

Engineering Services

STI Electronics, Inc. AS9100 Recertification and Managing Risk

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STI Electronics, Inc. is one of the first companies to be certified to the new AS9100 Rev. D in 2017 and has now become one of the first companies to be recertified in 2018. One of the significant changes in Rev. D is the definition of risk management and the company's ability to define processes, procedures and materials that could introduce risk into the end product. The ability to identify risk and the variables that could impact the finished product is the challenge. This provides an opportunity for improvement to prevent suspect or defective product from being shipped to the end customer. AS9100 Rev. D is all



about identifying and creating checks and balances into the product build cycle to minimize variability that could be detrimental to the end product. Minimizing risk is not just an upper management responsibility but should be flowed down to the lowest levels of the organization as well as to the supply chain. Production and product risk can come in all shapes and sizes from internal process controls, material choices and handling, process capability and repeatability as well as employee training and capability. As companies strive to meet the new requirements of Risk Management of AS9100 Rev. D, they must develop matrices for measuring the risk within the QMS system as well as in the product build and life cycle. The ability to develop measurement analysis for risk management is more than just the number of returns or warranty issues. This is definitely a fair measurement point but what truly identifies the risk is the checks and balances a company has implemented to ensure that their systems are catching and preventing issues, escapes or production variability. STI uses a unique TRIAD approach in reviewing and developing build and production processes. The Triad is made up of the Director of Quality, Front End Engineering and Manufacturing Engineering. Each representative has equal say in the development of the build, verification/inspection and testing of the product before it is shipped to the customer. The Triad must all be in agreement as to process and verification of the finished product. This Triad approach ensures that all facets of the product build cycle is reviewed but more importantly all three must agree and have equal authority. STI's AS9100 QMS is the foundation the Triad uses for developing

processes and procedures and verification that truly represent the three major disciplines necessary to build quality product reliably and consistently from lot to lot and job to job.

Risk management should be viewed as a measurement tool to see if processes are improving quarter to quarter and year to year. Is the QMS system aiding in identifying weaknesses and variability in the production build system (Manufacturing System) as well as in your quality management system (QMS)? STI initially viewed risk management as just another element to AS9100 but after deep thought and consideration, realize it is the measurement matrix as well as review tool to ensure all aspects of the build cycle are reviewed equally. There should be checks and balances put in place to ensure consistency and repeatability and data matrices to measure, capture and minimize systemic or operational mistakes that puts the end product at risk. The ability to identify and quantify risk is the key to eliminating mistakes that could jeopardize the end product. The following AS9100 sections were added to increase the risk management awareness within AS9100 Rev. D to insure the company has a plan to address risk within the QMS as well as the operational processes.

- a. Risks and Opportunities are covered under Section 6.1 of the AS9100D Aerospace Standard (QMS and the Organization)
- b. Operational Risk Management is covered under

Section 8.1.1 of the AS9100D Aerospace Standard (Operational Processes)

An organization must have a risk plan that addresses risks in their AS9100D QMS from the beginning of the process (quoting, feasibility, analysis), the middle processes (operational process) and finally the end of the process (warranty period). This all-inclusive risk mitigation plan helps you identify and quantify risk throughout the complete operational life cycle of the delivered product. The key change is in the ability to quantify and measure risk; severity and probability are the matrix data points for quantifying and qualifying the risk at each process in the operational life cycle. Internal and external risk factors should be identified and evaluated for potential impact. Internal risks may be related to Personnel, Product Design, Equipment, Material, Regulatory and Statutory. As risk management is reviewed and incorporated, it becomes obvious the very far reaching influences and variables on the operation. The ability to quantify and qualify risk becomes a new thought process that must then be incorporated from the top down and flow it throughout the organization. STI and the Triad as well as upper management have now incorporated it into our quarterly QMS reviews and have flowed it down into planning and feasibility analysis before we accept and build a job. STI Triad and QMS has added Risk management and mitigation into our documented controlled forms (Feasibility/Quoting Forms, Failure Mode and Effect Analysis) as well as into our manufacturing philosophy to help us design and build a better product for our customer.

If you would like more information on our

**AS9100 REV. D
QMS Plan**

please feel free to call

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