# Qualification of Inspection Techniques for Detecting Leaks in Pouched Medical Devices at Company XYZ

by

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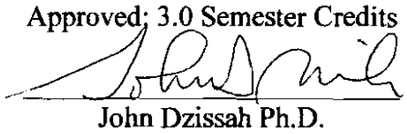

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## ABSTRACT

The medical device manufacturing industry utilizes Nylon/Tyvek® pouches as packaging for terminally sterilized medical devices. Several test methods are recognized to test the physical strength of the seal and the integrity of the sterile barrier. Such tests include tensile testing of the seal, visual inspection of the seal using unaided eye, and dye penetration testing. A series of experiments will be conducted to qualify whether the Quality Assurance inspectors at Company XYZ can correctly identify pouches that have been intentionally created with breaches in the sterile barrier seal (channel leak) and weak seals. Statistical techniques such as capability analysis and attribute gage repeatability and reproducibility (gage R&R) will be employed throughout the experiments.

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## Acknowledgments

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# Chapter I: Introduction

## *Statement of the Problem*

Company XYZ is involved in the manufacture and packaging of terminally sterilized medical devices. Packaging inspection and testing are conducted by the Quality Assurance department to verify seal integrity via various methods. Three test methods performed at Company XYZ are tensile testing, visual inspection, and dye penetration testing. Company XYZ requires that the test methods are reliable in detecting leaks in the sterile barrier. Formal studies have not been documented on the effectiveness of these inspection techniques in detecting breaches in the sterile barrier seal (channel leak) and weak seals.

## *Purpose of the Study*

The purpose of the experiments will be to qualify whether the Quality Assurance inspectors at Company XYZ can correctly identify pouches that have been intentionally created with breaches in the sterile barrier seal (channel leak) and weak seals.

## *Assumptions of the Study*

Based on the outcome of the experiments conducted, one assumption is that the Quality Assurance inspectors that participated in this study will be representative of all trained Company XYZ Quality Assurance inspectors. The experiments will not be repeated for all Quality Assurance inspectors or new hires.

## *Limitations of the Study*

This study and results herein are only valid for pouched medical devices. To qualify other packaging types such as blister packed medical devices, an additional study would be necessary.

*Definition of Terms*

Attribute gage repeatability and reproducibility (R&R) – The R&R stands for repeatability and reproducibility. Repeatability means that the same operator, measuring the same thing, using the same gage, should get the same reading every time. Reproducibility means that different operators, measuring the same thing, using the same gage, should get the same reading every time (Chew, 2007).

Channel – a small continuous open passage across the width of a package seal through which microorganisms could pass (DDL, 2008).

Dye Penetrant – An aqueous solution of dye and a surfactant designed to penetrate and indicate a defect location in time prior to the onset of wicking which could mask its presence (DDL, 2008).

Maximum seal strength – maximum force per unit width of seal required to separate progressively a flexible material from a rigid material or another flexible material, under the test conditions (ASTM F 88 – 07, 2007).

Cpk – The process capability index, which accounts for process centering (Breyfogle, 2003).

Process Capability – The six standard deviation (sigma) range of a process's inherent variation; for statistically stable processes only, where the standard deviation (sigma) is usually estimated by R-bar/d2 (Breyfogle, 2003).

Pouch – Nylon/Tyvek® packaging.

Seal – result of joining surfaces together (ISO 11607-1, 2006).

Seal integrity – characteristics of the seal, which ensures that it prevents the ingress of microorganisms under specified conditions (ISO 11607-1, 2006).

Seal strength – mechanical strength of the seal (ISO 11607-1, 2006).

Specimen cutter – Tool used to cut tensile test specimens to a width of 1.00 inches wide.

Sterile – free from viable microorganisms (ISO 11607-1, 2006).

Sterile barrier system – the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide and acceptable microbial barrier, and to allow for aseptic presentation (ISO 11607-1, 2006).

Tensile testing machine – A testing machine of the constant rate-of-jaw separation type. The machine shall be equipped with a weighing system that moves a maximum distance of two percent of the specimen extension within the range being measured (ASTM F 88 – 07, 2007).

Tensile testing technique A: Unsupported – Each tail of the specimen is secured in opposing grips and the seal remains unsupported while the test is being conducted (ASTM F88 – 07, 2007).

Vendor seal – heat seal performed by pouch manufacturer that is present on three sides of the pouch.

Wicking – The migration of liquid into the body of a fibrous material (DDL, 2008).

# Chapter II: Literature Review

This chapter will discuss the statistical concepts of a process capability study and attribute gage repeatability and reproducibility (GR&R). Both statistical techniques were used in the experiments contained within this study to analyze the data.

*Process Capability Study*

A process capability study is a method of determining the ability of a process that runs within statistical control to consistently achieve the desired results. Two commonly used process capability indices are Cp and Cpk. The capability index Cp only measures the variability within the process, or the spread of the data. The process capability index Cpk measures the variability within the process and how close the process is to the specification limits, or centering of the data (Tague, 2005). Processes where the Cp and Cpk are equal mean that the data is perfectly centered within the specification. A larger process capability index is desired as this means the distribution of the data is tighter. In the case of a process with a high Cpk, the data has a normal distribution and is centered within the specification. Cpk is one method of comparing the results of experiments from two different processes on how well they meet the specification (Tague, 2005). The equations for calculating Cp and Cpk are listed below:

$$Cp = \frac{USL - LSL}{6s}$$

$$Cpk \quad \min\left[\frac{USL - \bar{x}}{3s}, \frac{\bar{x} - LSL}{3s}\right]$$

Figure 1: Equations for Cp and Cpk (NIST, n.d.)

*Gage Repeatability and Reproducibility (Attribute)*

In order to qualify an inspection gage or visual inspection technique for use, an attribute gage repeatability and reproducibility (R&R) is often used. When performing the attribute gage R&R study, the decision the appraiser has to make is to accept or reject the part. There is no measurement of the level of acceptance (Breyfogle, 2003). An attribute gage R&R study can be conducted by selecting thirty samples of parts, about half should be considered acceptable and half considered rejects. Each appraiser will inspect the thirty parts and record on a data collection sheet whether the part was acceptable or rejectable. This is repeated with a second appraiser and then repeated again with both appraisers. If all four results agree, the inspection method or gage is acceptable for use and the gage R&R passes (Breyfogle, 2003). In order to perform a successful attribute gage R&R, it is crucial that there is clearly defined quality criteria and that all involved are adequately trained in the inspection technique.

# Chapter III: Methodology

Three experiments will be conducted at Company XYZ in order to qualify whether the Quality Assurance inspectors at Company XYZ can correctly identify pouches that have been intentionally created with breaches in the sterile barrier seal (channel leak) and weak seals. The three experiments that will be conducted will be tensile testing, visual inspection, and dye penetration testing.

The tensile testing will be conducted using an existing holding fixture and tensile testing machine. The test method will be tensile testing per ASTM F88 – 07, technique A. Using a specimen cutter, 1.00 inch +/- .010 inch wide samples will be cut from the left, center, and right sections of the seal. Capability studies will be conducted from each location within the seal to compare pouches that have a seal failure with pouches that have acceptable seals.

The criteria for visual inspection for seal quality will focus on the detection of channel leaks that compromise the sterile barrier. Attribute gage repeatability & reproducibility (R&R) will be used to analyze the data collected. Generally, an attribute gage R&R percentage of greater than ninety is acceptable (Chew, 2007). Data will be collected on attribute gage R&R worksheets and will be analyzed using Minitab statistical analysis software.

Dye penetration testing will be conducted per Company XYZ standard work instruction SWI-001. The test method will be described in greater detail in the data collection procedures section.

## *Subject Selection and Description*

The Nylon/Tyvek® pouches selected for this experiment was chosen because it is used in Company XYZ's highest volume sterile pouch application. Tensile testing, visual inspection, and

dye penetration testing were chosen for the study because they are tests that are currently utilized as acceptance activities for pouched medical devices.

*Data Collection Procedures*

Sample pouches will be created for each of the three experiments. Pouches will be sealed in Company XYZ's clean room using an impulse sealer and commercially available Nylon/Tyvek® pouches. Sample pouches will be created under homogenous conditions for each sample group. These conditions included the same lot number of pouches, same individual operating the sealing equipment, and same equipment parameters for each sample group. This limits the amount of external variation that could influence the experiment.

The Quality Assurance inspectors that will participate in this experiment are inspectors that are familiar with the Nylon/Tyvek® pouches. These inspectors are considered independent of this study and they do not have a vested interested in the results.

All data will be recorded on manual data entry sheets and then transferred to electronic files for data analysis and plotting. All inspection was completed in the Quality Assurance laboratory at Company XYZ under identical lighting conditions.

*Tensile Testing*

Thirty pouches will be sealed using nominal operating conditions for the impulse sealer. These conditions are seal bar temperature, dwell time, pressure, and release temperature. Thirty pouches will be sealed at low impulse sealer settings that cause questionable seal integrity. Using the specimen cutter, 1.00 inch +/- .010 inch wide samples will be cut through the seal in the left, center, and right positions of the pouch. Tensile testing will be conducted on thirty left, center, and right positions from the nominal operating conditions group, with the data grouped by sample location. Process capability (Cpk) values will be calculated using Minitab statistical

analysis software per location. Descriptive statistics will be calculated using Microsoft Excel. The experiment will be repeated for the thirty left, center, and right positions from the pouches sealed at the low impulse sealer settings that cause questionable seal integrity. Cpk values for each position will be compared to determine if tensile testing allows Quality Assurance inspectors at Company XYZ to differentiate between an acceptable seal and a reject seal.

*Tensile test data collection sheet*

| Sample # | Left (lbs. F) | Center (lbs. F) | Right (lbs F) |
|---|---|---|---|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |
| 7 | | | |
| 8 | | | |
| 9 | | | |
| 10 | | | |
| 11 | | | |
| 12 | | | |
| 13 | | | |
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| 24 | | | |
| 25 | | | |
| 26 | | | |
| 27 | | | |
| 28 | | | |
| 29 | | | |
| 30 | | | |

Table 1: Tensile test data collection sheet

*Visual Inspection*

Fifteen pouches will be sealed without a channel leak present and fifteen pouches will be sealed with a .003" wire in the seal. The wire will then be removed from the seal resulting in an approximate .003" channel leak. The thirty pouches will be combined and numbered randomly in the corner with numbers one through thirty. The channel leak vs. no channel leak status of the pouch will be recorded on a separate document for use in reviewing the visual inspection spread sheets.

The 30 pouches will be inspected in the Quality Assurance laboratory at Company XYZ under normal laboratory lighting. The viewing distance is to be arms length (18 to 24 inches) using unaided eye. Magnification is not permitted for the visual inspection experiment. The visual inspection experiment is not a timed experiment, so inspectors are encouraged to take their time in determining if they consider the pouch seal acceptable or if it has a channel leak. Prior to conducting the inspection, the inspectors will be shown five examples of channel leaks. The examples will have arrows pointing to the area of concern so the inspectors are clear on what the inspection criteria is. The inspectors will record their results on the visual inspection data collection sheets for further analysis.

*Visual inspection data collection sheet*

| Sample # | Trial #1 | Trial #2 |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | | |
| 16 | | |
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| 18 | | |
| 19 | | |
| 20 | | |
| 21 | | |
| 22 | | |
| 23 | | |
| 24 | | |
| 25 | | |
| 26 | | |
| 27 | | |
| 28 | | |
| 29 | | |
| 30 | | |

Table 2: Visual inspection data collection sheet

*Dye Penetration Testing*

Thirty pouches will be sealed without a channel leak present and thirty pouches will be sealed with a .003" wire in the seal. The wire will then be removed from the seal resulting in an approximate .003" channel leak. The pouches will be divided into to two groups of pouches, fifteen with channel leaks and fifteen without channel leaks. The combined groups of pouches will be randomly numbered and the pouch status, channel leak vs. no channel leak, will be recorded on a separate document for use in determining if the inspector's evaluation was correct.

The pouches are prepared for the dye penetration test by cutting away excess material above the seal area so that there is approximately .125" exposed. This is not a critical dimension, rather it saves on the dye penetration solution and it makes the test go more quickly. The seal is dipped into a tray of the dye enough to wet the edge of the pouch. The pouch is removed from the dye and held up above the tray of dye for 20 seconds. The inspector must make a determination of leak vs. no leak within the first 20 seconds after the test. Tyvek® is comprised of a web of fibers, which allow wicking of the dye through capillary action. A channel leak if present will appear almost immediately, with dye traveling up through the channel leak and showing up inside the pouch seal. Any dye that appears to be inside the pouch after approximately one minute will be due to the wicking effect and is not considered a defect. The inspector will record the result of the inspection on the dye test data sheet.

*Dye test data collection sheet*

| Sample # | Result |
|---|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
| 14 | |
| 15 | |
| 16 | |
| 17 | |
| 18 | |
| 19 | |
| 20 | |
| 21 | |
| 22 | |
| 23 | |
| 24 | |
| 25 | |
| 26 | |
| 27 | |
| 28 | |
| 29 | |
| 30 | |

Table 3: Dye test data collection sheet

*Data Analysis*

A number of statistical analyses were used in this study. Minitab version 15.1 and Microsoft Excel 2000 were used to analyze the data. Process Capability Index (Cpk) was used to quantify and compare the tensile testing data. Attribute gage repeatability and reproducibility (gage R&R) was used in the analysis of the visual inspection experiment. The dye penetration test is analyzed by comparing the result of the inspector's test with the known standard. The dye penetration test is a destructive test that cannot be replicated with the same sample.

*Limitations*

This study is limited to the researcher's time performing the experiments at Company XYZ.

# Chapter IV: Results

*Tensile Testing Results*

| Sample # | Left (lbs. F) | Center (lbs. F) | Right (lbs F) |
|---|---|---|---|
| 1 | 1.094 | 1.144 | 1.128 |
| 2 | 1.242 | 1.160 | 1.160 |
| 3 | 1.062 | 1.094 | 1.258 |
| 4 | 1.226 | 1.160 | 1.128 |
| 5 | 1.160 | 1.226 | 1.094 |
| 6 | 1.274 | 1.194 | 1.128 |
| 7 | 1.144 | 1.144 | 1.258 |
| 8 | 1.094 | 1.094 | 1.160 |
| 9 | 1.292 | 1.094 | 1.128 |
| 10 | 1.160 | 1.194 | 1.176 |
| 11 | 1.078 | 1.144 | 1.144 |
| 12 | 1.194 | 1.210 | 1.078 |
| 13 | 1.194 | 1.242 | 1.144 |
| 14 | 1.258 | 1.194 | 1.112 |
| 15 | 1.128 | 1.094 | 1.160 |
| 16 | 1.128 | 1.094 | 1.078 |
| 17 | 1.144 | 1.210 | 1.210 |
| 18 | 1.078 | 1.094 | 1.094 |
| 19 | 1.160 | 1.112 | 1.160 |
| 20 | 1.062 | 1.062 | 1.094 |
| 21 | 1.112 | 1.160 | 1.112 |
| 22 | 1.194 | 1.030 | 1.160 |
| 23 | 1.176 | 1.226 | 1.078 |
| 24 | 1.144 | 1.046 | 1.144 |
| 25 | 1.078 | 1.194 | 1.194 |
| 26 | 1.210 | 1.194 | 1.112 |
| 27 | 1.274 | 1.160 | 1.094 |
| 28 | 1.046 | 1.094 | 1.094 |
| 29 | 1.078 | 1.226 | 1.194 |
| 30 | 1.194 | 1.210 | 1.242 |

Table 4: Nominal sealing process data

| Sample # | Left (lbs. F) | Center (lbs. F) | Right (lbs F) |
|---|---|---|---|
| 1 | 0.752 | 0.670 | 0.604 |
| 2 | 0.538 | 0.538 | 0.522 |
| 3 | 0.392 | 0.392 | 0.474 |
| 4 | 0.392 | 0.408 | 0.474 |
| 5 | 0.408 | 0.376 | 0.358 |
| 6 | 0.424 | 0.376 | 0.392 |
| 7 | 0.408 | 0.392 | 0.440 |
| 8 | 0.342 | 0.392 | 0.326 |
| 9 | 0.358 | 0.376 | 0.408 |
| 10 | 0.310 | 0.376 | 0.408 |
| 11 | 0.358 | 0.294 | 0.342 |
| 12 | 0.342 | 0.310 | 0.392 |
| 13 | 0.342 | 0.342 | 0.424 |
| 14 | 0.376 | 0.294 | 0.456 |
| 15 | 0.358 | 0.294 | 0.326 |
| 16 | 0.342 | 0.294 | 0.376 |
| 17 | 0.310 | 0.244 | 0.376 |
| 18 | 0.294 | 0.310 | 0.342 |
| 19 | 0.294 | 0.310 | 0.342 |
| 20 | 0.358 | 0.326 | 0.424 |
| 21 | 0.342 | 0.358 | 0.538 |
| 22 | 0.310 | 0.358 | 0.408 |
| 23 | 0.342 | 0.342 | 0.456 |
| 24 | 0.342 | 0.392 | 0.392 |
| 25 | 0.342 | 0.326 | 0.440 |
| 26 | 0.474 | 0.294 | 0.358 |
| 27 | 0.358 | 0.326 | 0.376 |
| 28 | 0.342 | 0.358 | 0.490 |
| 29 | 0.376 | 0.342 | 0.392 |
| 30 | 0.376 | 0.342 | 0.424 |

Table 5: Low sealing process data

| Left (lbs. F) | Center (lbs. F) | Right (lbs F) | |
|---|---|---|---|
| 1.046 | 1.030 | 1.078 | **min** |
| 1.292 | 1.242 | 1.258 | **max** |
| 1.156 | 1.150 | 1.144 | **mean** |
| 0.070 | 0.060 | 0.052 | **std. dev** |

Table 6: Nominal sealing process statistics

| Left (lbs. F) | Center (lbs. F) | Right (lbs F) | |
|---|---|---|---|
| 0.294 | 0.244 | 0.326 | **min** |
| 0.752 | 0.670 | 0.604 | **max** |
| 0.377 | 0.358 | 0.416 | **mean** |
| 0.087 | 0.079 | 0.066 | **std. dev** |

Table 7: Low sealing process statistics

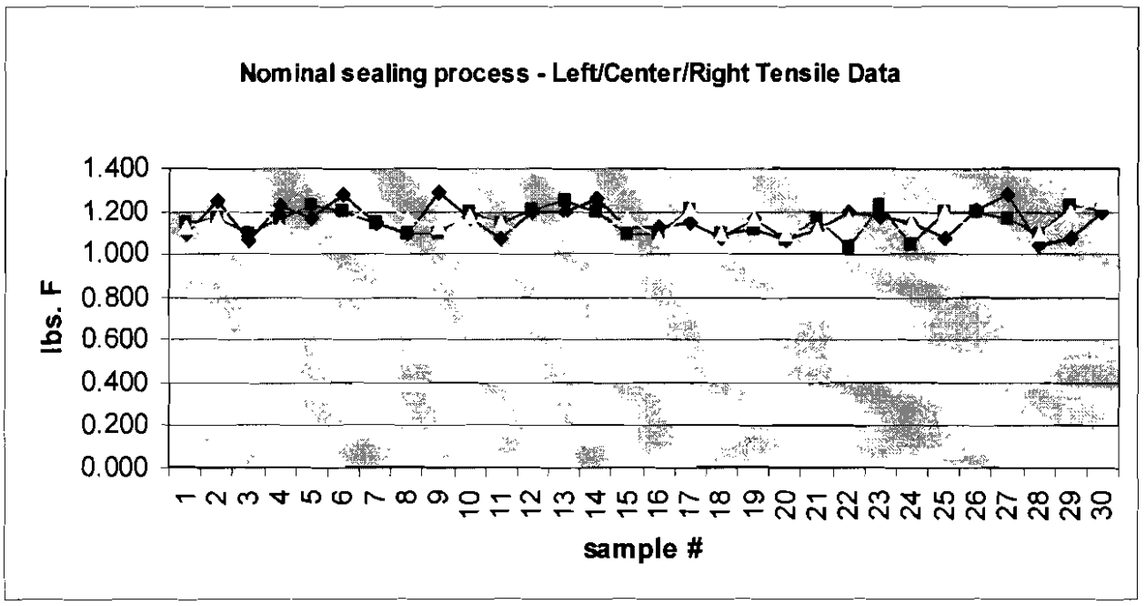


Figure 2: Nominal sealing tensile data plot per subgroup

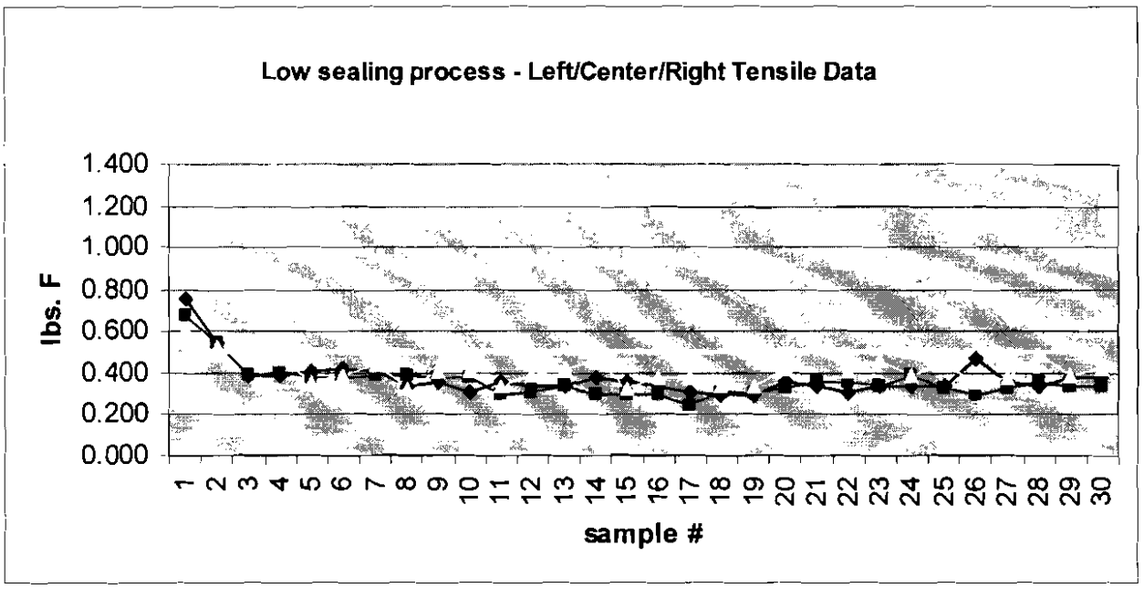


Figure 3: Low sealing tensile data plot per subgroup

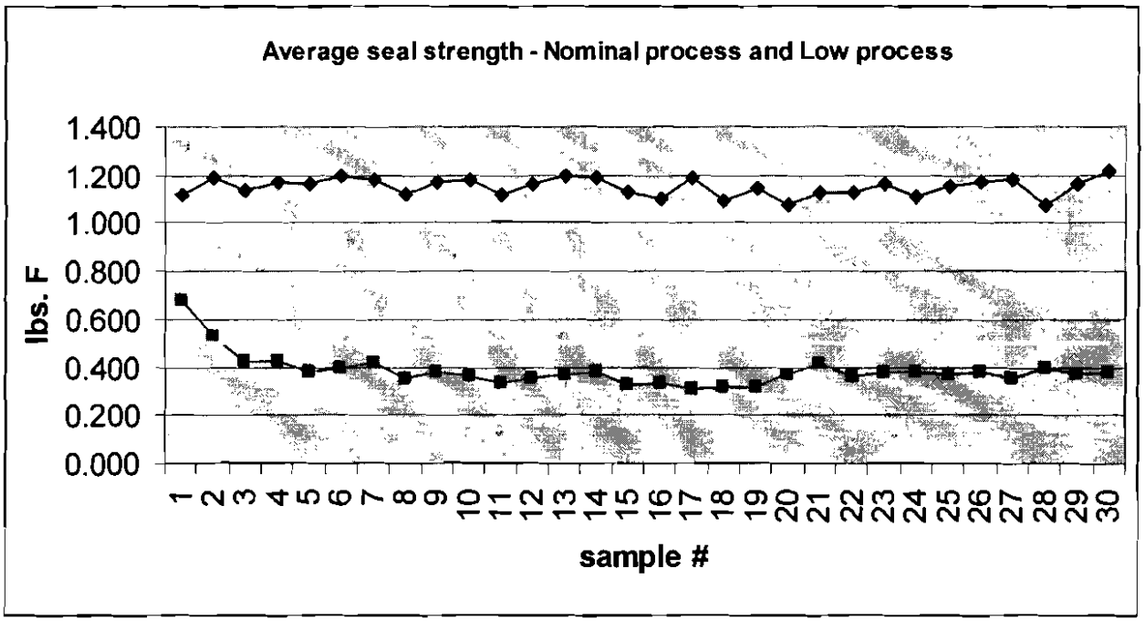


Figure 4: Average sealing tensile data plot – nominal vs. low process

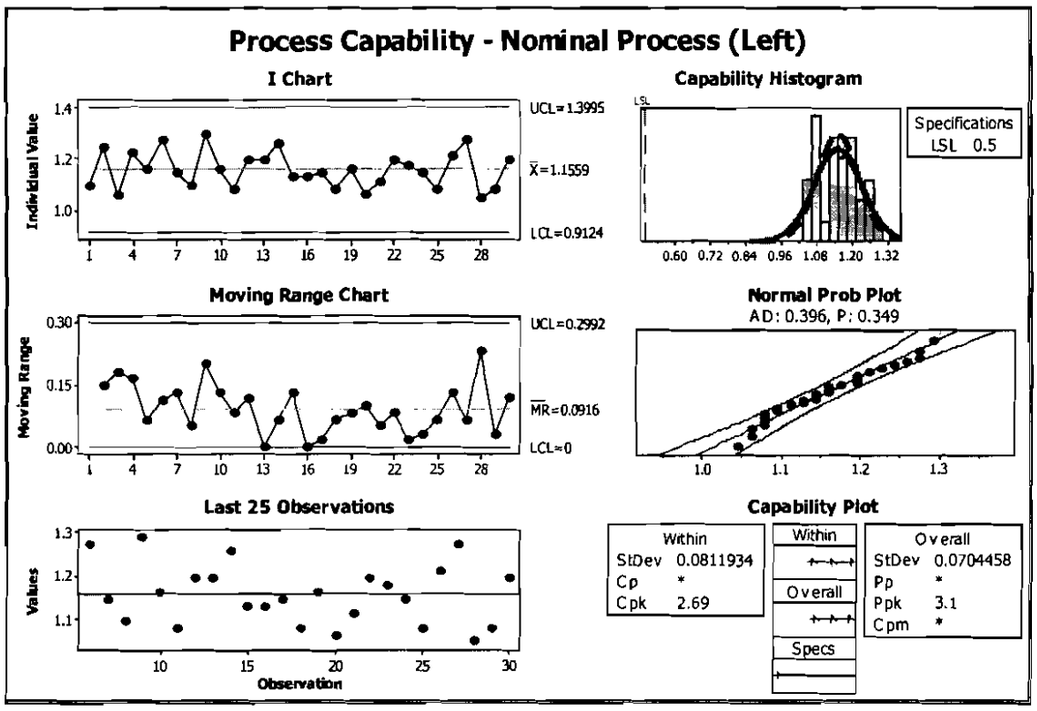


Figure 5: Process capability six-pack of nominal process (left)

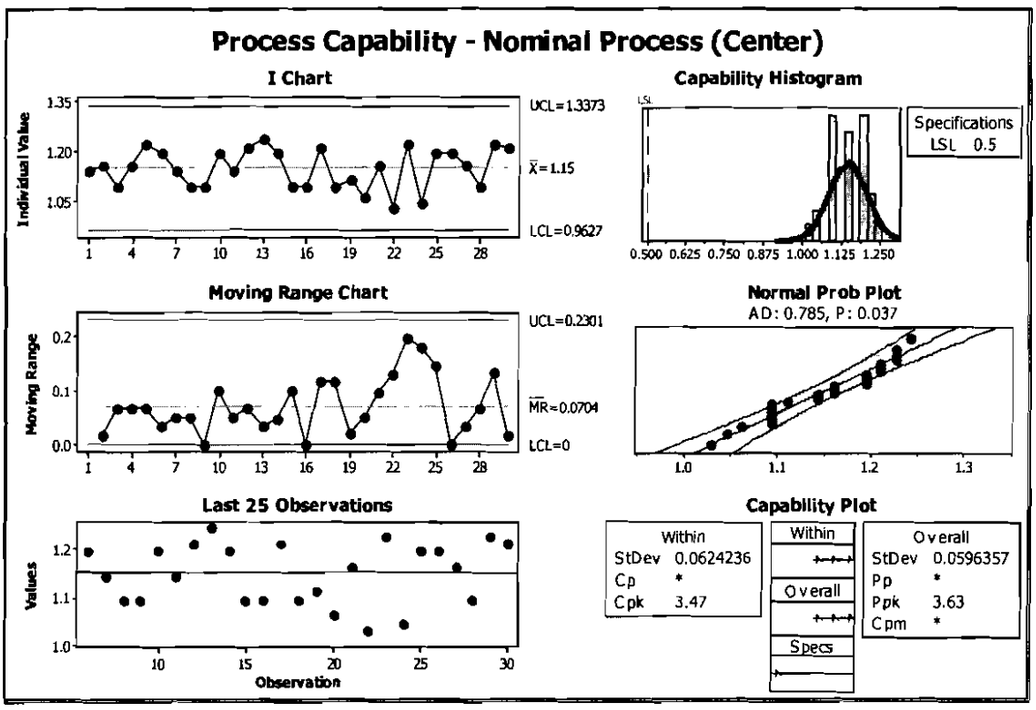


Figure 6: Process capability six-pack of nominal process (center)

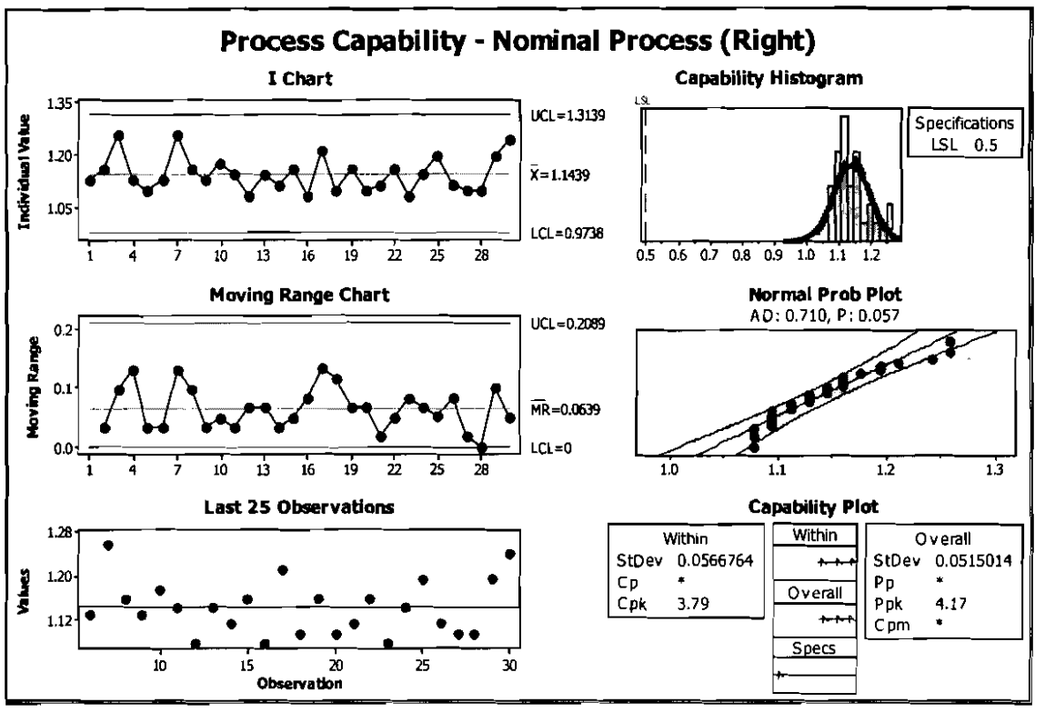


Figure 7: Process capability six-pack of nominal process (right)

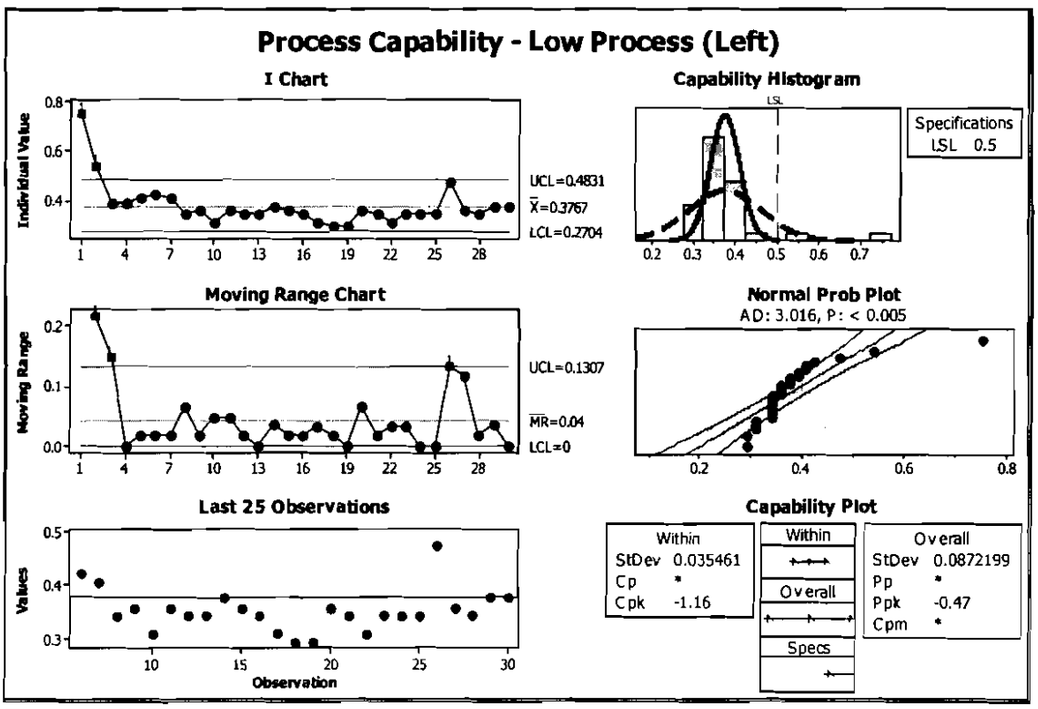


Figure 8: Process capability six-pack of low process (left)

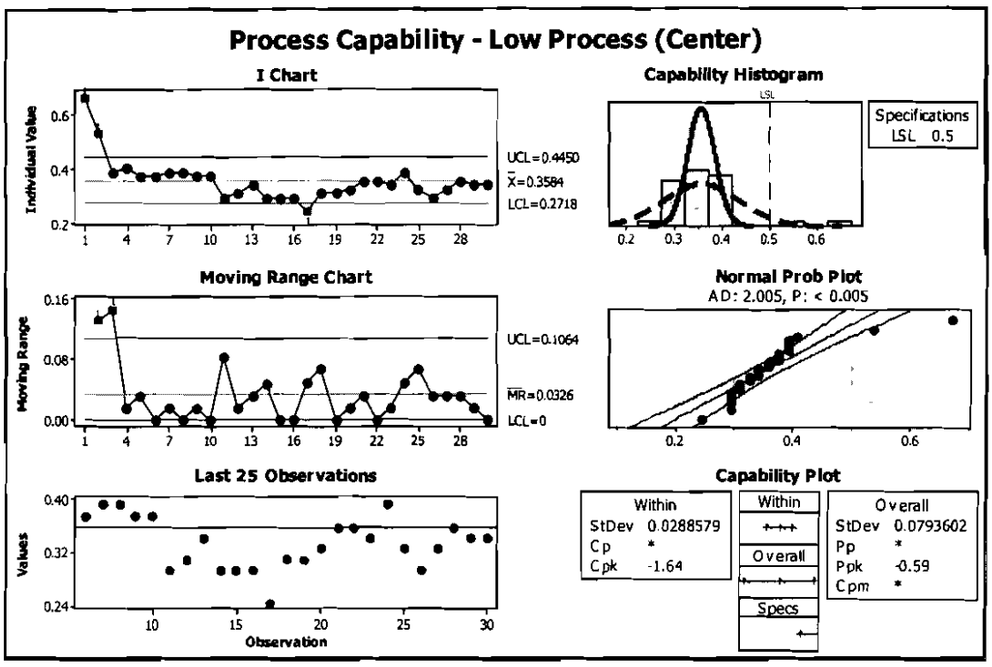


Figure 9: Process capability six-pack of low process (center)

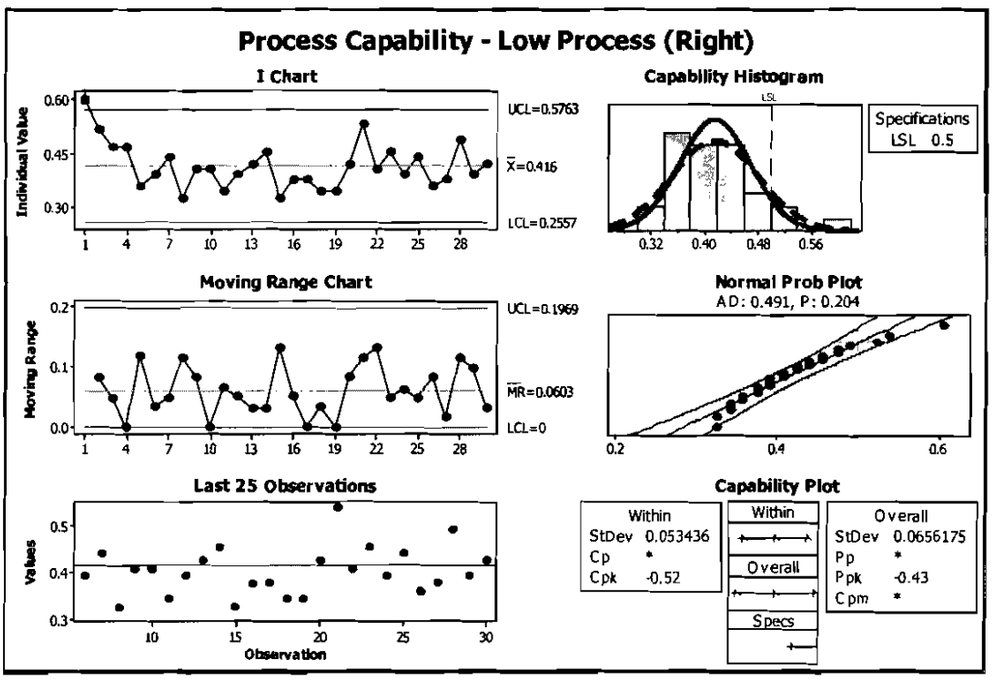


Figure 10: Process capability six-pack of low process (right)

| Position | Nominal process Cpk | Low process Cpk |
|---|---|---|
| left | 2.69 | -1.16 |
| center | 3.47 | -1.64 |
| right | 3.79 | -0.52 |

Table 8: Tensile test Cpk comparison table

*Visual Inspection Results – Inspector #1*

| Sample # | Attribute Key | Trial #1 | Trial #2 |
|---|---|---|---|
| 1 | NC | NC | NC |
| 2 | C | C | C |
| 3 | C | C | C |
| 4 | NC | NC | NC |
| 5 | C | C | C |
| 6 | NC | NC | NC |
| 7 | C | C | C |
| 8 | C | C | C |
| 9 | C | C | C |
| 10 | NC | NC | NC |
| 11 | NC | NC | NC |
| 12 | C | C | C |
| 13 | NC | NC | NC |
| 14 | NC | NC | NC |
| 15 | C | C | C |
| 16 | NC | NC | NC |
| 17 | NC | NC | NC |
| 18 | C | C | C |
| 19 | C | C | C |
| 20 | NC | NC | NC |
| 21 | NC | NC | NC |
| 22 | C | C | C |
| 23 | C | C | C |
| 24 | NC | NC | NC |
| 25 | NC | NC | NC |
| 26 | C | C | C |
| 27 | NC | NC | NC |
| 28 | NC | NC | NC |
| 29 | C | C | C |
| 30 | C | C | C |

C = channel leak / NC = no channel leak

Table 9: Visual Inspection Results – Inspector #1

*Visual Inspection Results – Inspector #2*

| Sample # | Attribute Key | Trial #1 | Trial #2 |
|---|---|---|---|
| 1 | NC | C – Type I error | C – Type I error |
| 2 | C | C | C |
| 3 | C | C | C |
| 4 | NC | NC | NC |
| 5 | C | C | C |
| 6 | NC | NC | NC |
| 7 | C | C | C |
| 8 | C | C | C |
| 9 | C | C | C |
| 10 | NC | NC | NC |
| 11 | NC | NC | NC |
| 12 | C | C | C |
| 13 | NC | NC | NC |
| 14 | NC | C – Type I error | NC |
| 15 | C | C | C |
| 16 | NC | C – Type I error | NC |
| 17 | NC | NC | NC |
| 18 | C | C | C |
| 19 | C | C | C |
| 20 | NC | NC | NC |
| 21 | NC | NC | NC |
| 22 | C | C | C |
| 23 | C | C | C |
| 24 | NC | NC | NC |
| 25 | NC | C – Type I error | NC |
| 26 | C | C | C |
| 27 | NC | NC | NC |
| 28 | NC | NC | NC |
| 29 | C | C | C |
| 30 | C | C | C |

C = channel leak / NC = no channel leak

Table 10: Visual Inspection Results – Inspector #2

*Minitab Attribute Agreement Analysis for Attribute Data (attribute Gage R&R)*

Within Appraisers

Assessment Agreement

| Appraiser | # Inspected | # Matched | Percent | 95 % CI |
|---|---|---|---|---|
| 1 | 30 | 30 | 100.00 | (90.50, 100.00) |
| 2 | 30 | 27 | 90.00 | (73.47, 97.89) |

# Matched: Appraiser agrees with him/herself across trials.

**Each Appraiser vs Standard**

Assessment Agreement

| Appraiser | # Inspected | # Matched | Percent | 95 % CI |
|---|---|---|---|---|
| 1 | 30 | 30 | 100.00 | (90.50, 100.00) |
| 2 | 30 | 26 | 86.67 | (69.28, 96.24) |

# Matched: Appraiser's assessment across trials agrees with the known standard.

Assessment Disagreement

| Appraiser | # 1 / 0 | Percent | # 0 / 1 | Percent | # Mixed | Percent |
|---|---|---|---|---|---|---|
| 1 | 0 | 0.00 | 0 | 0.00 | 0 | 0.00 |
| 2 | 1 | 6.67 | 0 | 0.00 | 3 | 10.00 |

# 1 / 0: Assessments across trials = 1 / standard = 0.
# 0 / 1: Assessments across trials = 0 / standard = 1.
# Mixed: Assessments across trials are not identical.

Between Appraisers

Assessment Agreement

| # Inspected | # Matched | Percent | 95 % CI |
|---|---|---|---|
| 30 | 26 | 86.67 | (69.28, 96.24) |

# Matched: All appraisers' assessments agree with each other.

All Appraisers vs Standard

Assessment Agreement

| # Inspected | # Matched | Percent | 95 % CI |
|---|---|---|---|
| 30 | 26 | 86.67 | (69.28, 96.24) |

# Matched: All appraisers' assessments agree with the known standard.

Figure 11: Minitab attribute agreement analysis

*Attribute Agreement Analysis*

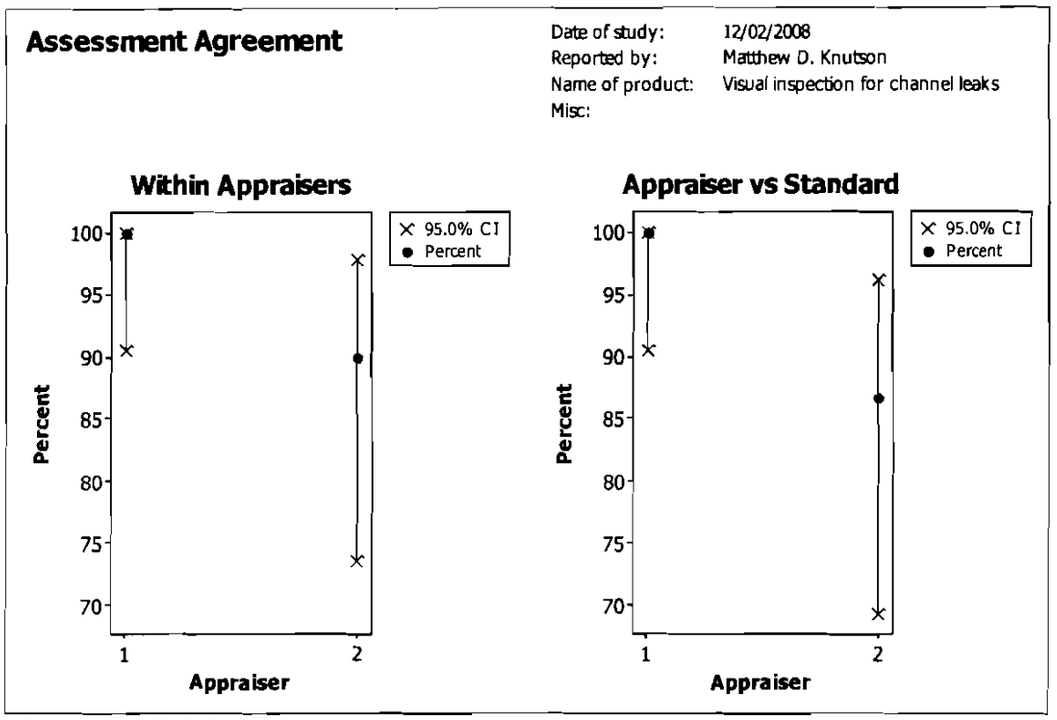


Figure 12: Minitab assessment agreement

Inspector #1 agreed with him/herself 30 out of 30 times, or 100% of the time. Inspector #2 agreed with him/herself 27 out of 30 times, or 90% of the time. The 95% confidence interval for Inspector #1 was (90.50, 100.00). The 95% confidence interval for Inspector #2 was (73.47, 97.89).

Inspector #1 agreed with him/herself and the known standard 30 out of 30 times, or 100% of the time. Inspector #2 agreed with him/herself and the known standard 26 out of 30 times, or 86.67% of the time. The 95% confidence interval for Inspector #1 was (90.50, 100.00). The 95% confidence interval for Inspector #2 was (69.28, 96.24).

Inspector #1 and Inspector #2 agreed with each other and the known standard 86.67% of the time.

*Dye penetration test results – Inspector #1*

| Sample # | Attribute Key | Inspector #1 |
|---|---|---|
| 1 | NC | NC |
| 2 | C | C |
| 3 | C | C |
| 4 | NC | NC |
| 5 | C | C |
| 6 | NC | NC |
| 7 | NC | NC |
| 8 | C | C |
| 9 | NC | NC |
| 10 | C | C |
| 11 | C | C |
| 12 | NC | NC |
| 13 | NC | NC |
| 14 | C | C |
| 15 | NC | NC |
| 16 | NC | NC |
| 17 | C | C |
| 18 | C | C |
| 19 | NC | NC |
| 20 | NC | NC |
| 21 | C | C |
| 22 | NC | NC |
| 23 | C | C |
| 24 | NC | NC |
| 25 | C | C |
| 26 | C | C |
| 27 | NC | NC |
| 28 | NC | NC |
| 29 | C | C |
| 30 | C | C |

C = channel leak / NC = no channel leak

Table 11: Dye test data – Inspector #1

*Dye penetration test results – Inspector #2*

| Sample # | Attribute Key | Inspector #2 |
|---|---|---|
| 1 | NC | NC |
| 2 | C | C |
| 3 | C | C |
| 4 | NC | NC |
| 5 | C | C |
| 6 | NC | NC |
| 7 | NC | NC |
| 8 | C | C |
| 9 | NC | C |
| 10 | C | NC |
| 11 | C | NC |
| 12 | NC | C |
| 13 | NC | NC |
| 14 | C | NC |
| 15 | NC | C |
| 16 | NC | C |
| 17 | C | NC |
| 18 | C | NC |
| 19 | NC | C |
| 20 | NC | NC |
| 21 | C | C |
| 22 | NC | NC |
| 23 | C | C |
| 24 | NC | C |
| 25 | C | NC |
| 26 | C | NC |
| 27 | NC | C |
| 28 | NC | C |
| 29 | C | C |
| 30 | C | NC |

C = channel leak / NC = no channel leak

Table 12: Dye test data – Inspector #2

| Dye penetration test - Inspector #1 |
| --- |
| n=30 |
| 15 out of 15 pouches with .003" channel leaks identified correctly |
| 15 out of 15 pouches without channel leaks identified correctly |

Table 13: Dye test results – Inspector #1

| Dye penetration test - Inspector #2 |
| --- |
| n=30 |
| 15 out of 15 pouches with .003" channel leaks identified correctly |
| 15 out of 15 pouches without channel leaks identified correctly |

Table 14: Dye test results – Inspector #2

# Chapter V: Discussion

Company XYZ Quality Assurance inspectors perform three test methods for detecting breaches in the sterile barrier seal (channel leak) and weak seals. These test methods are tensile testing, visual inspection, and dye penetration testing. The purpose of the study was to qualify Quality Assurance inspectors to perform these three tests to accurately identify if the seal is acceptable.

## *Limitations*

This study and results herein are only valid for pouched medical devices. To qualify other packaging types such as blister packed medical devices, an additional study would be necessary.

## *Conclusions (tensile testing)*

The tensile testing experiment that compared data sets from pouches sealed at nominal process conditions with pouches that were sealed at low process conditions proved conclusively that Quality Assurance inspectors can easily detect a weak seal. The minimum tensile test result required at Company XYZ for this application is 0.50 lbs. Company XYZ considers Cpk values of greater than 1.67 to be acceptable for seal strength. Negative Cpk values demonstrate a low process capability while positive Cpk values demonstrate increased process capability.

The nominal process condition data showed Cpk ranging from a low of 2.69 (left position) to a high of 3.79 (right position). Minimum, Maximum, and Mean were calculated for each of the positions. The lowest value recorded for any of the three positions was 1.030 lbs. (center position), which is twice the minimum requirement.

The low process condition data showed Cpk ranging from a low of -1.64 (center position) to a high of -0.52 (right position). Minimum, Maximum, and Mean were calculated for each of

the positions. The lowest value recorded for any of the three points was 0.244 lbs. (center position), which is less than half the minimum requirement.

As can be seen on Figure 4: Average sealing tensile data plot – nominal vs. low process, there are two distinct data groups. All the data points for the nominal process are above the minimum value of 0.50 lbs. and all but the first two data points are below the minimum value of 0.50 lbs. The two data points from the low process that were slightly above the 0.50 lbs. minimum can be attributed to test preparation error. The group of nominal pouches were sealed at a steady pace prior to beginning to seal the group of pouches at the low process parameters. The low pouches were sealed immediately after the first group of pouches so there was residual heat left in the aluminum seal bar. It took until the third cycle to stabilize the temperature of the seal bar. This would not have been apparent to the person preparing the test samples. It does, however, demonstrate the resolution of our test method.

*Conclusions (visual inspection)*

The visual inspection experiment was a non-destructive test where two inspectors each took 30 pouches and visually inspected them for channel leaks. The results of each test were recorded on the provided data sheets and compared to the master document.

Inspector #1 correctly identified 100% of the pouch seals with channel leaks and 100% of the pouches without leaks. The pouches were again randomized and a second replication of the experiment was conducted by inspector #1. Again, the inspector correctly identified 100% of the pouch seals with channel leaks and 100% of the pouches without leaks.

Inspector #2 correctly identified 100% of the pouch seals with channel leaks and incorrectly identified four out of fifteen pouches as having channel leaks when they did not. This Type I error is considered a false positive and is not considered to be an inspection failure. The

pouches were again randomized and a second replication of the experiment was conducted by inspector #2. Again, the inspector correctly identified 100% of the pouch seals with channel leaks and incorrectly identified only one out of fifteen pouches as having channel leaks when they did not.

Both inspectors correctly identified 100% of the pouch seals with channel leaks. The testing proved conclusively that Quality Assurance inspectors can detect a .003" channel leak using the visual inspection test method.

*Conclusions (dye penetration)*

The dye penetration experiment was a destructive test where two inspectors each took an independent sample of 30 pouches containing both pouches that had .003" channel leaks and ones sealed with no leaks and performed the dye penetration inspection per Company XYZ standard work instructions. The results of each test were recorded on the provided data sheets and compared to the master document. Both inspectors accurately identified 100% of the pouch seals with channel leaks. The testing proved conclusively that Quality Assurance inspectors can detect a .003" channel leak using the dye penetration test method.

*Recommendations*

Although the three inspection methods for detecting breaches in the sterile barrier seal (channel leak) and weak seals utilized at Company XYZ are considered qualified for use, they still rely on the inspector to properly identify a defective and non-defective seal. One area that deserves additional research is automated seal inspection. By taking the subjectivity of the inspector out of the equation and utilizing automated inspection technology, a company can reduce the likelihood of rejecting an acceptable seal and accepting a defective seal. There is commercially available equipment that uses non-contact ultrasound waves to analyze and accept

or reject user defined quality criteria. The equipment can detect both visible and invisible defects and seal leaks. The machines can be configured to 100% inspect product or can be used as an off-line Quality Assurance inspection step (PTI, n.d.). This type of equipment is used primarily in the food packaging industry, but is gaining popularity in the medical device manufacturing industry.

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