# Improving Metrology Calibration Frequency and Traceability

Jan W. Gonzalez, Jennifer Oduwole, Christopher Aguirre / Dr. Niechen Chen, Dr. Christine Nguyen

Department of Industrial and Systems Engineering, College of Engineering and Engineering Technology, Northern Illinois University

Northern Illinois University

## Introduction

At Paragon Medical, the Quality Control Lab have been operating without data to support many of the process flows.

Employees are uncertain of the calibration frequency for gauges depending on batch size of 250 pcs or 1000 pcs (depending on gauge type). There also seems to be difficulty amongst the operators of keeping track of how many times a pin was used during manufacturing of a part. Paragon Medical is also having trouble identifying how often to calibrate the gauge.

The Keyence, OGP, Hawk, and Zeiss CMM calibration work instructions need validation to ensure that they meet the standard practices provided by vendors with current practice.

In addition, the department would like the team to apply 5S to various parts of the department such as the CMM setup as well as fixture and probe storage. The contractor will be responsible for developing and documenting a labeling system to assist in effective traceability of pin/ plug/ thread gages and other areas of the Metrology department.

## Objectives

The project will focus on the following goals:

### Validate gauge calibration frequency

- Analyzing tool wear and calibration dimensions.
- Improve calibration tracking and counts.

### Improve CMM set-up time

- Create work instructions to improve calibration times and reliability.
- Transition to a standardized process for CMM inspections.

### Improve metrology and Q/C lab

- Maximize storage for less used fixtures and probes based on used frequency.
- Implement identification system to fixtures and have a set-up guide to eliminate set-up guess work.

## Analysis and Results

### Calibration Frequency and Traceability

For this thread gage specifically, it requires 100% inspection which means every part that is made that requires this thread gage for inspection is checked no matter the order size of the customer. This is standard for this size and gage type. The only thing that the tool use count does not contain is the amount of uses for final inspection. Only in process parts are inspected and recorded. But for final inspection they are inspected but the tool use is not recorded in the EQMS.

To account for this there are two approaches; approach one: removes missing data points and conduct the reliability analysis. Approach two: during each section of missing data take an average of production rate and actual number of days between each missing point and place the average production rate to mimic the final inspection use.

*Table 1: Survival probabilities for approach 1*

| | | 95.0% Normal CI | |
|---|---|---|---|
| Time | Probability | Lower | Upper |
| 250 | 0.934950 | 0.825149 | 0.981792 |
| 500 | 0.836660 | 0.666836 | 0.937048 |
| 750 | 0.748285 | 0.522537 | 0.900023 |
| 1000 | 0.672900 | 0.406521 | 0.871261 |

*Table 2: Survival probabilities for approach 2*

| | | 95.0% Normal CI | |
|---|---|---|---|
| Time | Probability | Lower | Upper |
| 250 | 0.946223 | 0.877569 | 0.976875 |
| 500 | 0.922839 | 0.841753 | 0.963261 |
| 750 | 0.904925 | 0.813790 | 0.952717 |
| 1000 | 0.889896 | 0.789670 | 0.944005 |

After analyzing the reliability analysis, we can conclude that increasing the tool use count from 250 uses till next validation of 500 is acceptable.

### Work Instructions

Through creating, updating, and validating the CMM work instructions, standardization has been established within the inspections department. The approved work instructions allow for improvements in calibration times and reliability. The updated work instructions for the Keyence, OGP, and Hawk machines now contain lower-level calibration instructions. These work instructions include mitigation measures, images, and set up instructions that reflect Paragon's current practices. The Zeiss work instructions have been verified for its first revision.

### 5S+1 Fixtures & Probes

The implementation of 5S+1 was done by adding a picture displaying all the contents inside of the storage cabinets on the outside of door. This will help the technician find what they need before opening the door, while keeping the inside organized because of the lack of rummaging inside to find what the technician needs. Labels were added to give each probe a designated home. This reduces the time it takes for each technician to locate the probes that they require for the set-up. Other small implementations were used to improve the process. A final time study was conducted to determine the updated time it takes a technician to execute an "in process" set-up. The updated time it took the technician was 7 minutes, which reduced the original time by 13 minutes. A cost analysis was performed, saving the company $21 per each "in process" set-up.

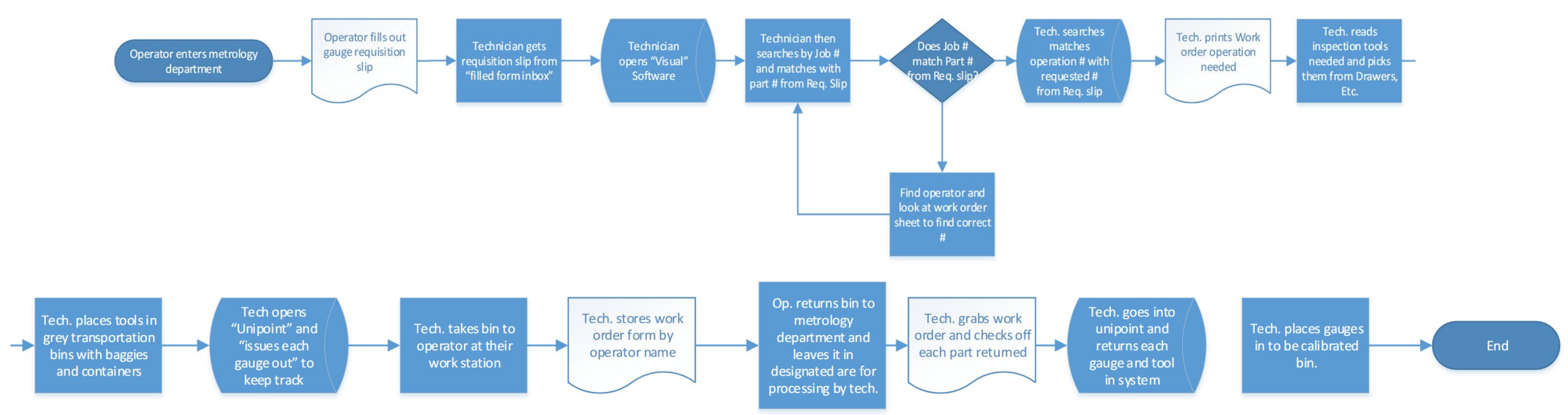


*Figure 1: Process Map of Current Process*

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## Recommendations

Our recommendations are to continue to develop the automated gage requisition report that we have developed with IT. This will save $6200 a year in just removing a redundant process that will also save 3720 minutes at minimum.

Another recommendation is to increase the gage calibration frequency from 250 uses to 500. based on the reliability analysis conducted there is an 83% and 92% of tool survival with the increase. This will reduce the number of calibrations conducted each day to almost every other day.

Using the 5S+1 audits and teachings on the CMMs a baseline set up was 20 minutest that was cut down to 7 minutes with a savings of $21 per in process set up conducted.

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