Development of a generic tool condition monitoring validation methodology

Barry Ronan¹,⁴, Jonathan Downey¹,⁴, Liam O’Shea⁴, Dr Paul O’Leary², Dr Denis O’Sullivan³, Dr Ramesh Raghavendra³

1. Schivo Precision, Cork Road, Waterford, Republic of Ireland
2. Flexible Wireless Group, Waterford Institute of Technology, Cork Road, Waterford, Republic of Ireland
3. South Eastern Applied Materials Research Centre, Waterford Institute of Technology, Cork Road, Waterford, Republic of Ireland
4. Department of Engineering Technology, Waterford Institute of Technology, Cork Road, Waterford, Republic of Ireland.

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>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
<th>Participant type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schivo Precision</td>
<td>Ireland</td>
<td>SME</td>
</tr>
<tr>
<td>Waterford IT (WIT)</td>
<td>Ireland</td>
<td>RTD</td>
</tr>
<tr>
<td>IDT Solutions</td>
<td>Norway</td>
<td>SME</td>
</tr>
<tr>
<td>Warsaw University of Technology (WUT)</td>
<td>Poland</td>
<td>RTD</td>
</tr>
<tr>
<td>Tulino CTM</td>
<td>Italy</td>
<td>SME</td>
</tr>
<tr>
<td>University of Naples</td>
<td>Italy</td>
<td>RTD</td>
</tr>
<tr>
<td>Gjovic University (GUC)</td>
<td>Norway</td>
<td>RTD</td>
</tr>
</tbody>
</table>
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.

![REALISM project work package overview](image1.png)

**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.

![TCM system overview](image2.png)

**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.

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 predetermined 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”.

![GHTF Process Validation Decision Tree](image)

**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.

6. REFERENCES