

Metrologized LLC

Fostering Metrology Excellence for professional and business success

ANISH SHAH

Founder and Chief Metrology Officer

2883 Ironwood Blvd
Chaska MN 55318
612-309-7196
mgmtsuccess@gmail.com
www.metrologized.com



National Association for Proficiency Testing
"Proficiency Testing Tools for the Metrology Community"

ABSTRACT

Proficiency testing covering the technical scope of a testing laboratory has been a key requirement to gain and maintain accredited status. The testing criteria, though has significant qualification requirements, is only subject to an extended timeline primarily driven by the business needs. This once every so many years testing does not challenge the software revisions and changes that are frequently implemented by a CMM user, both at a testing lab or at a quality lab within a manufacturing organization. Current CMM artifact used as the proficiency test model provides a valuable set of data for a CMM user and its' comparison model brings forth the strengths and deficiencies for that user. If adopted within the quality testing methods of a regulated industry quality lab using a CMM, it can serve as a tool to validate the CMM software and provide objective evidence using a least burdensome approach, as required by FDA. This poster will share the authors' approach on extracting the much needed evidence to support software validation at CMM installation and beyond.

BACKGROUND

Automated CMMs have been around for over 60 years, soon to be followed by application software that can program, inspect, and report measured results, thus allowing CMM to gain widespread use [1]. Mathematical algorithms easily allowed establishing geometric shapes such as cylinders, cones, planes, circles and intersection of planes. But the end users soon realized thru the GIDEP (Government-Industry Data Exchange Program) alert of August 1988, that certain algorithms used by the CMMs tested did not calculate the desired feature correctly per the Dimensioning and Tolerancing Standard, ANSI Y14.5. NMIs (National Metrology Institutes) around the world worked hard to put in place a feature-software certification service, which is currently actively used by the CMM and third party application software industry. FDA' GPSV [2] guidance repeatedly calls for validation effort commensurate with complexity and risk. When it comes to the end-user, in the FDA regulated industry, the intended use of the software is still lacking its rigor, potentially questioning the validity of the measurement results produced. The IQ, OQ, PQ approach recommended by FDA for software validation, although sequential, has left a significant burden on the device manufacturer to prove that the CMM and accompanying software is fit for use. Proficiency Testing using known artifacts if the first step in validating the CMM software ability to compute measured results within the uncertainty stated by the end-user and when compared to the peers. Results from this study can lead to drastically decreased software validation times as well as enable increased measurement accuracy.

TESTING AND EQUIPMENT

Interlaboratory comparison is defined as organization, performance, and evaluation of tests to demonstrate technical competence on the same or similar items by two or more laboratories in accordance with predetermined conditions. Proficiency Testing and Inter-Laboratory testing, or ILC/PT as it is often known, is - under APLAC and ILAC requirements - mandatory where it exists. While it is a benchmarking exercise, and for that reason it is used to establish a laboratory's performance in a manner independent of the assessment process, it can serve as a valuable tool to validate software, when used with adequate care and process. CMM test artifact is shown in Figure 1, with the primary intent of being able to measure geometric features (including line and point) such as cone, cylinder, plane, circle, and sphere. Participant, upon successful enrollment into the ILC/PT program, is required to follow the necessary instructions in completing the measurements and reporting results, along with reporting the associated measurement uncertainty (@k=2) for each measurement[3]. Validation can be accomplished by comparing the results with appropriate reference values, which have been generated using statistical techniques, with satisfactory E_n values as well as Z scores. Company (end-user) specific documentation is generated, including details (name, revision, build, etc.) of the software used and controlled to completed a successful validation.



FIGURE 1. CMM TEST ARTIFACT USED IN PROFICIENCY TESTING

A NOVEL APPROACH IN USING PROFICIENCY TESTING DATA TO VALIDATE CMM SOFTWARE FOR THE REGULATED INDUSTRY

Anish Shah¹, Charles Ellis²
¹Metrologized LLC, Chaska, MN, USA
²NAPT, Edina, MN, USA

NORMALIZATION

To compare a measured value, its relationship with an established reference value and its published "uncertainty" must be determined [5]. Figure 2 provides a clear view of the reported measurement, using the laboratory's established method for measuring and evaluating that particular feature, within the software of use. Normalized Error designated as E_n , is the ratio of the deviation between the reported value and the reference value to the root sum square of their associated uncertainties. Putting this into perspective, as the reported measurement uncertainty approaches the uncertainty reported by the reference laboratory; the closer the reported value must be to the reference value. Satisfactory results will yield an $E_n < 1$. To further add clarity, the E_n is charted for all reported data points showing the dispersion around the ± 1 acceptable range.

$$E_n = \frac{x_{lab} - x_{Ref}}{\sqrt{U_{lab}^2 + U_{Ref}^2}}$$

where:

x_{lab} is the value reported by the participating laboratory

x_{Ref} is the reference value

U_{lab} is the uncertainty reported by the participating laboratory

and

U_{Ref} is the uncertainty of the reference value

The uncertainties shall be expressed using k=2, which corresponds to a 95% coverage

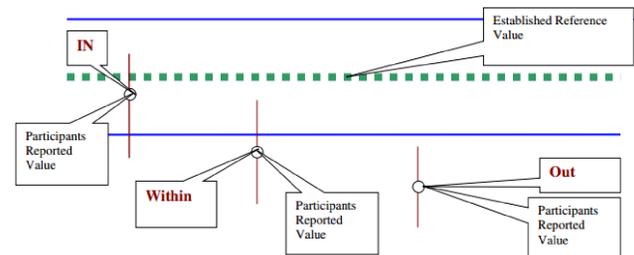


FIGURE 2. REPRESENTATIVE VIEW OF THE PARTICIPANTS REPORTED VALUE

RESULTS

The laboratory (in this case the inspection group using the CMM) shall following proper dimensional planning procedures as well as use optimal measurement methods and evaluations to report the measured result. A careful comparison with reference value, and upon calculating a satisfactory E_n number provides reasonable confidence for the end-user that the software has met the intended use and thus could be considered validated for that feature. Similar assessments are made for all other geometric features, allowing a successful software validation document to be generated. A representative data sheet [4] is shown in Figure 3, where the high-lighted data is the result for the CMM and software under consideration.

FINAL REPORT: BLOCK COMPARISON						
Dimensional Inspection/NAPE-CMM-106		OUTLIERS EXCLUDED		Report Date: 3/20/16		
XXXX				Date of Participation in ILG/PE: XXXX/2/00X		
Measurement Description: 4) Sphere (outside) Diameter						
Discipline: Dimensional - Inspection						
Nominal Value: 1.5			Measurement Units: in			
Established Reference Value: 1.50000			Established Reference Uncertainty: 0.00015			
Mean Value (Satisfactory Results): 1.49992			Mean Uncertainty (Satisfactory Results): 0.00064			
Mean Value (All Participants): 1.49992			Mean Uncertainty (All Participants): 0.00064			
Test ID #	Reported Value	Reported Uncertainty	In	S/U	I/O	Z-Score
B16672	1.49999 in	0.00033 in	-0.02	S	I	-0.06
B16680	1.49988 in	0.00048 in	-0.23	S	I	-1.21
* B17045	1.50023 in	0.00073 in	0.31	S	W	2.43
B17123	1.49997 in	0.00032 in	-0.07	S	I	-0.27
* B17130	1.49990 in	0.00120 in	-0.82	S	W	-10.35
B17186	1.50000 in	0.00006 in	0.05	S	I	0.08
B17187	1.50000 in	0.00006 in	0.04	S	I	0.06
B17353	1.50011 in	0.00013 in	0.58	S	I	1.18
B17381	1.49994 in	0.00015 in	-0.27	S	I	-0.58
B17382	1.49993 in	0.00077 in	-0.08	S	I	-0.69
B17714	1.49984 in	0.00032 in	-0.44	S	W	-1.62
B17760	1.49999 in	0.00156 in	0.00	S	I	-0.06
B17761	1.49992 in	0.00063 in	-0.12	S	I	-0.79
B17795	1.50000 in	0.00157 in	0.00	S	I	0.04
B17853	1.49986 in	0.00055 in	-0.24	S	I	-1.42
B17939	1.50000 in	0.00130 in	0.00	S	I	0.04

FIGURE 3. MEASUREMENT RESULTS FOR SPHERE DIAMETER, IN COMPARING WITH OTHER LABS (CMMs)

Additional criteria can be set : satisfactory performance is indicated as $Z < 2$, unsatisfactory performance is indicated as $Z > 3$ and questionable performance is anything between $Z < 2$ and $Z > 3$, where $Z\text{-Score} = (x_{lab} - x_{Ref}) / \text{Standard Deviation}$

To examine the accuracy of CMM, feature specific data is plotted for participating CMM user, thus allowing each participant a basis for evaluation and perhaps improvement of measurement performance. These values are then interpreted using an interaction plot shown in Figure 4. It also illustrates measurement issues for 2 different CMMs (labs), and when compared with other similar plots for all other geometric features, necessary corrective action, including improvement in the overall measurement process, might be warranted. A potential issue with drift or bias after a successful calibration of the CMM might also be brought forth through this PT.

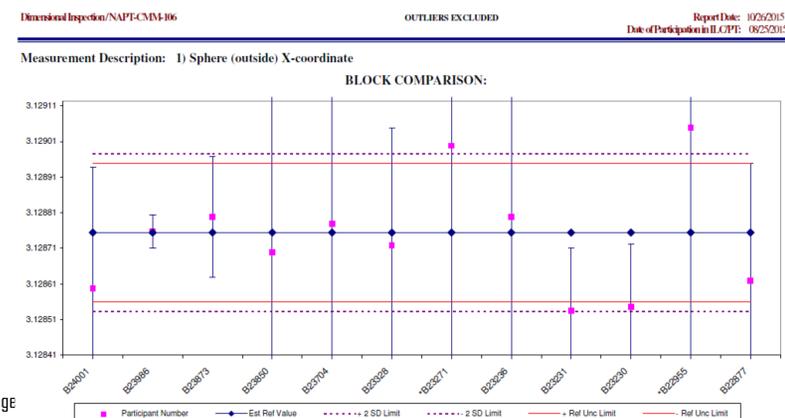


FIGURE 4. INTERACTION PLOT OF MEASURED VALUES FOR X-COORDINATE OF THE SPHERE FOR MULTIPLE CMMs

Intuitively, these trends are normal. Looking at interaction of the results for a given feature from different CMMs, it is obvious that differences in measurement techniques are the reason for the spread, while each individual uncertainty is the ability for that CMM user to control the amount of error introduced into that particular measurement. It is interesting to note that little difference in the data might imply that proper procedures are being followed in conducting this test.

CONCLUSION & RECOMMENDATIONS

While the OEM of the CMM software might take due diligence and reasonable testing to provide a user-friendly and mathematically stable software, the end user is still responsible to prove the software for its' intended use, i.e., dimensional inspection and verification. Use of the CMM ILC/PT with satisfactory results provides a valid approach to documenting objective evidence for software validation as well as revalidation. It facilitates risk management, as required by published national and international standards, especially when the data is compared to other test participants.

Following a successful CMM calibration, the use of PT is recommended to establish by objective evidence that process equipment and sub-systems are capable of consistently operating within established limits and tolerances.

NMIs and OEMs of CMMs may opt in to participate in this PT, maintaining the confidentiality of the participating lab, to build further confidence on valid results amongst the end-users.

REFERENCES

- [1] John A. Bosch 1995 Coordinate Measuring Machine and Systems
- [2] US CDRH 2002 General Principles of Software Validation; Final Guidance for Industry and FDA staff
- [3] NAPT 2015 Dimensional Inspection CMM ILC/PT Instruction Sheet
- [4] NAPT 2015 Dimensional Inspection CMM ILC/PT Final Report
- [5] NAPT 2015 Supplemental to ILC/PT Reports
- [6] NIST 2005 Weights and Measures Division Quality Manual for PT/ILC



MEASUREMENT ACCURACY and the IMPACT on society

2016 NCSL WORKSHOP & SYMPOSIUM
July 24 - 28, 2016 | Saint Paul, Minnesota

Tutorial Program July 24-25
Exhibition Hall July 25-28
Technical Program July 26-28