

Design and Implementation Process to Optimize Raw Material Inspection Methods

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Abstract — *VitalTech Innovation, LLC is a medical device company targeted to patients diagnosed with scoliosis or other medical conditions that affects the spinal/cervical system by significantly improving the management and quality of life for patients. Innovative instrumentation, such as pedicle screws and rods, allows for more effective stabilization of the spine during surgical operations. These medical innovations collectively contribute to enhanced patient care, enabling earlier detection, personalized treatment plans, and improved surgical outcomes for individuals living with spinal/cervical conditions. The implementation of the DMADV which stands for (Define, Measure, Analyze, Design and Verify) methodology is suitable for this research which aim to optimize inspection methods during the process of Incoming in the VitalTech Innovation, LLC. The area of Incoming hold a significant importance for receiving and inspecting raw materials, chemical agents, and other components. By applying the methodology of DMADV, our objective is to diligently define the precise goals and optimization requirements. This involves a comprehensive measurement of the existing inspection processes, followed by a thorough analysis to identify potential areas for improvement.*

Key Terms — *DMADV Method, Inspection Method, Raw Material, Sampling Plan, Stainless-Steel Rods.*

PROBLEM STATEMENT

Based on the current inspection methods activities at Incoming Inspection area, for raw materials, specifically titanium and stainless steel, present a challenge in terms of optimization, with a notable discrepancy in the sample sizes between the two materials, particularly evident in the inspection of stainless-steel rods. The existing procedures lack uniformity, as the larger sample size for stainless-

steel rods introduces inefficiencies and potentially disproportionate resource allocation in the inspection process. This discrepancy raises concerns about the precision and effectiveness of the quality control measures for stainless-steel, a critical material in various industrial applications. Therefore, addressing the disparity in sample sizes and optimizing the inspection methods for both titanium and stainless-steel rods becomes imperative to ensure consistent and reliable quality standards across all raw materials utilized in manufacturing processes.

Inspectors currently gather data through the Inspection Management System (IMS) during the evaluation of titanium and stainless-steel rods. This data collection is a crucial step in the inspection process, as it serves as the basis for the subsequent decision-making by inspectors regarding the acceptance or rejection of the rods. The acceptance criteria for the sampling plan are established in accordance with the guidelines outlined in VitalTech Innovation, LLC procedures. These procedures, adhere to the standards set forth by the International Organization for Standardization (ISO), specifically the ISO 2859-1. Ensuring alignment with ISO 2859-1 guidelines and following VitalTech Innovation, LLC procedures reinforces the commitment to maintaining high-quality standards in the inspection of raw materials, particularly titanium and stainless-steel rods, contributing to the overall integrity of the manufacturing processes.

RESEARCH DESCRIPTION

The quality control process, it is imperative that every inspector undergoes comprehensive training on how to collect data and what resources. One crucial aspect of this process involves the meticulous measurement of rods at three distinct points: each end and the center, to guarantee precision in their

dimensions. This inspection method of three points ensures a thorough assessment of the rod's dimensions. The inspector's role extends beyond measurements; they must also diligently examine the rods for any signs of damage incurred during shipment or scratches that might compromise the integrity of the material.

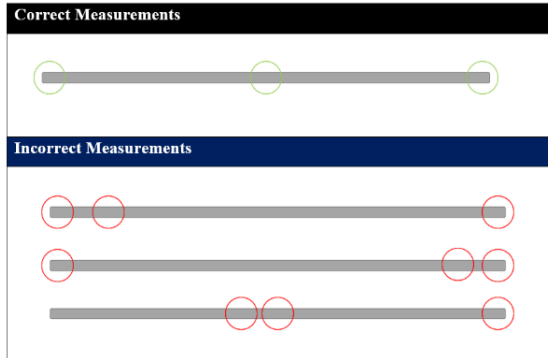


Figure 1
Illustration for Inspection Methods

Furthermore, suppliers must provide a certificate of conformance alongside the delivered rods. This certificate of conformance serves as an official assurance that the rods meet the specified acceptance criteria for both mechanical and chemical properties. It acts as a tangible statement to the quality control measures implemented by the supplier, assuring stakeholders that the rods adhere to the stringent standards set forth for their designated applications. It is through the collective efforts of well-trained inspectors and diligent suppliers that the data collection process achieves reliability and accuracy in assessing the rods' dimensions for purpose in upholding the integrity and reliability of the entire inspection method process.

RESEARCH TIMELINE

DMADV method and its role in supporting the design and implementation of optimized inspection methods in the Incoming Inspection area, specifically through the reduction of sampling size, was initiated in September 2023. This research identification of the problem statement and the execution of the Define phase, determine project's

objectives and scope. In the subsequent month, measure phase was performed to gather data, providing essential variable characteristic for later analysis during the Analyze phase.

Following the data collection phase, the research transitioned into the Analyze phase, where the gathered data was evaluated to identify patterns and inefficiencies. Subsequently, based on the findings, the research advanced into the Verification phase. During this phase, a comprehensive verification process was carried out to validate the efficiency of proposed sampling plan, reduced sampling plan for stainless-steel rods utilizing the MIL-STD-105E. The Verification phase played an important role in ensuring that the proposed sampling size aligned with the research objectives, contributing significantly to the optimization of the Incoming Inspection area.

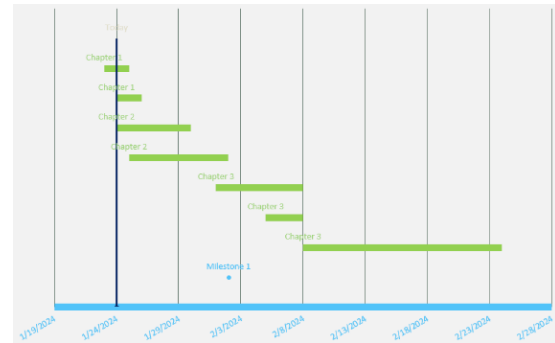


Figure 2
Project Timeline

RESEARCH CONTRIBUTIONS

Implementing an optimized inspection method for raw materials contributes multiple benefits for organizational efficiency and financial savings. A key aspect involves providing comprehensive training programs for inspectors, equipping them with the skills and knowledge required to adeptly apply the new inspection method. This not only enhances workforce proficiency but also ensures a standardized approach to raw material inspection throughout the organization.

The optimized method plays a critical role in reducing waste by identifying of defects in the production process. This approach not only

minimizes resource wastage but also mitigates the potential for downstream issues. From a financial perspective, the impact is significant. Firstly, the reduction in waste translates into cost savings, and secondly, the improved efficiency in the inspection process enhances overall productivity. Therefore, the implementation of an optimized inspection method for raw materials is a strategic initiative that not only increase quality control process but also delivers financial benefits, and reduce waste down production downstream line.

LITERATURE REVIEW

The paper, *Introducing an Efficient Sampling Method for National Surveys with Limited Sample Sizes: Application to a National Study to Determine Quality and Cost of Healthcare*, discusses the advantages and limitations of the proposed method, emphasizing the need for expert involvement in variables selection and result evaluation. The efficiency gain is measured by proxy measures of targeted health conditions, emphasizing the importance of including comprehensive prior information in future studies. The authors acknowledge the limitations of the study, such as the representativeness of sampling results and the external validity of the method, suggesting areas for future research and improvement.

The study presented by Mahboubeh Parsaeian and colleagues addresses the challenge of conducting national surveys with limited sample sizes, focusing on the quality and cost of healthcare in Iran. Small sample sizes often lead researchers to sample from a single or few settings, limiting the generalizability of findings. The paper introduces an efficient sampling method utilizing data mining techniques, specifically hierarchical clustering and model-based clustering, to create homogeneous strata of districts based on health-related variables. The objective is to design a sampling method that produces generalizable results at the country level, even with a small sample size [1].

Based on the methods applied, the data comprised twenty proxy variables related to health

services demands, structures, and outcomes across 413 districts in Iran. The researchers employed hierarchical clustering and model-based clustering to create strata, comparing the validity of these methods. The efficiency of the selected method was evaluated through simulation. The proposed sampling design was then applied to a national study, the "Iran Quality of Care in Medicine Program" (IQCAMP), focusing on the quality and costs of medical care for eight selected diseases.

The clustering methods divided districts into clusters, with model-based clustering outperforming hierarchical clustering in terms of internal and stability validity. The selected method improved efficiency up to 1.7 times compared to simple random sampling (SRS) in the simulation. The clusters were characterized by key health indicators such as the probability of death from stroke, chronic obstructive pulmonary disease (COPD), and in-hospital mortality rate.

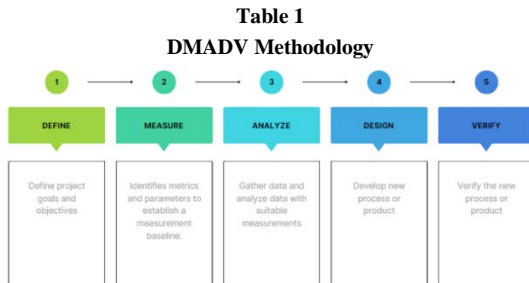
In the realm of survey methodology, the integration of data mining techniques, particularly the utilization of model-based clustering, has emerged as a powerful tool for refining sampling methodologies. By employing model-based clustering, the study successfully curtailed the number of strata, a pivotal factor in survey research, thereby streamlining the sampling process. Notably, the heightened efficiency of the proposed method was evidenced through a comparison with simple random sampling (SRS), showcasing its superiority in optimizing resource utilization and sample representativeness at the national level. This innovative approach doesn't merely offer a more efficient sampling strategy; it goes a step further by identifying crucial variables that play a pivotal role in classifying districts, providing invaluable insights for targeted and nuanced analyses.

The use of data mining, specifically model-based clustering, enhanced the efficiency of the sampling design, reducing the number of strata and increasing the representativeness of the sample. The proposed method not only demonstrated higher efficiency compared to SRS but also identified crucial variables for classifying districts. The study

concludes that this innovative sampling design is an efficient alternative to conventional stratified sampling, particularly beneficial for surveys with small sample sizes in resource-limited settings.

METHODOLOGY

The DMADV methodology to perform the Design and Implementation Process to Optimize Raw Material Inspection Methods. This methodology is part of Six Sigma's tools we used to evaluate the problem statement mentioned prior. The DMADV (Define, Measure, Analyze, Design, Verify) methodology stands as a systematic and structured approach to process improvement and product development, particularly prevalent in fields such as product development and quality management. Table 1 briefly describes the five (5) phases of the DMADV methodology.



The implementation of DMADV methodology for a new process must meet acceptance requirements to ensure a successful implementation. The benefits of DMADV are various – it enhances efficiency by eliminating redundancies and streamlining processes, ensures consistency in outcomes through standardized practices, reduces errors and defects through rigorous analysis, and ultimately leads to improved product quality. Additionally, DMADV encourage a culture of continuous improvement within an organization, as it encourages ongoing refinement and optimization. Its structured nature enables organizations to identify challenges, adapt to evolving circumstances, and stay ahead in a dynamic business industry.

- **Define phase:** In the Define phase, the inspection process for rods particularly focusing on titanium and stainless-steel rods is a notable

discrepancy between in the sampling plan for both rods. The definition phase is crucial for establishing the foundation of the inspection project, including outlining objectives, scope, and key metrics. The existing procedures lacks consistency, as the sample sizes allocated for these materials exhibit notable differences, with a particularly evident imbalance in the inspection of stainless-steel rods. This inconsistency introduces challenges in ensuring a standardized process evaluation of both materials. Addressing these discrepancies in the Define phase becomes an effective inspection methodology, ensuring that the sampling plan aligns with the specific characteristics and acceptance criteria requirements of titanium and stainless-steel rods.

- **Measure phase:** A systematic and data-driven approach is essential to quantify the existing processes and evaluate the performance of the inspection methods, aligning with the principles of Six Sigma. Utilizing tools such as statistical analysis, process mapping, and data collection, the Measure phase aims to establish a baseline for the current state of the inspection methods procedures from VitalTech Innovation, LLC. Six Sigma emphasizes the importance of accurate and reliable data to identify areas of improvement and assess the efficiency of the inspection methods. The resources utilized in this phase may include statistical software such as Minitab, measurement devices, and process mapping tools. By implementing these Six Sigma tool resources, organizations can gain a comprehensive understanding of the strengths and weaknesses in their inspection methods, setting the stage for data-driven decision-making and targeted improvements in subsequent phases of the process.
- **Analyze phase:** The principles of Six Sigma involves a performing gather of data to identify root causes of inefficiencies or defects during the process of inspection methods at Incoming Inspection Area. Statistical analysis is a crucial role in this phase, allowing for a deeper

understanding of the process performance. Resources identified in this phase include statistical software such as Minitab, which facilitate data analysis through tools like regression analysis, process capability, and others. These resources aid in uncovering patterns, trends, and potential correlations within the inspection method process. The Analyze phase is a critical juncture where Six Sigma principles guide the identification of key issues for strategic interventions to enhance the overall effectiveness of inspection methods.

- **Design phase:** The objective is to strategically reduce inspection points and lower the sampling plan for raw material specifically stainless-steel rods received at Incoming Inspection, particularly focusing on variable characteristics, by incorporating the Acceptable Quality Limit (AQL) principles. This phase is informed by Six Sigma methodologies, aiming to optimize the inspection method process for efficiency without compromising the reliability of quality control. Designing a streamlined inspection plan involves careful consideration of AQL levels, which define the maximum acceptable defect rate. Leveraging statistical techniques and tools such as statistical process control (SPC) charts and others, organizations can identify key variables that significantly impact product quality and perform the inspection plan accordingly. By strategically implementing AQL for variable characteristics, the Design phase ensures a balanced approach, reducing the number of inspection points while maintaining a stringent focus on critical quality attributes. This approach not only enhances efficiency but also aligns with Six Sigma's overarching goal of achieving consistent and high-quality outcomes in manufacturing processes.
- **Verify phase:** This phase ensures that the alterations made during the Design phase align with the identified goal for efficiency without compromising the integrity of quality control. Organizations leverage various verification techniques, including process audits, statistical

analysis, and performance metrics, to assess the impact of the modified inspection method plan. The verification process involves systematically comparing the outcomes of the newly implemented plan against predetermined specifications and objectives. By performing reporting the results of the execution, organizations gain adequate insights into the success of the initiative, identifying any remaining challenges or areas for improvement. The Verification phase serves as the final checkpoint, providing a comprehensive evaluation of the effectiveness of the streamlined inspection methods plan and offering valuable data for ongoing process optimization and continuous improvement efforts without impacting the integrity for quality control.

RESULTS AND DISCUSSION

This section outlines the analysis of results and discusses the established problem, demonstrate how the design and implementation of the *Design and Implementation Process to Optimize Raw Material Inspection Methods* were accomplished through the application of the DMADV methodology for this research.

Define

In the Define phase, the inspection process for rods particularly focusing on titanium and stainless-steel rods is a notable discrepancy between in the sampling plan for both rods. The definition phase is crucial for establishing the foundation of the inspection project, including outlining objectives, scope, and key metrics. However, in the context of rod inspection, there is a discrepancy in the sampling plans applied to titanium and stainless-steel rods. The existing procedures lack consistency, as the sample sizes allocated for these materials exhibit notable differences, with a particularly evident imbalance in the inspection of stainless-steel rods. This inconsistency introduces challenges in ensuring a standardized process evaluation of both materials.

Addressing these discrepancies in the Define phase becomes effective inspection methodology, ensuring that the sampling plan aligns with the specific characteristics and acceptance criteria requirements of titanium and stainless-steel rods.

Measure

In the Measure phase, a thorough strategy is employed to ensure adherence to the Standard Operating Procedure (SOP) implemented by VitalTech, LLC. A sample size (n) of 30, including 10 stainless-steel rods, is measured to confirm compliance with rigorous quality control standards. Each stainless-steel rod undergoes measurements at three (3) key points, reflecting a strict evaluation process aligned by following acceptance criteria requirements. To ensure comprehensive data collection, the diameter of each individual rod is measured at three specific points (both ends and the center), facilitating a thorough examination of its physical properties. This systematic approach not only conforms to the procedure established by VitalTech, LLC but also ensures a robust evaluation process, offering valuable insights into the quality and consistency of the stainless-steel rods inspection methods. Based on the sampling size and measurement points underscores a commitment to precision and adherence to established protocols in the assessment of these critical components.

Table 2
Stainless-Steel Rod Diameter

Stainless-Steel Diameter (in)				
1.5021	1.5016	1.5017	1.5031	1.5023
1.5019	1.5014	1.5021	1.5020	1.5021
1.5018	1.5021	1.5021	1.5017	1.5024
1.5021	1.5012	1.5030	1.5016	1.5012
1.5012	1.5013	1.5012	1.5015	1.5011
1.5030	1.5019	1.5032	1.5021	1.5010

The execution of this phase involved the utilization of various statistical data tools to ascertain the current state of inspection methods in the incoming area. Focusing on variable characteristics, a meticulous sampling plan was implemented for the

evaluation of stainless-steel rods, with the overarching goal of ensuring compliance with the minimum requirement of 95/95. Through the application of statistical techniques, the inspection process aimed to provide a comprehensive understanding of the variability and quality of the incoming stainless-steel rods. This strategic approach not only enhances the efficiency of the inspection methods but also aligns with the stringent standards set by the 95/95 requirement, where there is 95% confidence that at least 95% of the entire population of stainless-steel rods meets the specified criteria.

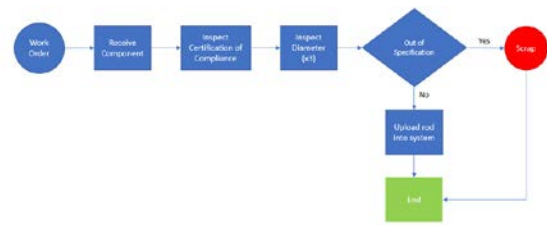


Figure 3
Process Flow for Purchasing Components

In the incoming area for raw materials and subcomponents, the inspection process is meticulously designed to ensure the quality and conformity of the received items. Upon receipt, each raw material or subcomponent undergoes a comprehensive inspection that includes evaluation of critical characteristics such as dimensions, mechanical, and chemical composition. For this specific process of inspection method that is categorized as a variable characteristic involves the use of calibrated measurement tools, and adherence to specified standards, guaranteeing that only materials meeting the predetermined criteria are accepted into the production process.

Analyze

In the Analyze phase of inspection methods, a performing gather of data to identify root causes of inefficiencies or defects during the process of inspection methods at Incoming Inspection Area. Statistical analysis is a crucial role in this phase to identify the process performance. Resources identifies in this phase include statistical techniques,

such as process capability, pareto chart and others. These resources aid in uncovering patterns, trends, and potential correlations within the inspection method process.

- Pareto charts** were applied to the evaluation of stainless-steel rods to visually highlight and prioritize the most significant factors affecting quality. By graphically representing the frequency and impact of various characteristics, the Pareto charts facilitated a focused analysis, allowing for targeted improvements in the production and inspection processes of stainless-steel rods.

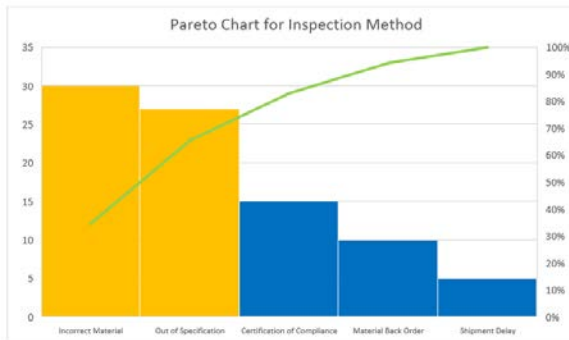


Figure 4
Pareto Chart Results

The analysis of results indicates that the primary contributing factor to potential problems with stainless steel rods is the receipt of incorrect material. This suggests that rods may fall out of specification, which indicated that the material does not meet with specification criteria. Addressing and rectifying issues related to material accuracy to ensures compliance and maintaining the desired quality standards for stainless-steel rods.

- Process capability** refers to the ability of a manufacturing process to consistently produce products that meet specifications criteria. When applied to stainless-steel rods, assessing process capability involves analyzing key characteristics such as diameter in three specific points (both end and center) to ensure that the manufacturing process consistently delivers rods within specified tolerances. By measuring and understanding process capability, manufacturers can identify areas for

improvement, optimize production, and enhance the overall quality of stainless steel rods.

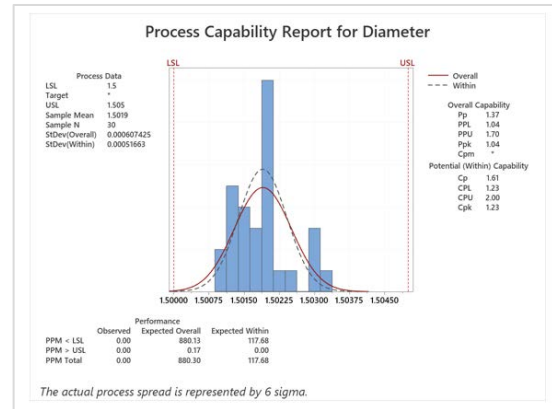


Figure 5

Process Capability for Diameter

Based on the results of process capability, the stainless-steel rod's diameter exhibits a process performance index (ppk) value of 1.04, signifying conformity to the acceptance criteria specified for diameter in compliance with the specifications.

- Probability Plot Chart** – distribution probability plot is a graphical representation of the probability distribution of a set of data, allowing for a visual assessment of its distribution characteristics. When applied to stainless steel rods, this plot can be used to analyze key parameters such as dimensions specifically diameter, providing insights into the distribution patterns and aiding in the identification of any deviations from specifications meeting criteria.

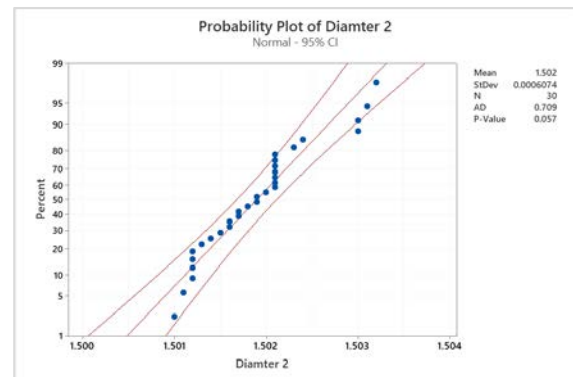


Figure 6

Probability Plot of Stainless-Steel Diameter

In this analysis, the null hypothesis presents that the data complies with a normal distribution. Given the p-value of 0.057, is greater than the significance level of 0.05, the decision is made not to reject the null hypothesis. Therefore, it is not possible to assert that the data does not conform to a normal distribution based on these results for the stainless-steel diameter rods.

Design

In the Design phase of inspection methods, the objective is to strategically reduce inspection points and lower the sampling plan for raw material specifically stainless-steel rods received at Incoming Inspection, particularly focusing on variable characteristics, by incorporating the Acceptable Quality Limit (AQL) principles. This phase is informed by Six Sigma methodologies, aiming to optimize the inspection method process for efficiency without compromising the reliability of quality control. Designing a streamlined inspection plan involves careful consideration of AQL levels, which define the maximum acceptable defect rate. Leveraging statistical techniques and tools such as statistical process control (SPC) charts and others, organizations can identify key variables that significantly impact product quality and perform the inspection plan accordingly. By strategically implementing AQL for variable characteristics, the Design phase ensures a balanced approach, reducing the number of inspection points while maintaining a stringent focus on critical quality attributes. This approach not only enhances efficiency but also aligns with Six Sigma's overarching goal of achieving consistent and high-quality outcomes in manufacturing processes [2].

Verify

For the verification phase it is recommended the implementation Acceptable Quality Level (AQL) as a crucial measure in quality control processes. Based on ISO 2859-1, the AQL serves as a standard for determining the acceptable number of defective components during random sampling quality inspections. The AQL provides a clear indication of

the tolerable defect rate in a given production batch or lot. Adopting the AQL in quality assurance protocols ensures a systematic approach to assessing product quality, helping to maintain consistency and reliability by setting predetermined standards for acceptable levels of defects during inspections. This recommendation aligns with industry best practices and contributes to the overall enhancement of product quality control standards.

The current sampling plan for stainless-steel rods perform 100% inspection. However, the recommendation considering the implementation of the Acceptable Quality Level (AQL) standard to optimize the sampling plan. By adopting the AQL approach, the recommended sampling plan may involve a reduced inspection size. This reduction not only is beneficial to inspection methods but also contributes to minimizing operational waste. The AQL standard allows for a more efficient and targeted assessment of product quality, balancing the need for thorough inspection methods with the practicality of reducing unnecessary inspection efforts. This strategic adjustment aligns with the goal of enhancing operational efficiency, ensuring high-quality standards, and minimizing resource utilization. Therefore, promoting a more sustainable and effective quality control process for stainless-steel rods.

Lot size (Number of ordered products)	Q ₁ General Inspection Levels			Q ₂ Special Inspection Levels			
	I	II	III	S-1	S-2	S-3	S-4
2 → 8	A	A	B	A	A	A	A
9 → 15	A	B	C	A	A	A	A
16 → 25	B	C	D	A	A	B	B
26 → 50	C	D	E	A	B	B	C
51 → 90	C	E	F	B	B	C	C
91 → 150	D	F	G	B	B	C	D
151 → 280	E	G	H	B	C	D	E
281 → 500	F	H	J	B	C	D	E
501 → 1 200	G	J	K	C	C	E	F
1 201 → 3 200	H	K	L	C	D	E	G
3 201 → 10 000	J	L	M	C	D	F	G
10 001 → 35 000	K	M	N	C	D	F	H
35 001 → 150 000	L	N	P	D	E	G	J
150 001 → 500 000	M	P	O	D	E	G	J
500 001 → 1 000 000	N	O	R	D	E	H	K

ISO 2859-1, ANSI/ASQ Z1.4, MIL-STD 105E, Single Sampling Plan

Figure 7
Sample Size Code Letter

In accordance with MIL-STD-105E, retrieved from *ANSI Sampling Tables for Inspections*, a lot size of 200, the designated code letter is D. This corresponds to a special inspection level S-3, indicating a specific set of sampling procedures and acceptance criteria determine to the defined

characteristics and requirements of the inspected lot [3].

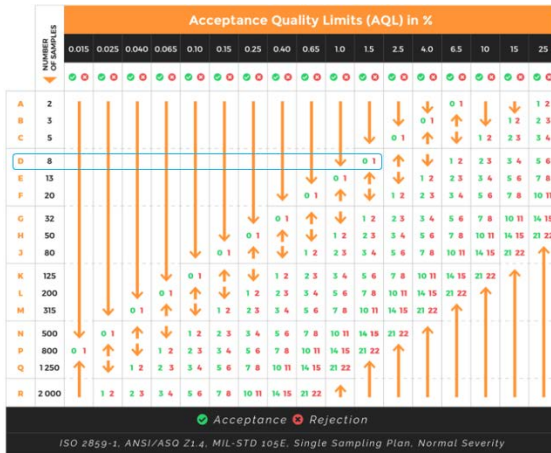


Figure 8
Sampling and Acceptance Limits

The code letter D, as per MIL-STD-105E, retrieved *Sampling Plan Standards for Quality Control* that corresponds to specific sampling and acceptance criteria. Based on the previous chart, referring to the sampling and acceptance limits, the application of code letter D aligns with a major defect limit of 1.5%. This means that for a lot size of 200, the acceptable level of major defects during inspection should not exceed 1.5%. The product acceptance is having zero defects, while allowing for the tolerance of up to one major defect to avoid rejection. Adhering to these specifications ensures a quality control approach, emphasizing the importance of maintaining high standards while allowing for a reasonable margin of acceptance specification limits [4].

Considering the code letter D, the recommended sampling size would be $n=9$, signifying a departure from performing a 100% inspection approach. This adjustment allows for a more efficient and statistically significant sampling method to assess product quality while reducing the inspection sampling size.

CONCLUSION

Based on the results mentioned prior, the critical role of material requirements, specifically mechanical and physical properties for stainless-

steel rods its important since can contributes for potential risk issues. The risk of rods falling out of specification establish the importance of identifying the issues related to material requirements, emphasizing the material inspection methods process to ensure compliance with quality control standards.

Examining the process capability for the stainless-steel rod's diameter reveals a positive outcome, with a process performance index (ppk) value of 1.04 indicating conformity to acceptance criteria specified for diameter in compliance with specifications acceptance criteria. The evaluation of the null hypothesis, suggesting data compliance with a normal distribution, upholds this notion with a p-value of 0.057, leading to the decision not to reject the null hypothesis. This implies that the data for the stainless-steel diameter rods conforms to a normal distribution within the dimension acceptance criteria.

Furthermore, the inspection method process for rods at Incoming area, particularly focusing on titanium and stainless-steel rods, reveals a notable discrepancy in the sampling plan for both materials. However, the evaluation of rod inspection method, there is a discrepancy in the sampling plans applied to titanium and stainless-steel rods. The existing protocols lack consistency, introducing challenges in ensuring a standardized process evaluation for both materials. Addressing these discrepancies has becomes crucial for effective inspection methodology, ensuring that the sampling plan aligns with the specific characteristics and acceptance criteria requirements of titanium and stainless-steel rods.

In conclusion, the application of code letter D in quality control suggests a recommended sampling size of $n = 9$, marking a departure from the performing a 100% inspection approach for stainless-steel rods. This adjustment introduces a more efficient and statistically significant sampling method, enabling a thorough assessment of product quality while reducing the inspection sampling size. Embracing this approach aligns with industry

standards, striking a balance between quality control standards and operational efficiency.

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