WHEN CUSTOMER SPECIFICATIONS FOR A PRODUCT LIE OUTSIDE A PRODUCT’S MATERIAL PROPERTIES AND PROCESS CAPABILITY - A CASE STUDY

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To avoid losing a $12M client, a vendor addressed complaints that their disposable baby bottle liners failed hot water pressure tests and had widths outside specifications. The prescribed resin’s softening point was (980°C (208.40°F)). At the vendor’s testing site (580 meters above sea level) water boils at 97.20°C (207°F). At the client laboratory (11 meters above sea level) water boils at 99.40°C (211°F). Thus liners that met vendor specifications failed at the client’s laboratory. An alternative resin (softening point: 1070°C (2230°F)) was found to meet client specification. A process capability study revealed that the machines were incapable of producing liners to client specifications. Further investigation revealed that the complaints related to problems customers had extracting liners from the package. An out-of-round packaging core provided by another vendor was the cause of uneven extraction. Changing resins and ensuring cores were in-round resulted in meeting the client’s quality concerns.

Significance: Industrial Engineers, Operations Managers, and Quality Control Engineers must be aware that quality control may involve offering viable alternatives to the client after exploring the objectives the client was pursuing when they established their original specifications.

Keywords: Process capability, HWPT, softening point, conforms to specifications, client, customer, and vendor.

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1. INTRODUCTION

1.1 Focus
A manufacturing facility faced two separate quality control problems that had to be addressed in order to satisfy a major client. The two problems had distinctly different solutions. Researchers determined that one concern was a true internal quality control problem that required a significant change. The other problem was successfully addressed when they discovered that the client had misidentified the source of quality complaints and there was a solution to an issue that had appeared to be insoluble.

1.2 Product Background
The history of the product failures began at a sister plant in Cleveland, Ohio. The machinery currently in use at the Western North Carolina facility (Marshall) came from a facility that had been closed. The Cleveland facility sent 16 machines to the Marshall plant in 2001. These machines were the first baby bottle liner processing machines to arrive at Marshall. The disassembled machinery arrived in very poor condition with many damaged or missing parts. Thorough cleaning and repair was necessary prior to placing the machines into operation. Additionally, a considerable training effort was required to familiarize the Marshall employees with the new equipment. By February 2002, all machines were running at full production. Figure 1 illustrates one of the machines in operation. The machines convert raw material (resin pellets) into finished baby bottle liners that are printed and wrapped into spools of 80 liners each (figure 2). The manufacturing
procedure includes processing resin pellets by extrusion then blowing hot air to fabricate a film. The machines then press, cut, print, and roll the film into baby bottle liners.

The Marshall plant produces 118.29 and 236.59 ml liners. Other contracted vendors produce the shell of the baby bottle and a liner roll core. The liners, the shell and the core have specifications and tolerances set by the client. The liner’s design specifies that its opening must be able to fit over the top of the shell and be capped with a rubber bottle nipple so snugly that no leaks will occur. Figure 3 illustrates the pieces needed to construct a fully assembled baby bottle. The liner’s width specification and tolerances are 8.03671 cm +/- 0.17861 cm. Thus, the upper specification limit (USL) and the lower specification limit (LSL) are 8.21533 and 7.85813 cm respectively. The variable increment of 0.35723 cm is very small (tight) to allow the product to fit snugly over the pre-made plastic bottle shell. Since the bottle liners are disposable, not only does any one liner from a roll need to fit a particular bottle, but all the liners on a roll must fit any shell made for that specific size bottle.

![Extrusion Machine for Baby Bottle Liners](image1)

![Liners Wound on Core (80 Liners to a Spool)](image2)

To avoid the reader being confused with the parties involved in the quality control issues, they will be hereafter referred to as follows: the producer of the baby bottle liner (vendor), the final product manufacturer (client), and the retail customer (customer).

1.4 Quality Issues
The client was voicing repeated complaints about two separate quality issues. The first failure was inability of the liners to pass the prescribed hot water pressure test. Second was the failure of the liners to consistently conform to the tight size specifications, resulting in customer dissatisfaction when the liners would not dispense smoothly. The vendor performed tests to determine if the outcome would confirm the problems reported by the client.

1.4.1 Testing Methodology: Hot Water Pressure Test (HWPT)
The client complained that the bottle liners were not able to withstand the prescribed Hot Water Pressure Test (HWPT) specifications. The client company had specified the resin and the raw material vendor. Tests determined that the Vicat Softening Point of this particular low density polyethylene (LDPE) resin is 98 C (208.4 F). A Vicat Softening Temperature is the temperature at which a material experiences a "sudden and substantial decrease in hardness. The specimen is penetrated to a depth of 1 mm by a flat ended needle with a 1 sq. mm circular or square cross-section, under a 1,000 -gm load “(About.com, 2003). This thermal property relates to materials such as polyethylene that do not contain a definite melting point. The test’s conditions for acceptance challenge both the liner’s seal and sidewall strengths.
At a minimum of every four hours, inspectors pulled 12 baby bottle liners randomly from each machine for the HWPT. The test involved fitting the liners on baby bottle cylinders identical to those used by consumers. Figure 3 illustrates the components assembled to prepare a bottle for use. The test pressurized the liners internally with air and simultaneously immersed them in boiling water. The internal air pressure reached 17.65 grams per cm² to a depth of 19.05 cm for the 236.59 ml liners and 8.89 cm for the 118.29 ml liners. The samples are maintained at this pressure in the water bath for 60 seconds. A failure occurs when the liner’s wall or seal leaks air under pressure. Figure 4 illustrates a 236.59 ml liner seal failure.

The HWPT tests performed in the vendor’s locale did not confirm the client’s findings that the liners failed to maintain integrity at the boiling point. The client did not keep records of whether the sides or the seals were failing. They were not returning any of the failed liners. Their complaints were so nonspecific that the vendor had little information to use to address the quality issues.

1.4.2 Dispensing the Product

The client assembled and packaged the product after receiving the liners, then sent them to the marketplace. The client expected the end customer to be able to draw each liner from the package smoothly and evenly. The liner should not crimp at the package’s precut slot. A conforming dispensed product is illustrated in figure 5-left. In the figure’s center is a spool of 80 liners. A liner that crimped had the potential to result in dispensing failure (figure 5-right). The dispensing failure created the customer discontent. There were repeated instances of dispensing failure which the client ascribed to
unacceptable variation in liner width. Tests performed at the vendor’s confirmed that the liners were not consistently in conformance with the dimensions specified by the client.

2. METHOD

2.1 Analysis of HWPT failure

2.1.1 Voltage Regulators as Potential Source of HWPT failures

Engineers analyzed detailed records and theorized that voltage fluctuations in the machinery might cause the failures. They discovered that the local power company purposely reduced the voltage daily during high usage periods. During the summer and winter months, power usage surged due to the general use of air conditioning and heat pumps and the power company used voltage regulation to conserve energy. Because electricity heats the heater cartridges inside the seal dies, the failure to have a consistent specific voltage results in the sealing irons losing heat rapidly. During low voltage periods, the heater cartridges did not heat to the specified temperature which had the potential to cause the seals to fail. The engineers examined the equipment and observed the sealing process on a random basis.

![Figure 5. Liner Dispenser, Acceptable (left), Spooled Liners (center), and Unacceptable (right)](Permission granted by Liz McCarthy (photographer))

2.1.2 Problems with the Testing Procedure

In researching reasons why the failures were occurring in the client’s facility and not in the vendor’s, quality control engineers remembered that the boiling point of water differs because of altitude. The vendor is located at an altitude of 580 meters where water boils at 97.2°C (207°F) and the client is located 11 meters above sea level where water boils at 99.4°C (211°F) so there is a range of 2.2°C (4°F) between the respective boiling points. Thus, the tests at the vendor laboratory resulted in approving liners that would fail at the client’s facility. In order to increase the boiling temperature at the Marshall facility, engineers added glycerin to a separate hot water pressure tester. The normal boiling point of liquid occurs at the temperature where the vapor pressure is equal to one atmosphere. Because a nonvolatile solute has no tendency to escape from solution into the vapor phase, adding glycerin lowers the vapor pressure of the water. If the vapor pressure is lower, the temperature must be higher in order for the water to boil (Zumdahl, 1997). In addition, the boiling temperature is proportional to the amount of solute (glycerin) added to the solvent (water). Using these properties, the vendor was able to heat the solution to exactly 99.4°C (211°F). A mechanical agitator prevented the glycerin and water from separating. These modifications to the testing equipment allowed the Marshall facility to more closely replicate the testing conditions at the customer's testing laboratory and better analyze the problem (Lyda, 2002).

2.2 Dimensions

Once the vendor established that the liners were not meeting the client specifications for size, analysis was done to determine whether or not it was possible for the facility to meet the standards. The initial step in this process capability study was to go beyond a one-day observation and collect random independent samples that represented all production lines. Investigators chose the machine perceived to be ‘best’ with the most consistent performance record as the initial machine for testing. There would be no need to investigate other machines if this machine did not yield an acceptable \( C_p \).

2.2.1 Liner Width Data Collection
For this portion of the study, observers noted that the machine was producing the 236.59 ml disposable baby bottle liners with 80 liners per roll. Figure 1 shows the production machine. The estimated operating time of the machine was 168 hours per week; so the machine produced one roll every thirty minutes until it produced 180 rolls. Analysts divided the process by 3 hour time periods and tested 6 rolls per group. They selected five liners per roll for measurement using a blocked approach and a random number generator in Microsoft Excel to ensure that the selection was truly random. This design separated the 80 liners into 5 categories. A random number from each of those 5 categories was generated to select one sample per category. This procedure ensured that the sampling was truly random and represented the total roll and not anyone section of a given roll such as the beginning or ending. This sampling plan gave the analyst 900 individual samples. Each group of 30 liners, or six rolls, was then grouped to form one observation of 30 samples each representing a 3-hour operating period. The 2.54 cm mark on the ruler was used as the starting point for the measurement to ensure measurement accuracy. Measurements were taken at the printed 100ml mark on each liner.

2.2.2 Process Capability Ratio ($C_p$)

In order to verify the capability of newly installed machines, the process capability ratio ($C_p$) was calculated. This statistic allows the engineer or manager to determine if the current process is capable of meeting and keeping the specifications and tolerances set by the manufacturer (equation 1) (Lyda, et. al., 1999 and Yearout, et. al, 2000).

\[
C_p = \frac{USL - LSL}{6\sigma} \quad \cdots (1)
\]

Client out-of-width specifications provided the basic criteria for upper and lower tolerances that would guide the analyst in determining the $C_p$ statistic. If the assignable cause were the machines variability or some other factor associated with the process, the calculated $C_p$ statistic would conclude that the machines were not capable of meeting the client’s width specification and tolerances as described in paragraph 1.2. At the time that data was collected, only one of the machines had been completely overhauled and was producing a consistent product. Thus excessive variation in the process could be expected until all other machines could be overhauled and samples drawn to insure that the client’s width specification and tolerances were being met.

3. RESULTS

3.1 HWPT Failures:

3.1.1 Voltage Regulators

Analysts noted that the newer machinery was fitted with a voltage regulator as standard equipment and further noted that there was not one HWPT failure at the Marshall facility linked to this piece of machinery. Management installed voltage regulators on all other machines in mid-March 2003.

3.1.2 Glycerin

When the vendor simulated the conditions at Dover by adding glycerin to the Hot Water Pressure Tank, the customer selected two sets of 1,200 liners from their stock to be tested at both the Marshall and Dover facilities. Each set contained 600 236.59 ml liners and 118.29 ml liners to be tested in both the glycerin Hot Water Pressure tank and the traditional Hot Water Pressure tank. Table 1 displays the results of both water and glycerin testing at both the Marshall and Dover testing facilities.

<table>
<thead>
<tr>
<th>Liner and Test Type \ Test Facility</th>
<th>Marshall</th>
<th>Dover</th>
</tr>
</thead>
<tbody>
<tr>
<td>118.29 ml Water (percent failure)</td>
<td>0%</td>
<td>18.5%</td>
</tr>
<tr>
<td>118.29 ml Glycerin (percent failure)</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>236.59 ml Water (percent failure)</td>
<td>3%</td>
<td>21%</td>
</tr>
<tr>
<td>236.59 ml Glycerin (percent failure)</td>
<td>6%</td>
<td>7%</td>
</tr>
</tbody>
</table>

While the test results showed that the glycerin tank would be highly beneficial in matching the test results between the vendor and the client, the glycerin Hot Water Pressure tank proved to be extremely hazardous to the vendor’s employees. The extremely high temperatures and stickiness of the glycerin solution resulted in a risk that the solution would burn employees performing the tests. The facility discontinued use of the glycerin Hot Water Pressure tank after considering the implications of unsafe conditions.

3.1.3. Resin Specifications
The client had specified both the particular low density polyethylene (LDPE) resin and the raw material’s vendor. This particular LDPE has a Vicat Softening Point of 98°C (208.4°F). The test temperature (boiling water) at the client’s testing facility is 1.4°C (2.6°F) above the softening point. In attempt to determine assignable cause for HWPT failures, other available LDPE resins from the current raw material vendor with higher melting points (112°C) were tested. The vendor then tested medium density polyethylene (MDPE) resins with a Vicat Softening Point of 107°C (223°F) from a competing vendor. Further testing of available LDPE resins with higher melting points (112°C) acquired from the specified raw material vendor revealed that such resins could meet specifications at the vendor’s facility but would still have an unacceptable failure rate at the client’s testing facility. It became evident that the LDPE resins supplied by the current vendor would not meet client specifications (Lyda, 2002). The medium density polyethylene (MDPE) from a competing vendor met the customer's general raw material specifications and, with a Vicat Softening Point of 107°C (223°F), the HWPT results met the liner’s seal and wall strength specifications as well.

In addition to Vicat Softening Point testing, the vendor submitted samples to their Neenah Technical Center for further evaluation of the LDPE material. The Neenah facility conducted a Dynamic Mechanical Analysis (DMA) test. This particular DMA test measured the mechanical properties of the material (stiffness) and elongation as a function of temperature. The bolder line in figure 6 represents the percent difference in height as a function of temperature and the thinner line represents stiffness as a function of temperature. A tensile load of 2500 grams per square centimeter was applied to a sample at a continuum of temperatures, including the vendor and client test temperatures. The DMA results indicate that the modulus drops 23% in going from vendor test temperatures to client test temperatures (as indicated by the data points in the lower right-hand corner of the graph). In addition to the DMA testing, a Differential Scanning Calorimeter (DSC) Heat of Fusion test was performed in order to determine the percent of crystalline still intact at a range of temperatures. The DSC test measures temperatures and heat flows as thermal energy is applied to the material. The bolder line depicts percent area (or percent of crystalline no longer intact) as a function of temperature.

The thinner line depicts heat flow as a function of temperature. The DSC results in figure 7 show that at the 99.4°C (211°F) boiling point, only 2/3 of the crystal structure of the LDPE remains available to resist the test pressure. Analysts wondered how any of the liners passed the HWPT in only 2/3 of the crystal structure remained intact at the Dover test temperature. The posited explanation is that fluctuations in the film thickness affected the quality of the seal. The film for the baby bottle liners was on average 55.8 microns thick, but the thickness naturally varied. When the film was thinner, the seal grew weaker. The thicker film had a much higher probability of passing the HWPT at the 99.4°C (211°F) test temperature (Lyda, 2002).

### 3.2 Analyzing Dimensional Problems

Once the data for liner size was collected, the first step was to determine if the sample width variation and the width means were in control. If the sample variation chart (s-bar chart) was out of control, then the means chart (X-bar chart) would not be prepared until assignable cause of unacceptable variation could be determined. The thirty x-bars with their respective standard deviations were the averages of the 30 liners tested in each 3-hour time slot. The $C_p$ was calculated using the customer’s specified USL/LSL of 8.21533 and 7.85813 cm respectively.

#### 3.2.1 s-chart

The s-chart, figure 8, was compiled by using the standard deviation of each group. This chart was used to determine if the standard deviation, variation, of the process is an assignable cause for the x-bar chart to not be in control. Calculated control limits using an s-bar 0.0895547 cm were 0.125377 and 0.053733 cms for the upper control limit (UCL) and lower control limit (LCL) respectively (Grant and Leavenworth, 1996). As figure 8 illustrates, the standard deviation of the process has six out of control points. Thus the processes variation is too extreme to warrant constructing an x-bar chart.

#### 3.2.2 X-bar Chart

Since it was determined by the s-chart that the variation was out of control, it was not appropriate to prepare an X-bar chart. Since s-bar is used in the calculations of the X-bar charts upper and lower control limits, any analysis of the X-bar chart would be confounded with variation error (Grant and Leavenworth, 1996). Once the variation was under control, an X-bar chart would be prepared.

#### 3.2.3 $C_p$ Calculations

The $C_p$ is the critical statistic that determines whether or not a process is capable of meeting the specification and tolerances that the process requires. In this case the upper specification limit set by manufacturer is 8.21533 cm and the lower specification limit is 7.85813 cm. The first step in calculating the process capability was to obtain an estimated standard deviation ($\delta$). This estimate was made by using the formula (2) shown below and Table C, FACTORS FOR ESTIMATING $\delta$ FROM R-bar, s-bar, OR $\delta_{rms}$-bar AND $\delta$, FROM R-bar, recommended by Grant and Leavenworth (1996).
The estimated $\delta$ calculated was initial step in determining process capability is to calculate the $C_p$. In this study the resulting $C_p$ is 0.665 (calculated from equation 1). Thus the process is "not capable" with the current limits and standard deviation because the $C_p$ is less than the industry standard of 1.33.

4. DISCUSSION

4.1 Resin Specification Change

Once it was determined that the LDPE resin was incapable of meeting the client’s HWPT criteria, the vendor began discussions with the client to determine the rationale for this specification. The purpose of the HWPT criteria is to differentiate the customer’s product from those of all other competitors. The client’s rationale was that their liners would pass this test more frequently because of the inherent strength of the bottom seal. Thus, could be advertised as a superior product. The idea was that the product could be advertised as follows; “Even when submerged in boiling water, your
baby’s bottle will not leak”. It also was discovered that for the past 15 years, the client had complained that the liners were not meeting HWPT standards. Corresponding to this 15 year period, the LDPE resin was being supplied by the current material vendor. The client was initially unwilling to change specifications, material vendor, or resin type.

Further research discovered that during that same time period there had been only one customer liner failure reported. It must be noted that this failure was not due to the liner’s failing the HWPT criteria but was due to the customer placing the liner into a microwave. Product warning labels and instructions clearly prohibit this practice.

The client’s marketing team was presented with bags made of both the LDPE resin and the MDPE resin. Unaware of the differences in the bags, the marketing team preferred the medium density resin to the low-density resin. The salesmen believed the MDPE film to have superior optical properties in comparison to the LDPE liners (note the haze in the spooled liners in figure 5). The MDPE liners had better clarity, which is a term that describes the measure of transmitted light through the film. This is qualitatively determined by reading distant text through the film. The MDPE liners also had lower haze, a term that describes the cloudiness of the film, or the amount of scattered light. This, too, is qualitatively judged by looking at an object through the film. Based upon the limit to the inherent capabilities of the LDPE resin, the client made the decision that to maintain HWPT criteria and to produce a superior product it was necessary to cancel the current resin contract and establish a contract for the MDPE resin with a new raw material vendor. Since this decision there have been no more HWPT failures.

The cost of the LDPE resin was $0.63 per pound and the cost of the new formulation was $0.69 per pound, resulting in an annual cost of $9000 per year. That additional cost had to be weighed against the total value of the contract. With the existing number of product returns, it was economically infeasible for the vendor to continue the contract. Unless the quality issues could be resolved the product line would have to be discontinued, resulting in losing a $2.4 million per year contract. Over the five year period of the contract, removal of this product line would mean $12 million less revenue.

4.2 Product Dimensions
Based on the inherent variability in the “blown film” process and the age of the machines, it was very unlikely that the existing process or equipment was capable of lowering the standard deviations by 50%. \((\sigma = 0.04475 \text{ cm})\). Inability to reduce this variability was not due to inadequate machine set-up, inattentive operations, improper calibration, or inadequate maintenance, so simple quality control efforts were not sufficient to bring it into control.

Concurrent with this capability analysis, an economic analysis was conducted to determine if it were feasible to make a capital investment in new machine or process technology that would produce a product to meet the client’s width specification and tolerances. Capraro and Yearout (2004) developed a model that would provide engineers and managers with a tool based upon Taguchi methods that would assist in determining if such investments in the process or equipment would be economically feasible. Using this technique, it was determined that, even if the technology and equipment were readily available, such a capital investment would not be economically feasible.

If the relationship with the client were to continue, then the client would need to consider relaxing specifications to meet the \(C_p\) of 1.33. The tolerances based upon the standard deviations obtained by this study would have to be changed to +/- 0.35861 cm. The range between the USL and LSL must be 0.7172 cm. The existing range between tolerances was only 0.3572 cm. If the specified mean of 3.16406 was kept as the target (center of the specification limits) then the process would be deemed capable \((C_p = 1.33)\). This recommendation was initially rejected by the client.

4.2.1 Analysis of the Specifications
Specifications and tolerances are set to ensure quality for the customer who purchases the product. The end customers were not having difficulty fitting the liners over the bottle nor were they having trouble with the liners sealing when they assembled the bottle. Instead, they were annoyed when the liners failed to dispense properly. Investigations into the specific complaints indicated that the root cause of customer complaints was a packaging issue.

The number one quality error is “Defining quality in terms of your goals instead of your customers’ needs and wants. Standards and policies were set by management without input from customer” (Russell, 1990). Some of the liners did not fit into the dispenser evenly but analysis and inspection showed that the problem was not caused by the variation from the extremely tight specifications for width but was caused by variations in core alignment. Figure 9 illustrates one of the cores (8.84 cm long by 1.65 cm in diameter with a wall thickness of 0.15 cm) that are used to roll the liners during the production process.

![Figure 9: Liner Roll Core](permission granted by Liz McCarthy (photographer))

Figure 10 illustrates a comparison. The roll on the right meets client specifications and is evenly rolled. The roll on the left, is an unacceptable processed roll where the edges of the roll are uneven, compromising the dispensing of the product. Figure 11 shows a packaged product where the core was evenly rolled on center on the right side of the picture. The example on the left shows a packaged product that where the liners are unevenly rolled. Note that the core is visible. Since liners that are unevenly rolled crumple when pulled from their dispenser (box), the customer is inconvenienced. The customer is not concerned about the dimensions of the liner if the functions are not compromised. The liner width, as long as it fits in the bottle and no leakage occurs, is not important except for the ease of obtaining a liner from its dispenser. The client and the vendor jointly determined that liner width was not a critical quality measure. Russell (1990) emphasizes that specifications and tolerances that are not important to customer expectations should not be a matter of measurement or concern. To ensure that the cores would hold true center while rolling liners in the production process, the client and vendor worked to develop specifications and tolerances for the cores that created conditions where the cores were in round and did not exceed a specified length.

5. CONCLUSIONS

The improvement in seal quality due to voltage regulation and the adoption of the new raw material vendor that could supply an acceptable MDPE resin (Vicat Softening Point of 107°C (223°F)) resulted in the product passing the HWPT test at both in the vendor’s and the client’s laboratories. Not only did the seals withstand this test, but the liner’s sidewalls during simulated feeding and storage were tested and proved to meet customer expectations.

Since it was determined that the assignable cause for customer complaints about dispensing was not the liner width but the packaging cores, it was recommended to the client that the liner width specification and tolerances be changed. The inherent variability in the liner width was a random variation due to the nature of the process and the age and technology of the machinery. As stated earlier this recommendation was initially rejected by the client. To obtain a process capability ($C_p$) of 1.33 with this inherent variability would require, if even available, new process technology and machinery. It was determined that such a capital investment would not be economically feasible nor would it achieve customer expectations. Therefore, both the client and the vendor ultimately rejected the width specifications and tolerances as an appropriate measure for quality.
As long as no leakage occurred, liner width was not a customer issue. Once the packaging cores were in conformance and the process was meeting the targeted nominal mean ($p_0$) on the core, the liners were conforming to customer expectations. Since these changes have been made there have been no major customer complaints on dispensing liners from their packages.

6. INSIGHTS FOR PACTITIONERS

This study illustrates to industrial engineers, operations managers, and quality control engineers that, when searching for assignable causes, they should not simply focus on the data that are the easiest to collect nor on data that are most commonly collected. A variety of alternatives and potential assignable causes may need to be examined. When possible, the first variables to examine should be those variables that may result in products not meeting customer expectations. The initial focus should be the product’s purpose, then customer convenience. In this case the vendor and the client worked together to see that purpose and convenience drove specifications and tolerances.

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8. REFERENCES


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