 3	73.81%	80.00%	68.00%
Turning 3	90.48%	95.00%	85.00%
Turning 3	100.00%	100.00%	102.00%
Turning 4	11.90%	20.00%	17.00%
Turning 4	45.24%	40.00%	34.00%
Turning 4	69.05%	60.00%	51.00%

Trial #	Actual Measurement	Operator Opinion	tc/T
Turning 5	14.29%	20.00%	17.00%
Turning 5	47.62%	50.00%	34.00%
Turning 5	66.67%	65.00%	51.00%
Turning 5	71.43%	80.00%	68.00%
Turning 5	90.48%	90.00%	85.00%
Turning 5	107.14%	100.00%	102.00%
Turning 6	11.90%	20.00%	17.98%
Turning 6	28.57%	35.00%	35.96%
Turning 6	45.24%	50.00%	53.95%
Turning 6	61.90%	60.00%	71.93%
Turning 6	69.05%	75.00%	89.91%
Turning 7	11.90%	15.00%	17.98%
Turning 7	30.95%	40.00%	35.96%
Turning 7	54.76%	50.00%	53.95%
Turning 7	78.57%	70.00%	71.93%
Turning 7	85.71%	80.00%	89.91%

Table 8-11: Measured vs Operator vs ΔT = tc/T Boring Data

Trial #	Actual Measurement	Operator Opinion	tc/T
Boring 1	17.86%	15.00%	17.00%
Boring 1	25.00%	30.00%	34.00%
Boring 1	46.43%	50.00%	51.00%
Boring 1	57.14%	60.00%	68.00%
Boring 1	82.14%	90.00%	85.00%
Boring 1	107.14%	100.00%	102.00%
Boring 2	21.43%	15.00%	17.00%
Boring 2	25.00%	25.00%	34.00%
Boring 2	57.14%	50.00%	51.00%
Boring 2	71.43%	75.00%	68.00%
Boring 2	82.14%	90.00%	85.00%
Boring 2	107.14%	100.00%	102.00%
Boring 3	17.86%	15.00%	17.00%
Boring 3	28.57%	25.00%	34.00%
Boring 3	46.43%	40.00%	51.00%
Boring 3	67.86%	60.00%	68.00%
Boring 3	82.14%	90.00%	85.00%
Boring 3	107.14%	100.00%	102.00%
Boring 4	17.86%	20.00%	17.00%
Boring 4	35.71%	40.00%	34.00%
Boring 4	53.57%	60.00%	51.00%
Boring 5	14.29%	15.00%	14.29%

Trial #	Actual Measurement	Operator Opinion	tc/T
Boring 5	42.86%	40.00%	28.57%
Boring 5	50.00%	50.00%	42.86%
Boring 5	57.14%	60.00%	57.14%
Boring 5	71.43%	80.00%	71.43%
Boring 5	82.14%	90.00%	85.71%
Boring 5	92.86%	100.00%	100.00%
Boring 6	17.86%	15.00%	17.00%
Boring 6	25.00%	30.00%	34.00%
Boring 6	28.57%	35.00%	51.00%
Boring 6	42.86%	50.00%	68.00%
Boring 6	71.43%	80.00%	85.00%
Boring 6	92.86%	100.00%	102.00%
Boring 7	14.29%	15.00%	17.00%
Boring 7	21.43%	20.00%	34.00%
Boring 7	46.43%	50.00%	51.00%
Boring 7	53.57%	60.00%	68.00%
Boring 7	64.29%	70.00%	85.00%

8.4 Appendix D – Calculations

Variation within the Mechanical Properties of the Tooling

Table 8-12: One Way ANOVA - Turing Tool

Method

Null hypothesis	All means are equal
Alternative hypothesis	At least one mean is different
Significance level	α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	7	Tip 1, Tip 2, Tip 3, Tip 4, Tip 5, Tip 6, Tip 7

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	6	0.04791	0.007985	0.43	0.850
Error	28	0.51624	0.018437		
Total	34	0.56415			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.135784	8.49%	0.00%	0.00%

Means

Factor	N	Mean	StDev	95% CI
Tip 1	6	0.2533	0.1328	(0.1398, 0.3669)
Tip 2	6	0.2417	0.1514	(0.1281, 0.3552)
Tip 3	6	0.2800	0.1285	(0.1664, 0.3936)
Tip 4	3	0.1767	0.1206	(0.0161, 0.3373)
Tip 5	6	0.2783	0.1372	(0.1648, 0.3919)
Tip 6	4	0.1800	0.1140	(0.0409, 0.3191)
Tip 7	4	0.2175	0.1513	(0.0784, 0.3566)

Pooled StDev = 0.135784

Tukey Pairwise Comparisons

Grouping Information Using the Tukey Method and 95% Confidence

Factor	N	Mean	Grouping
Tip 3	6	0.2800	A
Tip 5	6	0.2783	A
Tip 1	6	0.2533	A
Tip 2	6	0.2417	A
Tip 7	4	0.2175	A
Tip 6	4	0.1800	A
Tip 4	3	0.1767	A

```
Means that do not share a letter are significantly different.


Tukey Simultaneous Tests for Differences of Means

Difference of  Difference       SE of                                    Adjusted
Levels           of Means  Difference        95% CI       T-Value   P-Value
Tip 2 - Tip 1     -0.0117      0.0784  (-0.2606, 0.2372)     -0.15     1.000
Tip 3 - Tip 1      0.0267      0.0784  (-0.2222, 0.2756)      0.34     1.000
Tip 4 - Tip 1     -0.0767      0.0960  (-0.3815, 0.2282)     -0.80     0.983
Tip 5 - Tip 1      0.0250      0.0784  (-0.2239, 0.2739)      0.32     1.000
Tip 6 - Tip 1     -0.0733      0.0876  (-0.3516, 0.2049)     -0.84     0.979
Tip 7 - Tip 1     -0.0358      0.0876  (-0.3141, 0.2424)     -0.41     1.000
Tip 3 - Tip 2      0.0383      0.0784  (-0.2106, 0.2872)      0.49     0.999
Tip 4 - Tip 2     -0.0650      0.0960  (-0.3698, 0.2398)     -0.68     0.993
Tip 5 - Tip 2      0.0367      0.0784  (-0.2122, 0.2856)      0.47     0.999
Tip 6 - Tip 2     -0.0617      0.0876  (-0.3399, 0.2166)     -0.70     0.991
Tip 7 - Tip 2     -0.0242      0.0876  (-0.3024, 0.2541)     -0.28     1.000
Tip 4 - Tip 3     -0.1033      0.0960  (-0.4082, 0.2015)     -1.08     0.930
Tip 5 - Tip 3     -0.0017      0.0784  (-0.2506, 0.2472)     -0.02     1.000
Tip 6 - Tip 3     -0.1000      0.0876  (-0.3783, 0.1783)     -1.14     0.910
Tip 7 - Tip 3     -0.0625      0.0876  (-0.3408, 0.2158)     -0.71     0.991
Tip 5 - Tip 4      0.1017      0.0960  (-0.2032, 0.4065)      1.06     0.935
Tip 6 - Tip 4       0.003       0.104  ( -0.326,  0.333)      0.03     1.000
Tip 7 - Tip 4       0.041       0.104  ( -0.288,  0.370)      0.39     1.000
Tip 6 - Tip 5     -0.0983      0.0876  (-0.3766, 0.1799)     -1.12     0.916
Tip 7 - Tip 5     -0.0608      0.0876  (-0.3391, 0.2174)     -0.69     0.992
Tip 7 - Tip 6      0.0375      0.0960  (-0.2673, 0.3423)      0.39     1.000

Individual confidence level = 99.64%
```

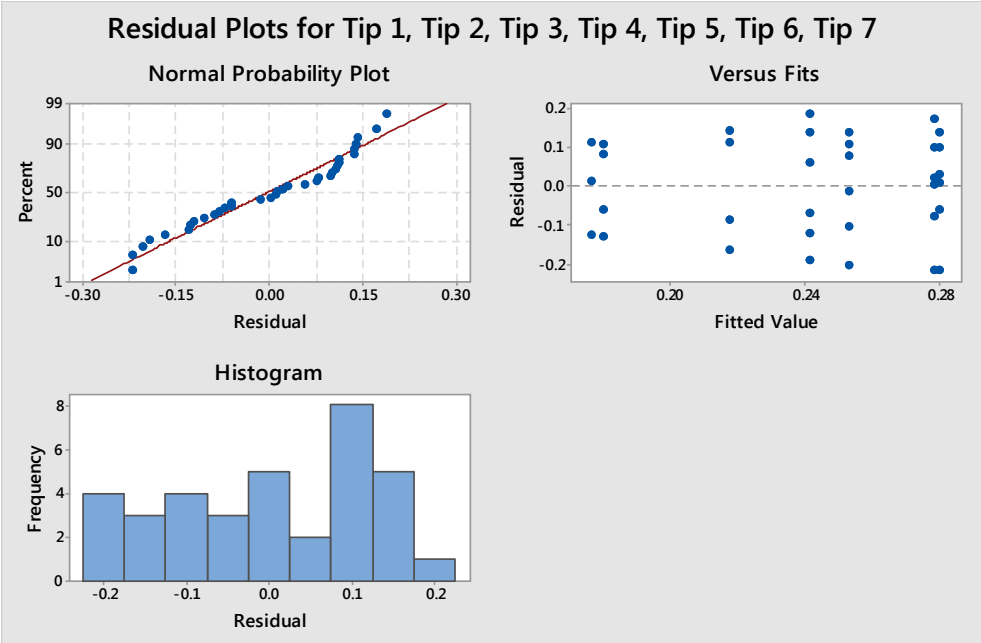


Figure 8-1: Residual Plots - Turning Tool

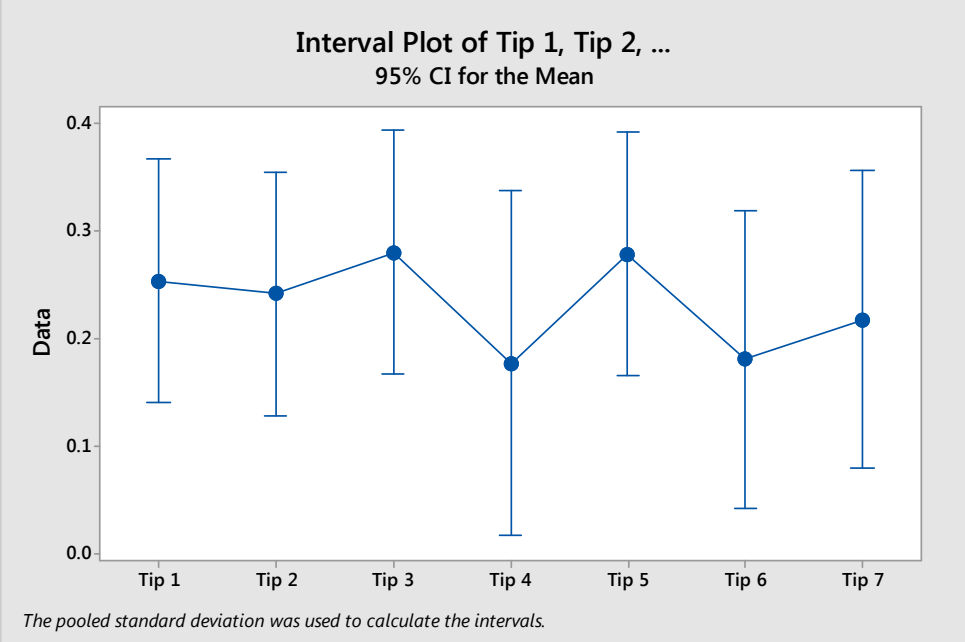


Figure 8-2: Interval Plot - Turning Tool

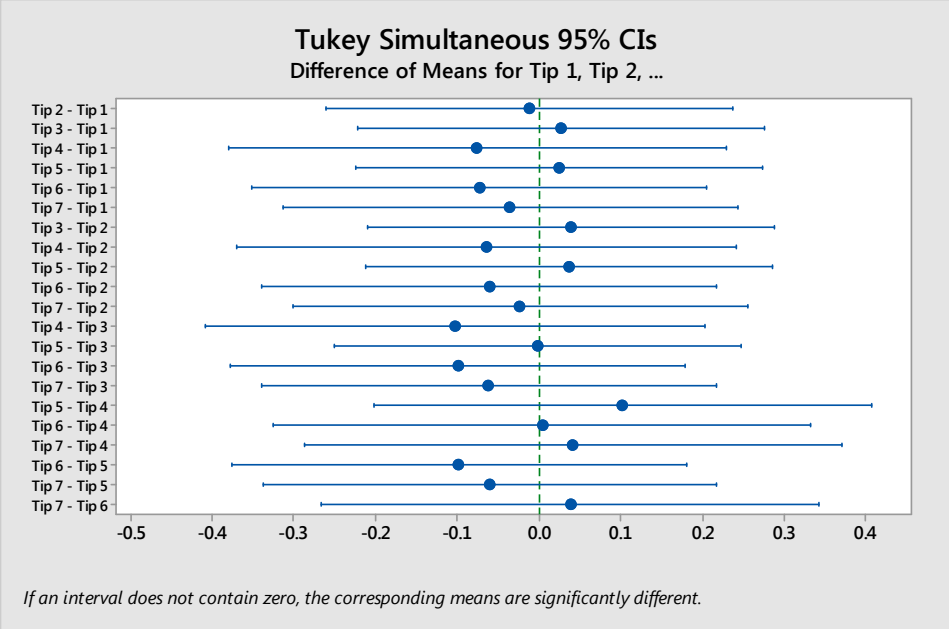


Figure 8-3: Tukey Simultaneous 95% CI's - Turning Tool

Table 8-13: One Way ANOVA - Boring Tool

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05
Rows unused             2

Equal variances were assumed for the analysis.


Factor Information

Factor  Levels  Values
Factor       7  Tip 1, Tip 2, Tip 3, Tip 4, Tip 5, Tip 6, Tip 7


Analysis of Variance

Source  DF   Adj SS    Adj MS  F-Value  P-Value
Factor   6  0.01878  0.003130     0.44    0.846
Error   30  0.21323  0.007108
Total   36  0.23201


Model Summary

        S   R-sq  R-sq(adj)  R-sq(pred)
0.0843070  8.09%      0.00%       0.00%


Means

Factor  N    Mean   StDev       95% CI
Tip 1   6  0.1533  0.0927  (0.0830, 0.2236)
Tip 2   6  0.1700  0.0934  (0.0997, 0.2403)
Tip 3   6  0.1633  0.0946  (0.0930, 0.2336)
Tip 4   3  0.1000  0.0500  (0.0006, 0.1994)
Tip 5   6  0.1583  0.0791  (0.0880, 0.2286)
Tip 6   5  0.1400  0.0886  (0.0630, 0.2170)
Tip 7   5  0.1120  0.0597  (0.0350, 0.1890)

Pooled StDev = 0.0843070
```

Tukey Pairwise Comparisons

```
Grouping Information Using the Tukey Method and 95% Confidence

Factor  N    Mean  Grouping
Tip 2   6  0.1700  A
Tip 3   6  0.1633  A
Tip 5   6  0.1583  A
Tip 1   6  0.1533  A
Tip 6   5  0.1400  A
Tip 7   5  0.1120  A
Tip 4   3  0.1000  A

Means that do not share a letter are significantly different.
```

Tukey Simultaneous Tests for Differences of Means

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Tip 2 - Tip 1	0.0167	0.0487	(-0.1368, 0.1702)	0.34	1.000
Tip 3 - Tip 1	0.0100	0.0487	(-0.1435, 0.1635)	0.21	1.000
Tip 4 - Tip 1	-0.0533	0.0596	(-0.2413, 0.1347)	-0.89	0.971
Tip 5 - Tip 1	0.0050	0.0487	(-0.1485, 0.1585)	0.10	1.000
Tip 6 - Tip 1	-0.0133	0.0511	(-0.1743, 0.1477)	-0.26	1.000
Tip 7 - Tip 1	-0.0413	0.0511	(-0.2023, 0.1197)	-0.81	0.982
Tip 3 - Tip 2	-0.0067	0.0487	(-0.1602, 0.1468)	-0.14	1.000
Tip 4 - Tip 2	-0.0700	0.0596	(-0.2580, 0.1180)	-1.17	0.898
Tip 5 - Tip 2	-0.0117	0.0487	(-0.1652, 0.1418)	-0.24	1.000
Tip 6 - Tip 2	-0.0300	0.0511	(-0.1910, 0.1310)	-0.59	0.997
Tip 7 - Tip 2	-0.0580	0.0511	(-0.2190, 0.1030)	-1.14	0.912
Tip 4 - Tip 3	-0.0633	0.0596	(-0.2513, 0.1247)	-1.06	0.934
Tip 5 - Tip 3	-0.0050	0.0487	(-0.1585, 0.1485)	-0.10	1.000
Tip 6 - Tip 3	-0.0233	0.0511	(-0.1843, 0.1377)	-0.46	0.999
Tip 7 - Tip 3	-0.0513	0.0511	(-0.2123, 0.1097)	-1.01	0.949
Tip 5 - Tip 4	0.0583	0.0596	(-0.1297, 0.2463)	0.98	0.955
Tip 6 - Tip 4	0.0400	0.0616	(-0.1542, 0.2342)	0.65	0.994
Tip 7 - Tip 4	0.0120	0.0616	(-0.1822, 0.2062)	0.19	1.000
Tip 6 - Tip 5	-0.0183	0.0511	(-0.1793, 0.1427)	-0.36	1.000
Tip 7 - Tip 5	-0.0463	0.0511	(-0.2073, 0.1147)	-0.91	0.968
Tip 7 - Tip 6	-0.0280	0.0533	(-0.1962, 0.1402)	-0.53	0.998

Individual confidence level = 99.64%

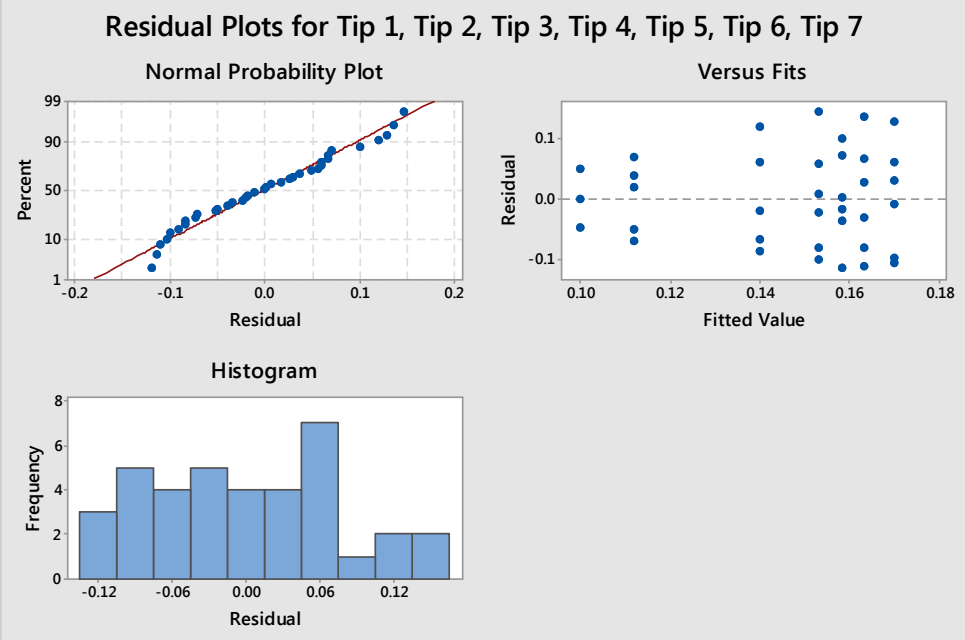


Figure 8-4: Residual Plots - Boring Tool

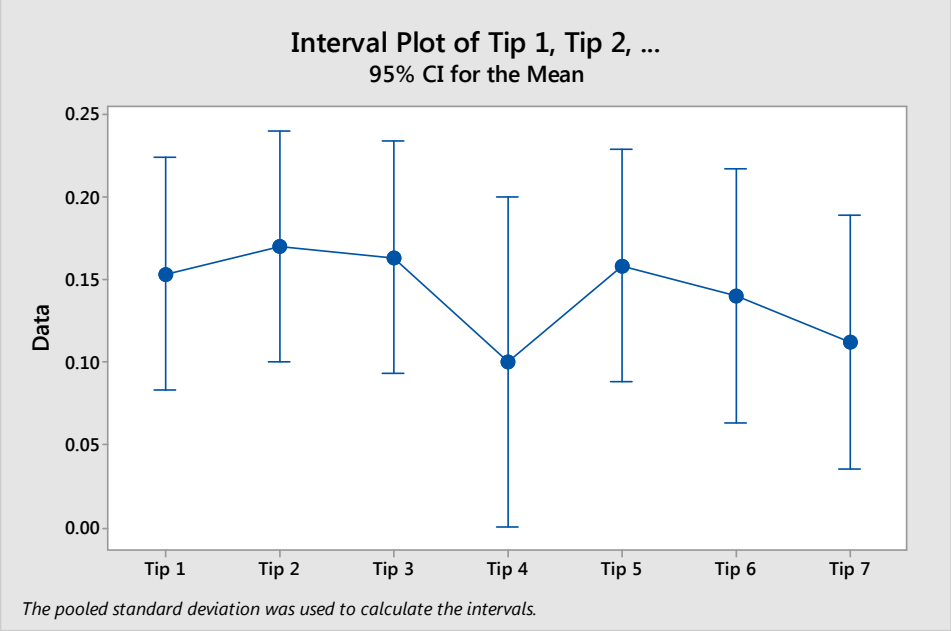


Figure 8-5: Interval Plot - Boring Tool

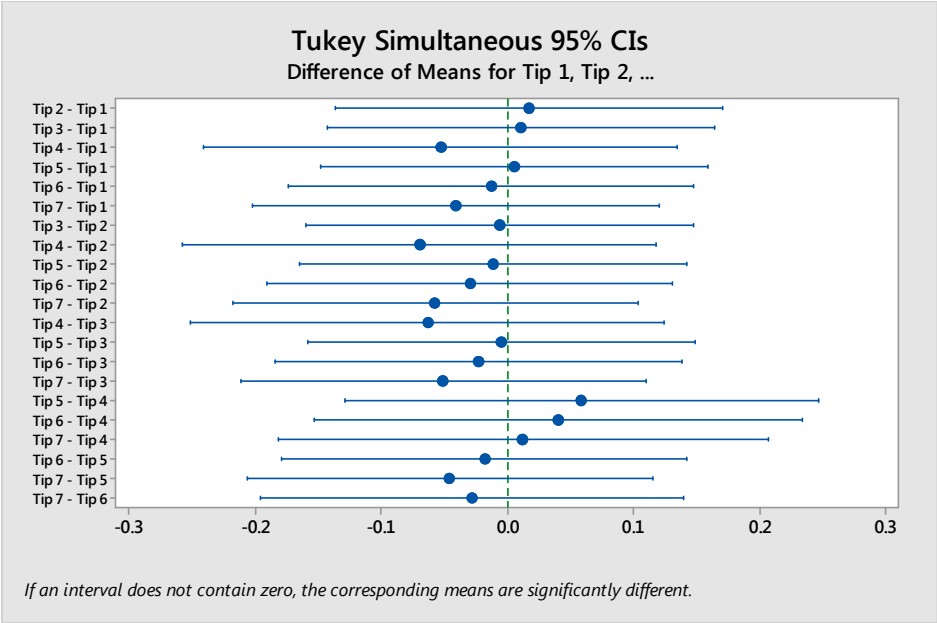


Figure 8-6: Tukey Simultaneous 95% CI's - Boring Tool

Table 8-14: One Way ANOVA - Drilling Tool

```
Method

Null hypothesis         All means are equal
Alternative hypothesis  At least one mean is different
Significance level      α = 0.05
Rows unused             1

Equal variances were assumed for the analysis.


Factor Information

Factor  Levels  Values
Factor       6  Drill 1, Drill 2, Drill 3, Drill 4, Drill 5, Drill 6


Analysis of Variance

Source  DF   Adj SS    Adj MS  F-Value  P-Value
Factor   5  0.01469  0.002937     0.39    0.855
Error   32  0.24391  0.007622
Total   37  0.25860


Model Summary

        S   R-sq  R-sq(adj)  R-sq(pred)
0.0873059  5.68%      0.00%       0.00%


Means

Factor   N    Mean   StDev       95% CI
Drill 1  7  0.1729  0.0971  (0.1056, 0.2401)
Drill 2  7  0.1829  0.0918  (0.1156, 0.2501)
Drill 3  7  0.1686  0.0875  (0.1014, 0.2358)
Drill 4  7  0.1471  0.0883  (0.0799, 0.2144)
Drill 5  7  0.1500  0.0816  (0.0828, 0.2172)
Drill 6  3  0.1100  0.0458  (0.0073, 0.2127)

Pooled StDev = 0.0873059
```

Tukey Pairwise Comparisons

```
Grouping Information Using the Tukey Method and 95% Confidence

Factor   N    Mean  Grouping
Drill 2  7  0.1829  A
Drill 1  7  0.1729  A
Drill 3  7  0.1686  A
Drill 5  7  0.1500  A
Drill 4  7  0.1471  A
Drill 6  3  0.1100  A

Means that do not share a letter are significantly different.


Tukey Simultaneous Tests for Differences of Means
```

Difference of Levels	Difference of Means	SE of Difference	95% CI	T-Value	Adjusted P-Value
Drill 2 - Drill 1	0.0100	0.0467	(-0.1312, 0.1512)	0.21	1.000
Drill 3 - Drill 1	-0.0043	0.0467	(-0.1455, 0.1369)	-0.09	1.000
Drill 4 - Drill 1	-0.0257	0.0467	(-0.1669, 0.1155)	-0.55	0.993
Drill 5 - Drill 1	-0.0229	0.0467	(-0.1641, 0.1184)	-0.49	0.996
Drill 6 - Drill 1	-0.0629	0.0602	(-0.2452, 0.1195)	-1.04	0.900
Drill 3 - Drill 2	-0.0143	0.0467	(-0.1555, 0.1269)	-0.31	1.000
Drill 4 - Drill 2	-0.0357	0.0467	(-0.1769, 0.1055)	-0.77	0.971
Drill 5 - Drill 2	-0.0329	0.0467	(-0.1741, 0.1084)	-0.70	0.980
Drill 6 - Drill 2	-0.0729	0.0602	(-0.2552, 0.1095)	-1.21	0.829
Drill 4 - Drill 3	-0.0214	0.0467	(-0.1627, 0.1198)	-0.46	0.997
Drill 5 - Drill 3	-0.0186	0.0467	(-0.1598, 0.1227)	-0.40	0.999
Drill 6 - Drill 3	-0.0586	0.0602	(-0.2409, 0.1238)	-0.97	0.923
Drill 5 - Drill 4	0.0029	0.0467	(-0.1384, 0.1441)	0.06	1.000
Drill 6 - Drill 4	-0.0371	0.0602	(-0.2195, 0.1452)	-0.62	0.989
Drill 6 - Drill 5	-0.0400	0.0602	(-0.2223, 0.1423)	-0.66	0.985

Individual confidence level = 99.51%

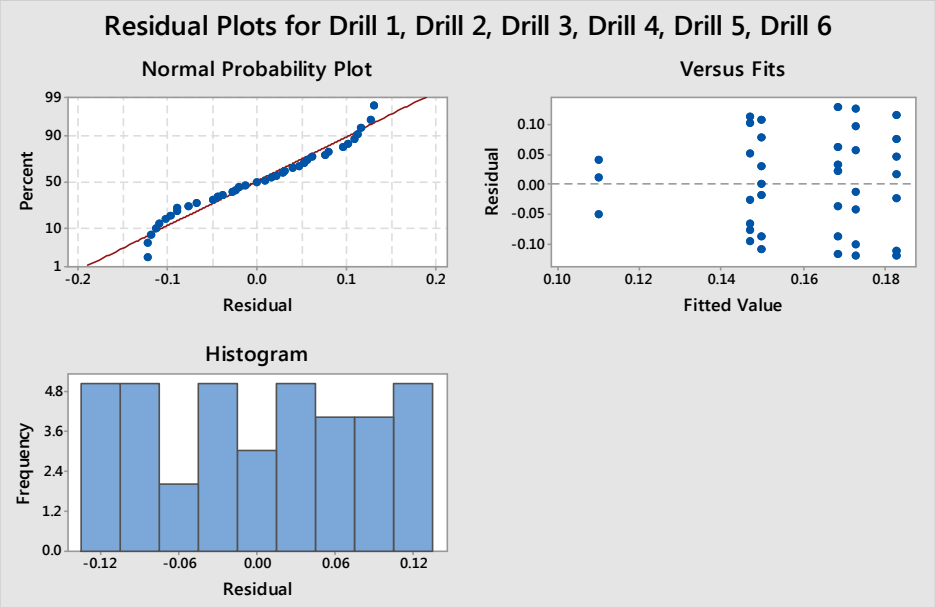


Figure 8-7: Residual Plots - Drilling Tool

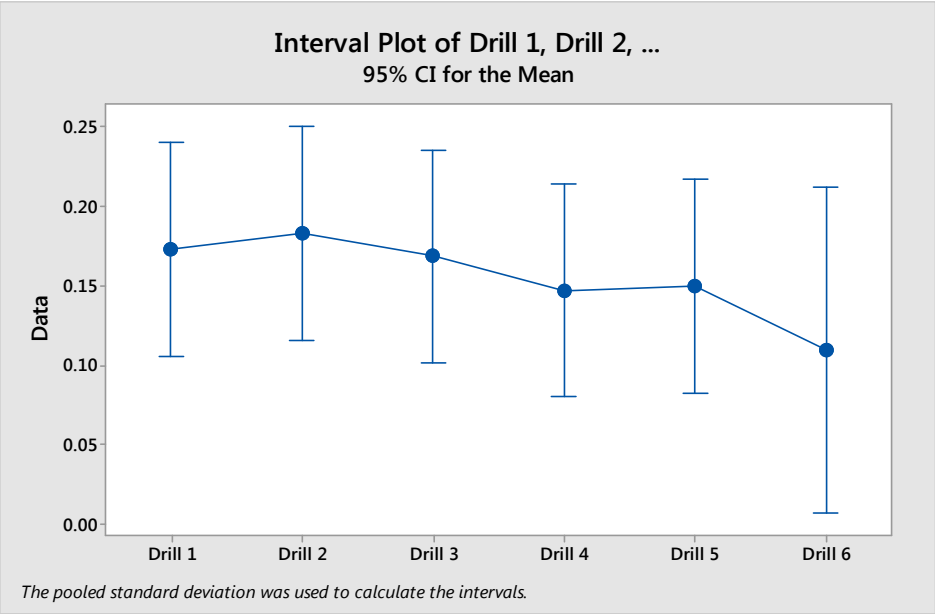


Figure 8-8: Interval Plot - Drilling Tool

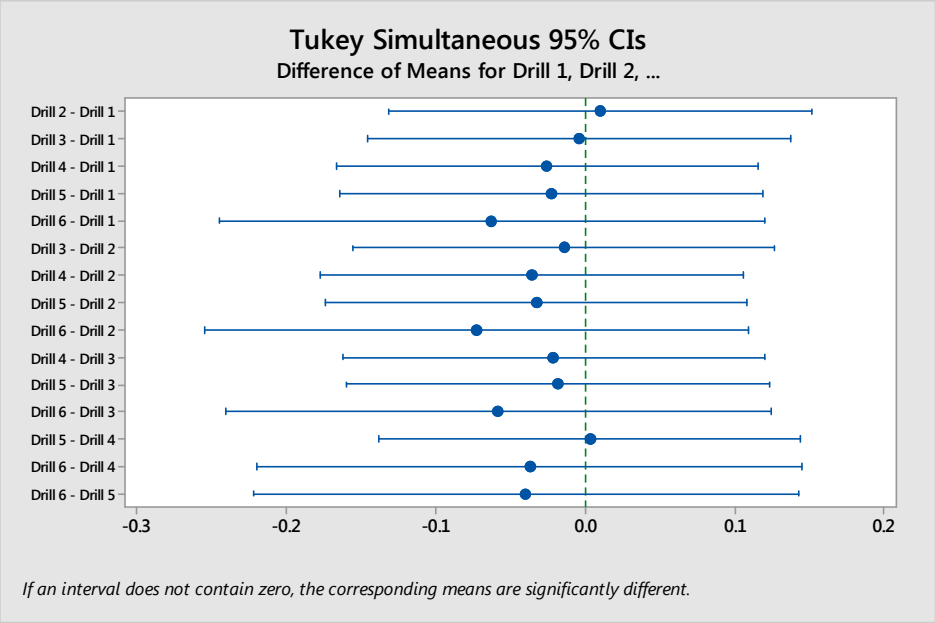


Figure 8-9: Tukey Simultaneous 95% CI's - Drilling Tool

Variation within Operator Training

Table 8-15: Paired T-Test Operator Opinion vs Measured Data - Turning Trial

```
Paired T for Operator Opinion - Actual Measurment

                      N    Mean   StDev  SE Mean
Operator Opinion     37  0.5905  0.2781   0.0457
Actual Measurment    37  0.5701  0.2988   0.0491
Difference           37  0.0204  0.0626   0.0103


95% CI for mean difference: (-0.0005, 0.0413)
T-Test of mean difference = 0 (vs ≠ 0): T-Value = 1.98  P-Value = 0.055
```

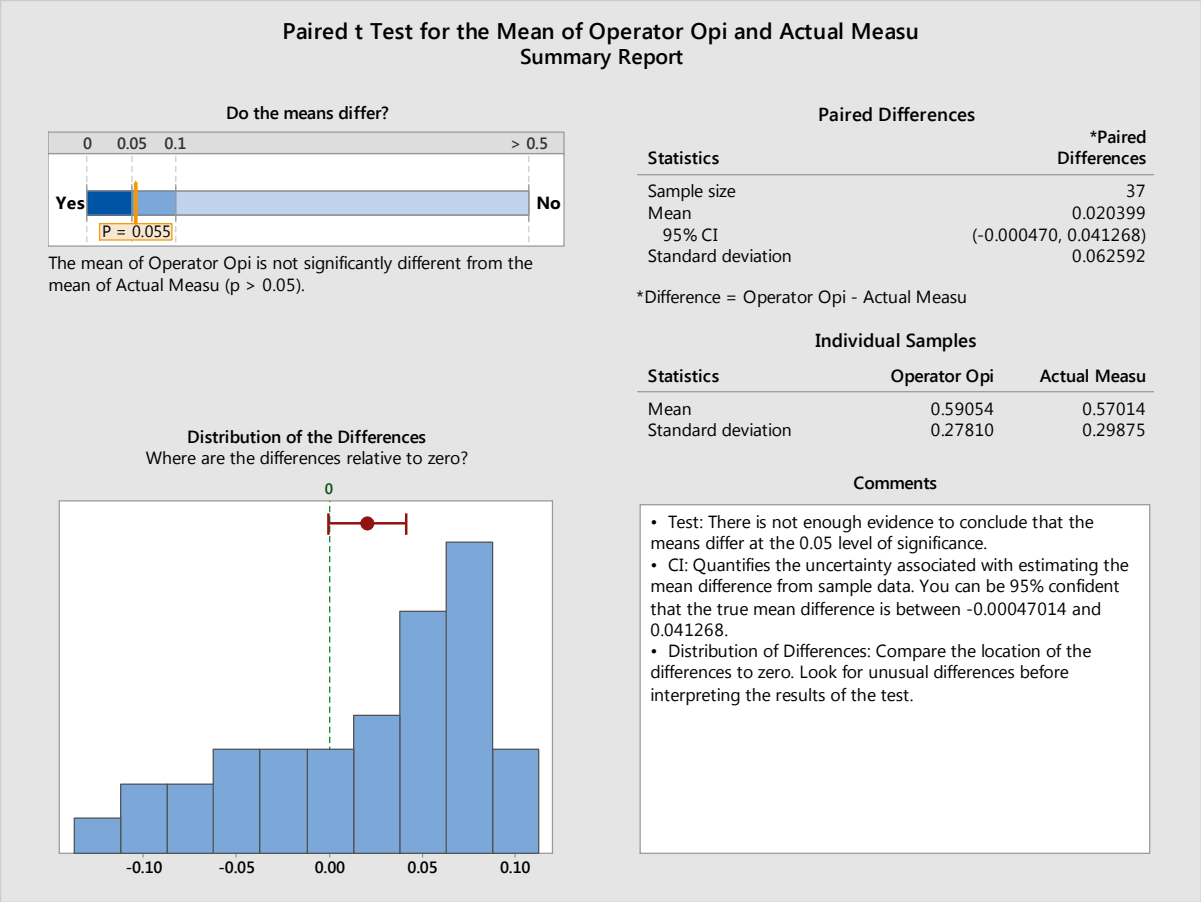


Figure 8-10: Summary Report Paired T-Test Turning Trial

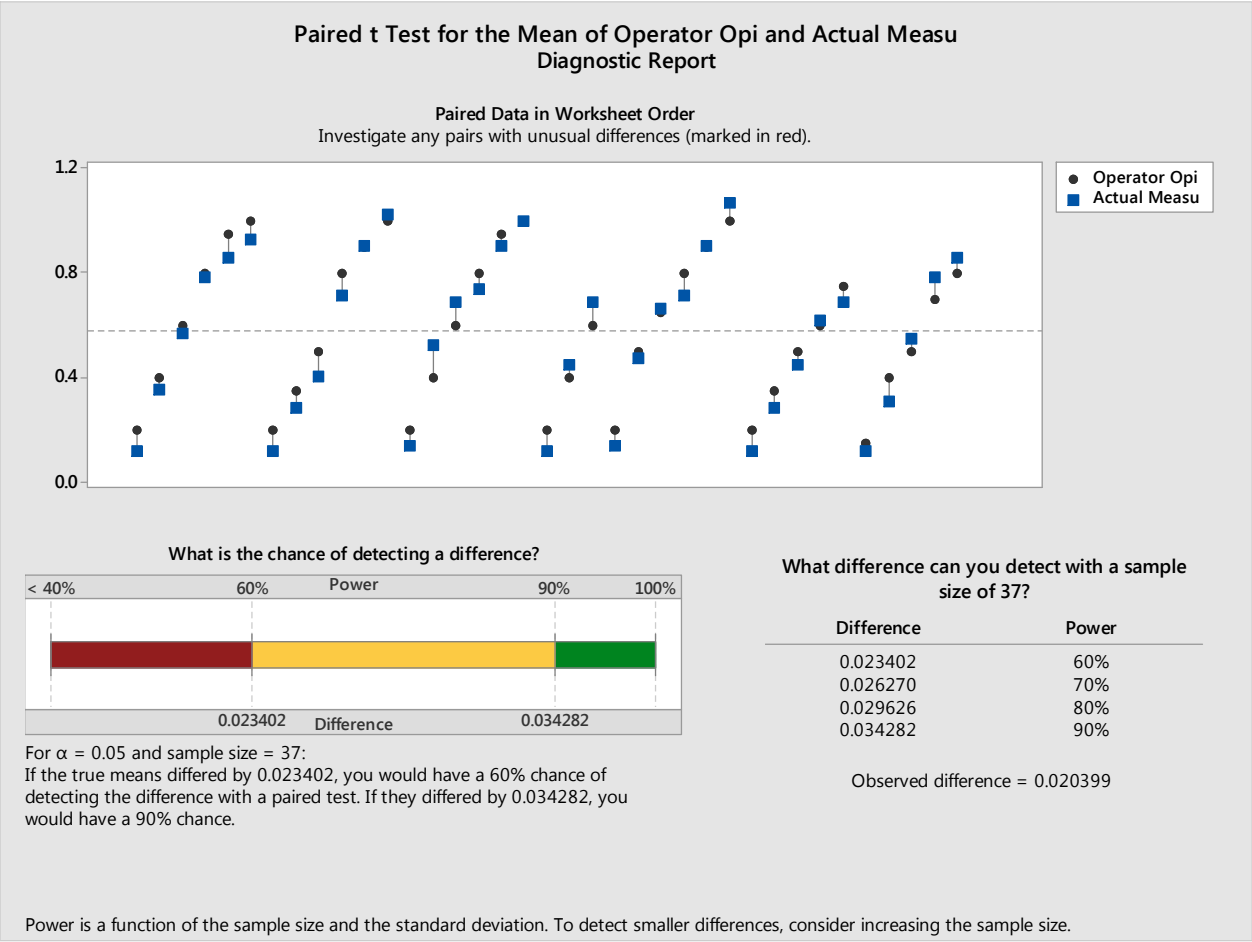


Figure 8-11: Diagnostic Report Paired T-Test Turning Trial

Table 8-16: Paired T-Test Operator Opinion vs Measured Data - Boring Trial

```
Paired T for Operator Opinion - Actual Measurement

                      N     Mean    StDev  SE Mean
Operator Opinion     39   0.5410   0.2960   0.0474
Actual Measurement   39   0.5247   0.2851   0.0457
Difference           39  0.01630  0.05440  0.00871


95% CI for mean difference: (-0.00133, 0.03393)
T-Test of mean difference = 0 (vs ≠ 0): T-Value = 1.87  P-Value = 0.069
```

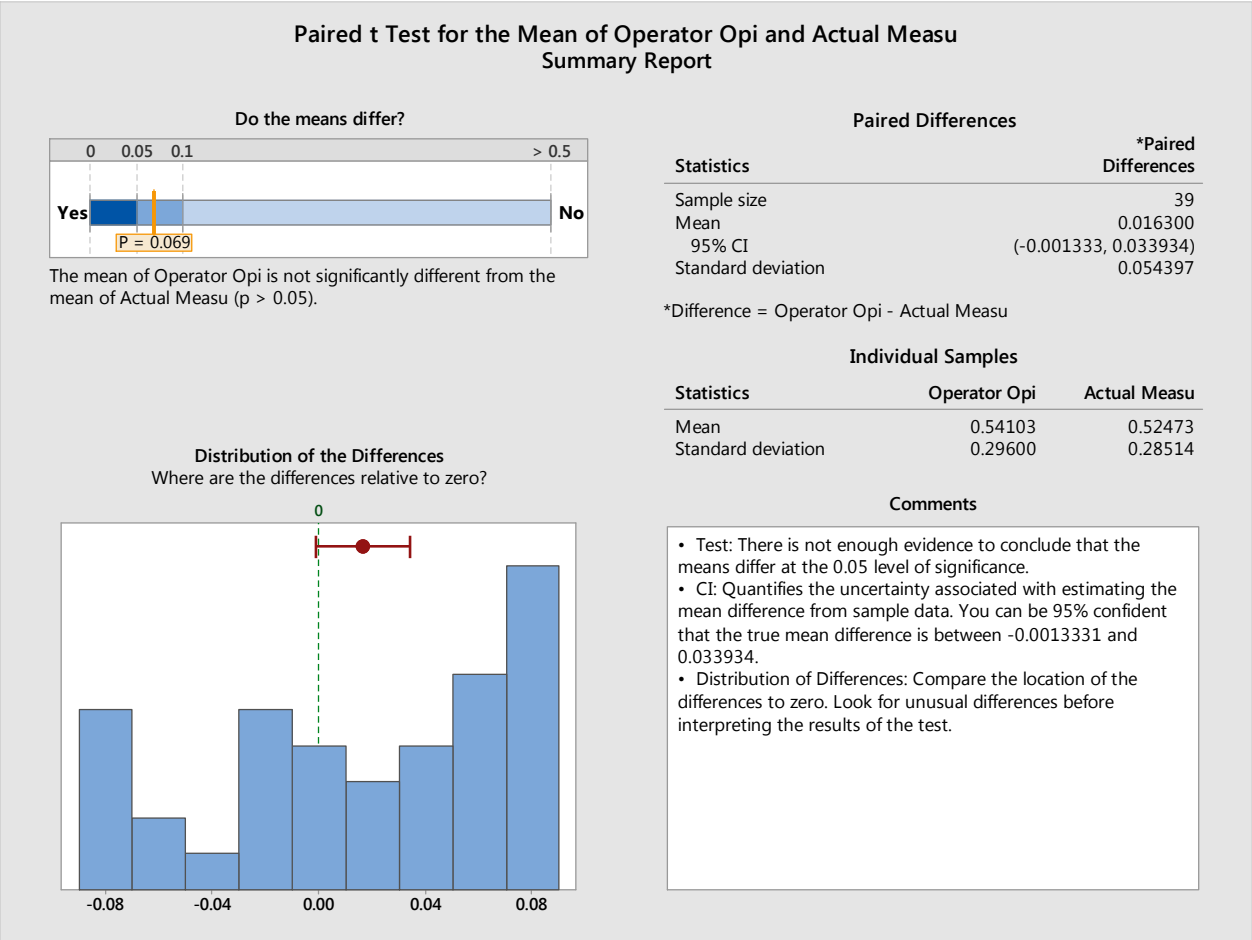


Figure 8-12: Summary Report Paired T-Test Boring Trial

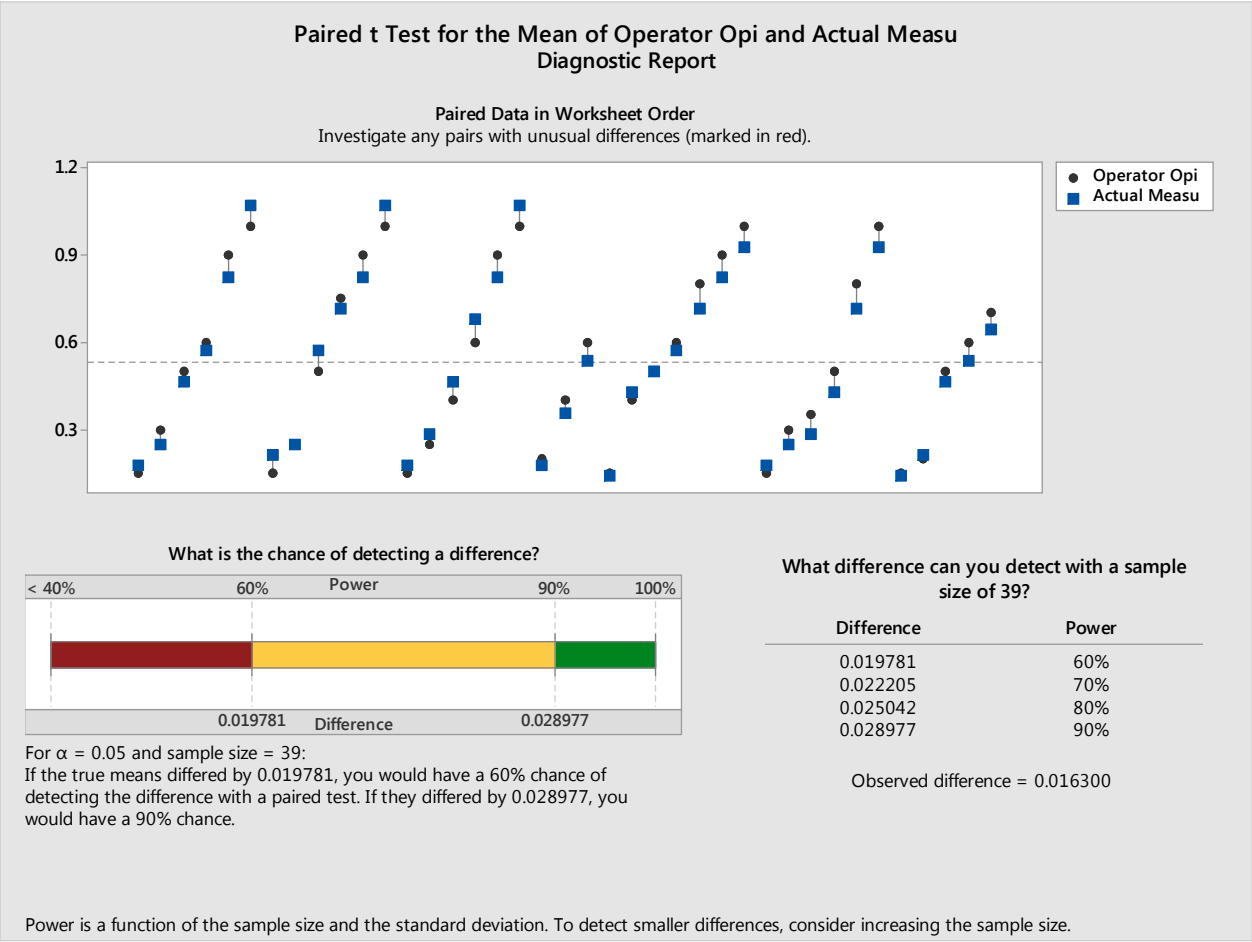


Figure 8-13: Diagnostic Report Paired T-Test Boring Trial

Table 8-17: Paired T-Test Operator Opinion vs Measured Data - Drilling Trial

```
Paired T for Operator Opinion - Actual Measurement

                      N      Mean    StDev  SE Mean
Operator Opinion     38    0.5711   0.2949   0.0478
Actual Measurement   38    0.5735   0.2992   0.0485
Difference           38  -0.00240  0.04564  0.00740


95% CI for mean difference: (-0.01740, 0.01260)
T-Test of mean difference = 0 (vs ≠ 0): T-Value = -0.32  P-Value = 0.748
```

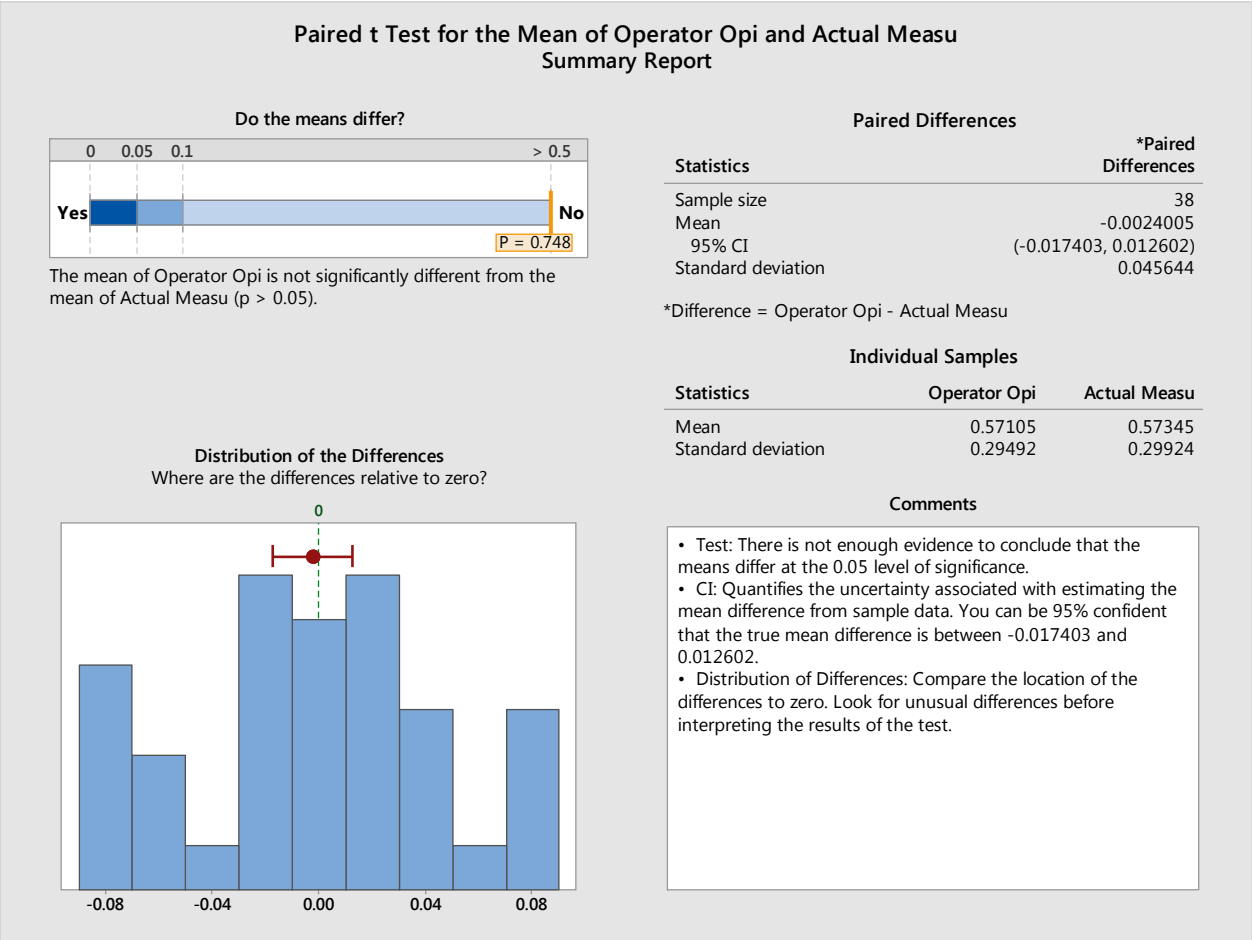


Figure 8-14: Summary Report Paired T-Test Drilling Trial

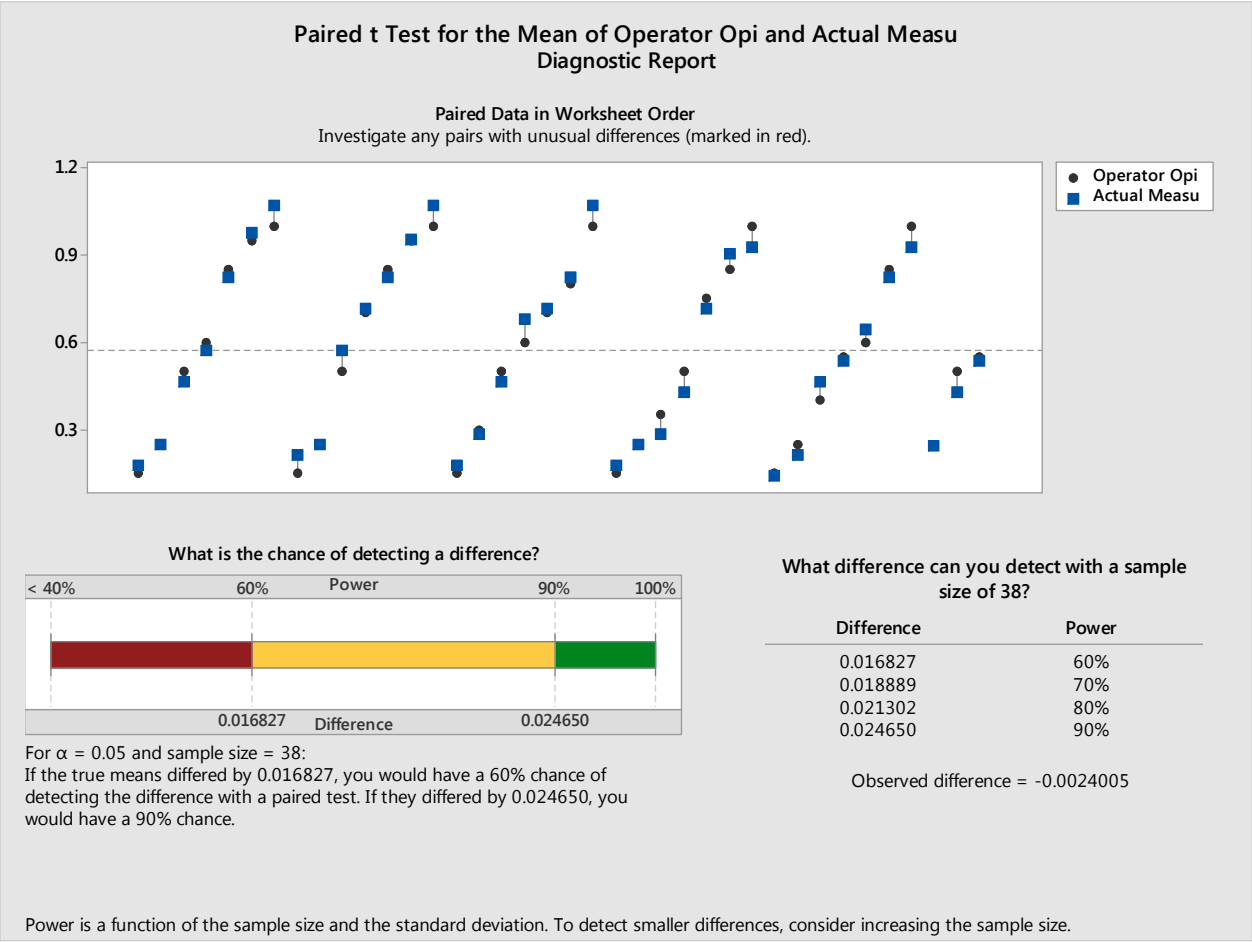


Figure 8-15: Diagnostic Report Paired T-Test Drilling Trial

Process Qualification - Final Results

Table 8-18: Regression Analysis - Turning Tools

Regression Analysis: Tool 1 - Ver 1 versus Tool 1 - Turning

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.55804	0.55804	44.96	0.003
Tool 1 - Turning	1	0.55804	0.55804	44.96	0.003
Error	4	0.04965	0.01241		
Total	5	0.60768			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.111409	91.83%	89.79%	83.85%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	0.137	0.104	1.32	0.258	
Tool 1 - Turning	1.050	0.157	6.71	0.003	1.00

Regression Equation

Tool 1 - Ver 1 = 0.137 + 1.050 Tool 1 - Turning

Regression Analysis: Tool 1 - Ver 2 versus Tool 1 - Turning

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.36866	0.36866	23.46	0.008
Tool 1 - Turning	1	0.36866	0.36866	23.46	0.008
Error	4	0.06287	0.01572		
Total	5	0.43153			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.125370	85.43%	81.79%	73.36%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	0.155	0.117	1.33	0.254	
Tool 1 - Turning	0.854	0.176	4.84	0.008	1.00

```
Regression Equation

Tool 1 - Ver 2 = 0.155 + 0.854 Tool 1 - Turning
```

Regression Analysis: Tool 2 - Ver 1 versus Tool 2 - Turning

```
Analysis of Variance

Source              DF  Adj SS   Adj MS  F-Value  P-Value
Regression           1  0.2025  0.20249     7.36    0.053
  Tool 2 - Turning   1  0.2025  0.20249     7.36    0.053
Error                4  0.1101  0.02751
Total                5  0.3125


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.165873  64.79%     55.98%      24.81%


Coefficients

Term               Coef  SE Coef  T-Value  P-Value   VIF
Constant          0.153    0.160     0.96    0.393
Tool 2 - Turning  0.636    0.235     2.71    0.053  1.00


Regression Equation

Tool 2 - Ver 1 = 0.153 + 0.636 Tool 2 - Turning
```

Regression Analysis: Tool 2 - Ver 2 versus Tool 2 - Turning

```
Analysis of Variance

Source              DF  Adj SS   Adj MS  F-Value  P-Value
Regression           1  0.2557  0.25568     9.29    0.038
  Tool 2 - Turning   1  0.2557  0.25568     9.29    0.038
Error                4  0.1101  0.02751
Total                5  0.3657


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.165871  69.91%     62.39%      39.37%


Coefficients

Term               Coef  SE Coef  T-Value  P-Value   VIF
Constant          0.153    0.160     0.96    0.394
Tool 2 - Turning  0.715    0.234     3.05    0.038  1.00
```

```
Regression Equation

Tool 2 - Ver 2 = 0.153 + 0.715 Tool 2 - Turning
```

Regression Analysis: Tool 3 - Ver 1 versus Tool 3 - Turning

```
Analysis of Variance

Source              DF   Adj SS   Adj MS  F-Value  P-Value
Regression           1  0.09677  0.09677     6.68    0.061
  Tool 3 - Turning   1  0.09677  0.09677     6.68    0.061
Error                4  0.05797  0.01449
Total                5  0.15473


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.120381  62.54%     53.17%      16.79%


Coefficients

Term               Coef  SE Coef  T-Value  P-Value   VIF
Constant          0.403    0.115     3.50    0.025
Tool 3 - Turning  0.436    0.169     2.58    0.061  1.00


Regression Equation

Tool 3 - Ver 1 = 0.403 + 0.436 Tool 3 - Turning
```

Regression Analysis: Tool 3 - Ver 2 versus Tool 3 - Turning

```
Analysis of Variance

Source              DF   Adj SS    Adj MS  F-Value  P-Value
Regression           1  0.26726  0.267264    35.24    0.004
  Tool 3 - Turning   1  0.26726  0.267264    35.24    0.004
Error                4  0.03034  0.007584
Total                5  0.29760


Model Summary

        S    R-sq  R-sq(adj)  R-sq(pred)
0.0870865  89.81%     87.26%      78.63%


Coefficients

Term               Coef  SE Coef  T-Value  P-Value   VIF
Constant         0.2115   0.0835     2.53    0.064
Tool 3 - Turning  0.725    0.122     5.94    0.004  1.00
```

```
Regression Equation

Tool 3 - Ver 2 = 0.2115 + 0.725 Tool 3 - Turning
```

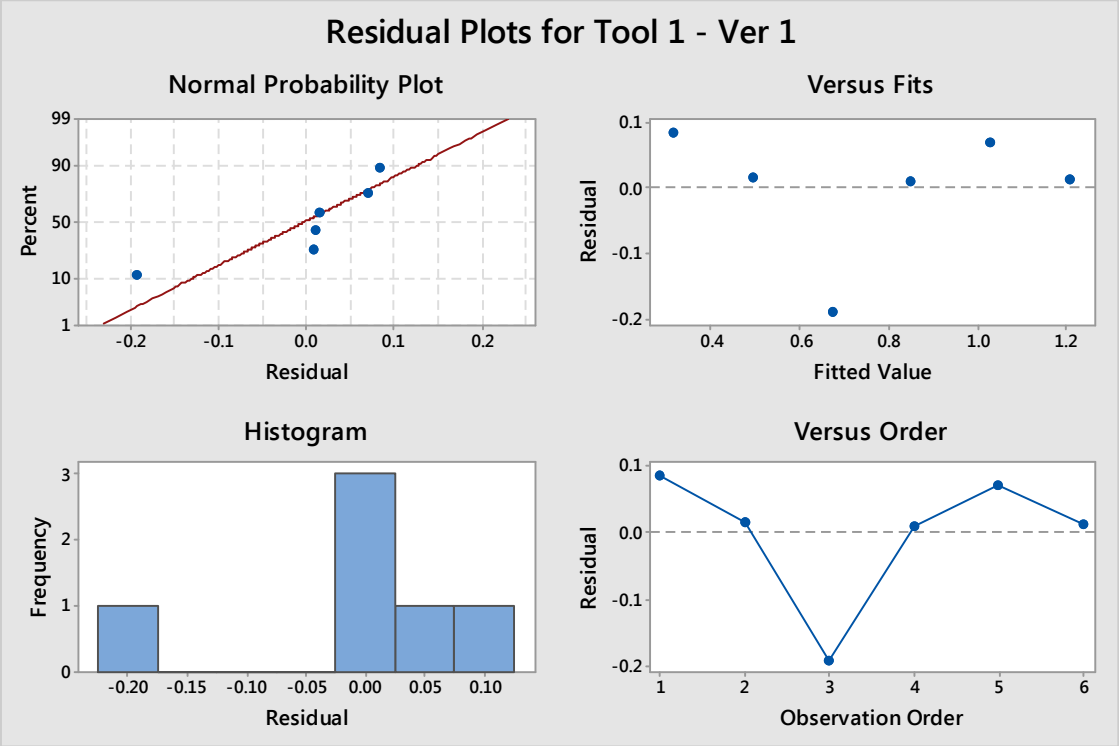


Figure 8-16: Residual Plots Tool 1 - Version 1

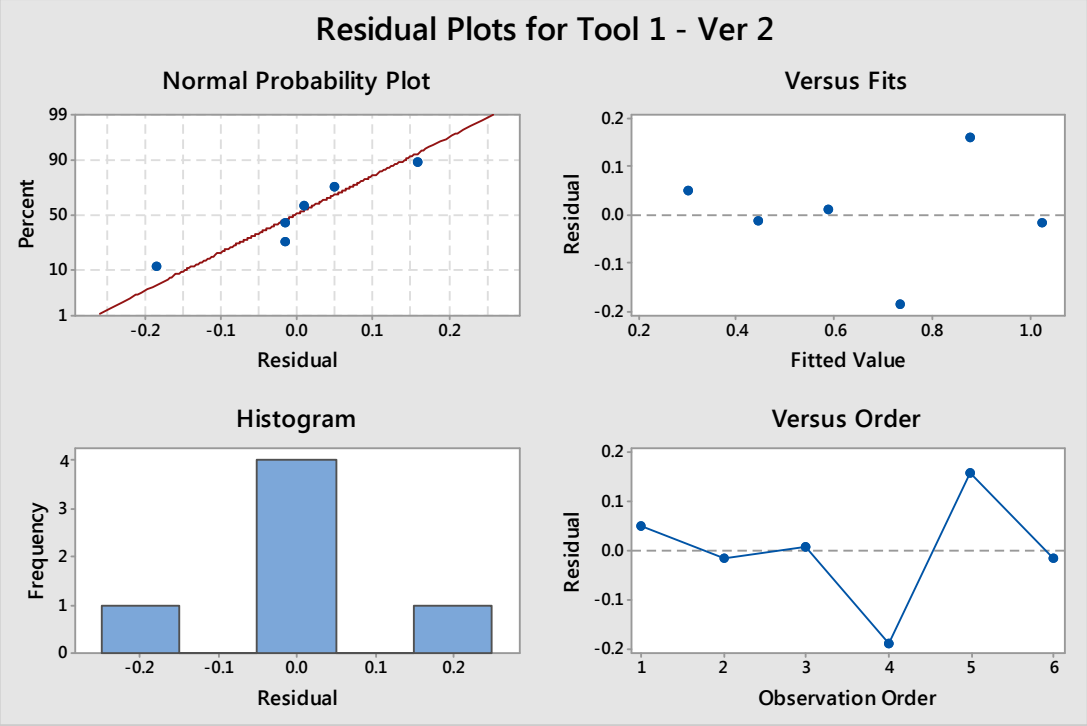


Figure 8-17: Residual Plots Tool 1 - Version 2

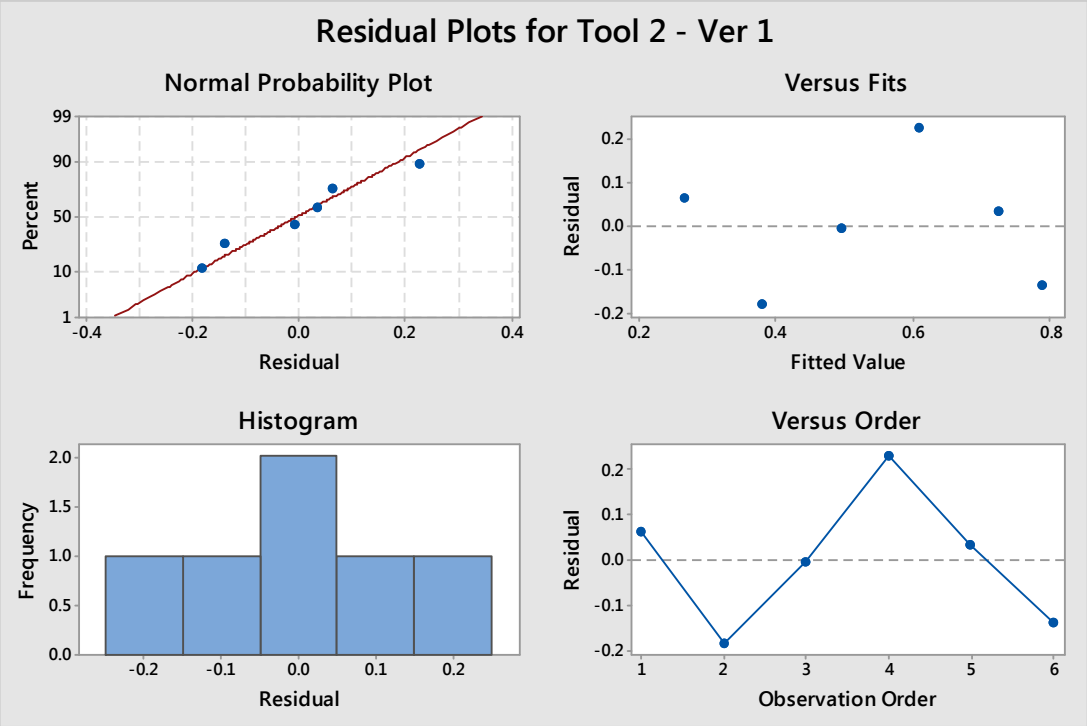


Figure 8-18: Residual Plots Tool 2 - Version 1

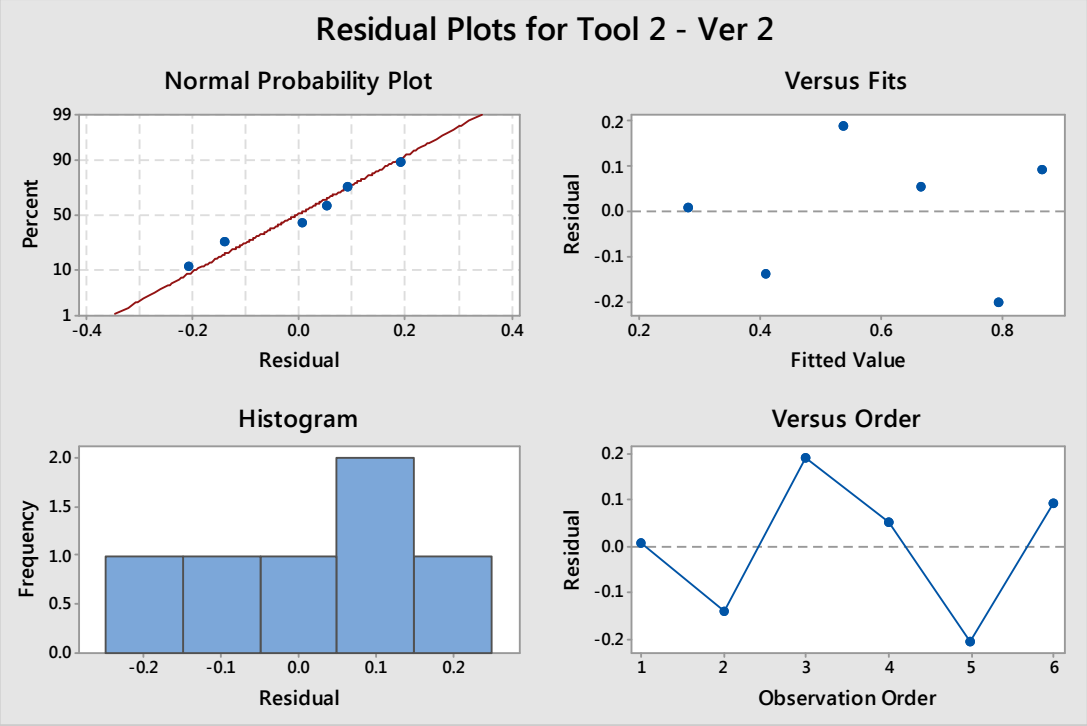


Figure 8-19: Residual Plots Tool 2 - Version 2

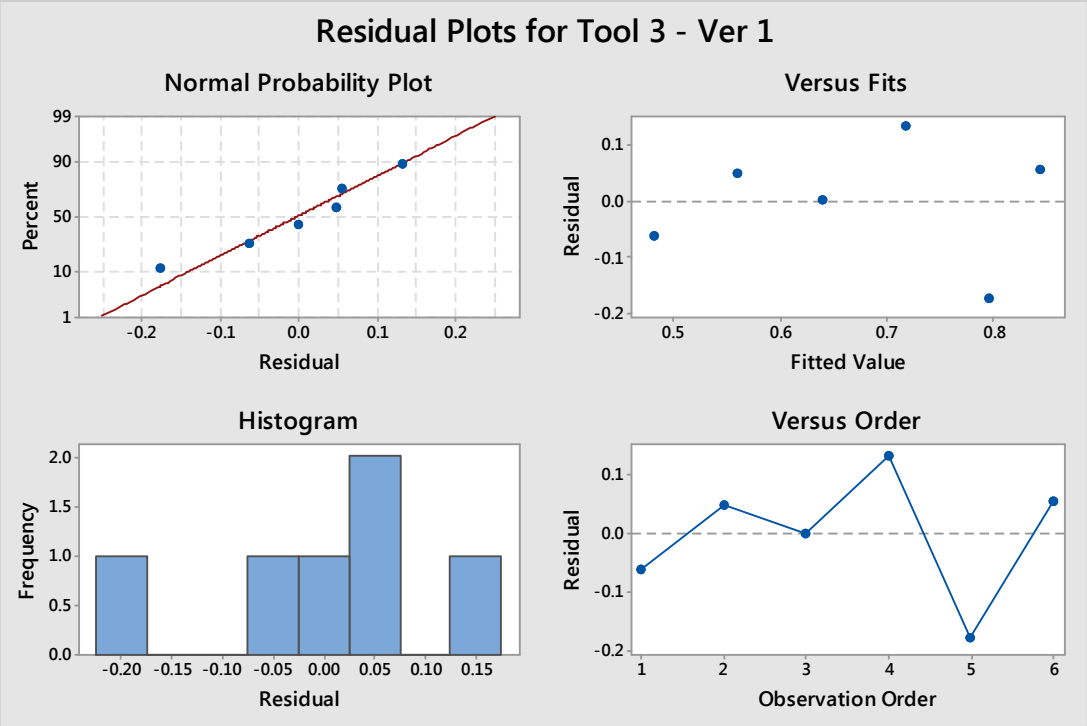


Figure 8-20: Residual Plots Tool 3 - Version 1

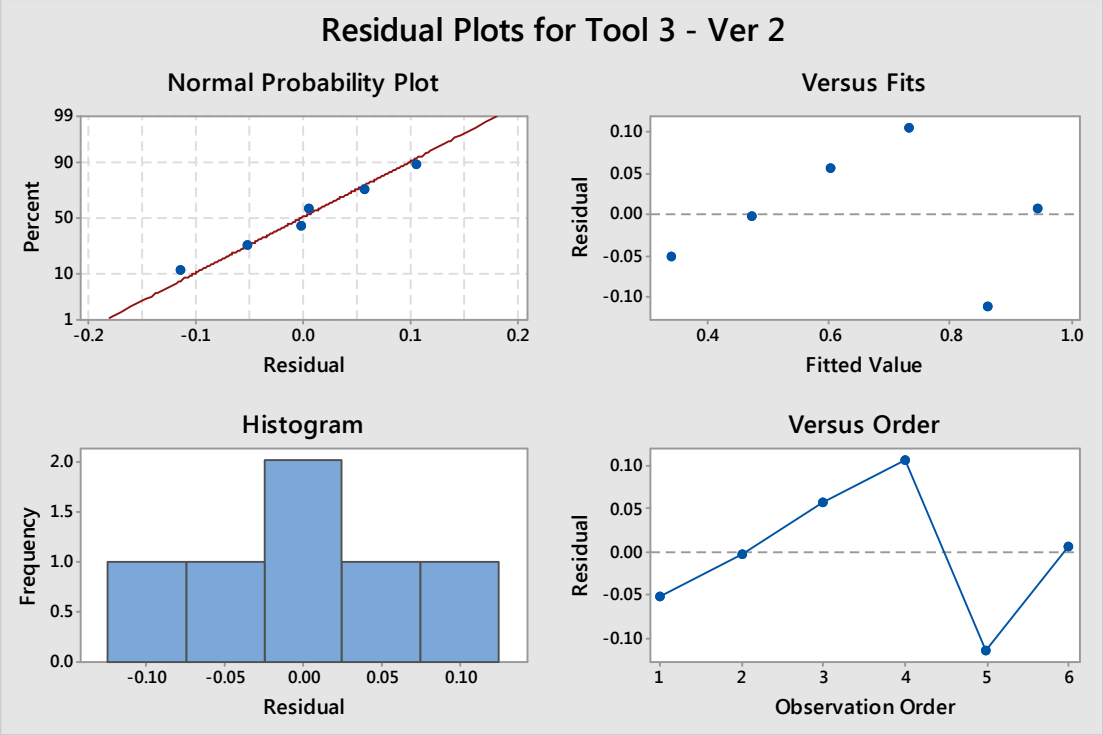


Figure 8-21: Residual Plots Tool 3 - Version 2

Table 8-19: Regression Analysis - Boring Tools

Regression Analysis: Tool 1 - Ver 1 versus Tool 1 - Boring

Stepwise Selection of Terms

α to enter = 0.15, α to remove = 0.15

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.4080	0.40801	12.55	0.017
Tool 1 - Boring	1	0.4080	0.40801	12.55	0.017
Error	5	0.1625	0.03251		
Total	6	0.5705			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.180293	71.51%	65.82%	24.03%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	-0.226	0.152	-1.48	0.199	
Tool 1 - Boring	0.845	0.239	3.54	0.017	1.00

Regression Equation

```
Tool 1 - Ver 1 = -0.226 + 0.845 Tool 1 - Boring
```

Regression Analysis: Tool 1 - Ver 2 versus Tool 1 - Boring

```
Stepwise Selection of Terms

α to enter = 0.15, α to remove = 0.15


Analysis of Variance

Source             DF    Adj SS    Adj MS  F-Value  P-Value
Regression          1  0.624014  0.624014   490.80    0.000
  Tool 1 - Boring   1  0.624014  0.624014   490.80    0.000
Error               5  0.006357  0.001271
Total               6  0.630371


Model Summary

        S    R-sq  R-sq(adj)  R-sq(pred)
0.0356571  98.99%     98.79%      97.85%


Coefficients

Term                Coef  SE Coef  T-Value  P-Value   VIF
Constant         -0.0014   0.0301    -0.05    0.964
Tool 1 - Boring   1.0450   0.0472    22.15    0.000  1.00


Regression Equation

Tool 1 - Ver 2 = -0.0014 + 1.0450 Tool 1 - Boring
```

Regression Analysis: Tool 2 - Ver 1 versus Tool 2 - Boring

```
Stepwise Selection of Terms

α to enter = 0.15, α to remove = 0.15


Analysis of Variance

Source             DF   Adj SS   Adj MS  F-Value  P-Value
Regression          1  0.10569  0.10569     5.48    0.079
  Tool 2 - Boring   1  0.10569  0.10569     5.48    0.079
Error               4  0.07711  0.01928
Total               5  0.18280


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.138842  57.82%     47.27%       0.00%


Coefficients
```

```
Term               Coef  SE Coef  T-Value  P-Value   VIF
Constant         -0.122    0.129    -0.94    0.399
Tool 2 - Boring   0.457    0.195     2.34    0.079  1.00


Regression Equation

Tool 2 - Ver 1 = -0.122 + 0.457 Tool 2 - Boring
```

Regression Analysis: Tool 2 - Ver 2 versus Tool 2 - Boring

```
Stepwise Selection of Terms

α to enter = 0.15, α to remove = 0.15


Analysis of Variance

Source             DF    Adj SS    Adj MS  F-Value  P-Value
Regression          1  0.381841  0.381841   277.27    0.000
  Tool 2 - Boring   1  0.381841  0.381841   277.27    0.000
Error               4  0.005509  0.001377
Total               5  0.387350


Model Summary

        S    R-sq  R-sq(adj)  R-sq(pred)
0.0371099  98.58%     98.22%      95.82%


Coefficients

Term               Coef  SE Coef  T-Value  P-Value   VIF
Constant         0.0380   0.0345     1.10    0.333
Tool 2 - Boring  0.8689   0.0522    16.65    0.000  1.00


Regression Equation

Tool 2 - Ver 2 = 0.0380 + 0.8689 Tool 2 - Boring
```

Regression Analysis: Tool 3 - Ver 1 versus Tool 3 - Boring

```
Stepwise Selection of Terms

α to enter = 0.15, α to remove = 0.15


Analysis of Variance

Source             DF   Adj SS    Adj MS  F-Value  P-Value
Regression          1  0.04096  0.040960     7.05    0.077
  Tool 3 - Boring   1  0.04096  0.040960     7.05    0.077
Error               3  0.01744  0.005813
Total               4  0.05840
```

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.0762452	70.14%	60.18%	0.00%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	-0.0520	0.0800	-0.65	0.562	
Tool 3 - Boring	0.376	0.142	2.65	0.077	1.00

Regression Equation

Tool 3 - Ver 1 = -0.0520 + 0.376 Tool 3 - Boring

Regression Analysis: Tool 3 - Ver 2 versus Tool 3 - Boring

Stepwise Selection of Terms

α to enter = 0.15, α to remove = 0.15

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.272250	0.272250	446.31	0.000
Tool 3 - Boring	1	0.272250	0.272250	446.31	0.000
Error	3	0.001830	0.000610		
Total	4	0.274080			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.0246982	99.33%	99.11%	98.45%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	0.0030	0.0259	0.12	0.915	
Tool 3 - Boring	0.9706	0.0459	21.13	0.000	1.00

Regression Equation

Tool 3 - Ver 2 = 0.0030 + 0.9706 Tool 3 - Boring

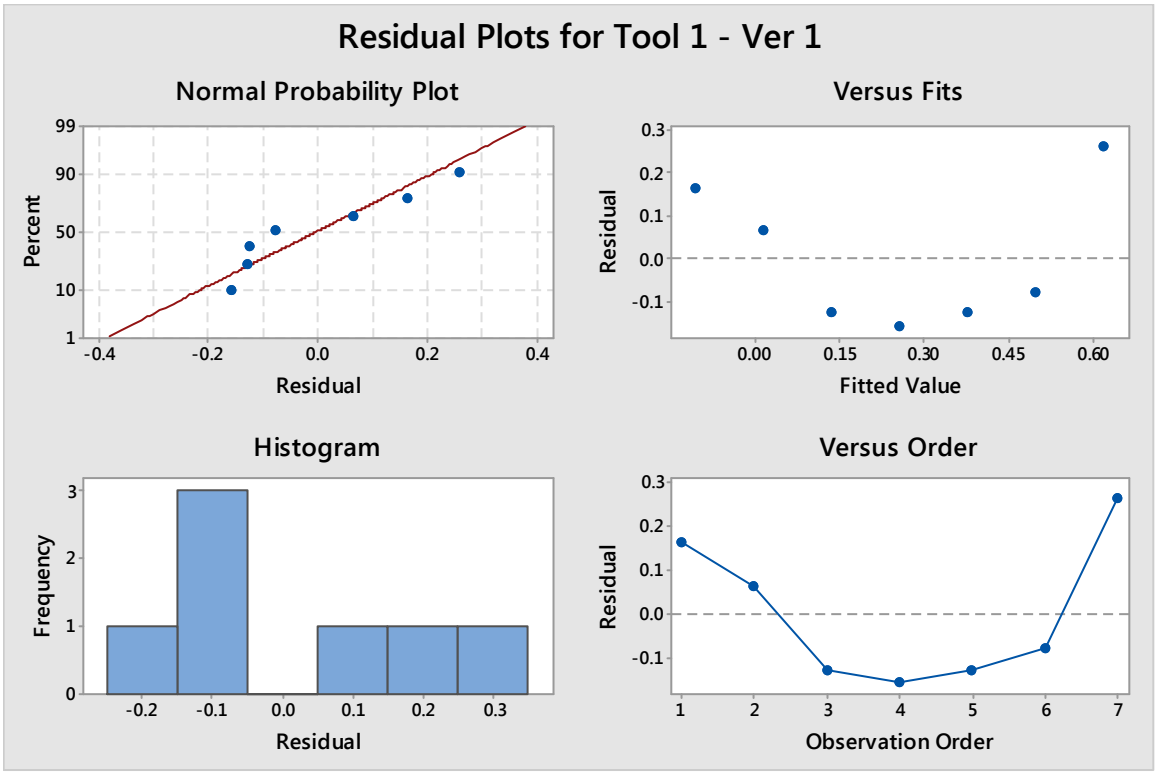


Figure 8-22: Residual Plots Tool 1 - Version 1

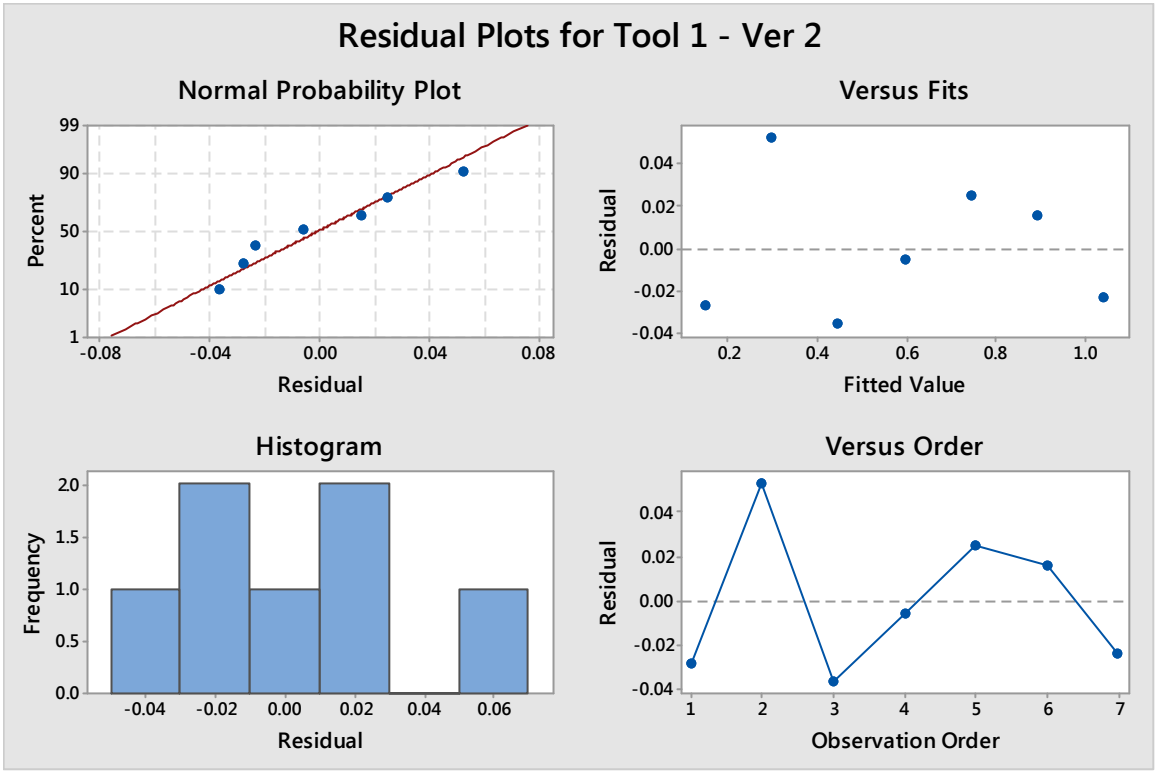


Figure 8-23: Residual Plots Tool 1 - Version 2

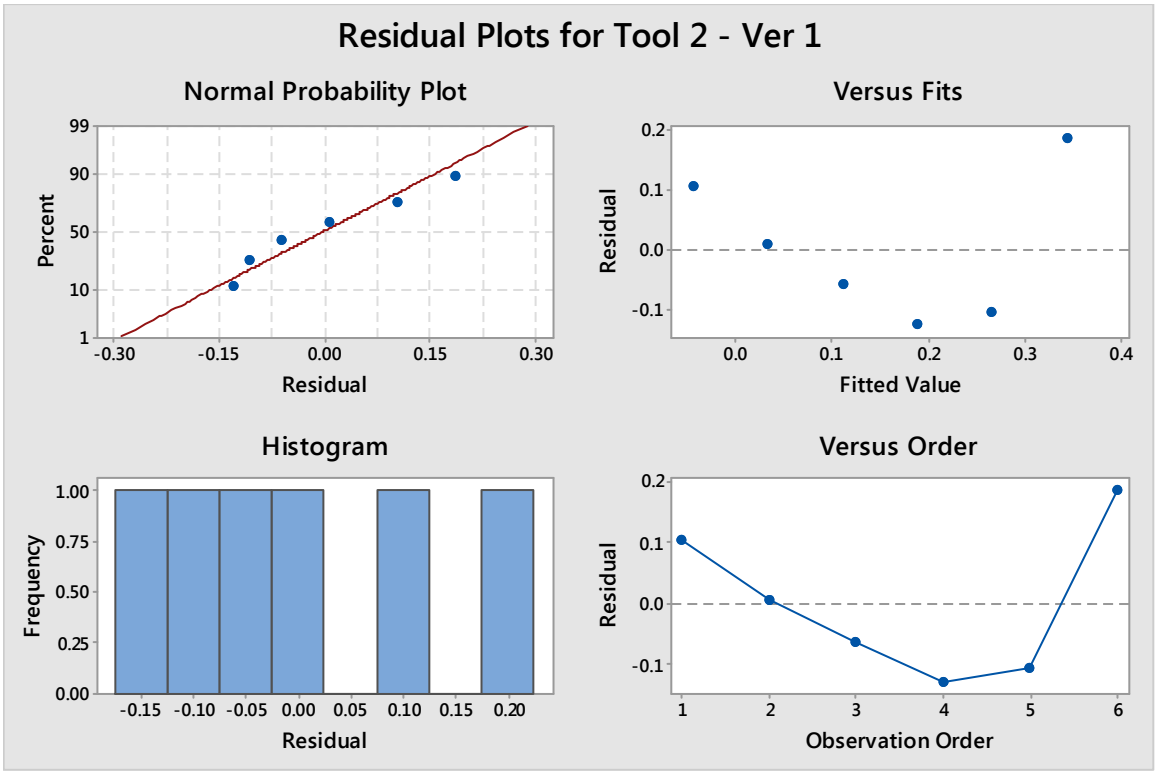


Figure 8-24: Residual Plots Tool 2 - Version 1

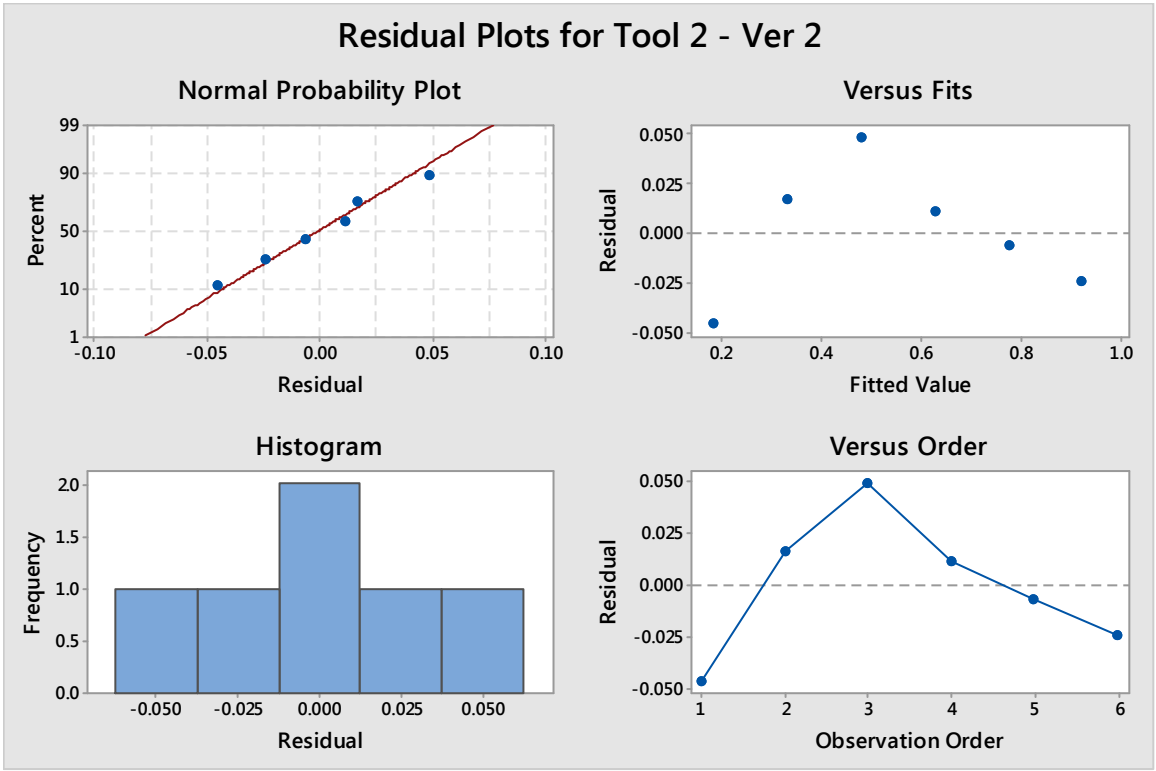


Figure 8-25: Residual Plots Tool 2 - Version 2

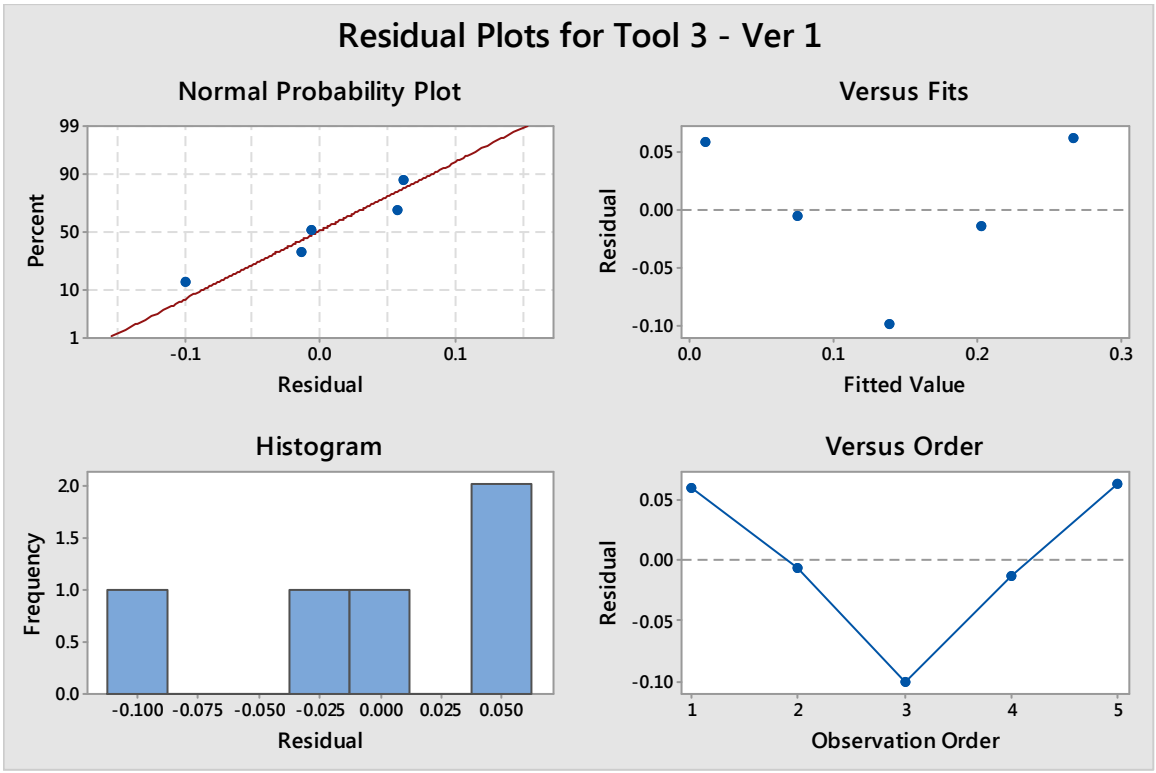


Figure 8-26: Residual Plots Tool 3 - Version 1

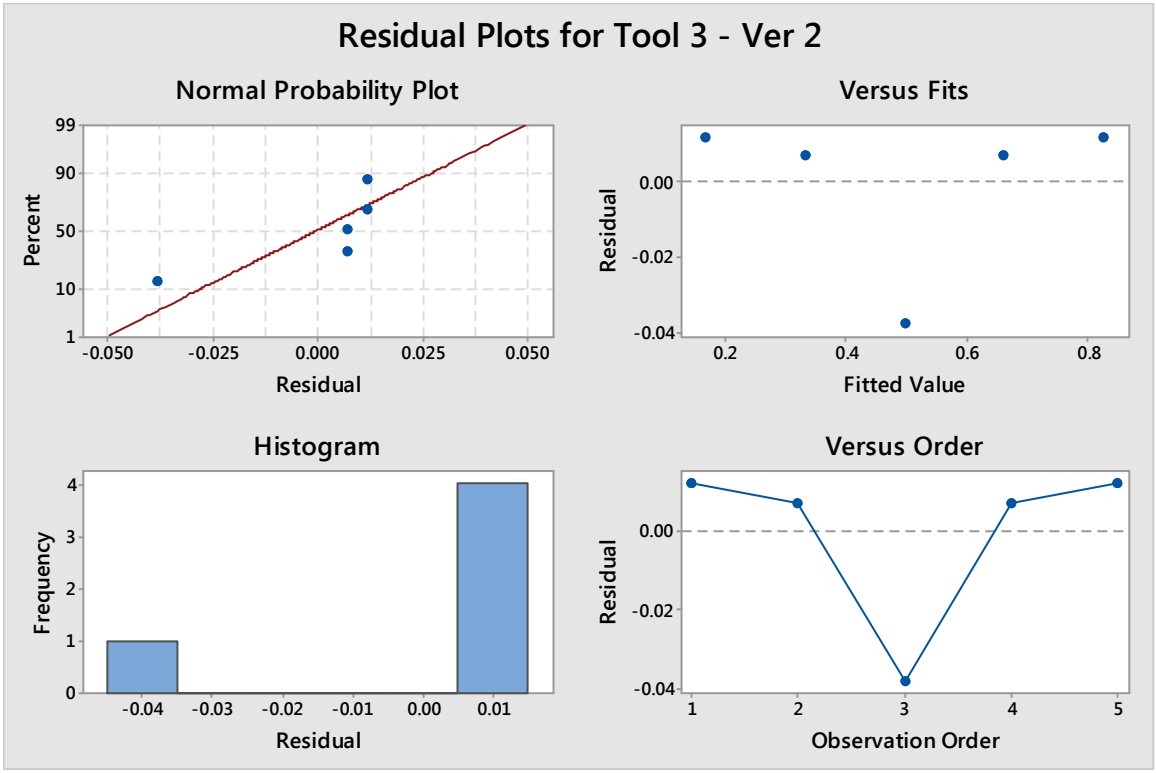


Figure 8-27: Residual Plots Tool 3 - Version 2

Table 8-20: Regression Analysis - Drilling Tools

Regression Analysis: Tool 1 - Ver 1 versus Tool 1 - Drilling

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.000089	0.000089	0.09	0.779
Tool 1 - Drilling	1	0.000089	0.000089	0.09	0.779
Error	5	0.005082	0.001016		
Total	6	0.005171			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.0318815	1.73%	0.00%	0.00%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	1.0871	0.0269	40.35	0.000	
Tool 1 - Drilling	0.0128	0.0430	0.30	0.779	1.00

Regression Equation

Tool 1 - Ver 1 = 1.0871 + 0.0128 Tool 1 - Drilling

Fits and Diagnostics for Unusual Observations

Obs	Tool 1 - Ver 1	Fit	Resid	Std Resid	
4	1.0300	1.0943	-0.0643	-2.18	R

R Large residual

Regression Analysis: Tool 1 - Ver 2 versus Tool 1 - Drilling

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.1808	0.1808	1.22	0.319
Tool 1 - Drilling	1	0.1808	0.1808	1.22	0.319
Error	5	0.7400	0.1480		
Total	6	0.9208			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.384699	19.64%	3.56%	0.00%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF

```
Constant           0.124    0.325     0.38    0.718
Tool 1 - Drilling  0.574    0.519     1.11    0.319  1.00


Regression Equation

Tool 1 - Ver 2 = 0.124 + 0.574 Tool 1 - Drilling
```

Regression Analysis: Tool 1 - Ver 3 versus Tool 1 - Drilling

```
Analysis of Variance

Source               DF   Adj SS    Adj MS  F-Value  P-Value
Regression            1  0.61213  0.612129    64.79    0.000
  Tool 1 - Drilling   1  0.61213  0.612129    64.79    0.000
Error                 5  0.04724  0.009449
Total                 6  0.65937


Model Summary

        S    R-sq  R-sq(adj)  R-sq(pred)
0.0972038  92.84%     91.40%      85.97%


Coefficients

Term                 Coef  SE Coef  T-Value  P-Value   VIF
Constant          -0.0471   0.0822    -0.57    0.591
Tool 1 - Drilling   1.056    0.131     8.05    0.000  1.00


Regression Equation

Tool 1 - Ver 3 = -0.0471 + 1.056 Tool 1 - Drilling
```

Regression Analysis: Tool 2 - Ver 1 versus Tool 2 - Drilling

```
Analysis of Variance

Source               DF  Adj SS   Adj MS  F-Value  P-Value
Regression            1  0.2642  0.26423     2.74    0.159
  Tool 2 - Drilling   1  0.2642  0.26423     2.74    0.159
Error                 5  0.4821  0.09642
Total                 6  0.7463


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.310520  35.40%     22.48%       0.00%


Coefficients

Term                Coef  SE Coef  T-Value  P-Value   VIF
Constant           0.569    0.262     2.17    0.083
Tool 2 - Drilling  0.694    0.419     1.66    0.159  1.00
```

```
Regression Equation

Tool 2 - Ver 1 = 0.569 + 0.694 Tool 2 - Drilling


Fits and Diagnostics for Unusual Observations

      Tool 2
Obs  - Ver 1    Fit   Resid  Std Resid
  1    0.160  0.666  -0.506      -2.23  R

R  Large residual
```

Regression Analysis: Tool 2 - Ver 2 versus Tool 2 - Drilling

```
Analysis of Variance

Source               DF    Adj SS    Adj MS  F-Value  P-Value
Regression            1  0.001889  0.001889     0.01    0.908
  Tool 2 - Drilling   1  0.001889  0.001889     0.01    0.908
Error                 5  0.633054  0.126611
Total                 6  0.634943


Model Summary

       S   R-sq  R-sq(adj)  R-sq(pred)
0.355824  0.30%      0.00%       0.00%


Coefficients

Term                 Coef  SE Coef  T-Value  P-Value   VIF
Constant            0.616    0.301     2.05    0.096
Tool 2 - Drilling  -0.059    0.480    -0.12    0.908  1.00


Regression Equation

Tool 2 - Ver 2 = 0.616 - 0.059 Tool 2 - Drilling
```

Regression Analysis: Tool 2 - Ver 3 versus Tool 2 - Drilling

```
Analysis of Variance

Source               DF   Adj SS   Adj MS  F-Value  P-Value
Regression            1  0.08470  0.08470     6.45    0.052
  Tool 2 - Drilling   1  0.08470  0.08470     6.45    0.052
Error                 5  0.06564  0.01313
Total                 6  0.15034


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.114580  56.34%     47.61%       0.00%
```

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	0.3429	0.0968	3.54	0.017	
Tool 2 - Drilling	0.393	0.155	2.54	0.052	1.00

Regression Equation

Tool 2 - Ver 3 = 0.3429 + 0.393 Tool 2 - Drilling

Regression Analysis: Tool 3 - Ver 1 versus Tool 3 - Drilling

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.2264	0.2264	1.06	0.412
Tool 3 - Drilling	1	0.2264	0.2264	1.06	0.412
Error	2	0.4288	0.2144		
Total	3	0.6552			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.463018	34.56%	1.84%	0.00%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF
Constant	1.499	0.664	2.26	0.152	
Tool 3 - Drilling	-0.855	0.832	-1.03	0.412	1.00

Regression Equation

Tool 3 - Ver 1 = 1.499 - 0.855 Tool 3 - Drilling

Regression Analysis: Tool 3 - Ver 2 versus Tool 3 - Drilling

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Regression	1	0.03448	0.03448	0.10	0.782
Tool 3 - Drilling	1	0.03448	0.03448	0.10	0.782
Error	2	0.69420	0.34710		
Total	3	0.72867			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
0.589152	4.73%	0.00%	0.00%

Coefficients

Term	Coef	SE Coef	T-Value	P-Value	VIF

```
Constant           0.373    0.844     0.44    0.702
Tool 3 - Drilling   0.33     1.06     0.32    0.782  1.00


Regression Equation

Tool 3 - Ver 2 = 0.373 + 0.33 Tool 3 - Drilling
```

Regression Analysis: Tool 3 - Ver 3 versus Tool 3 - Drilling

```
Analysis of Variance

Source               DF   Adj SS   Adj MS  F-Value  P-Value
Regression            1  0.02919  0.02919     0.24    0.676
  Tool 3 - Drilling   1  0.02919  0.02919     0.24    0.676
Error                 2  0.24829  0.12414
Total                 3  0.27748


Model Summary

       S    R-sq  R-sq(adj)  R-sq(pred)
0.352339  10.52%      0.00%       0.00%


Coefficients

Term                Coef  SE Coef  T-Value  P-Value   VIF
Constant           0.248    0.505     0.49    0.672
Tool 3 - Drilling  0.307    0.633     0.48    0.676  1.00


Regression Equation

Tool 3 - Ver 3 = 0.248 + 0.307 Tool 3 - Drilling
```

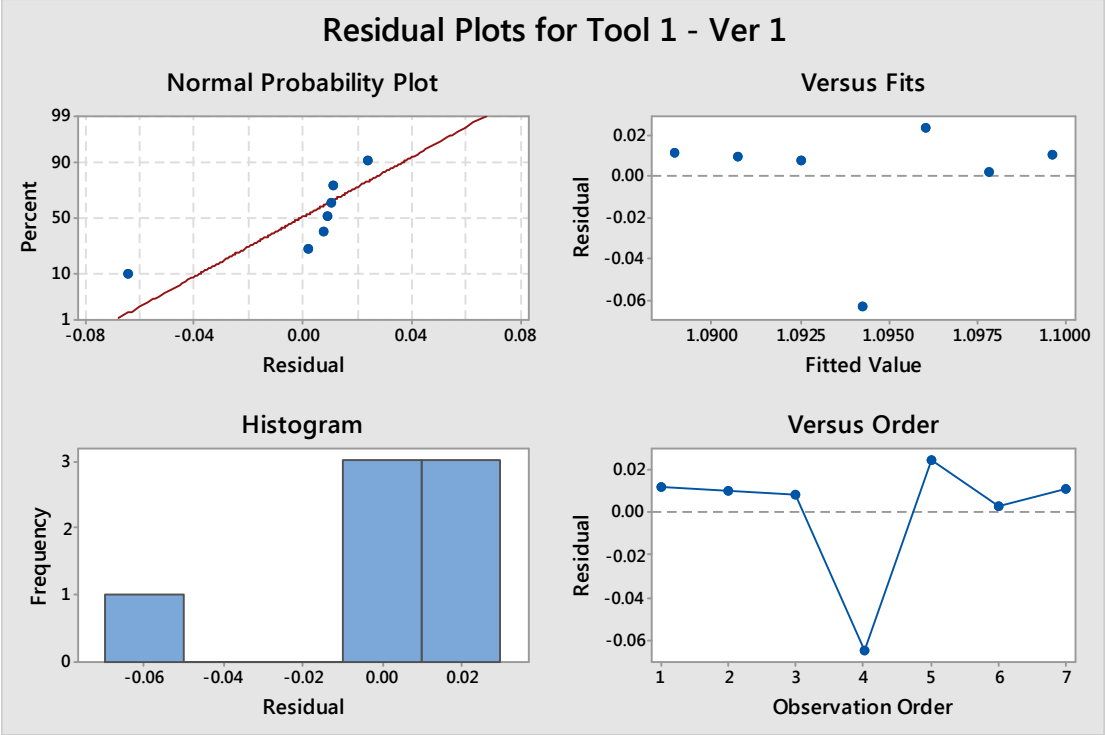


Figure 8-28: Residual Plots Tool 1 - Version 1

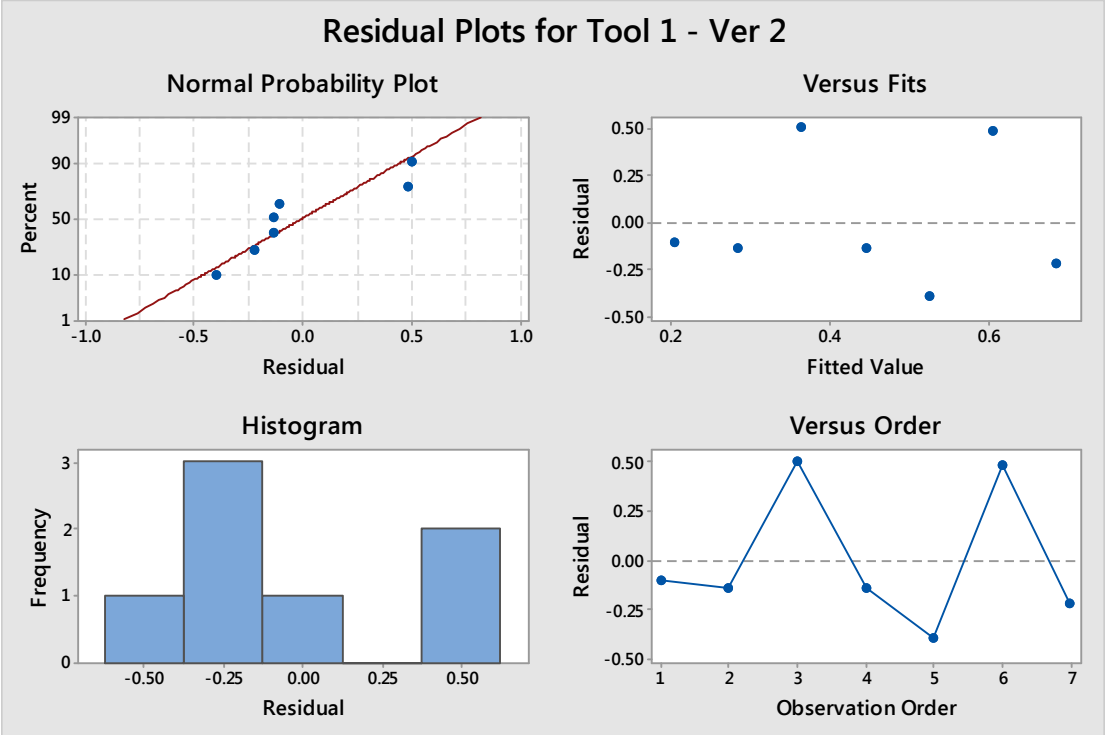


Figure 8-29: Residual Plots Tool 2 - Version 2

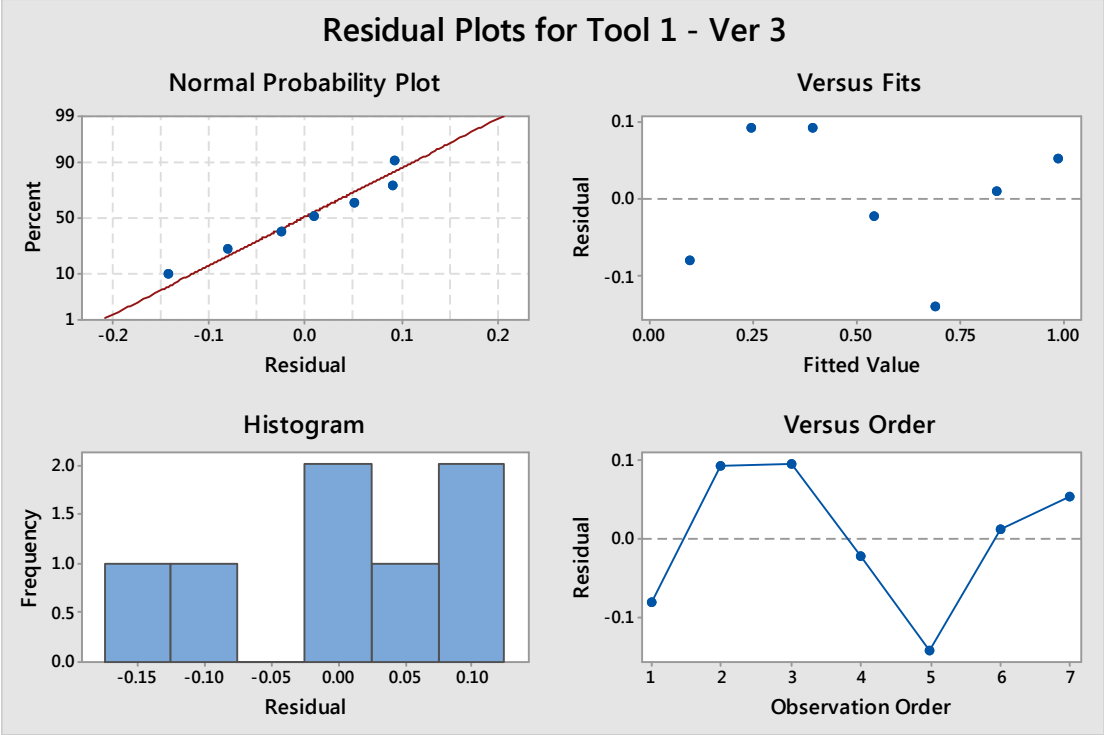


Figure 8-30: Residual Plots Tool 1 - Version 3

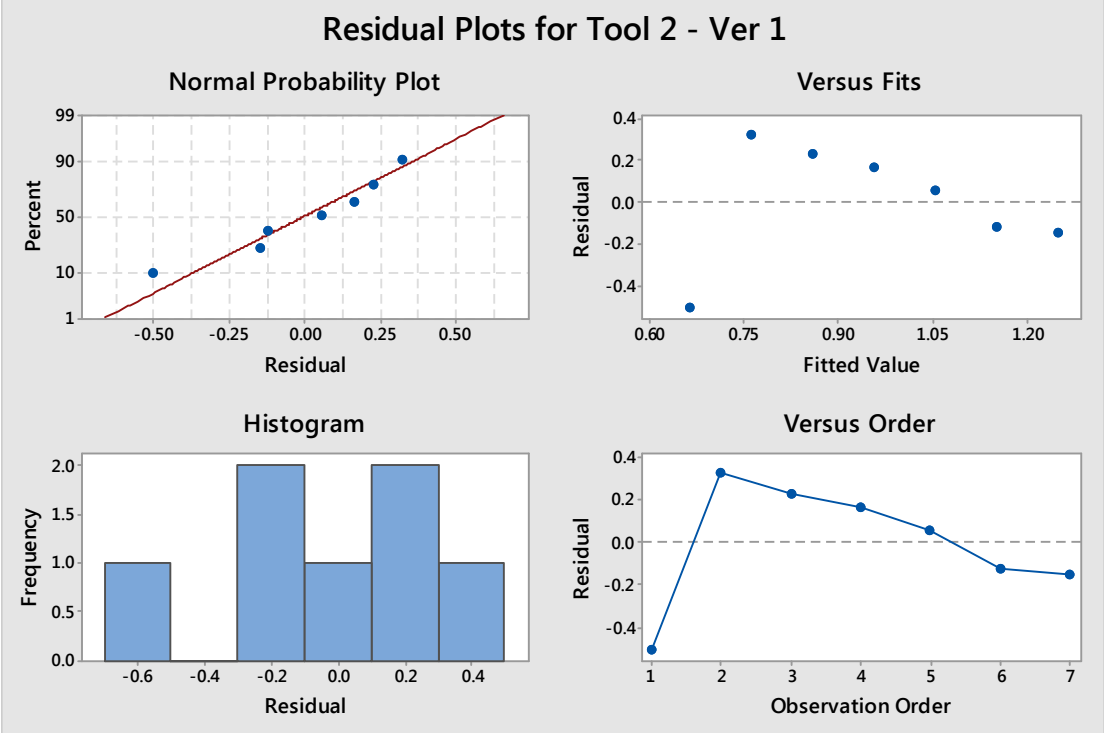


Figure 8-31: Residual Plots Tool 2 - Version 1

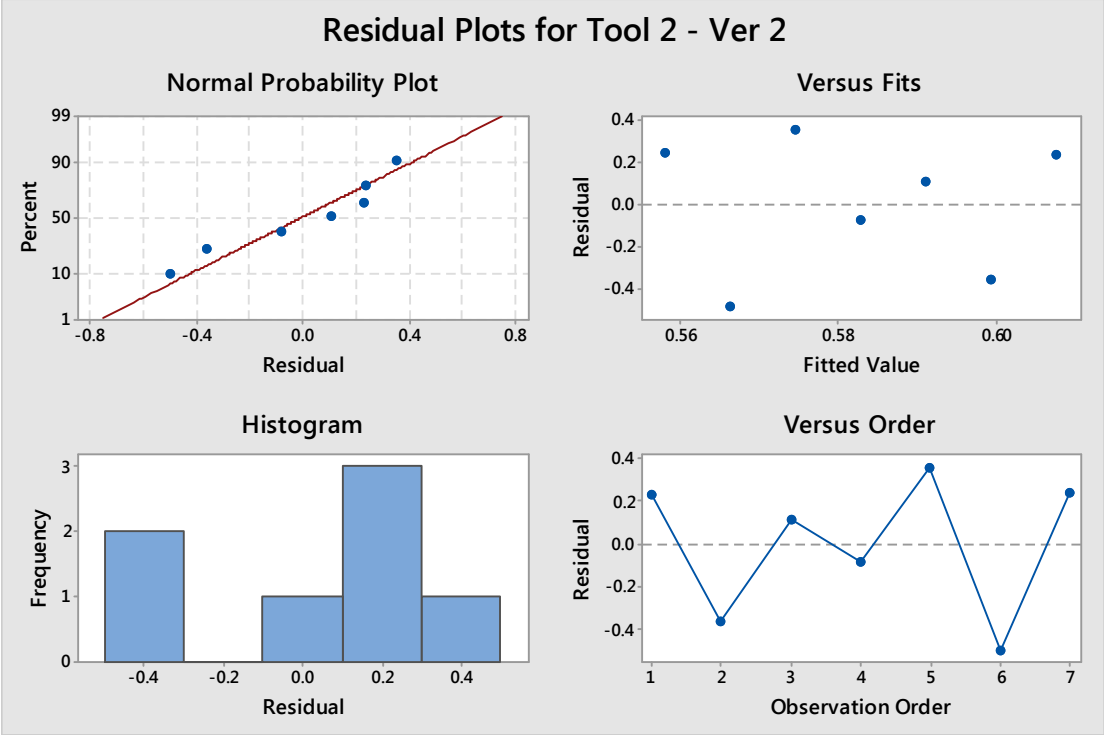


Figure 8-32: Residual Plots Tool 2 - Version 2

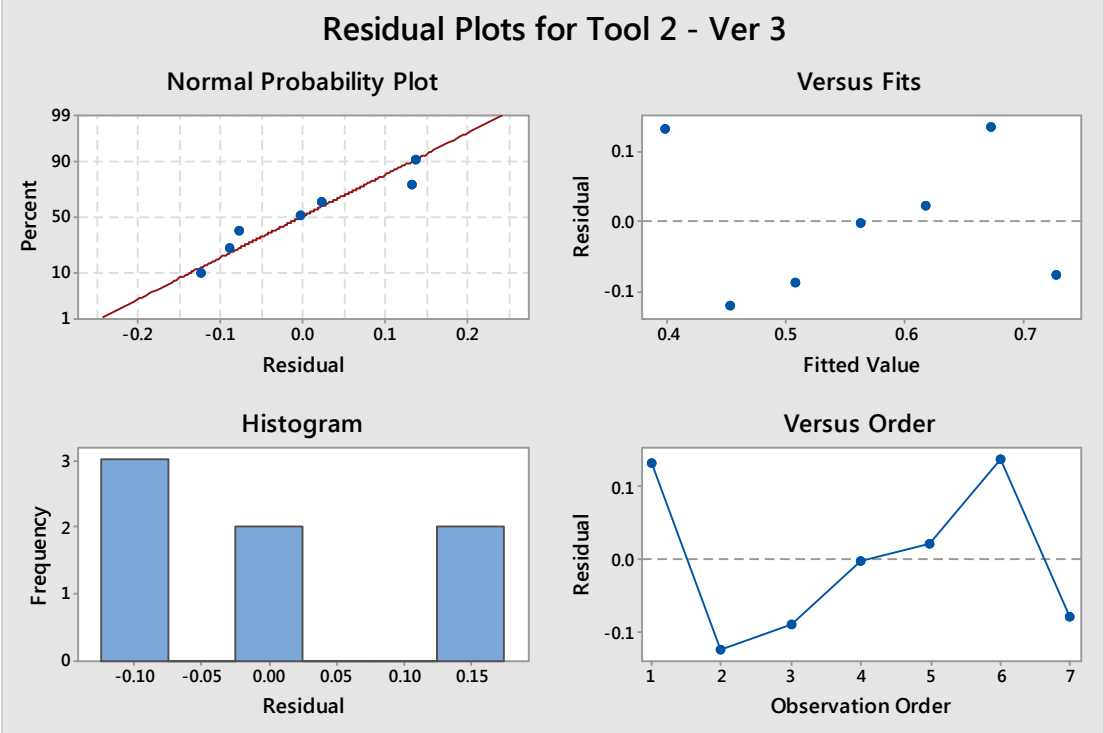


Figure 8-33: Residual Plots Tool 2 - Version 3

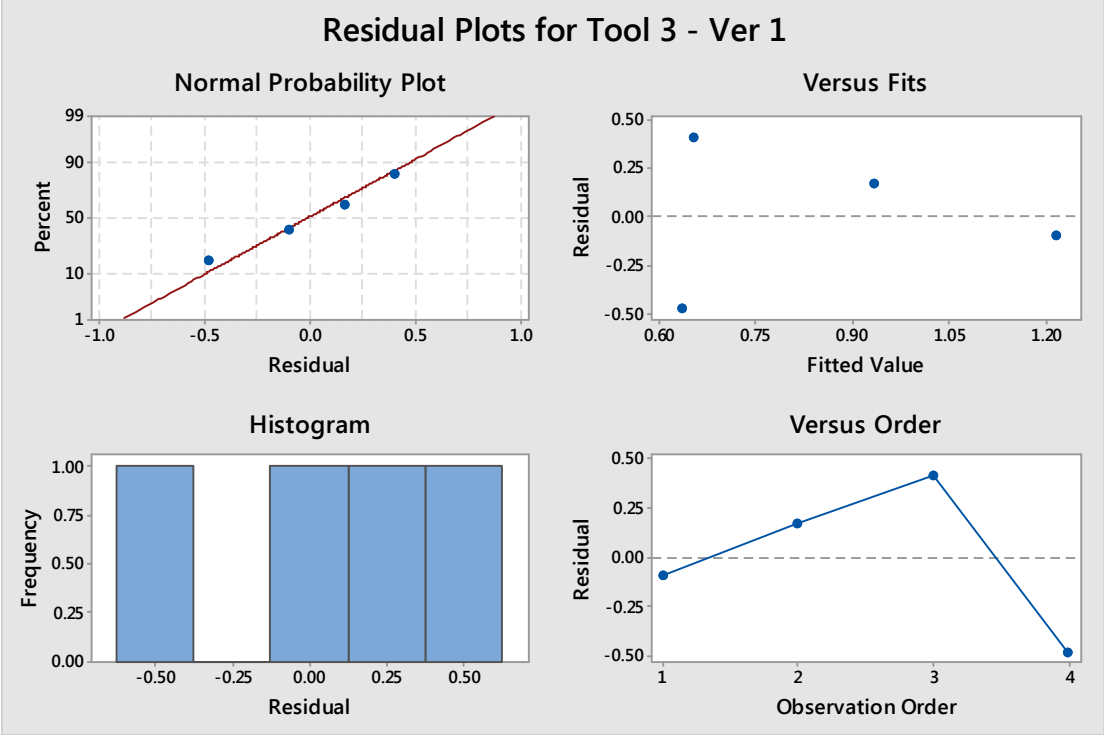


Figure 8-34: Residual Plots Tool 3 - Version 1

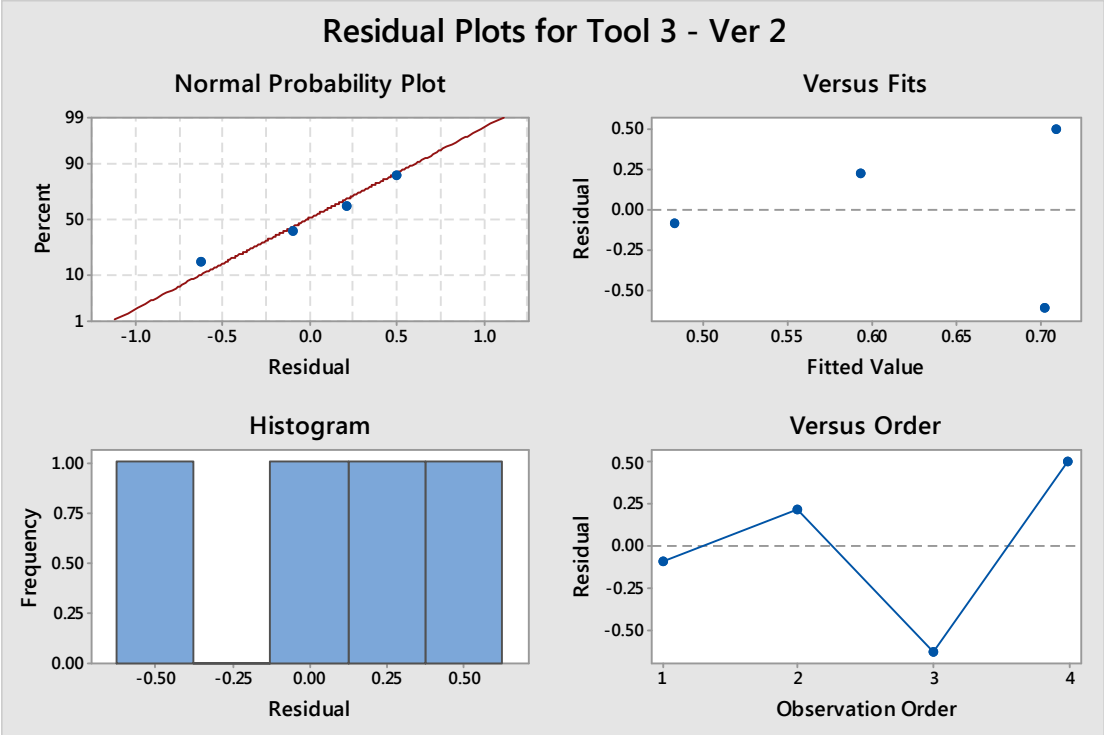


Figure 8-35: Residual Plots Tool 3 - Version 2

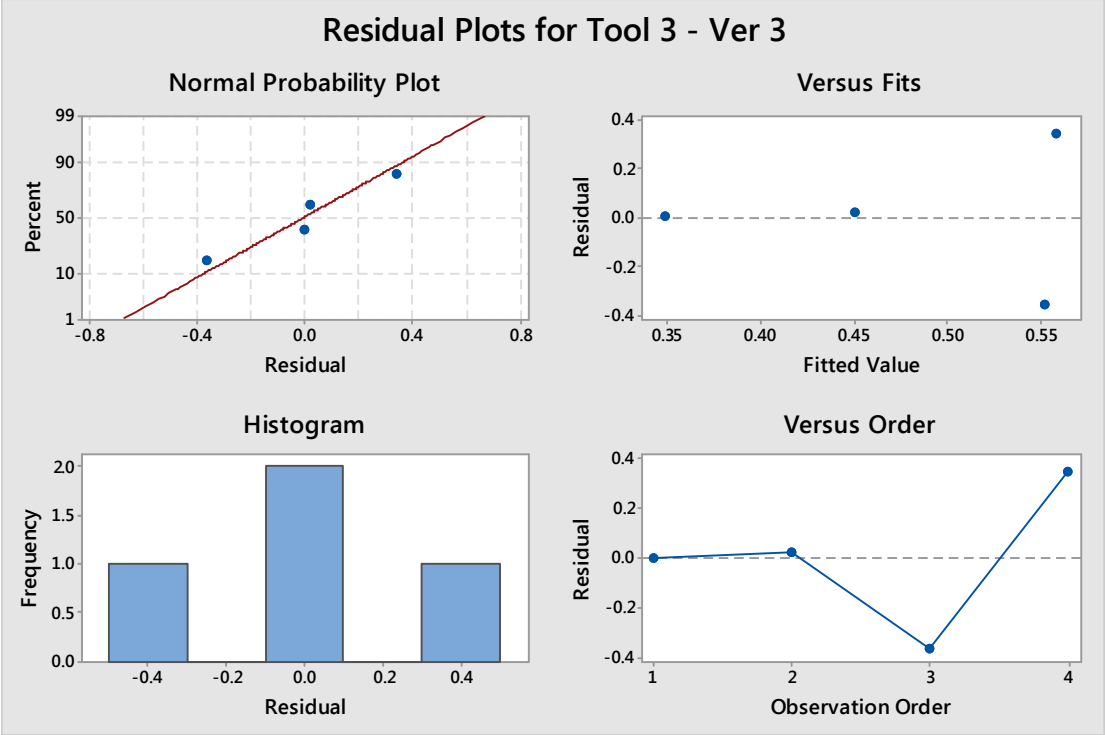
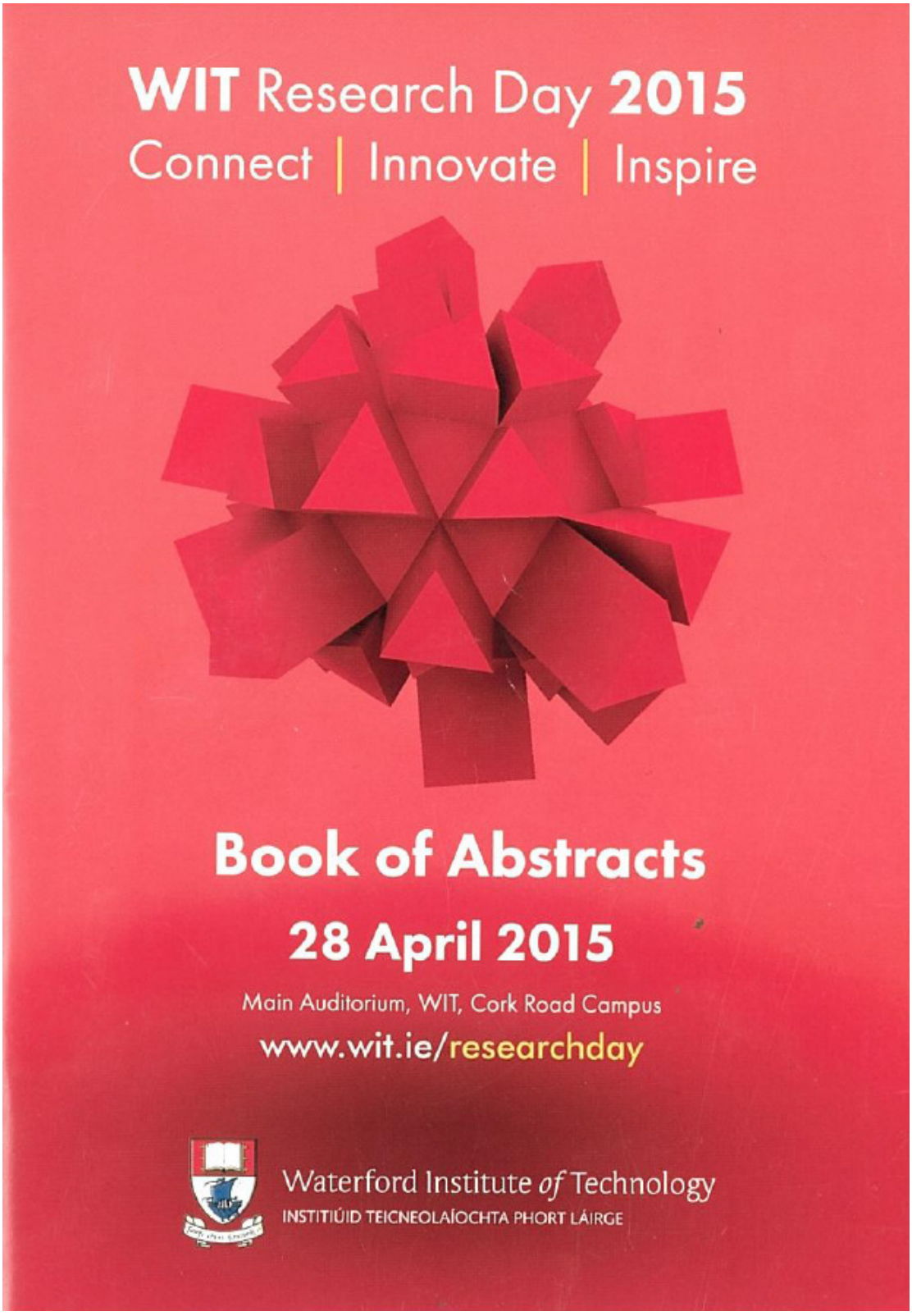


Figure 8-36: Residual Plots Tool 3 - Version 3

8.5 Appendix E – Papers & Presentations

WIT Research Day – Waterford Institute of Technology (28th April 2015)



WIT Research Day 2015 | Poster Presentation

Poster 13

Development of a generic tool condition monitoring validation methodology

Barry Ronan, Liam O'Shea, Paul O'Leary
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This research paper brings GMP validation techniques to bear on a system that monitors the tool wear aspect of CNC machining, known as Tool Condition Monitoring (TCM), with a view to improving the overall performance of the process. The work is being carried out in tandem with an EU FP7-funded project that will install force, acoustic and vibration sensors on selected CNC machines in Ireland, Poland, Italy and Norway. The validation techniques are focused on the medical devices sector, primarily because the medical devices sector is bound by Good Manufacturing Practices (GMP's), which are mandatory regulatory requirement. Medical devices manufactured for U.S. distribution must be in compliance with these regulations. GMPs are enforced in different parts of world by different regulatory bodies; some of the more recognizable bodies would be U.S. Food and Drug Administration (FDA), the World Health Organization (WHO) and the European Union (EU). Validation is an essential part of good manufacturing practices and the approach of bringing GMP validation techniques to TCM has not yet been implemented in this industry, which otherwise relies heavily on validation.

The TCM consists of a 3-axis force sensor, an acoustic emission sensor, 3-axis accelerometer, a data acquisition card, an industrial portable computer, custom Data Logging Software and custom Control Software, linked back to a Human Machine Interface (HMI). The areas of equipment validation, Computerized Systems Validation, Control Systems Validation and Process Validation have been considered and reviewed against regulatory requirements. The validation process consists of identifying and testing all aspects of a process that could affect the final product. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required quality specifications throughout the product lifecycle. In this paper we focus on the process validation design, qualification and ongoing monitoring phases and the associated regulatory requirements of GMP validation.

One of the unique elements of this research is the incorporation of a Case-Based Reasoning (CaBR) control system into the TCM, and the application of the validation model to CaBR, an area which has received little attention in literature. The system shall be trained by machine operator, during the setup process, to identify when a tool is at end of life and based on this data shall make its own decisions around the degree of tool wear. Validation of the CaBR system shall establish whether an individual test case has been solved correctly through benchmarking against learned information and operator expectation.

Development of a Generic Tool Condition Monitoring Validation Methodology

SCHIVO ...engineering Partnerships

Barry Ronan (✉ bronan@schivogroup.com)
WIT Student Number 98688936
Supervisors: Mr. Liam O'Shea, Dr. Paul O'Leary

Introduction

This research brings GMP validation techniques to bear on a system that monitors the tool wear aspect of CNC machining, known as Tool Condition Monitoring (TCM), with a view to improving the overall performance of the process. The work is being carried out in tandem with an EU FP7 funded project that will install force, acoustic and vibration sensors on selected CNC machines in Ireland, Poland, Italy and Norway.

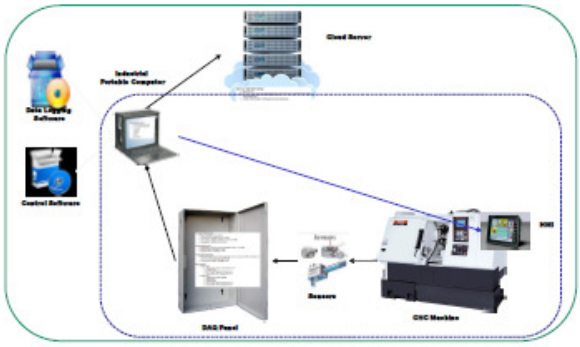

Figure 1. Schematic of the TCM System

Purpose

Validation is an essential part of good manufacturing practices and the approach of bringing GMP validation techniques to TCM has not yet been implemented within this industry, which otherwise relies heavily on validation.

The validation techniques are focused on the medical devices sector, primarily because the medical devices sector is bound by Good Manufacturing Practices (GMP's), which are mandatory regulatory requirements.

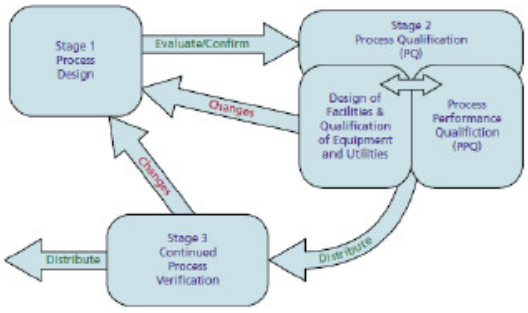

Figure 2. Process Validation

TCM Equipment

The TCM system consists of:

- 3-axis force sensor
- Acoustic emission sensor
- 3-axis accelerometer
- Data acquisition card
- Industrial portable computer
- Custom data logging software
- Custom control software
- Human machine interface (HMI)

One of the unique elements of this research is the incorporation of a Case-Based Reasoning (CaBR) control system into the TCM, and the application of the validation model to CaBR, an area which has received little attention in literature.

Figure 3. CNC Turning

Method

The validation process consists of identifying and testing all aspects of a process that could affect the final product. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required quality specifications throughout the product lifecycle.

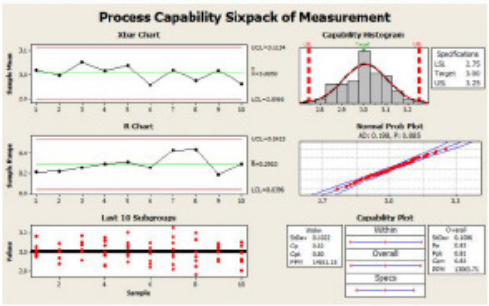

Figure 4. Capability Analysis

International Manufacturing Conference - Queens University Belfast (3rd-4th Sept 2015)

Development of a generic tool condition monitoring validation methodology

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ABSTRACT

Good manufacturing practices (GMP) are enforced in different parts of the world by regulatory bodies; some of the more recognizable bodies being the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO) and the European Union (EU). Validation is an essential part of GMP and the approach of bringing GMP validation techniques to Tool Condition Monitoring (TCM), in the medical devices industry, which relies heavily on validation, has received little attention in literature. Validation involves identifying and testing all aspects of a process that could affect the final product quality/safety and demonstrating with a high degree of assurance that uniform product will be produced, that meets the required quality specifications throughout the product lifecycle.

The focus of this paper is on the selection of whether validation or verification is the best approach for the Tool Condition Monitoring (TCM) system, which consists of a 3-axis force sensor, an acoustic emission sensor, 3-axis accelerometer, a data acquisition card, an industrial portable computer, custom Data Logging Software and custom Control Software, linked back to a Human Machine Interface (HMI).

One of the unique elements of this system is the incorporation of a neural network based Case-Based Reasoning (CaBR) control system into the TCM, an area which has received little attention in literature.

KEYWORDS: Tool Condition Monitoring, GMP Validation, CNC Machining

1. INTRODUCTION

There has, for many years, been considerable research into the monitoring and control of CNC machining processes. This research has been continued by the consortium engaged in the REALISM project, an EU-FP7 funded project which is investigating the toolwear aspect of machining, known as Tool Condition Monitoring, with a view to improving the operator's insight into toolwear.

In precision engineering, cutting tool condition has a large effect on the accuracy and surface finish of machined parts. Currently, poorly finished machined parts associated with toolwear are usually only detected at the end of the machine cycle, by which time the product may be simply of lower quality or even only of scrap value. Machining of parts is primarily performed by Computer Numerical Control (CNC) machines, which if equipped with real-time monitoring, machining parameters could even be adjusted, in real-time, to compensate for toolwear and the tools could be replaced at appropriate intervals before they reach end of tool life. This would result in both better control over the machining process and would also lead to a significant reduction in scrap rates.

CNC machines are used to manufacture product for various industries, including aerospace, automotive, medical devices and oil & gas. For most CNC industries, voluntary certification is sought, when they determine that the certification is beneficial to their operations. Examples of voluntary certifications include ISO 9001:2008 Quality Management System, ISO 13485:2012 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes and AS 9100C:2008 Quality Management Systems – Requirements for Aviation, Space and Defence Organisations.

CNC Companies, on the other hand who are manufacturing for the medical devices sector are bound by GMP's or Good Manufacturing Practices. GMPs are a mandated regulatory requirement by, for example, the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO) and the European Union (EU). Therefore, in the case of companies that are manufacturing medical devices for U.S. distribution, they must be in compliance with these regulations.

1.1 Overview of the REALISM Project

The REALISM project has participants across a number of EU member states. The consortium partners are listed in Table 1.

Table 1: The REALISM consortium

Name	Country	Participant type
Schivo Precision	Ireland	SME
Waterford IT (WIT)	Ireland	RTD
IDT Solutions	Norway	SME
Warsaw University of Technology (WUT)	Poland	RTD
Tulino CTM	Italy	SME
University of Naples	Italy	RTD
Gjovic University (GUC)	Norway	RTD

The REALISM project consortium work packages are broken down as detailed in Figure 1. While the focus of this paper is WP7 – Validation and Evaluation, the success of this work package requires both process and component information and understanding from all the other work packages.

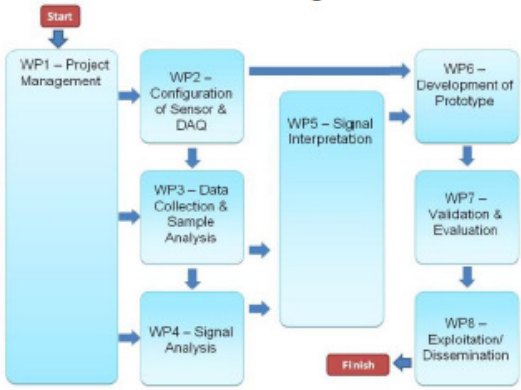

Figure 1: REALISM project work package overview

1.2 Overview of the TCM System

The TCM consists of a 3-axis force sensor, an acoustic emission (AE) sensor, a 3-axis accelerometer, data acquisition system, an industrial portable computer, custom data logging software and custom control software linked back to a human machine interface (HMI). A schematic overview of the system is detailed in Figure 2. The sensors have initially been deployed on a Mazak Quickturn Nexus 200II machine at Schivo Precision based in Waterford, Ireland, with future deployments planned at IDT Solutions, Norway and Tulino CTM, Italy.

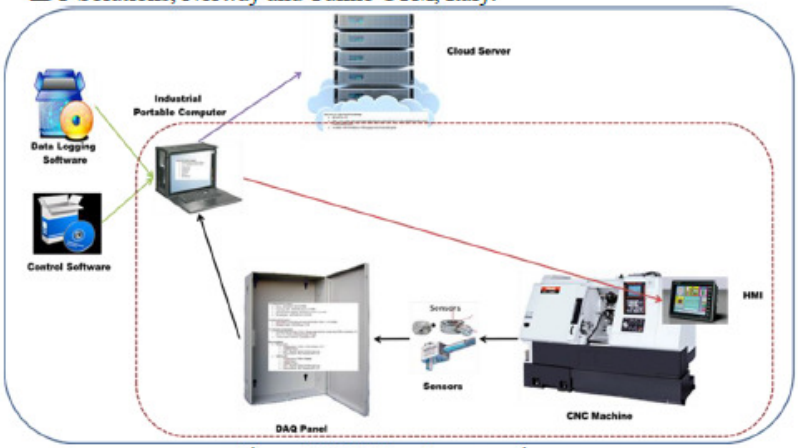

Figure 2: TCM system overview

2. VERIFICATION VS VALIDATION

Companies who pursue voluntary certification generally opt for certification to the baseline standard ISO 9001. This ISO 9001 standard and also the more specific standards of ISO 13485 (medical devices) and AS9100 (aviation, space and defence) all introduce the concepts of validation and verification, specifying that:

"The organization shall validate any processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement".

The ISO 9000:2005 standard provides definitions of such concepts and, specifically for this case, defines verification as "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled" and validation as "confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled".

In considering whether the output cannot be verified by subsequent monitoring or measurement, initially the prospect that the project may be classified as a special process was considered. According to Brecken [1], processes where the resulting output cannot be verified by subsequent monitoring or measurement are frequently referred to as "special processes". ISO 9001:1994 in fact included the term "special process", until it was superseded by the 2000 version of the standard. Thus ISO 9001:2008, clause 7.5.2, now refers to special processes as "processes requiring validation." It's important to note at this point that all special processes must be validated. Validation of special processes provides confidence that the process is fully understood and the output will achieve consistent results against the required specifications. In addition, within the aerospace industry, Nadcap accreditation is fast becoming a global requirement for suppliers using special processes. Nadcap accreditation is a contractual requirement, and not a mandatory AS/EN9100 requirement, and involves a stringent audit by Performance Review Institute (PRI) personnel.

Within the aerospace and oil and gas industries, 100% inspection are more frequently commonplace and sampling inspection is used less. Neither voluntary nor regulatory certification bodies offer any clear guidance on what verification actually means nor do they clearly define exactly what the term "verified" means. However, the most commonly accepted method of verification within the CNC industry is through 100% inspection. The standards stipulate that the organization shall only "validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement".

Verification can be thought of as a method of testing that provides assurance at a point in time that a product will do what it is intended to do without causing another problem. Validation on the other hand provides

measurable evidence that over time the product will work properly. In the medical devices industry, process validation is generally seen as the endpoint of all validation activities, as illustrated in Figure 3.

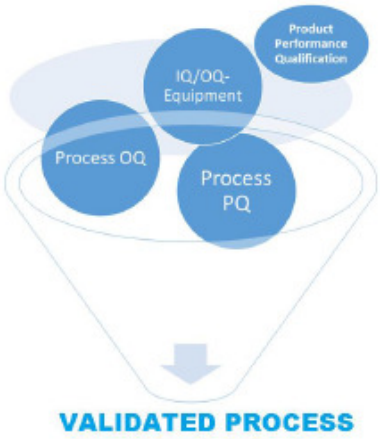

Figure 3: Process Validation Funnel Diagram

Verification, through 100% inspection, is commonplace across the aerospace and the oil and gas industries. In the medical industry, this approach is usually not taken, instead a lower rate of inspection, based on validations which use statistical analysis of the process is more commonplace. The focus of this paper has therefore been narrowed to the medical devices industry, which is mandated by Good Manufacturing Practices (GMP) and in which validation is a regulatory requirement.

Helle et al [2] suggest that the three most often referred to definitions of process validation are those presented by the European Agency for the Evaluation of Medicinal Products (EMEA), the US Food and Drug Administration (FDA) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and that the three definitions are very similar, with the difference being that

"the FDA expresses a minor uncertainty of the concept, despite the efforts of validation, by stating that process validation only provides a high degree of (not absolute) assurance that the process will produce the intended product".

Through comparison it can be summarized that validation is, documented evidence, showing that if we have a process with specific predetermined parameters and we constantly input the same parameters to the process, we will consistently achieve an output from that process that meets our pre-determined specifications.

Typically validations are based on knowledge collected through process development activities or process experience over a period of time. Therefore there is a body of knowledge about the process, generally in the form of statistical analysis. Verification on the other hand is completed at a

point in time, i.e. Part A gets inspected followed by Part B, Part C etc.. No knowledge of the process is gathered, other than the fact that each individual part passed or failed inspection. Without statistical knowledge of the process it can be difficult to have confidence in lower level statistical sampling and therefore the cost of 100% inspection needs to be absorbed into the manufacturing process. Another important point to mention is that 100% verification is also never 100% effective. For example, Juran [3] (1935) estimated that 100% inspection was only 80% effective. However, by 1979 Sinclair [4] demonstrated that not only was Juran correct in his statement that 100% inspection was not 100% effective, but even worse that he was optimistic with his estimation of 80% effectiveness.

In applying validation to the REALISM project, several aspects are taken into account. The TCM consists of a 3-axis force sensor, an acoustic emission (AE) sensor, a 3-axis accelerometer, a data acquisition system, an industrial portable computer, custom data logging software and custom control software linked back to a HMI. While systems may be rule or knowledge based in their decision making, here the control software incorporates a neural network Case-Based Reasoning (CaBR) system, which requires the operator to initially teach the TCM by identifying when a pre-determined number of tools are worn. From this teaching, the TCM will compare the learned results against process conditions, gathered from the sensors, allowing the system to make decisions around the degree of toolwear present on the cutting tool. Gupta et al [5] propose that "Validation of knowledge-based system has received great attention from researchers in the last several years", that "however, the majority of the reported validation work to date has centered around rule-based systems" and that "published literature that deals with validation of Case-Based Reasoning (CaBR) systems is indeed scarce". This will present challenges from a TCM validation perspective.

Validation of the CaBR system shall establish whether an individual test case has been solved correctly through benchmarking against learned information acquired from operator expectation. Gupta et al [5] suggest that this consists of determining two basic parameters, the Result Acceptability Criteria (RAC), and the System Validity Criteria (SVC). The RAC serves to determine whether an individual test case has been solved correctly by the CaBR system. It is the distance between the system solution and the benchmark standard that are then measured.

The TCM has a direct impact on the quality of the product being produced, because if the TCM does not correctly interpret the process conditions there is a significant risk non-confirming or even scrap product being produced. The Global Harmonisation Task Force (GHTF) [6] provides a decision tree which helps in the determination of whether a process should be validated or verified. Although a simple illustration, it provides an effective roadmap for identifying the decision whether to verify or validate by asking two questions: "Is the process output verifiable?" and "Is verification sufficient and cost effective?" The cost effectiveness verification

is an extremely important consideration Snow et al [7] suggest that:

"In many cases it may be more cost effective to validate the process upfront and to understand and control variation, thereby improving process capabilities, increasing yields and lowering scrap. This however is a business decision that needs to be taken early in the process development phase".

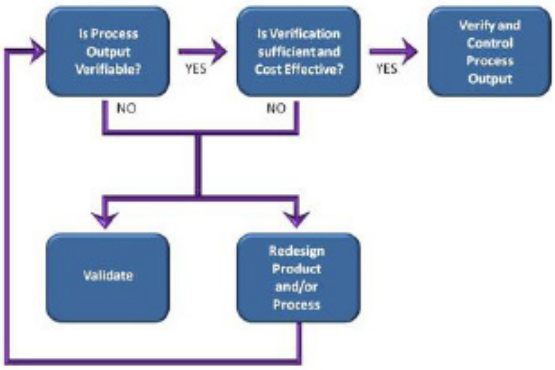

Figure 4: GHTF Process Validation Decision Tree

3. FUTURE WORK

Even at this early stage, it seems likely that the GHTF and Good Automated Manufacturing Practices (GAMP) guidelines will be used as the roadmaps for the TCM validation activities.

It must be noted that GHTF and GAMP produce guidelines, not regulations; the goal of these guidelines is the standardization of regulation across the world. In addition to the guidelines above, because each geographical area actively regulates medical devices using their own unique regulatory framework, consideration will also be given to the individual regulations and three key focus areas which will remain, at all times, when validating this TCM:

- Compliance Focus - Documented evidence that all our systems operate as specified and comply with relevant national and international regulations
- Business Focus – Validating a system and product that we fully understand and which perform predictably
- Patient Focus – Producing safe, functional and effective devices

From a compliance and patient perspective, different validation approaches and life cycles from a selection of regulatory bodies shall be considered for use. From a business focus perspective, process development

testing will be performed to gather deeper process knowledge and key influencing parameters, and their relationships.

4. CONCLUSIONS

The case for validation over verification for the TCM process has been presented. Next steps in terms of its implementation on the EU FP7 REALISM project have been outlined; the results will be presented in a future paper.

5. ACKNOWLEDGEMENTS

The authors would like to thank our colleagues in the REALISM project for their ongoing efforts.

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