Design and Implementation of ISO:9001 Standards at Sigma 6 Electronics, Inc.

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ABSTRACT

ISO 9001 certification is a very long process that can take even the most dedicated team years to complete. For smaller companies such a process could be costly, confusing, and arduous. While many resources exist, it takes nearly the same amount of effort to tailor fit the examples as it does to create a whole new set.

The purpose of this senior project is to research examples and help fit them to a small manufacturing company, Sigma 6 Electronics, Inc. An interlinked, or combined, quality manual/procedures were chosen to aid Sigma 6 Electronics through making the documentation clear and perfectly understandable. Through analysis of the data collected from manufacturing, it was determined that there was a large amount of variability in specific non-standard processes. The core of the ISO 9001 certification is the promotion of quality through standard processes and transparency. Through the application of the Quality Manual, Quality Operating Procedures, and Standard Work A3's, Sigma 6 Electronics should see an increase in quality parts while maintaining a reasonable production level.

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PROJECT INTRODUCTION

Problem Statement

Sigma 6 Electronics is a membrane switch manufacturer that now wants to become ISO 9000 compliant. This project intends to focus and guide Sigma 6 to reach ISO 9000 compliance and, in the process, help the company define and increase the quality of their parts for their customers. ISO 9000 certification is important for any company to attain. Such a certification demonstrates a company's commitment to continuous improvement.

On a more intimate scale, Zodiac Aerospace is requiring suppliers to become ISO 9000 certified: Sigma 6 Electronics is one of their suppliers. The importance of compliance or certification cannot be understated. Traceability is very important in the aerospace industry. For instance, if a part's specification is changed and it gets overlooked, who is to blame? Ideally, the part could be traced back to a contracted company; did we get an engineering change notice (ECN)? If the answer is no, then there are faulty quality standards being applied at the company. All parts are equally important when the end application is something as critical as aerospace equipment.

The design of this project is focused for Sigma 6 Electronics; however, the results and documentation could be useful for any small company that has not made significant progress on ISO 9000 compliance. Although most of this project will not be tailored as wide as some books and other resources might be, the ideas and results should be applicable to a wide variety of industries or companies. The basic concepts and principles will be outlined in a way that should be easy to follow for any company.

The result of this project should be a significant and meaningful change in management and quality practices at Sigma 6 Electronics. The changes that will be suggested will be determined from the findings that will be discussed later in this report.

Justification

There are many books, websites, and documents that assist in ISO 9000 compliance. Most of these works of reference are focused on large companies, or companies that are not representative of Sigma 6 Electronics. Applying such works to a small company like Sigma 6 Electronics could cause problems. Sigma 6 and it's employees have detailed one requirement for us: to assist in the process of becoming ISO 9000 compliant. By the end of the project, Sigma 6 Electronics should have most, if not all of the necessary resources to become ISO 9001 certified.

The modules included in this project are as follows: a set of documents that are required by ISO 9000 (such as a Quality Control Manual herein known as QCM or QM), a Revision Control Log (herein known as RCL), a process flowchart, the analysis of parts as they apply to the process cycle and ISO 9000 management, work instructions, and the application of tools and business practices to improve business functionality as specified by ISO 9000. These tools and documentation are just the framework for ISO 9000 certification. Management and employees must be committed to continuous improvement for the framework to be applied correctly.

Table I. Hierarchy of Project Requirements

#	Description of Requirements	Score (1-4)
1	ISO Compliant	4
2	Focused Information (relate to S6E)	3
3	Apply to Management	3
4	Seamless Integration	2
5	Conform to Supplier Specifications	3
6	Quality of Work	4
7	Quantity of Work	2

Importance Scale: 1 – Low Importance, 4 – High Importance

Related Work

There are two subsections that are relevant to related works of this project. One of which is ISO 9000 certification, or audit-related, books and tools. These works discuss *how* to get ISO 9000. In order to design a guide on what steps to take, it is important to know what the end goal is. These works focus on the history, importance, and requirements of ISO and how they can be accomplished. Second, what other "roadmaps" or "guidelines" exist for companies? These works will typically be general with no focus on a specific company but, in general, have reliable information to utilize. In these works there are sample documents that can be used as reference for a more specific application of ISO 9000. With these two subsections of documents a more tailored example can be made for a specific company. Examples from companies that have already attained ISO 9001 certification will also be used as a "roadmap" to help guide the focus of the project more.

Objectives

The main goal of this project is to design the framework for a small company that needs guidance on their quality management system (herein; QMS). This goal is divided into three smaller sub-goals: define ISO 9000 certification, relate and compare it to current practices, and implement documentation and solutions. The reach, or long-term goal, is to control the changes to see the impact on the process. Throughout these steps, 10 recurring products will be analyzed for their profit and documented for their process. While it is possible that no, or little, change occur, if the integration of the standards is done based on the spirit of ISO then there should be some form of improvement even if it is quality of life at the facility.

Contribution

This project's contribution to Sigma 6 Electronics and to other companies could be substantial. The specific application of this senior project will be dependent on the user. However, where possible, a more general approach will be taken so that the tools and findings of this project could be applied to many companies, not just Sigma 6 Electronics. As such, the Sigma 6 Electronics processes will be an example that the works and findings can be applied to.

Scope of Project

The scope of this project is as follows: help Sigma 6 Electronics become ISO 9000 compliant through the use of easy-to-use documentation and tools. These changes should be reflected in the everyday work environment at Sigma 6 Electronics. The scope does not include results of implementation; however, a follow-up will be conducted a few months after the project's close.

SECTION II
REVIEW OF LITERATURE

This project's goal is to help small companies achieve ISO 9000 compliance through the use of specially designed solutions and tools. Sigma 6 Electronics, Inc. will be used as an example facility that will implement the ISO 9000 framework designed here. Research and literature review is key to any project, but, for this project it is even more imperative. As we are not experts on ISO 9000 requirements, extensive research on what ISO 9000 requires must be conducted. After this research the knowledge gained can be applied to the Sigma 6 Electronics facility and process to aid in the certification process.

The literature review is aimed to educate us about the ISO 9000 certification in order for us to understand what is required in applying it to Sigma 6 Electronics. Though this is the core of the research, additional research about typical processes and management decisions will also be highlighted. This information will help shape the alternative solutions section. With multiple examples, there should be a few that directly apply to Sigma 6 Electronics.

History of ISO 9000

"Companies seeking registration in the early 1990s were reacting to either customer demand or an impression that the developing European Community (Now European Union) would soon demand ISO 9000 registration as a prerequisite to doing business in Europe" (Peach, 2003). The term 'ISO' in fact stands for the 'International Organization for Standardization', so many would presume that the acronym should be 'IOS'. However, there are two reasons why this is not the case. Tricker (2005) states that the first is that 'iso' in Greek means 'equal' (and this mirrors ISO's aim to develop standards that will enable organizations to be on an equal footing and, therefore, conveys the idea of equality). The second (and probably the main reason) is that 'ISO' is spelt the same (and, therefore, has the same acronym) in most languages spoken by the members of the original organization.

Tricker (2005) believes that the majority of small firms are either unable to or unwilling to undertake the complicated procedures required to achieve certification and registration to ISO

9000. With this thought in mind, British Standards Institution (BSI) launched (in 1994) a low-cost, no-fuss BSI/QA Small Business Service.

Overview ISO 9000

First, we need to know exactly what ISO 9000 is. Johnson (1997) states that ISO 9000 is a series of quality assurance standards that were created by the International Organization for Standardization, based in Geneva, Switzerland. In the United states, the representative to the IOS (International Organization for Standardization) is the American National Standards Institute (ANSI). It was implemented on January 1, 1993 in Europe, "ISO 9000 is the recognized, accepted, and (for certain products) mandated quality system standard…" states Johnson (1997). Although ISO 9000 is the quality system standard in Europe, the EU calls it EN 29000. Johnson (1997) says that harmonized variants of the ISO 9000 standard have been adopted by more than 110 nations. Johnson (1997) also stresses that ISO 9000 is a customer driven process: "ISO 9000 is not a product standard, but a quality system standard. It applies not to products or services, but to the processes that creates them. It is designed and intended to apply to virtually any product or service made by any process anywhere in the world. To achieve this generic state, ISO 9000 refrains, to the greatest extent possible, from mandating specific methods, practices, and techniques. It emphasizes principles, goals, and objectives. All of these focus on one objective, the same objective which drives every business: meeting customer expectations and requirements."

The main idea behind ISO 9000 standards is that they insure a stable level of variability and management in a company with certification. The ISO 9000 Handbook emphasizes that this is most important to companies that do business overseas, more specifically, Europe. In the case of Sigma 6 Electronics, the take away from this is; that regardless of trade outside the US, industries they work with expect a high level of conforming product and know that Sigma 6 can deliver on that promise.

One of the most important points that Arpad Gaal (2001) makes is how necessary management commitment is. As it is with lean or six sigma projects - restructuring the management environment is often difficult to get approved. The process, he argues, must be fully accepted by management (Gaal, 2001). So, as the project progresses, management commitment

will be assessed and documented. Non-commitment could render an ISO 9000 project powerless and all of the advantages gained from ISO compliance would be lost.

Importance of ISO 9000

The ISO 9000 certification is an important part of any business model. The ISO 9000 Handbook, edited by Robert Peach, gives details explaining the benefits and requirements of this industry standard that can be applied to the process at Sigma 6 Electronics. The handbook states: "In many industries, meeting and exceeding the requirements of ISO 9000 standards is recognized as essential in an ever more competitive marketplace" (Peach, 2003). ISO 9000 certification adds another reason for companies to trust a manufacturing environment. This is especially important for Sigma 6 Electronics to understand in order to progress and grow as a company. Such a certification can help retain old business or gain new business.

Gordon V.R. Holness, CEO, Board Member, and 32 industry veteran, also highlighted key important aspects. In 2001 he wrote an article to the ASHRAE committee posing the reason to move from TQM programs to ISO 9000 certification. This article discusses many important facets of ISO 9000. The first is W. Edwards Deming's 14 points for management.

Table II: Deming's 14 Points

Create consistency of purpose towards improvement of product and service.	End the practice of awarding business on the basis of price tag.
Cease dependence on mass inspection. Require, instead, statistical evidence that quality is built in.	Adopt the new philosophy We can no longer live with commonly accepted delays, mistakes, defective materials, and defective workmanship.
Find problems. It is management s job to work continually on the system.	Drive out fear, so that everyone may work effectively for the company.
Institute modern methods of training on the job.	Break down barriers between departments.
Eliminate numerical goals, posters, and slogans for the work force, asking for new levels of productivity without providing methods.	Institute modern methods of supervision of production workers. The responsibility of foremen must be changed from numbers to quality.
Eliminate work standards that prescribe numerical quotas.	Institute a vigorous program of education and retraining.
Remove barriers that stand between the hourly worker and his right to pride of workmanship.	Create a structure in top management that will push every day on the above 13 points.

Deming is known for many tools used in business. His most well-known is the plan-do-check-act cycle, or PDCA cycle. The 14 points for management are partially built into the ISO 9000 standards and help promote a healthy company. Gordon Holness (2001) also cites Philip. B. Crosby's 14 points to quality improvement. These 28 points are important for a business to consider and apply directly to the goals of ISO 9000 and continuous improvement, which will be discussed in a later section.

The drive towards quality-led production now means that today's major purchasers are not just expecting a quality product but are also demanding proof that a company is capable of producing quality services. Tricker (2005) states that… this is possibly the single most important requirement for a manufacturer, company or supplier. ISO 9001 helps companies meet quality demands, while satisfying typical management requirements. These two facets of ISO 9000 help companies in terms of variability, but, as we will discuss later, ISO 9000 does not improve your quality, it just helps reduce variability.

Small Business Applications

ISO 9001:2000 for Small Businesses: Implementing Process-approach Quality Management by Arpad Gaal is a strong piece of supporting literature. This book discusses the nuances of implementing ISO 9000, and supporting articles, to a small company. Arpad Gaal makes solid points about processes and management while giving examples of documentation. He argues that a two tier level approach to a small company's quality management system, or QMS, reduces paperwork and confusion (Gaal, 2001). Such principles apply to Sigma 6 Electronics as a large amount of process waste occurs when documentation and process steps are poorly designed. Through the combination of ISO 9000 QOPs and streamlined flowchart examples Gaal makes large strides in applying ISO 9000 to small businesses rather than, "focus[ing] on getting parts out the door". A combination of a two-tier approach and simple documentation should create more useful tools.

However, Just because a company has the ISO 9000 certification, doesn't mean it has good quality, it just means it has a consistent quality throughout the product line (Singels et.al., 2001). ISO 9000 standards are used to design a standard of work that produces less variability. It is possible for companies to produce worse quality parts. That said, there are a few ways to prevent cumbersome processes from overwhelming the system. One such way is that the employees should own the process. In other words: the employees should know the process better than the written QOPs. While the process is known well by the employees at Sigma 6 Electronics they do not own the process. This could be a concept that could be explored throughout this project; namely, in the work instructions section. Such ownership makes employees feel like they have a stake in the project and, often, gives way to process improvement championed by the employees.

Advantages of ISO 9001 Certification

Now that we understand what ISO 9000 is and about the origins, we need to know why we are implementing this process for Sigma 6 Electronics. Johnson (1997) notes that ISO 9000 certification provides confidence to three people: the customers directly, the customers indirectly (via third-party assessments and quality system registration), and company management and staff. Providing confidence to your customers is a huge benefit and is truly the reason why Sigma 6 Electronics wants ISO 9000 certification. Customers want the highest degree of quality

possible, and ISO 9000 will fulfill that expectation. Johnson (1997) states that this confidence is the result of a three-part, never-ending cycle: planning, control, and documentation.

Crosby's and Deming's points, discussed earlier, lead to a similar conclusion: shift ownership of the process to the workers. Although ISO 9000 provides a framework and design for quality, it does not ensure quality. For Gordon Holness the cost for a 400-person company was "in excess of $1.75 million; however, at the same time they began to put the customer first and less "top-down-driven" (Holness, 2001). The shift seen in most companies is customer-focused and it is largely driven by ISO 9000 practices. Though the cost of implementation might be large the long-term benefits are expansive.

Although this certification doesn't conclude high quality, there are several internal and external benefits to having ISO 9000 implemented. Internal benefits include process and structure organization which leads to improved efficiency and reduced cost (Singels et. al. 2001). External benefits such as having a competitive advantage against other companies is important to have when Sigma 6 Electronics wants to find new customers in the market.

Johnson also gives us three main reasons why someone would want ISO 9000 certification: The EU makes ISO 9000 registration mandatory for firms in your marketplace, your biggest customer requires ISO 9000 of all suppliers, or your major competitor has adopted ISO 9000. Sigma 6 Electronics falls in that middle category. Zodiac Aerospace, one of Sigma 6 Electronic's main customers is requiring that all of their suppliers be ISO 9000 certified or they will lose their business. Thus, it is imperative that Sigma 6 Electronics obtains this ISO 9000 certification as soon as possible. Johnson (1997) says that this is the biggest reason for obtaining ISO certification.

There are two avenues for application according to Johnson (1997): Quality management purposes, in which the facility adopts the standard as a blueprint for its internal quality system, and contractual purposes, in which a demonstrated quality system is a condition of a contract with a customer. Quality management applications of ISO 9000 do not involve firms outside the facility, while contractual applications requires involvement with outside agents called registrars. Johnson (1997) says there are numerous benefits of getting registered. One benefit of registration is that the facility regularly undergoes objective assessment by outside quality professionals. Also, there is a wider access to markets, it may help with competitive issues, and can also

potentially produce fewer audits in the future. These benefits of ISO 9000 certification help Sigma 6 Electronics in all areas of the company.

Profitability increases, market share expands, customer satisfaction increases, operating costs dramatically reduce, demand for your products and services are heightened, and employees experience better working conditions. Tricker (2005)

Limitations of ISO 9001 Certification

The short article "ISO 9000 series - certification and performance," is set in determining if the standard really does correlate to high quality products. "ISO certification gives no guarantee that the quality of products or services of an organization is better than the quality of other organizations" (Singels et.al., 2001). ISO 9000 does not give the company a higher quality part. ISO 9000 does give the company less variability from part-to-part if the spirit of the standards are embraced. The standards alone do not fix processes and only attempts at continuous improvement methods could help mend quality issues. This concept is best summarized as follows: just because a company has the ISO 9000 certification, doesn't mean it has good quality, it just means it has a consistent quality throughout the product line (Singels et.al., 2001).

Drawbacks are not limited to quality versus variability issues, they also include: more paperwork, certification costs, and neglect of personnel development. In addition, employees will have a set standard and rules that they must abide by, which inhibits creative and critical thinking that is sometimes necessary for workplace improvement (Singles et. al. 2001). This directly conflicts with the notion of shifting process ownership to the employees which, as discussed, is a key goal of present-day facilities. Inhibition of creative and critical thinking processes in the work place is counter-productive. It is important to help these two functions for continuous improvement in the workplace.

Despite all the limitations, small companies such as Sigma 6 Electronics may benefit more than a large company since their process takes less time and is scaled down. This means it is easier to find the pitfalls and shortcomings of the process. Achieving certification with a small company will help improve consistent quality of the end product but also help eliminate the occurrence of poor quality products thus overall having good quality.

Registration

Registration of ISO 9000 will be a 6 step process for Sigma 6 Electronics, according to The Handbook (2003). This process includes: Application, Document Review, Preassessment, Assessment, Registration, and Surveillance. The application step starts with applying for registration of the standards. All documents must be organized to show process standardization, which is reported in the document review stage. Preassessment acts as a test before an audit takes place to ensure the standards are all in order. Assessment is where the manufacturer's process is reviewed and is given approval, conditional approval or disapproval. Once the process is approved, the registration phase is started and finalization of the ISO 9000 standard is put in place. Finally, surveillance is done after the process is registered as ISO 9000 compliant and in this step the company must focus on continually reinforcing its standard policies. The process of registration of ISO 9000 costs time and money but is more important to have if Sigma 6 wants to supply top tier companies (Peach, 2003).

Audit

The Approval and Audit stages are very important for Sigma 6 Electronics to understand in order to predict what will be asked of them and how to pass and receive the ISO 9000 certification. There are three important types of audits that can be conducted: First-Party Audits (internal), Second-Party Audits (customer), Third-Party Audits (external auditing organization). First-party audits would be practice audits that Sigma 6 Electronics would conduct themselves. Second-party audits would be practice audits that Zodiac Aerospace or another customer would conduct. Third-party audits would be an actual audit that an auditing company would conduct for ISO 9001 certification. *Table II* gives a comparison that explaining the difference between the audit types.

Table III. Audit-Type Comparison

	Cost	Ease	Repeatability	Accuracy
First-Party Audit	1	1	1	1
Second-Party Audit	2	3	3	3
Third-Party Audit	5	5	5	5

Intensity Scale: 1 – Low Intensity, 5 – High Intensity

As *Table III* shows, first-party audits are good to do before moving to second or third party audits. These audits are cheap and repeatable but suffer in accuracy. Second-party audits, while probably "free", still cost more man-hours than first-party audits and take more time, yet yield better results. Third-party audits are the expensive, time consuming, certification audits. Both first and third-party audits are practice audits for the final, external, audit.

Phases of an Audit: The audit phase includes planning, execution, reporting, and corrective action. Also known as PERC (Peach, 2003). These audit phases correlate to the plan-do-act-check or PDAC cycle that Demming helped create. The planning portion would involve supervisors and other facility management to design their planned audit example. Execution would require a few hours of time running a trial audit as planned in the plan phase. The results from the practice audit should be compiled into a report that is easy to read and can be distributed to employees and management. Lastly, from the sections of the audit that failed there should be a corrective action that takes place to fix any problems.

Purpose of an Audit: Compliance and improvement. "ISO 9000 audit will focus on meeting the spirit and the written word of the standards. Be sure the quality system in place works and build the system for continuous improvement" (Sanders et.al., 1997). Many auditors look for a company that matches the spirit of the ISO standards rather than the written word. The reason behind this is that if a company chooses to embrace the spirit they will have made it a core part of their company; however, if a company chooses to get certified had just has the documentation

and other practices in-place for audits then they have not truly understood the purpose of ISO 9000. In short: embrace the spirit of the ISO 9000 standards.

Continuous Improvement

The Handbook gives two principal standards that are most important to the assurance of quality products. One being product standards and the other being quality system standards. Adhering to these standards must be continual throughout the manufacturing process to in order to maintain or even improve quality (Peach, 2003). Product standards can also be seen as technical specifications where each piece of a product needs to have a clear set of operational definitions in order to create or replicate the process of manufacturing said product. Sigma 6 Electronics will need an organized set of technical standards that each employee can follow in order to ensure product replication and quality. Quality system standards include quality management systems which encompasses the process and procedures necessary to complete a job or product. Continuous improvement in both these areas by Sigma 6 Electronics will result in higher quality products and reduced defects.

Singels summarizes that implementing ISO 9000 standards do not improve quality of product alone (Singles et.al. , 2001). It serves as a great starting point towards quality improvement and in the process of registering these standards, the company might find several areas of improvement. As the process may not be improved directly at first, that aspect of continuous improvement ultimately results in quality products and a more efficient work structure (Singels et. al. 2001). In all, there are more beneficial advantages that come with the certification than disadvantages.

Quality Management Systems and Total Quality Management

The ideas and systems involved in ISO 9000 can be related to Total Quality Management (TQM) in a number of ways. Hongyi Sun (2000), who wrote the article Total Quality Management, ISO 9000 Certification and Performance Improvement, recommends "that ISO 9000 should be incorporated with the philosophy and methods of TQM." The methods addressed are that of continuous improvement, employee inclusion, customer satisfaction, etc., which are all included in the certification of ISO 9000. Because the principles of TQM are built into the core of ISO 9000 it is easier for companies that already have a solid TQM system to approach certification.

However, it has been an industry trend, as discussed with ASHRE, that many TQM based companies have been moving to ISO 9000 certification. “Researchers agree that TQM is a philosophy that stresses a systematic, integrated, and consistent perspective involving everyone and everything” (Sun, 2000).

SECTION III
ALTERNATIVE SOLUTIONS

It is important to consider alternative solutions and/or methods when working on a project. If a company was to focus on the first proposed plan, then that company blocks off other, maybe better, possibilities. There are three design alternatives with a few sub-section deliverable alternatives. This section will discuss the three design principals and other alternative solutions for the major ISO 9000 sub-sections. Once the sub-sections are selected as one that requires alternative methods then further work will be required to assemble examples from other companies or sources. The two sub-sections that will be addressed for alternatives is the Quality System Manual (QSM, or QM) and the Quality Operating Procedures (QOPs, or SOPs).

Quality System Manual Alternatives

There are different ways to approach a company Quality Manual and specific ways benefit specific companies or size of companies better. The three ways that will be focused on are: incorporated, segregated, and a combination. These methods could be further broken down into smaller chunks with the striations being: internal examples, external examples, no example, and internal plus external examples. A breakdown as detailed above will provide and excellent starting position for documentation to be taken and adopted. The Quality Manager at Heli-Cal, a Santa Maria ISO certified company, highly suggested a strong look into a semi-segregated system of documentation, or a combination strategy. Further, the Quality Manager and Vice President of High End Seating Solutions (HESS), a Santa Ana ISO certified company, suggested a segregated system. The next three sections discuss the major differences in the systems.

Incorporated Quality Manual Design: An incorporated Quality Manual typically will have quality procedures that are located as sub sections of the Quality Manual. These procedures will be of similar writing but will not be standalone documents. The benefits of an incorporated design are increased readability and aid in audit situations. While this method of design would be

good for a large company that needs the information in one place, this is not an ideal design for a small company.

Segregated Quality Manual Design: A segregated Quality Manual design is the exact opposite of an incorporated Quality Manual. The quality procedures in a segregated design are completely detached from the Quality Manual. The readability of a segregated Quality Manual is as good as an incorporated design; however, from an audit standpoint, it is easier to have either references (combination), or have the procedures integrated (incorporated).

Combination Quality Manual Design: A combination Quality Manual design takes design concepts from both the integrated and the segregated Quality Manual designs. Within the combination Quality Manual there will be section references located as in-text-citations. These references will use quality procedures as support or as a location of a specific process.

Now that the three sections are fully defined the properties, or major characteristics, can be categorized and rated on a scale. The major categories that are important are: readability, usefulness, audit compliance, and small company applicability. This is the rating scale that will be used to determine the overall usefulness of the different methods and approaches in the Solutions section.

Quality Operating Procedure Alternatives

Besides the Quality Manual design there is also the Quality Operating Procedure (QOP) design. These sections are large procedural documentation of the process to produce a quality part. This means that nearly all sections of the QOP's require a large volume of input, as they vary from company to company. To break down these sections and assist Sigma 6 Electronics in the best way possible the sections were segregated into categories. These categories were rated based on the level of input required. It is important to determine what parts of a whole require the most amount of time and dedication to make a realistic estimate.

Table IV. Dispersion of Quality Operating Procedures (QOPs)

Research Required (Example)	**Research Required and Explanation**	**Explanation Only**
Contract Review	Document and Data Control	Control of Customer Supplied Product
Product Identification and Traceability	Control of Purchases (Internal)	Inspection and Test Control
Performance Standard, Processing Control	Control of Inspection, Measuring, and Test Equipment	Internal Quality Audits
	Control of Non-conforming Product	
	Inspection and Test Status	
	Management Review	

After this general categorization it was decided that the sub-sections located in the Explanation Only category needed to be addressed directly by Sigma 6 Electronics. In the final documentation these sections will be outlined and described but not individual detailed. Research required and explanation will include both a good example from other Quality Operating Procedures along with a description or questions about individual elements that can then be reviewed by Sigma 6 Electronics. Finally, Research Required sub-sections required merely an example. Most of these sections do not change largely from company to company and require less input from Sigma 6 Electronics to complete. Through this categorization alternatives would include moving elements from one column to the other.

SECTION IV
RESULTS

There are three elements that needed to be delivered on to aid in the process of ISO 9001 compliance for Sigma 6 Electronics: a Quality Manual, standardized work, and Quality Operating Procedures (QOPs, or SOPs). These elements and the results are further explained below.

Quality Manual

One requirement of the ISO 9000 quality standard is the documentation of quality statements. These are typically organized in a Quality Manual. The Quality Manual is intended to describe Sigma 6 Electronics' quality system and will be used by employees as well as auditors. The Quality Manual consists of a quality policy (the approach that Sigma 6 takes on quality), measurable quality objectives (what Sigma 6 plans to achieve, and how they will assess or measure if they did or not), and documented procedures to control how things are done.

Good examples were chosen by looking at industry quality manuals to give Sigma 6 Electronics an idea of what is acceptable. There are good quality manual examples out there, but there are also some bad ones, care must be taken when choosing which examples needed to be presented. One quality manual was taken from Micro Memory Bank, Inc. which is a wholesale computer memory manufacturer and the other from High End Seating Solutions, LLC, which is a motorcycle seat manufacturer. These were chosen to draw inspiration from because they are companies of similar size and industry to Sigma 6 Electronics.

While creating the quality manual, certain aspects from each example were included in Sigma 6 Electronics' quality manual or modified to fit Sigma 6 Electronics' needs. While the Quality Manual needs to address certain aspects, as mentioned above, the actual look of the quality manual is completely up to the company. There are no strict guidelines telling you how you must arrange your quality manual, giving the company the ability to tailor the quality manual specifically to their needs. Companies tend to have quality manuals that fall under one of these three categories: incorporated, segregated, and combined. To briefly recap, an incorporated

quality manual will have quality procedures that are located as sub sections of the Quality Manual and is typically used by large companies as the information is all in one place. A segregated Quality Manual has the quality procedures completely detached from the Quality Manual and is good for small companies, but bad for auditing. *Table V* compares the quality manual properties and the design options discussed.

Table V. Quality Manual Properties vs Quality Manual Design

Quality Manual Design	Readability	Usefulness	Audit	Small Company Applicable	Total
Incorporated	2	1	3	1	7
Segregated	2	3	2	3	10
Combination	3	2	3	2	10

Scale: 1-3

The Quality Manual designs that have the highest score (*see Table V*) are segregated and combination. While a segregated approach would be as beneficial, it was decided that a combination Quality Manual would be used, because there are section references located as in-text-citations. These references use quality procedures as support or as a location of a specific process, which can be very helpful. This design seemed most relevant to Sigma 6 Electronics because it fits their small company needs while also addressing auditing concerns. Furthermore, this design was adapted by Helical and High End Seating Solutions, LLC, two companies who have already been ISO 9001 certified and both stressed that this was the best and most convenient design for smaller companies.

The Sigma 6 Electronics quality manual consists of eight sections, including the six mandatory sections. These six sections include: document control procedure, records procedure, internal audit procedure, control of non-conformance procedure, corrective action procedure and preventive action procedure. Other sections were added that added value to the Quality Manual, which includes resource management and a definitions section. The definitions section is a little different from most quality manuals, but including some key terms that would be seen throughout the quality manual was beneficial because people with no background in ISO 9000 can read and understand the quality manual. At the end of the quality manual there is Quality

System Manual Revisions approval sign off sheet that needs to be filled out whenever a revision is made to the document. See Appendix C for an example of the quality manual that was designed for Sigma 6 Electronics.

Standard Work

Part of the standardization of processes is creating standard time. While at the Sigma 6 Facility, processing times were taken for specific processes. Among these processes were: dome assembly, hand lamination, and electrical testing. The results from the data are shown in *Figure 1.*

Descriptive Statistics: Hand Lamination, Machine Lamination, Dome Assembly

Variable	N	N*	Mean	SE Mean	StDev	Minimum	Q1	Median
Hand Lamination	520	0	84.25	1.30	29.70	48.00	53.25	80.50
Machine Lamination	520	0	180.12	0.461	10.52	168.00	168.00	182.00
Dome Assembly	520	0	65.179	0.190	4.324	60.000	60.000	65.000

Variable	Q3	Maximum
Hand Lamination	119.00	128.00
Machine Lamination	194.00	194.00
Dome Assembly	65.000	72.000

Figure 1

Descriptive statistics gives both the mean and the standard deviation. The standard deviation of the samples gives the variation from the mean. This is not an accurate measurement of variation if used to compare against different mean values. If the sample standard deviation is divided by the sample mean then the resulting value is a proportion of variation based on the mean known as the coefficient of variation. The equation can be seen in *Figure 2.*

$$Coefficient\ of\ Variation(CV) = \frac{Sample\ Standard\ Deviation}{Sample\ Mean}$$

Figure 2

The coefficient of variation (CV) yields smaller values when the standard deviation is much smaller than the sample mean, in more simple terms: “less variation per mean unit”. Through this calculation, it was found that processes with more innate standardized procedures, dome assembly (0.066) and machine lamination (0.059), yielded a smaller variation where the non-

standardized process, like hand lamination (0.35), yielded a larger variation (see appendix A for all calculations).The purpose of standard work is to maintain the level of production at a pace that is reasonably accomplished by all employees; this is typically referred to “shortest repeatable time”. If there is a large amount of variation in the time it takes to complete a task that task needs to be better defined or outlined; there is room for improvement.

Improvement in processes can be developed in many different areas. It is important to note that a faster time does not necessarily translate into a better process. It is possible to shortcut the process to improve throughput while decreasing quality. That is the essence of standard work. Because not all processes are perfect, it should be maintained that input and requests for changes (see QOP 002) should be not only accepted but greatly encouraged. Process changes should come from the people most familiar to the process. After this is done, an Amendment to Procedures (ie: Form A-009), can be filled out and processed. While operator input is encouraged, all suggested techniques should be vetted by engineering, production, and quality. The goal of this is to increase throughput while maintaining quality standards. These changes should be documented on the standard work charts (A3/A4 size posters) and the revision history should be updated. See Appendix E for an example of a standard work procedure that was designed for Sigma 6 Electronics’ machine lamination process. Standard work charts were also created for dome assembly, hand lamination, LED assembly, and crimping.

Quality Operating Procedures

The Quality Operating Procedures (QOPs) are a large deliverable that spans all quality aspects of a business. Because the nature of the procedures require intimate detail of Sigma 6 Electronics’ process some of the QOPs are more general examples as discussed in the alternative methods and solutions. Some segments offer greater insight with an overview/explanation directly linking the procedure to Sigma 6 Electronics; whereas, others give merely an example section.

SECTION V
CONCLUSION

In this section a main overview of the project tasks, observations, problems and related IT work are addressed. The group's processes in tackling tough issues involved in the project are summarized and future work that must be done in order to fulfill ISO 9001 compliance has also been documented here. Learning objectives that have been met is also a big part of the project goals.

Summary of Tasks

Sigma 6 Electronics is seeking ISO 9001 certification because large customers (such as Zodiac Aerospace) are requiring them to be compliant in order for them to maintain status as a vendor. This senior project will not get Sigma 6 Electronics certified, but instead it serves as an aid to set the process in motion. Not only will it help this company but also other small business seeking the same certification may benefit. Over the course of the project there were five main tasks that were covered.

For the ISO 9001 certification guideline project, the team did the following (all of which are required for compliance):

Created Quality Operating Procedures (QOP's): Quality Operating Procedures were made for general quality control purposes. Examples of this are: Control of Purchases and Product Identification and Traceability. Each QOP is used to give a detailed description of how certain operation tasks are carried out. Not only is it very important for a customer to see, but it also helps Sigma 6 Electronics become more organized. There were 9 different QOPs to fill out that the group split up and worked on.

Created the Quality Systems Manual (QSM): The QSM is an overview of the how quality is instilled in the company which includes the "Quality Policy" and references specific QOP's. Reviewing other quality manuals from companies that had already been certified with the ISO 9001 standard was useful to ensure each section was designed appropriately. The team also set

out to talk to Leeroy McChesney at Helical and Derek Geisen at High End Seating Solutions to go over the specifics of their completed quality manual.

Conducted Statistical Analysis: During the second visit to the Sigma 6 Electronics plant, data was collected on the timing of key processes. Time data for machine lamination, hand lamination, and dome assembly were taken from the start of the process to the end. Several

Standardized Work at the Plant: Scott took the team through each of the major processes and gave detailed instructions on how to do each one. The processes included; Lamination (Machine, Hand and Panel lamination), Crimping, Dome Assembly, and LED Assembly. Each step was documented and recorded then written guidelines were made so that any employee can replicate it. The idea behind standardizing work is so that if there is a problem or defect in the end product it can be traced back to the source within the process and can easily be fixed.

Reporting: Documentation of each step in how to become ISO 9001 certified was conducted by the team. Discussing topics of importance with Sigma 6 Electronics' Account Holder, Scott Houseman, was important to identify areas of concern and to show where improvements shall be made.

Learning Objectives

An important first step was to determine what exactly becoming ISO 9001 compliant entailed. Extensive research, through a variety of sources, was used to dissect the process of attaining certification as well as the opportunities and drawbacks that come with it. Becoming educated on the "in's and out's" of the process of implementation was key to ensure the project was completed to its fullest potential.

After a firm understanding of what ISO 9001 involved, the team learned how to apply it to a small company, Sigma 6 Electronics. Visiting the plant was important to see where improvements should be made. Seeing the process first hand helped visualize how to standardize and write work instructions. Working with a company also gave the benefit of a real life scenario.

Visits to other certified companies such as Helical and High End Seating Solutions were a beneficial learning tool to see what a facility that is ISO 9001 certified should look like. These manufacturing companies could then be compared to that of Sigma 6 Electronics and improvements would be more recognizable.

Quality Management Systems (QMS) are customer focused and aim to achieve high levels of product satisfaction. If a customer is unsatisfied, the product or service they receive is known as a defect. The main goal is to reduce these defects and come up with reliable products as Sigma 6 aims to do.

Problems

One of the main challenges with this project was coming up with statistical data that was required for the final report. Since the overall goal was to aid in ISO 9000 compliance, there was no direct need for time data or statistical analysis. However, a section of the project goals included standard work application. A component of standard work is standard time. During the second visit to the Sigma 6 facilities, processing times were taken from key processes. This was difficult because each employee did his or her job a little differently because the work was not yet standardized allowing for a statistical comparison to be made.

Early in the project, communication struggled and made deadlines difficult because of other work intensive classes. Meeting with Dr. Eric Olsen to reach a solution helped resolve the issue and the team began to work better together.

As Sigma 6 Electronics is a running business, at times it was difficult to arrange times to talk or meet with the project supervisor from the facility. Even though feedback was not always prompt, the team continued on other sections of the report and project to ensure it could be completed in a timely manner.

The final challenge was creating job descriptions for each employee. It is required by the ISO 9000 certification body that everyone have a specific job description and set of responsibilities; however, Sigma 6 Electronics does not have official recordings of each position. During the final audit employees may be asked what their job is and must answer promptly in order to fulfill that requirement. There should be someone designated as the quality engineer, supervisor, process engineer, etc. A level of organization shall be put in place once the ISO 9000 standard is implemented but there is still work to be done.

Future Work

With the completion of the Quality Systems Manual, Quality Operations Procedures, Statistical Analysis and Standardized Work the project sections were compiled and sent back to Scott Houseman of Sigma 6 (project supervisor). A follow up with the finished report including compliance of standards at the facility shall be done in the future. Implementation of ISO 9001 shall be carried out over the next few months. The process is never really complete since it is a continuous improvement process.

The next step before audits take place is to come up with job descriptions for the employees as noted in the Quality Manual and to complete the sections in the Quality Operating Procedures (QOPs, or SOPs) with specific facility information.

Training of the employees is an important step once job descriptions have been identified. Each employee should be taught the importance of the ISO 9001 standard. Standard work documents should also be followed to ensure quality in each product. This implies that the supervisor must know how the process should be completed and apply spot-Corrective Action when the task is not being fulfilled correctly. Quality Management Systems require continual practice throughout the company.

Finally an internal audit shall be conducted to ensure every step of the manufacturing process is compliant with what the ISO standards represent. A worker from within Sigma 6 may do the internal audit but cannot evaluate his/her own work. After this audit it is highly suggested that Sigma 6 Electronics invites a customer, like Zodiac Aerospace, to do a second party audit.

Implementation

After the submission of all documents for project completion, Sigma 6 Electronics will be armed with all it needs to begin the certification process with ISO 9000. There are only a few places where the quality supervisor must add his/her own input to complete the documents.

Related IT Work

This project drew on many past Industrial Technology classes, which include IT 260 (Manufacturing Process), IT 303 (Lean Six Sigma), IT 403 (Quality Systems Management), IT 407 (Applied Industrial Product Design), IT 410 (Operations Planning and Control), and IT 411 (Industrial Safety & Quality Program Leadership).

Table VI. Related Course Work

Industrial Technology Courses		
Course	**Course Application**	**Skills/Knowledge Used**
IT 303	3	Lean Six Sigma principles were used to conduct statistical analysis and improve quality of the manufacturing process. The use of color-coding QOP sections was used to organize the project tasks. Also improving process controls at each phase of the manufacturing system helps reduce defects and get closer to a six-sigma level.
IT 403	3	Lean Six Sigma tools were introduced/reinforced to conduct statistical analysis and improve the quality of the manufacturing process. Information gained on lean tools such as standard work really helped the project, as standard work was one of our deliverables to Sigma 6 Electronics.
IT 411	3	The ISO 9001 standard is a Quality Management System, which was covered extensively in the IT 411 (previously IT 311) course. Using what was learned from this class improved the understanding of quality systems as a whole. Quality systems are constantly followed in order to improve a process and improve the health of a business as a whole.
Support Courses		
BUS 391	1	The use of Excel spreadsheets to create and organized data. Also to make the Gantt chart.
STAT 217	1	Conducting statistical analysis for time studies.

General Education Courses		
ENGL 145	2	Reasoning, Argumentation, and Writing helped us build a persuasive report and other technical write-ups.
COMS 102	2	Using effective communication skills with others involved in the implementation process.

*Note: Usage scale indicates how much the course applied to the project. 1 being "Slightly Used," 2 being "Moderately Used" and 3 being "Frequently Used"

These core classes helped prepare the team to know what to expect and also guide us to complete the report in a professional fashion.

Conclusive Observations

Sigma 6 Electronics has a long way to go to fully comply with the ISO 9001 standards. The project's intention was not to get this company certified but more to pave the way and set Sigma 6 Electronics in the right direction. There were many areas for improvement at the plant that the team noticed at each visit. Becoming compliant with ISO 9001 will ensure quality in the products it produces and in turn will improve process performance. It should be known that any quality system is a continuous process and there is always room for improvements even after certification. Using what was learned from visits to other certified facility gave good examples on what the future of Sigma 6 holds in store. The team learned important problem solving skills and how to work together to complete this extensive project. Most importantly, the project simulated a real world work situation where the group was challenged to "learn by doing."

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APPENDIX

A. COEEFICIENT OF VARIATION CALCULATION

$$Coefficient\ of\ Variation(CV) = \frac{Sample\ Standard\ Deviation}{Sample\ Mean}$$

$$CV\ for\ Hand\ Lamination = \frac{29.70s}{84.25s} = 0.35$$

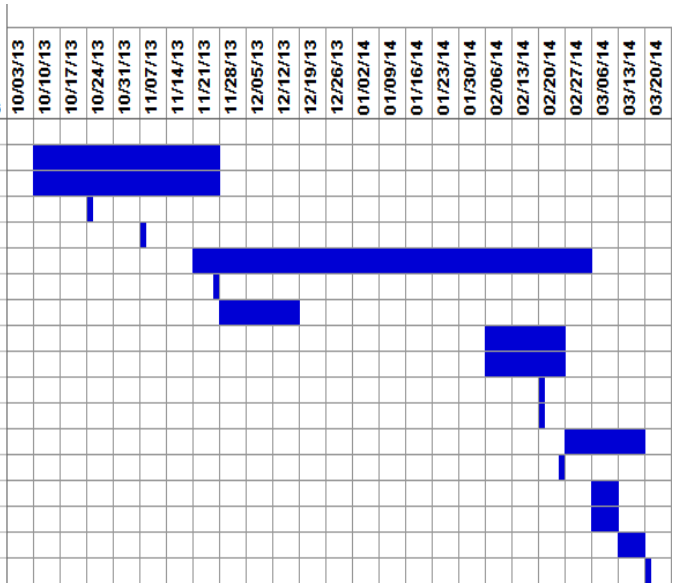
$$CV\ for\ Machine\ Lamination = \frac{10.52s}{180.12s} = 0.059$$

$$CV\ for\ Dome\ Assembly = \frac{4.32s}{65.18s} = 0.066$$

B. GANTT CHART

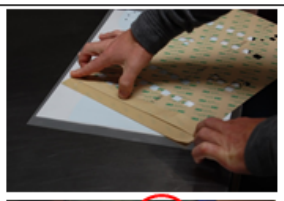
Senior Project - ISO 9001 Cert

No.	Description	Start	End	Duration (Days)	Who	% Complete	Predecessors
1	Into Meeting	11/26/13	11/26/13	1	ALL	100%	
2	Lit Research	10/7/13	11/25/13	50	TEAM	100%	
3	Introduction	10/7/13	11/25/13	50	TEAM	100%	
4	Plant Visit 1	10/21/13	10/21/13	1	G, S	100%	
5	P. Report 1	11/1/13	11/1/13	1	K	100%	
6	Alternatives	11/19/13	3/1/14	103	TEAM	100%	
7	P. Report 2	11/25/13	11/25/13	1	K	100%	
8	QOP BB	11/25/13	12/14/13	20	TEAM	100%	
9	QOP Edits	2/6/14	2/25/14	20	K	100%	
10	QSM	2/6/14	2/25/14	20	G, S	100%	
11	Plant Visit 2	2/17/14	2/17/14	1	TEAM	100%	
12	HESS Visit	2/17/14	2/17/14	1	TEAM	100%	
13	Std. Work	2/24/14	3/14/14	19	TEAM	100%	
14	P.Report 3	2/19/14	2/19/14	1	TEAM	100%	
15	Pres. Prep	3/1/14	3/9/14	9	TEAM	100%	
16	Poster Prep	3/1/14	3/9/14	9	TEAM	100%	
17	Presentation	3/13/14	3/13/14	1	TEAM	100%	
18	END	3/14/14	3/14/14	1	ALL	100%	



C. STANDARD WORK EXAMPLE

STANDARD OPERATIONS PROCEDURE			DATE AS OF: 3/4/2014		PAGE 1 OF 1
PROCESS NAME: MACHINE LAMINATING		APPROVAL SIGNATURE	MANAGER		TEAM LEADER
OPERATIONS NAME: MEMBRANE/OVERLAY ASSEMBLY		RK			ROSA

SEQ.	OPERATION SEQUENCE	KEY POINTS	SAFETY POINTS	ILLUSTRATION
1	CLEAN MEMBRANE OR POLYESTER OVERLAY WITH CLOTH			
2	PEEL BACK LAMINATE	SHOULD NOT MORE MORE THAN HALF THE PART		
3	PLACE LAMINATE SIDE ON MEMBRANE OR OVERLAY	ALIGN TO GUIDE MARKS, HOLES, OR BUTTONS		
4	ADJUST LAMINATION MACHINE TO ALLOW THE ROLLERS TO ACCEPT THE MATERIAL		CLEAR HANDS AND FORIGEN MATERIAL FROM THE ROLLERS	
5	HOLD THE ADHESIVE AT A LARGE ANGLE (PICTURED)			
6	ROTATE THE WHEEL TOWARDS YOUR PERSON			
7				
8				

PROTECTION EQUIPMENT: NONE REQUIRED	SEQUENCE	REVISION	REV. REASON
		1	
OTHER POINTS OR SPECIAL MENTION: **SUPERVISOR SHOULD MAINTAIN CORRECT PROCESS STEPS**			

D. QUALITY SYSTEM MANUAL

Sigma 6 Electronics

1890 E Miraloma Ave., Ste. E/F
Placentia CA 92870

ISO 9001
Quality Systems Manual

Revision: #
Issue Date: (Month Day, Year)

Introduction

Sigma 6 Electronics, Inc., a manufacturer of Membrane Switches and Elastomeric Keypads, headquartered in San Diego, California. Its divisions have established a Quality Operating System, in the effort to fully satisfy the needs of its customers and to continuously improve the quality management of the company.

Sigma 6 Electronics, Inc. is dedicated to achieving the following objectives:

▪ Ensure that our customers are provided with industry-best products that meet or exceed their requirements.

▪ Ensure that quality improvement is the responsibility of every employee.

▪ Establish continuous quality improvement as the basic principle of the Quality Operating System.

The purpose of this manual is to document the company's Quality Operating System, to instruct and guide employees whose actions affect product quality, and to inform customers of the controls that have been implemented to assure product quality.

Sigma 6 Electronics' goal is to better satisfy requirements, conduct better business practices and improve overall management of the company by implementing a Quality Management System.

This system adheres to the requirements of the international standard ISO 9001 (2000). The quality management system goes through each step of the manufacturing process of Sigma 6 and improves the quality of operation.

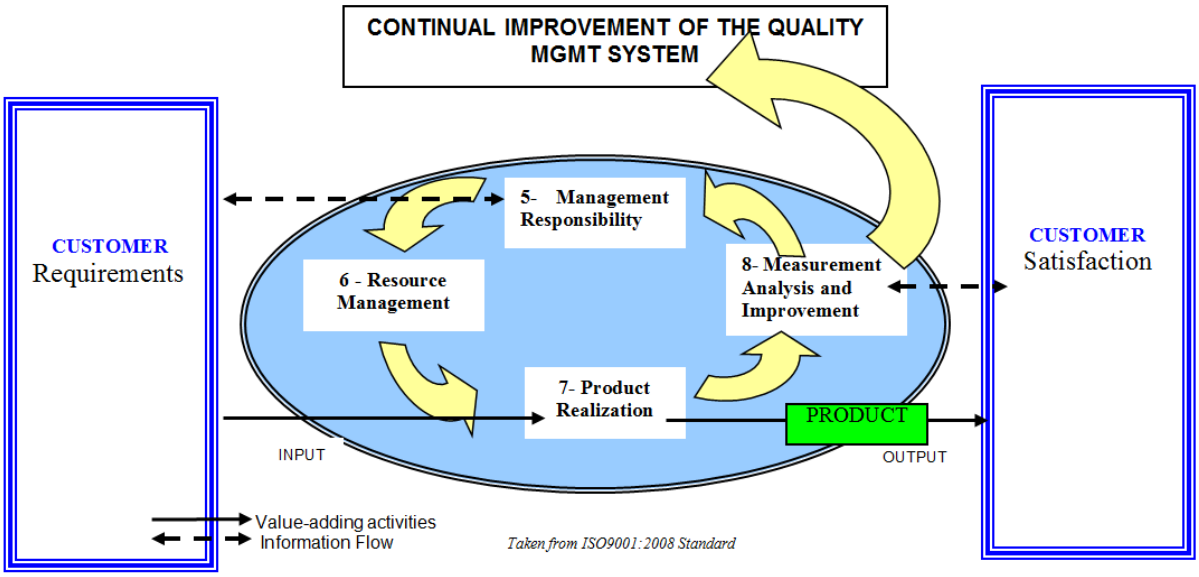
Index

Section 1: Scope

1.1 General

Sigma 6 Electronics, Inc. “Sigma 6” is an electronic component manufacturer focused on the research, design and manufacturing technologies around membrane switches, graphic overlays, rubber keypads and touch switches. This document outlines our current quality system.

1.2 Application



Mission Statement

Sigma 6 is a company focused on fast service, quality products and competitive pricing. We promote total customer satisfaction through company-wide continuous improvement of our products and related services. We are to maintain a company with a favorable work environment; one which is continually contributing to the satisfaction of its customers and employees.

Section 2: References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/ISO/ASQ Q9000-2000, Quality Management Systems
- American National Standard ANSI/ISO/ASQ Q9001-2000, Quality Management Systems - Guidelines for Performance Improvement
- High End Seating Solutions, LLC Quality Manual and other important documents
- Micro Memory Bank, Inc. Quality Systems Manual

Section 3: Definitions

3.0 Quality Management Systems Definitions (alphabetical)

- **Audit:** Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
- **Continual Improvement:** Recurring activity to increase the ability to fulfill requirements.
- **Corrective Action:** Action taken to eliminate the cause of a detected nonconformity or other undesirable situation
- **Customer Satisfaction:** Customer's perception of the degree to which the customer's requirement have been fulfilled
- **Deviation:** a specific customer authorization issued prior to the manufacture of a product to allow departure from a defined design requirement for a specific number of units for a specific duration.
- **Efficiency:** Relationship between the result achieved and the resources used.
- **Material Review Board (MRB):** a board whose members are responsible for deciding the disposition of all discrepant material.
- **Nonconforming:** is any condition that violates the requirements of a specification, process, or procedure.
- **Preventative Action:** Action taken to eliminate the cause of a potential nonconformity or other undesirable potential situations.
- **Procedure:** Specific way to carry out an activity or a process.
- **Quality:** Degree to which a set of inherent characteristics fulfill requirements.
- **Quality Control:** Part of quality management focused on fulfilling quality requirements.
- **Quality Management System:** Management system to direct and control an organization with regard to quality.
- **Quality Objective:** Something sought, or aimed for, related to quality. Generally based on the organization's quality policy, and specified for relevant functions and levels in the organization.
- **Quality Policy:** Overall intention and direction of the organization related to quality as formally expressed by top management.
- **Repair:** a non-conforming product that cannot be further processed to meet a specified requirement without written approval from the customer.
- **Rework:** a non-conforming product that can be reprocessed under defined conditions to meet a specified drawing requirement.
- **Standardized work:** Giving a process specific instructions on how to carry out the task in order to ensure it is done the same way each time.
- **Waiver:** a written request sent to a customer to disposition a non-conforming product.
- **Work Instructions:** Controlled document, which provides instruction on how to perform a specific task.

Section 4: Requirements

4.1 General Requirements

Sigma 6 Electronics has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2000. The system is maintained and continually improved through the use of quality policy, quality objectives, and audit results.

4.2 Documents Requirements

Contract Review

GENERAL

Each division is responsible for establishing procedures for contract review and for the coordination of these activities.

REVIEW

All customer orders (also referred to as contracts) are reviewed to assess if the customer's requirements are adequately defined and are well understood, and if the company has the capacity to meet those requirements. The customer service representatives are responsible for conducting contract reviews.

RECORD

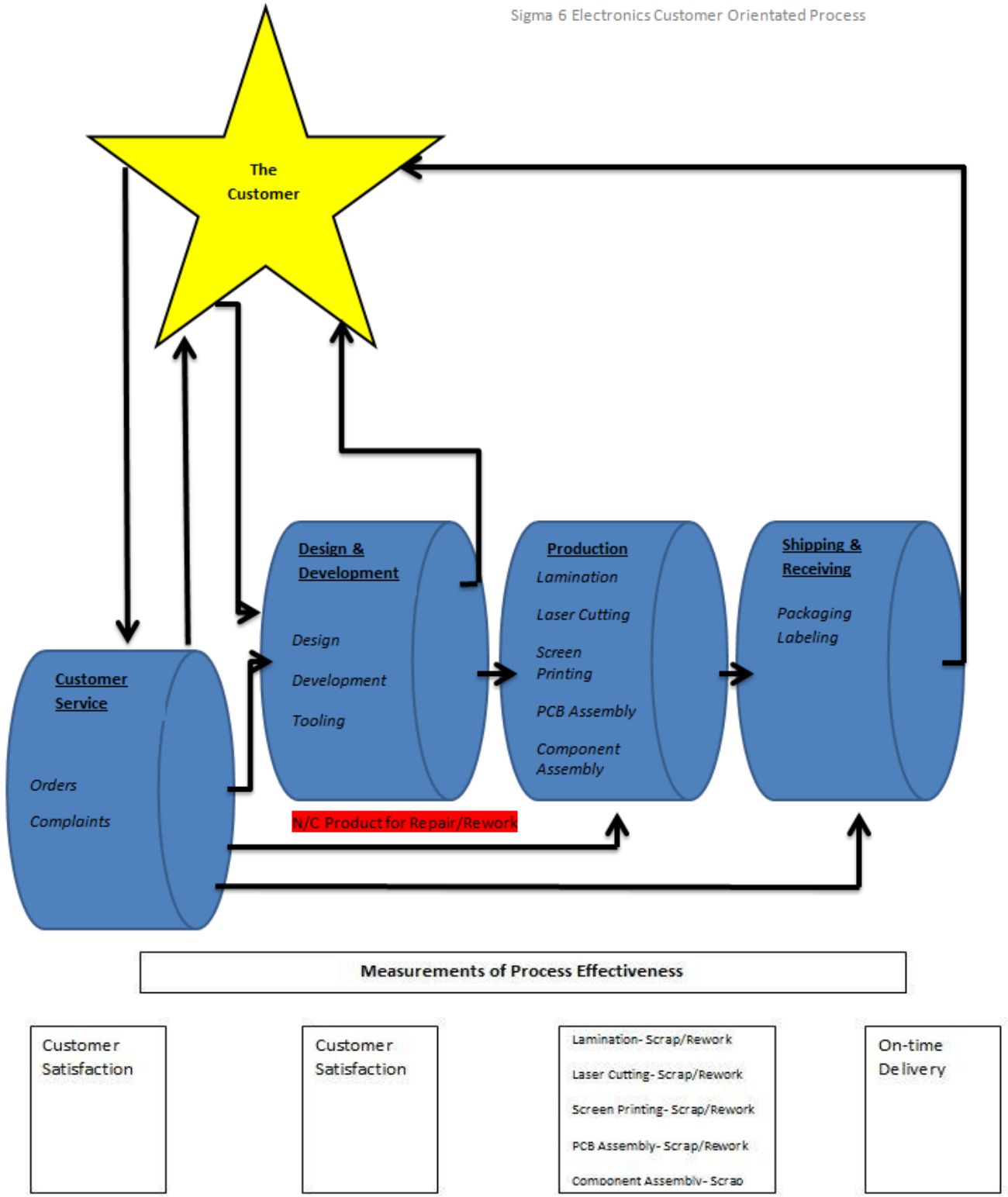
Customer service personnel file records of all orders received by customer.

Tier 1: Quality Manual and QOPs
Tier 2: Work Instructions
Tier 3: Forms/QMS Records

4.2.3 Control of Documents

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at point of use
- Ensuring that documents remain legible and readily identifiable
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose
- Keeping customer files confidential and organized so only the correct people are using according to ITAR provisions.

4.2.4 Control of Records



Section 5: Management Responsibility

5.1 Management Commitment

Management has been actively involved in implementing the quality management system. The growth of the QMS relies on the vision and strategic direction of the management commitment.

5.2 Customer Focus

Sigma Six Electronics strives to identify current and future customer needs to meet customer requirements and to exceed customer expectations.

5.3 Quality Policy

It is the policy of Sigma 6 Electronics, Inc. to supply quality products and services that conform to all established requirements and the expectations of our customers. We are further committed to a company-wide program for Continuous Quality Improvement.

This policy has been approved by the President/CEO, the Chairman, the Management Staff, and the President of each division of Sigma 6 Electronics, Inc. The policy has been incorporated into the Quality Operating System, and is understood, implemented, and maintained at all levels in the organization through internal training classes, audits, and management support.

5.4 Planning

Quality objectives are used to establish what efforts must be done in order to achieve the quality policy. Specific quality plans shall be made through supplier performance, release of product, and customer feedback.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Job descriptions define the responsibilities and authorities of each of the positions. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

5.5.2 Management Representative

The Quality Engineer serves as the management representative which has the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and applied.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as director with external parties such as customers or auditors on

matters relating to the QMS.

5.5.3 Internal Communication

Processes are established for communication within the organization. Department and management meetings shall be held on a regular basis including management review to ensure effectiveness of the QMS.

5.6 Management Review

5.6.1 General

Management review meetings should be held annually to assess the continuing QMS suitability, adequacy and effectiveness. This is also address opportunities for improvement and needed changes.

5.6.2 Review Input

Input topics of discussion

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective action
- Follow up actions from previous management reviews
- Recommendations for improvement

5.6.3 Review Output

Output topics of discussion

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibilities for required actions are assigned to members of the management review team. Due dates are recorded.

Section 6: Resource Management

6.1 Provision of Resources

Sigma Six Electronics has implemented a Quality Management System that complies with the ISO 9001 2000 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. Management determines and provides necessary resources to effectively maintain and continually improve the effectiveness of the quality management system and to enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Job descriptions are prepared that identify the qualifications required for each position that affects product quality.

6.2.2 Competence, Awareness and Training

6.3 Infrastructure

Sigma 6 Electronics provides and maintains an infrastructure needed to achieve conformity to product requirements. This includes building space, maintenance of production equipment, access to required utilities, and information systems. As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in preventive maintenance logs.

6.4 Work Environment

In order to achieve product conformance, a suitable work environment must be provided and maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Section 7: Product Realization

7.1 Planning of Product Realization

Quality planning is required before new products or processes are implemented. During this planning, management or assigned personnel identify the quality objectives and requirements for the product. They must also identify the processes, documentation and resources required, as well as verification, validation, monitoring, inspection and test requirements. This planning provides for documented quality plans, processes, procedures and design outputs.

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product

The sales department determines customer requirements before acceptance of an order. The sales department works with the customer to establish specific requirements for the product, delivery, and any possible post-delivery activities.

7.2.2 Review of Requirements Related to the Product

The Sales Development Coordinator or Production Manager reviews the order received from the customer to ensure:

- Sigma 6 Electronics has the capacity to meet the specified customer requirements
- The customer requirements have been adequately defined
- Any requirements not stated but are necessary for the product have been defined
- All differences are resolved prior to approval.

This review is documented on the Contract Review PO Checklist. Verbal orders are confirmed with the customer before being accepted, usually by repeating the order to the customer. Changes to contract/orders are received and reviewed. Any changes that were due to a change in customer requirements will be communicated to the appropriate areas of Sigma 6 Electronics.

7.2.3 Customer communication

Sigma 6 Electronics determines and implements effective arrangements for communicating with the customer regarding product information, inquiries, contracts or order taking (including amendments), and customer feedback, including complaints.

7.3 Design and Development

Sigma 6 Electronics does not have design and development. All products follow customer orders for development.

7.4 Purchasing

GENERAL

The Purchasing department of each division is responsible for the purchase of products and services, used to manufacture, package, or deliver product, which conform to all specifications. The Q.A. department will support the purchasing function with the analysis of products and suppliers as required.

EVALUATION OF SUPPLIERS

Suppliers are evaluated and selected on the basis of their ability to meet the company's requirements, which includes appropriate quality system requirements. The type and extent of control exercised by the company is dependent upon the type of product or service, its impact on the quality of the finished product, and the history of the supplier's performance. The company only purchases key components from qualified suppliers; non-critical parts and materials can be purchased from suppliers who deliver their standard catalog products.

PURCHASING DATA

Purchasing documents are prepared and maintained by the Purchasing Department. Purchasing documents clearly and completely describe ordered products. They include precise identification of the product and where applicable, any relevant specifications or drawings, verification or evidence of compliance. The Purchasing department reviews and approves all purchase orders for adequacy of specified requirements before release.

7.4.1 Purchasing process

Critical suppliers are required to comply with Sigma 6 Electronic's ISO requirements. Critical suppliers are identified on the Approved Supplier List and are defined as suppliers of materials that are critical to the quality and function of Sigma 6 Electronic's

products. These critical suppliers have been successfully qualified based on past performance, and are in good standing. Qualification may consist of an on-site audit, supplier survey, review of QMS certifications ISO 9001, or evaluation of samples, workmanship or history with Sigma 6. The performance of suppliers is evaluated on an on-going basis through incoming inspection results, production measurables, and customer complaints. Suppliers showing inadequate performance are requested to implement corrective actions.

7.4.2 Purchasing information

The Purchase Orders to critical suppliers clearly and completely describe requirements for ordered products. Purchase Orders may include requirements for approval of product, procedure, processes, and equipment, and/or requirements for qualification of personnel and quality management.

The Purchase Orders are reviewed and approved prior to release to ensure the information is adequate and correct. Purchase Orders are retained in accordance with the Control of Quality Records procedure included in the Quality Manual.

7.4.3 Verification of purchased product

Purchased products are verified upon receipt to ensure purchased products meet specified requirements. The receiving person performs a cursory review against the purchase order to verify supplier, part number, and general condition of the package. If receiving inspection is required specific work instructions will be initiated.

Purchased items may be inspected and accepted based on any of the following: Conformance to the purchase order, Certification of Analysis, Certificate of Compliance, or Receiving Inspection Work Instructions. Records of verification are maintained.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Production operations are conducted with the use of drawings, work instructions, suitable equipment, and monitoring and measurement devices. The appropriate Department Lead works with the staff to schedule production based on customer orders. The work priorities are determined based on the production schedules.

7.5.2 Validation of processes for production

Processes are validated where the output cannot be verified by subsequent monitoring or measurement. Process validation requirements are determined as part of the Design and Development Process, and include, as applicable, criteria for review and approval of the process, approval of equipment and qualification of personnel, specific methods and procedures, record requirements, and re-validation requirements.

7.5.3 Identification and Traceability

Product is appropriately identified throughout product realization. All materials and parts intended for incorporation into Sigma 6 Electronics products are readily identified by their configuration, location in the process, item number or singleness of type in inventory. When unique identification of the product is required, it will be established and records maintained. When product is monitored, measured or inspected the product

status is clear based on location in the process or identification or segregation.

7.5.4 Customer property

Sigma 6 Electronics takes care protecting the customers property, as well as their intellectual property and personal data. Customer tooling & products shall follow special controls as may be defined in the contract. If so requested by the customer, the customer-supplied tooling and products may be segregated and labeled to identify them as the customer's property. Any occurrence of loss, damage, deterioration, or unsuitability of customer-supplied products shall be reported back to the customer.

7.5.5 Preservation of Product

All raw material, components, products, and packaging materials are handled in an appropriate manner to prevent damage or deterioration and to maintain conformity to requirements. Storage areas should always be kept clean and neat. Components, labels, packaging materials, and finished products are stored and handled in a manner to prevent damage, loss, or deterioration. Outgoing shipments are packaged to prevent damage.

7.6 Control of monitoring and measuring devices

Includes:

- Measurements identification and selection of equipment
- Calibration
- Nonconforming equipment

Section 8: Measurement, Analysis and Improvement

8.1 General

Sigma 6 Electronics plans and implements measurement, analysis and improvement processes to demonstrate product conformity, insure the conformity of the QMS and continually improve effectiveness of the QMS. This is accomplished through the use of:

- Quality Objectives
- Product and process control data
- Internal Audits
- Management Review
- Customer Feedback / Satisfaction
- Supplier Performance
- Analysis of Product Failures

Conformity of the QMS is monitored and maintained using the internal audit system and management reviews.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Sigma 6 Electronics monitors customer feedback and satisfaction as measurements of the QMS performance, Customer complaints are tracked and reviewed. Customer feedback provides early warning of quality problems, and the information is fed to the corrective and preventative action is taken to correct the problem or complaint.

8.2.2 Internal Audit

Internal audits are planned and conducted at least once per year. Audit frequency may increase and focus may change taking into consideration the status and importance of the processes and areas to be audited and the results of previous audits. The purpose of the audits is to determine whether the QMS conforms to the established QMS requirements. Audits evaluate whether the system is effective and maintained.

Internal auditors are objective, impartial, and cannot audit their own work. All auditors must complete ISO 9001:2008 training, and may be Sigma 6 Electronics employees or outside contractors.

During the process-based audits, auditors evaluate whether the process outputs meet internal and/or external customer needs. During all audits, auditors seek objective evidence demonstrating whether the QMS requirements are being met. If something does not follow requirements, preventative and corrective action is carried out and documented.

8.2.3 Monitoring and Measurement of Processes and Analysis

Sigma 6 Electronics does not have a design and development process which this section is aimed to target.

8.2.4 Monitoring and measurement of product and analysis

Monitoring and measuring product characteristics to verify that final product requirements have been met. This is carried out at appropriate stages of the manufacturing process.

8.3 Control of Nonconforming Product

Includes:

- Supplier Nonconformities
- Assembly/Final Inspection
- Customer Returns - All Departments, All Products

GENERAL

All nonconforming products are identified, segregated, and prevented from being used or shipped until disposition. Each division is responsible for outlining procedures for identification, documentation, and segregation of nonconforming product.

IDENTIFICATION AND SEGREGATION

The process of and responsibility for identifying and segregating nonconforming product

depends on what stage the product is identified. Operators and inspectors in receiving inspection, production, and final inspection are responsible for segregating nonconforming product from the production flow and notifying the department(s) concerned. Identification is accomplished through the use of special markings, labels, tags or dedicated containers.

REVIEW, DOCUMENTATION, AND DISPOSITION AUTHORITY

All nonconforming products will be documented on receiving inspection files, material discrepancy notices, in-process inspection reports, production routers, or final inspection forms. Production personnel have authority to make the disposition decision for obvious cases of rework and scrap in all operations. Nonconforming product can be reworked to meet the specified requirements, scrapped, or accept with or without repair by concession (Use as is). All reworked product is re-inspected in accordance with all applicable procedures. Customer acceptance by concession of any nonconforming condition must be documented, including the actual condition.

8.4 Analysis of Data

Data about Customer Feedback / Satisfaction, Customer Complaints, Internal Audits, Product Conformity, trends of Process Performance, and Supplier Performance are analyzed to determine suitability of the Quality Management System and where continual improvement of the Quality Management System can be made. Analysis of the data is performed and any corrective or preventive actions, allocation of resources, or training should be implemented.

8.5 Improvement

8.5.1 Continual improvement

Sigma 6 Electronics identifies and implements any changes necessary to continually improve suitability and effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews. These changes are documented and tracked through the use of the Corrective and Preventive Action Request (CAPA) form.

8.5.2 Corrective action

The effective use of the corrective system is crucial to the success of Sigma 6' Quality Operating System. Corrective actions are initiated on a level corresponding to the risks encountered. Follow-ups are performed to ensure that corrective actions, including procedural changes, have been implemented and are effective.

The purpose of corrective actions is to prevent recurrence of a nonconformance or eliminate potential causes of a nonconformance. Data from production, quality, supporting operations and customer feedback are continually analyzed to detect and eliminate sources of problems. Each division is responsible for initiation of Supplier CAR's. Corrective actions may be initiated in the following cases:

▪Identification of a major nonconformity
▪Accumulation of minor nonconformities of similar character
▪Recurring problem with a process
▪A noncompliance observed during an internal, customer, or third party audit
▪Field reported problems
▪Customer complaints
▪ Nonconforming products delivered by suppliers
▪Identification of any other condition that does not comply with the documented Quality Operating System

All CAR's will be followed up by the initiating party to determine if the corrective action that has been implemented is effective.

8.5.3 Preventive action

Sigma 6 Electronics investigates potential nonconformities and takes action to eliminate their cause to prevent their occurrence. This is done by using the CAPA process Sigma 6 Electronic's Continual Improvement Initiatives, Sigma 6 Electronic's Project Management System, and Six Sigma methodologies.

The preventive action process includes:
• Determining potential nonconformities and their causes
• Evaluating the need for action to prevent occurrence of nonconformities
• Determining and implementing action needed
• Reviewing records of actions taken (within Non-Compliance 7-Steps, Continual Improvement Records)

After implementation of CAPA, the Director of Quality verifies or validates that the proposed actions were taken and were effective at correcting the problem and preventing re-occurrence without any adverse effects

QUALITY SYSTEM MANUAL
APPROVAL SIGN OFF SHEET

DOC. CONTROLLER APPROVAL/ DATE

Scott Houseman
Account Holder
MM/DD/YY

Isaac Fernandez

MM/DD/YY

E. QUALITY OPERATING PROCEDURES

Quality Operating Procedures (QOPs)

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Quality Operating Procedure (QOP) 001

Contract Review

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12/12/2013	0	Initiation of this Section	RK

Section I

1.0 Purpose

Evaluate "Request for Quote" (RFQ) in order to determine cost and capability.

2.0 References

RFQ Log – *A-005*
Quotation Form – *A-004*

3.0 Procedure

3.01 The Administrative Secretary shall:

1. Log in on the RFQ log *(ie: A-005)* the company's name, the RFQ number, and date.
2. Create RFQ folder it. Place it in RFQ documents along with quote form *(ie: A-004)*.
3. Give folder to *…(Account Holder? This is if you have sales people under you, Scott)*

3.02 The Account Holder shall:

Reviews RFQ content and determines whether the quote is in the company's interest. If not, decline the RFQ and return folder.

3.03 The Administrative Secretary shall:

Log out the RFQ on form A-005 by indicating the RFQ was declined. Notify the customer and file the RFQ folder.

3.04 The Account Holder shall:

1. Determine the quote process through involvement of manufacturing and engineering to help determine costs where necessary.
2. Fill out the quote form *A-004.*
3. Review the quote and make adjustments as needed.
4. Places contents back in folder and return it to the Administrative Secretary.

3.05 The Administrative Secretary shall:

1. Send the RFQ response to the customer.
2. Fill out the RFQ log *(ie: A-005).*
3. Place all documents that relate to this transaction in the RFW folder and file it. These files shall include: quote document, technical drawings, and any miscellaneous items.

Section II

1.0 Purpose

Make sure that the Purchase Order (PO) content information matches the tender. And to determine and document quality requirements imposed in the PO.

2.0 References

Purchase Order Review Sheet – *A-001*
Quotation Form – *A-004*
RFQ Log – *A-005*
Control of Customer Documents – *A-011*
Issue and Traceability of Drawings – *A-031*

3.0 Procedure

(From what I could tell engineering and production should not have direct access to technical drawings. To aid quality problems relating to revision numbers. If they do (because Sigma 6 Electronics is a split facility) then sales needs to maintain the online folder and make sure that the only drawings that can be downloaded are the most recent as per the Issue and Traceability of Drawings form *(ie: A-031).* A-031 needs to be updated as new drawings and revisions come in. It should contain columns with "obsolete date" "date destroyed" "date issued" and "area issued".)

3.01 The Administrative Secretary shall:

1. Input the receipt of the PO on the RFQ Log *(ie: A-005)*.
2. Review and determine accuracy against the tender.
3. Make up the PO folder and include the customer's name and PO number
4. Fill out Control of Customer Documents *(ie: A-011)* and attach to folder.
5. Make copies of PO and send it to Engineering, Production, and Quality.
6. Fill out Issue and Traceability of Drawings *(ie A-031)*.
7. Place the "Accepted" PO and the Form A-031 in the folder and file it back in the RFQ file.
8. Record the "Accepted" PO status on the RFQ log.

3.02 The Quality Engineer shall:

1. Review the PO sent from Sales to determine quality requirements.

2. Fill out requirements on the Purchase Order Review *(ie: A-001)*. *(Note: Scott, this section has to do with quality requirements. There might be some requirements such as special-care needs for a specific process. As an example a customer might require a specific tolerance requirement (in terms of minimal variation). These requirements noted also MUST be inspected at the end of production, or after the process that the requirements are applicable).*
3. Send out email with requirements to Engineering and Sales.
4. Make up the Inspection Product Folder.

3.03 Engineering shall:

1. Review the PO and the Purchase order Review Sheet *(ie: A-001)*.
2. Plan the processing layouts to fulfill PO requirements.
3. Prepare, review, and approve the Job Traveler and Operation Sheets.
4. Maintain master documents in Engineering Folder
5. Prepare Production Folder.

3.04 The Production Manager shall:

1. Issue the Production Folder.
2. Describe any special-case processes listed on the Job Traveler to the floor operators.

Section III

1.0 Purpose

Establish documented procedures for implementing contract amendments. Initiate processing and quality planning, based on the pending issuance of a formal Purchase Order (PO).

2.0 References

Document and Data Control – QOP 002
Control of Non-conforming Products – QOP 009
Performance Standard, Processing Control – QOP 012
Purchase Order Review Sheet – *A-001*
Blank Verbal Agreement Document – *A-003*
Quotation Form – *A-004*
RFQ Log – *A-005*
Non-Conforming Material Report – *A-006*
Amendment to Procedures – *A-009*
Control of Customer Documents – *A-011*
Issue and Traceability of Drawings – *A-031*

3.0 Procedure

3.01 The Administrative Secretary shall:

1. Input the receipt of the PO amendment on the RFQ Log *(ie: A-005)*.
2. Review the amendment for critical action items.
3. Prepare the Amendment Folder and attach it to the existing PO and RFQ folders.
4. Give Folders to Account Holder.

3.02 The Account Holder shall:

1. Review the amendment against the customer's PO in order to determine the cost impact to processing and product quality.
2. If no impact is found, record information on the amendment document and sign and date. Return the documents to the Administrative Secretary.

3.03 The Administrative Secretary shall:

1. Declares amendment "Accepted" and signs and dates it.

2. Send copy of amendment to Engineering, Quality, and Production
3. File the Amendment, RFQ and PO folders.
4. Fill out Form A-005

3.04 **The Account Holder shall**: When the amendment impacts processing and/or quality, do:

1. Figure out the cost.
2. Update the quote form *(ie: A-004)*.
3. Note that the amendment affected processing and/or quality and sign and date. Attach form A-004.
4. Plan customer's amendment. Note action items on a blank form *(ie: A-003)* and plan a meeting to address changes with production and engineering.
5. Return all documents to the Administrative Secretary.

3.05 **The Administrative Secretary shall:**

1. State the cost on company letterhead and have it signed by the Account Holder
2. Send the email to the customer. Place active folders on hold pending the customer.

3.06 **The Administrative Secretary shall:** After the receipt of cost is approved:

1. Stamp on the front of the amendment document "Accepted".
2. Update: Control of Document form *(ie: A-011)* and Issue of Traceability of Drawings *(ie: A-031)*.
3. Send amendment and its attachments to Engineering, Quality and Production
4. Place quote form back into the RFQ folder
5. File the RFQ, PO and Amendments folders and input the amendment activity on RFQ Log.

3.07 **The Quality Engineer shall:**

1. Review the amendment documents.
2. Determine Quality's action items and the impact on processing.
3. If impact occurred, revise the Purchase Order Review *(ie: A-001)*. *(Note: Scott, this section has to do with quality requirements. There might be some requirements such as special-care needs for a specific process. As an example a customer might require a specific tolerance requirement (in terms of minimal variation). These requirements noted also MUST be inspected at the end of production, or after the process that the requirements are applicable).*

4. Make copies of the Purchase Order Review and send to Engineering and Sales.

3.08 The Production Manager shall:

1. Review amendment documents and Purchase Order Review.

3.09 The Production Manager and Quality Engineer shall:

1. Draw up action items according to amendment requirements.
2. Discuss action items with Production Planning, Engineering, and Quality.
3. Implement all action items affecting PO amendments.
4. Carry out all internal document changes on the Amendment to Procedure Revision Change Log *(ie: A-009)* As per QOP 002 Section II.

Quality Operating Procedure (QOP) 002
Document and Data Approval and Issue

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Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

Section I

1.0 Purpose

To control the planning, approval, and issuance of the quality system's documents.

2.0 References

Revision Change Log (RCL)
Quality System Manual (QSM, QM)

2.0 Procedure

The Management Representative Shall:
Maintain all documentation relating to the Quality Management System and assign responsibilities under delegated authority. He/she shall enforce the following:

2.01 Maintain the Quality System Manual (QSM)

(Scott, similar to how the section after this is written is how this section must be written. It should be a step-by-step list on how to maintain the quality manual)

2.02 Maintain the Quality Operating Procedures (QOPs)

1. Each page in the Quality Operating Procedures (QOPs) shall have a header that must be updated when updating information within the QOPs. The header must include: subject, issue date, revision date and number, page number, and approval sign-off.
2. The QOP paragraphs must be structured in chronological order and the QOP sections must be constructed as work processes are sequenced.
3. Tasks that share similar characteristics shall be combined under one procedure. Each combined section shall be given a new paragraph header.
4. Links between the Quality Manual (QM or QSM) and the QOPs can be found through in-text citations and the reference document listed in paragraph 2.0 in each QOP section.
5. All QOP sections shall be reviewed and approved before release. QOPs are proprietary documents.

6. Change to a QOP shall be recorded and controlled on the specific Revision History page. Also, the Revision Change Log (RCL) should reflect any changes in the QOP sections.
7. Obsolete sections shall be removed and disposed, and replaced by the changed sections.

2.03 Maintain the System's Forms

1. Each form shall have a similar company-wide look with a clear title to represent the record. Signature and date lines are required on form proposals for sign off by those responsible to review and approve the work. All changes to forms should be highlighted and detailed.
2. Each form shall have its own unique reference number.
3. Change to a form shall be recorded and controlled on the specific Revision History cell. Also, the Revision Change Log (RCL) should reflect any changes to controlled forms.

2.04 Responsibility

The Quality Management System, which includes both the QSM and the QOPs, shall be maintained by the ____ *(often the Quality Manager)* assigned by the Management Representative.

Section II

1.0 Purpose

To maintain control over document and data changes.

2.0 References

Revision Change Log (RCL)
Quality System Manual (QSM, QM)
QOP 001, Contract Review
Blank Verbal Agreement Document – *A-003*
Amendment to Procedures – *A-009*

3.0 Procedure

Reporting Errors
Errors, either mistakes or misleading information, directly influence product quality. Therefore, this system is designed to remove them where they occur. Process owners are required to report errors to their immediate supervisors when discovered.

3.01 Customer Controlled Documents

Purchase Order amendments shall be implemented as defined in QOP 001 Section I. Customer initiated verbal changes shall be prohibited without proper documentation on a Blank Verbal Agreement Document *(ie A-003).*

3.02 Process Change Documents

Processing documentation and data changes must be carried out through the Amendment to Procedures form *(ie: A-009).* These changes must be signed and dated and documented in the Revision Change Log when the change takes effect.

3.03 Types of Processing Related Changes

3.03.1 Immediate and Provisional Document Changes

Explanation of Immediate and Provisional Document Changes

Overview

This section talks about the process of documentation changes. An example of the process can be found in the next paragraph. This section details the exact steps an employee (typically of the title "Quality Engineer") would make changes to documentation. These steps include both approval and un-approved.

Example of Immediate and Provisional Document Changes

1. The Process Engineer fills out a Process Amendment form *(ie: A-009)* and submits it to the supervisor. The supervisor reviews the change and signs and dates the "Reviewed By" section. The supervisor then forwards the document to the Quality Engineer.
2. The Quality Engineer Reviews the proposed change. If the Quality Engineer agrees with the supervisor and the Process Engineer he/she signs and dates "Accepted By". If the Quality Engineer does not agree he/she sends back notes for correction(s).
3. The Process Engineer now changes the master document(s), including revision levels. Submits the revised document(s) for review and approval to supervision. After approval he/she makes copies and returns the files. Then the Process Engineer:
    1. attaches one copy of the master document(s) to the Process Amendment *(ie: A-009)* form and submits said form to the Quality Engineer.
    2. distributes the copies to the affected departments.
    3. removes printed obsolete documentation while keeping one stamped "Obsolete" as background information.
    4. updates production folder(s)
    5. maintains both the Engineering and Production Folders
4. The Quality Engineer reviews documents sent by the Process Engineer and completes Process Amendment Form *(ie: A-009).*

3.03.2 Software Changes

Software changes are controlled as documents. Changes to these documents should be noted in the Revision Change Log

4.0 Change Control of The Quality System's Documents

General

Processing related documentation (Travelers, Operation Sheets, Software, and other set-up documents) have their changes applied through the Process

Amendment form *(ie: A-009)*. The quality system documents (QOPs, QSM, or Quality Policy) should be changed independently within its own structural system, through the individual revision history pages and the Revision Change Log. Typing and syntax errors can be corrected without formal change only if they do not impact quality and/or processing.

4.01 Changes to the Quality System's Documents

4.01.1 Direct Changes to the Quality System's Documents

*** See Next Paragraph****

4.01.2 Indirect Changes to the Quality System's Documents

(Not sure how to handle this section, this is different on a business-by-business case. Scott, determine how you would like to handle changes to this document and the QSM document. These changes will become necessary as both internal and external audits occur. Further, these changes are typically related to customer satisfaction, performance, or flow-down requirements. I will also note here that after further reading I think that you could remove indirect changes (as they are results in changes of Travelers, Operation Sheets etc... that impact the quality system) and just have a section titled "Changes to the Quality System's Documents". Also, these QOP sections are high on documentation and quality so please be advised that there should be a process of documentation involved with these changes.)

5.0 Revision Change Control of the Quality System's Documents

General

The quality system's documents are grouped in three separately controlled entities: the Quality Manual (QSM), the Quality Operating Procedures (QOPs), and the documentation forms. While each individual aspect is controlled in their respective revision history section, changes should also be reflected in the master Revision Change Log (RCL) that details all changes throughout the organization.

5.01 Revision Change to the Quality System Manual

(Again, Scott please determine how you would like to handle the process to make changes to the Quality System Manual. The steps should be listed here in a numbered format to match the style that we have been using here. I wrote sections

5.02 and 5.03 as "management representative" because it is possible that it would be someone in Michael's position who would be in charge of it, though it could be a Quality Engineer – this is something I would ask Israr to weigh in on.)

5.02 Revision Change to the Quality Operating Procedures

The Management Representative shall:

1. Make a copy of the "Revision History" page from the master of the affected Quality Operating Procedure. Cross out the current revision date on the copy and write the new revision number and date. Note the reason for revision.
2. Make necessary changes to the form.
3. Sign the document and then update the old version.
4. Locate the master Revision Change Log at ____ *(where is it kept?)*. Note the QOP number, date, revision number, signature, and nature of change.
5. Update the master copy with the new revision found at ___ *(where is it kept?)*.

5.03 Revision Change to the System's Forms

The Management Representative shall:

1. Make a copy of the "Revision History" page from the master of the affected form. Cross out the current revision date on the copy and write the new revision number and date. Note the reason for revision.
2. Make necessary changes to the form.
3. Sign the document and then update the old version.
4. Locate the master Revision Change Log at ____ *(where is it kept?)*. Note the QOP number, date, revision number, signature, and nature of change.
5. Update the master copy with the new revision found at ___ *(where is it kept?)*.

Section III

1.0 Purpose

Summarize the retention, maintenance, and responsibility in managing the Quality System's records.

2.0 References

All documents relating to the manufacturing quality parts.

2.0 Procedure

(Scott, this section is left open because it references all documents that are required to make a part. Job travelers, SCARs, NCMR, inspection etc.. These documents must be maintained by individuals. This section lists their job title and then lists what forms they are responsible to maintain. For example:

The Contract Administrative Secretary shall:

a) *Maintain and retain Form A-004 – RFQ Worksheet – under separate folder, identified by the prospective customer's name. The "RFQ Folder" shall contain all the documents that relate to the specified transaction.*
b) *Maintain and retain form A-005 – RFQ, PO, and Amendment Register under separate folder, identified by the same title. When the form is full, the next one shall be consecutively numbered. To avoid mixing the RFQ, PO, and Amendment entries on one form, it is expected that each title will have its own entry carried out separately on duplicates of the same form.*
c) *Etc…*

This should be listed for all documents used in the process stream, including sales and post-manufacturing forms)

Quality Operating Procedure (QOP) 003

Control of Purchases (Internal)

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Section I

1.0 Purpose

Design requirements for "good quality" that aid in reviewing and approving the issuance of product related internal Purchase Orders.

2.0 References

Blank Verbal Agreement Document – *A-003*
Nonconforming Material Report – *A-006*
Purchase Order – *A-017*
Supplier Survey Long – *A-026*
Supplier Survey Short – *A-035*
Incoming Inspection – *A-036*
Supplier Corrective Action Request – *A-037*

3.0 Procedure

Give specific directions that may be replicated by someone who doesn't know process.

3.01 Issuance of Internal Purchase Orders

Explanation of Issuance of Internal Purchase Orders

Overview

This section details the issuance of internal purchase orders and the process that it follows. The process involves the purchasing agent placing a purchase order (PO) and sending the PO to the Quality Engineer who reviews it for accuracy.

Key Points and Important Steps

Maintaining organization of purchase orders can be critical. It is important that the Quality Engineer become involved early on in the process to assure proper revision number in section 2.02, Review and Approval of Purchase Orders. This section also includes AS9000 quality checkpoints.

Example of Issuance of Internal Purchase Orders

The Purchasing Agent Shall:

1. Adhere to customer requirements such as subcontractor activities. Document on Purchase Order Review Sheet, which is given by the quality engineers at each quality check of the process. *(where are the files physically located? And how are they organized?)*
2. Give control number to the purchase order
3. Fill in info (phone number, address, ect.)
4. Give line item description and make sure all forms are accurate
5. Sign and Date purchase order
6. Forward to Quality Engineer

   Note: Aerospace specifications require extra documentation including "Right of Entry" provision (AS9000, par. 4.6.2). Also maintaining document flow-down to ensure subcontractors control the special processes that cannot be verified on the completed product. (ie. Internal components) (AS9000, par. 4.6.5). Decide responsible party regarding product verification and listing (AS9000, par. 4.6.4.4).

3.02 Review and Approval of Purchase Order by the Quality Engineer

Explanation of Review and Approval of Purchase Order by the Quality Engineer

Overview

This section details the process of reviewing a purchase order (PO). If something is incorrect this section describes who should be contacted (by title). If there are no incorrect items then the PO is signed and a copy is kept.

Key Points and Important Steps

The Quality Engineer must review and approve all line items and must be clear as to the contents of all POs. Furthermore, it is important for the Quality Engineer to both sign and retain a copy to eliminate any possible mistakes.

Example of Review and Approval of Purchase Order by the Quality Engineer

The Quality Engineer Shall:

1. Verify accuracy, clarity, and completeness of the technical information for each item issued by the purchasing agent. Confirm latest revision levels of the noted document. If incorrect, return order to Purchasing Agent for correction
2. When the content information is completely filled out, record the Purchase Quality Provisions for each item in the purchase order. (Include Source inspection as required). Sign and Date
3. Keep the "Quality" copy of the purchase order and return the rest to the purchasing agent

4. File the retained copy in the Supplier Product Folder
   Note: The above steps apply to any purchase order amendments as well. Special Processes must comply with the customer imposed purchase order requirement (AS9000, par. 4.6.2d)

3.03 Releasing Purchase Orders

Explanation of Releasing Purchase Orders

Overview

This section details the process of releasing purchase orders. Release to subcontractor and the maintenance of a personal filing system.

Key Points and Important Steps

Maintaining a clean and organized workspace should be a key goal and 5-S projects are a way to help fix unorganized workspaces. However, each individual step, like keeping files organized, helps.

Example of Releasing Purchase Orders

The Purchasing Agent Shall:

1. Send "Vendor" copy of purchase order to subcontractor with specified documents listed in the purchase order included.
2. Allocate other copies accordingly (Accounting, receiving, etc.)
3. Maintain individuals own purchase order to ensure document control on subcontractors
4. Keep contact and review Production Planning, Engineering, and Quality as required.

Note: The above steps apply to any purchase order amendments as well.

3.04 Maintenance of Supplier Product Folders

Explanation of Maintenance of Supplier Product Folders

Overview

This section details the process of maintaining supplier product folders. These folders contain specific documents and should detail the relationship between the company and the supplier. Any purchase orders, CAR forms, or supplier score cards should be kept in the individual company folders.

Key Points and Important Steps

Maintaining a clean and organized workspace should be a key goal. Purchase order copies should be placed in supplier product folders immediately and CAR/score cards should also be placed in supplier folders. While this folder 'could' be online it is highly suggested that physical records are kept.

Example of Maintenance of Supplier Product Folders

The Quality Engineer Shall:

1. For subcontractors that have a contractual relationship with the Company (Sigma 6 Electronics) a folder of suppliers' products should be set up.
2. Keep up to date suppliers' product folders
3. Records included in the suppliers' product folders:
   a. Self-survey, reviewed and approved *(Forms A-026 or A-035)*
   b. Copy of purchase orders and amendments *(Form A-017)*
   c. Subcontractors sent inspection reports
   d. NCMR related documents *(copy of Form A-006)*
   e. Supplier Corrective Action Request report *(Form A-037)*
   f. Product and quality related correspondence
   g. Source Inspection Reports *(Form A-036)*

   Note: AS9000, paragraph 4.6.1 "Note," provision is a standard requirement.

4.0 Control of Purchase Order Amendments

4.01 Issuance of Amendments

Explanation of Issuance of Amendments

Overview

This section details the process of the issuance of purchase order amendments. The process in which the amendments are handled should not vary between POs. It is possible that these amendments are returns from the Quality Engineer who found a mistake, or from the customer.

Key Points and Important Steps

It is important that the revision is communicated quickly and with urgency to the Quality Engineer and the shop floor. This section can mention (dependent on the stage of the process) who needs to be notified and by when.

Example of Issuance of Amendments

Note: Preliminary assessment of terms and conditions should be discussed with subcontractors prior to releasing purchase order amendments.

Purchasing Agent Instructions:

1. Obtain current purchase order package from subcontractor's file
2. Review purchase order and decide which line item has been impacted by the required amendment
3. Revise text in purchase order and ensure it is in line with amendment requirements. Ensure technical data is accurate. Sign and date the revisions.
4. Send revised purchase order with all technical documents attached to Quality Engineer.

4.02 Review and Approval of the PO Amendments by the Quality Engineer

Explanation of Review and Approval of the PO Amendments by the Quality Engineer

Overview

This section details the process of review and approval of purchase order amendments. This should be conducted in the same manner as normal PO approval.

Key Points and Important Steps

Standard work (or standardized work) should be instituted in many facets of business. However, this is an exact copy of the previous approval section and should not require any unique steps. Addition of unique steps would cause unnecessary burden.

Example of Review and Approval of the PO Amendments by the Quality Engineer

The Quality Engineer Shall:

1. Review and approve purchase order amendments in the same way as done previously in 2.02
2. Maintain Suppliers' Product Folders regarding purchase order amendments the same way as done previously in Section I, 3.04.

4.03 Releasing the Amended Purchase Orders

Explanation of Releasing the Amended Purchase Orders

Overview

This section details the process of releasing the amended purchase order. This should be conducted in the same manner as normal release.

Key Points and Important Steps

Standard work (or standardized work) should be instituted in many facets of business. However, this is an exact copy of the previous approval section and should not require any unique steps. Addition of unique steps would cause unnecessary burden.

Example of Releasing the Amended Purchase Orders

The Purchasing Agent Shall:

1. Release the amended purchase orders by following the release steps of the standard purchase orders as defined under 3.03
2. Follow up implementation schedule and related communication with subcontractors
3. Update subcontractors' file regarding amendments as needed
4. Keep in contact with Production Planning, Engineering, and Quality, as required.

Section II

1.0 Purpose

Define the quality requirements regarding evaluation of subcontractors (Suppliers).

2.0 References

Blank Verbal Agreement Document – *A-003*
Nonconforming Material Report – *A-006*
Purchase Order – *A-017*
Supplier Survey Long – *A-026*
Supplier Survey Short – *A-035*
Incoming Inspection – *A-036*
Supplier Corrective Action Request – *A-037*

3.0 Procedure

Give specific directions that may be replicated by someone who doesn't know process.

3.01 Selection of Suppliers (Subcontractors)

Explanation of Selection of Suppliers (Subcontractors)

Overview

This section details the process of selecting suppliers. It is important to partner with companies that have a similar goal. If a supplier has a stake in you doing well then there is a mutual level of commitment. A supplier like Form-X that has a high quality of work and a low-moderate lead time is a good supplier. However, a supplier that has a low quality of work with a long lead-time is not beneficial.

Key Points and Important Steps

It is important to have the Quality Engineer review the supplier and survey the process that the products will be taking. Also, it is important to establish lead times and scheduling requirements early on.

Example of Selection of Suppliers (Subcontractors)

The Purchasing Agent Shall:

1. Select suitable contactors.

a. Established contractors: base suitability on the already existing quality records from the Supplier Product Folders located in Quality. Observe previously demonstrated capability, product quality and delivery history and act accordingly;
b. New subcontractors: base the initial suitability by reviewing their availability background profiled on the Internet, or any records available from local Better Business Bureau, or recommendations from customers, and business associates.

2. Request Quality Engineering to determine subcontractors' capability by survey
3. Ensure procurement activities are in line with production scheduling requirements

Note: In urgent situations: Purchasing Agent should interact with Quality to evaluate and approve subcontractors at the same time internal purchase orders are received for approval. "Blind" approval should not be accepted.

3.02 Evaluation of Suppliers (Subcontractors)

Explanation of Evaluation of Suppliers, On-site Survey, Mail-in survey, and Subcontractor Rating

Overview

This section details the process of evaluating suppliers. It is important to always monitor the supplier output and quality. As-per Zodiac Aerospace's supplier requirements a Supplier Score Card must be filled out. This is a baseline metric card that details timeliness and quality (in terms of defects). This card must be mailed, or emailed, to each supplier on a regular interval. On-site surveys should be conducted on a timed schedule and evaluated and compared to previous visits.

Key Points and Important Steps

It is important to maintain good relationships to all customers and suppliers. Through the evaluation of companies and the ability to build stake relationships can be built. It is important to discuss and define what a corrective action report/request looks like and what requires a corrective action.

Example of Evaluation of Suppliers, On-site Survey, Mail-in survey, and Subcontractor Rating

The Quality Engineer Shall:

1. Review chosen subcontractors selected by the purchasing agent for evaluation and approval
2. Determine if selected subcontractors are either established or new suppliers.
3. Prepare for evaluation and approval process and carry out requirements
   a. Do on-site survey
   b. Or mail-in survey

3.02.1 On-Site Survey

The Quality Engineer Shall:

1. Contact subcontractor's Quality and arrange the date for the on-site survey
2. Review project specifics that are required for capability determinations in doing survey at the subcontractor.
3. Prepare necessary documents to take for conducting survey (Form-A026 or A-035). Go to subcontractor as scheduled
4. Conduct quality survey by following the forms and questions listed. Check off each item as found and note anything extra found
5. Review results with subcontractor's Quality Representative. Identify areas of improvement where there is non-conformance to standards and approval will not be achieved until these problems are fixed. If no violations have been found, inform the subcontractor.
6. Sign and Date survey and give a copy to subcontractor
7. After leaving subcontractor, submit completed survey form for final approval or auditing and include trip report on survey results to purchasing.
8. Make the Supplier Product Folder as required and file in the relevant survey and other related documents, including the trip report.

Note: Issuance and approval of purchase orders to subcontractors with outstanding corrective action requirements should not be done until the identified noncompliance has been corrected and implemented. Issue Form A-037 (Supplier Corrective action request) in order to verify compliance.

3.02.2 Mail-in Survey

The Quality Engineer Shall:

1. Send Survey Request (Form A-026) to the desired subcontractor. Attach a cover letter with the reason and importance for the survey requirements.
2. Review the returned survey request. Sign and Date
3. Forward signed Survey request to supervision for approval
4. Notify purchasing on approval or disapproval (on Form A-003)
5. File the approved Survey Request in the Supplier Product Folder

Note: Issuance and approval of purchase order(s) to subcontractors with outstanding corrective action requirements should not be done until the identified noncompliance has been corrected and implemented. Issue Supplier Corrective Action Request Form (Form A-037) in order to verify compliance.

3.03 Subcontractor Rating

Implementation
Quality Engineer Instructions:

1. Compile list of all the active subcontractors
2. Design a form with only two entries:

Vendor Rating

Vendor's Name	Violations
1. Zodiac Aerospace	1 2 3 4 5 6 7 8 9 10

3. Circle Number of violations each time the same vendor had been issued a Supplier Corrective Action Request (SCAR).
4. Keep contact with management in order to determine when it is necessary to "pull the plug".
5. Document the result of management's decision on *Form A-003.*
6. Notify subcontractor of final decision.
7. File all related papers in Supplier Product Folder.

Note: Consider alternative suppliers before disqualification of subcontractors.

Quality Operating Procedure (QOP) 004

Control of Customer Supplied Product

Contents **Page**

Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

Section I

1.0 Purpose

To control customer supplied products in accordance with the quality provisions of the Purchase Order and this procedure

2.0 References

3.0 Procedure

(Scott, this section should detail the process that the person receiving the delivered product should follow. They should receive the delivered product and sign delivery papers as required. And insure that the packing slip is true to the order. There should be a record (ie: Form A-015, Record of Received Materials) that is signed and dated. The product should be identifited with some marking, like a sticker or tag. Perform inspection based off an inspection form. This section should also contain the means/method for rejecting anything within that shipment.. Please review the table of contents for this section to see what the subsections should be.)

Quality Operating Procedure (QOP) 005

Product Identification and Traceability

Contents **Page**

Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

Section I

1.0 Purpose

To maintain control over the process of product identification and traceability.

2.0 References

Contract Review – QOP 001
Purchase Order Review Sheet – *A-001*

3.0 Procedure

Product identification and traceability is enforced for:
1. internal document control for product traceability
2. implementation of customer flow-down requirements.

3.01 Internal Control

General

3.01.1 Issuance of Product Related Documents

Contracts, Engineering, Purchasing, Planning, and Manufacturing shall:

1. Record the applicable document prior to issuance, the customer's name, the products part number and revision level, and the serial, batch or lot identifying numbers.
2. Update all the documents affecting the product when the customers issue Purchase Order Amendments as defined in QOP 001 Section Four.

3.01.2 Quality Provisions for Support Requirements

The Quality Engineer shall:

1. Ensures that the product-related inspection documents have been correctly identified.
2. Ensure the NCMR serial number has been recorded on every product related document. Identify the individual rejects.

3.02 Customer Flow-down Requirement

The Quality Engineer shall:

1. Define product traceability and marking requirements from the Purchase Order Review (Form A-001).
2. Place the flow-down description of product traceability and marking into the Job Traveler ad Operation Sheets.

Engineering shall:

1. Define product traceability and marking requirements in the Job Traveler and Operation Sheets as required by the customer's PO and Form A-001.
2. Include any PO Amendments impacting product marking into the Job Traveler and Operation Sheets.
3. Create detailed product drawings that show the critical dimensions that impact the drawing. If applicable, include: overlay, membrane, or PC board drawings.

Quality Operating Procedure (QOP) 006
Inspection and Test Control

Contents **Page**

Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

Section I

This Section details the process of first piece production approval. This occurs when a new batch is started. The purpose of this is to allow for the production manager to note that a part is produced the correct error and problems can be preemptively prevented. There should be a section that details who is responsible for this approval and how they note it (probably through a Quality Control check or a CQ check). There should also be a section describing what happens when there are issues with the first production piece. Finally, there should be a short segment about how you approve first production pieces from subcontractors.

Section II

First, First article quality requirements should be detailed in the Purchase Order Review Sheet (ie: Form A-001). The quality engineer should determine project specific quality requirements. The information generated through determining quality requirements (form A-001, and a blank multipurpose A-003 form etc..). Then the first article production folder should be issued to the floor by the production manager. Engineering and the production manager need to interact to make sure that the production is executed as per the quality requirements laid out by the quality engineer (these requirements are direct flow-down from the customer typically). There should also be an inspection report generated when the first article piece has passed through all of the steps of production. If the customer requires inspection of a first article note how you will arrange such an inspection (ie: visit at the facility or via mail). First article documentation should be stored in a separate location by the quality engineer to promote organization.

Section III

Performance Surveillance: Supervision shall be responsible for processing review performance results activities. Spot Corrective Action needs to be administered when the supervisor sees the process owners (or manufacturers) preforming the task in a different manor than that which is on standard work articles. This section should state all of the supervisor's locations s/he needs to check. For example, the supervisor must check all processing related documents (did the information get filled out? What information? And when?). Or (review that workmanship and other processing related requirements have been completed, verified and documented as per work instructions in the Job Traveler and operation sheet).

Section IV

The main propose of this section is focused on the final inspections and testing. Thorough documentation of every process, including past performance product's processing is needed for verification and acceptance. This mainly applies to completed parts that

adhere to the customer's Purchase Order requirements. Ensuring quality of each product makes this step crucial. The main steps include: Document Review, Final Product Verification, and Product Delivery. Each section in the process is conducted by the Quality Inspector who will gather the appropriate documents (such as the PO, job travelers, etc.) to review and approve. The inspector will also ensure are calibrated accordingly in order for acceptance then finally sent to the customer.

Section V

This section gives detailed instructions on what to do when products are returned due to defects/nonconformance. QOP's 004 and 009 are referred to frequently so it is useful to have them present when following through with the operations and forms. Documents for receiving should be signed and passed on to the Inspector. The customer-supplied product will be inspected to see if the reason for return matches the product non-conformance (as stated in QOP 004). A recall of the product may be necessary if non-conformance is present in the production process.

Section VI

Customer source inspection is addressed in this section. This applies to the presentation of documents and accepted final products that are made available for customers to review at either the Suppliers or the Subcontractor site. Folders should be organized for easy access. Products should be reviewed with the customer's Quality Department to verify Process controls.

Section VII

The last section of this Quality Operating Procedure is used for source control activities of subcontracted products. The steps involved are; Preparation for Source Inspection, Source Inspection Performance, and Product Handling After Source Inspection, which are all carried out by the quality engineer.

Quality Operating Procedure (QOP) 007

Control of Inspection, Measuring, and Test Equipment

Contents **Page**

Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

Section I

1.0 Purpose

Maintain control over inspection, measuring, and test equipment.

2.0 Procedure

General Requirement

Are tolerances known? The tolerances need to be confirmed before the equipment should be used. Tolerance also should be extended to any software that might be doing measurement calculations as well; such as, a laser cutter. This section should detail the understanding of the previous mentioned notions.

Accuracy of the tools should be traceable to standards (national, international, or documented "house standards"). The calibration of these tools should be based on some specified requirement (either: the manufacturer of the tool, or an internal assignment). This section should detail the understanding of the previous mentioned notions.

Calibration records are documented in _____ *(form? or location of record?)* the frequency of calibration of all identified measuring equipment shall be upheld and demonstrated. This section should detail the understanding of the previous mentioned notions. *(required to fulfill SAE AS 9000, par. 4.11.1.1) The calibration records shall be made available to customers or their representatives upon request* ***(SAE AS 9000, par. 4.11.1.1)***.

2.01 Controlling the Identification of Gages

The Calibration Technician shall: *(or insert another title)*

1. Label all inspection, measuring, and test equipment. (*Explain how ie: on the equipment container?, on the equipment?, etch into the metal or label the case? etc...)*
2. Uniquely identify the employee owned measuring and test equipment which they use to verify and accept the Company's product(s);
3. *(How do you control the inventory of the measuring and test equipment? What form(s) need to be filled out to obtain said test equipment and where is the "users" name documented?)*

4. Maintain correct and unique numbering for inspection, measuring, and test equipment and on all related documents. *(suggest listing all locations of said unique ID number)*
5. Do not reassign any issued ID number to any other equipment. New equipment should be given a new unique ID.
6. *(How do you identify equipment no longer suitable for measuring and test requirements, and: do you mark said test equipment or scrap it?)*

2.02 Controlling the Handling, Preservation, and Storage of Gages

The Calibration Technician shall: *(or insert another title)*

1. Maintain all the measuring and test equipment as well as document: comparative differences, unique ID, and insure integrity to;
2. Maintain the environmental condition in order to provide a suitable area for calibration, preservation and storage for measuring and test equipment. Manufacturer specifications on storage and handling should be maintained.
3. Maintain master document as per section 3.01.3. Maintain accurate "sign-in" and "return" logs with the unique ID number.
4. Provide instructions (documented or verbal) to employees demonstrating a lack of skill in handling or applying equipment.
5. Keep the Cross-Training document up to date, especially when instructions have been given.
6. *(How do insure that proper handling occurs? Supervision? Are the employees corrected on the spot (spot corrective action) or is there another method?)*

2.03 Controlling the Calibration of Gages

The Calibration Technician shall:

1.
2.
3.

(How does the technician calibrate the gages and when? Does the technician do this task only monthly? or yearly? What forms or reports are generated when this occurs? This information should be available for other companies to view as per AS9000. Where are the previously mentioned cycle time, or when is the review period?)

2.04 Controlling the Documentation of Gages

The Calibration Technician shall:

1. *(what form should be maintained? for the control of documentation? ie: "Employee Gage Calibration Record")*
2. Place a signed and dated calibration sticker on each measuring and test equipment according to the calibration and due date recorded on the Employee Gage Calibration Record *(ie: Form A-020)*. The following should be observed:
    a. do not place calibration stickers on an individual unit that belongs to a set. Do place the sticker on the box containing the equipment. *(Where is the document kept? How? Do you place the document in a sheet protector and then place in in a binder? What is the title on the binder? How are they organized?)*
    b. If a gage is to be used for reference only mark unit as "For Reference Only - Verify Before Use - Not for Product Acceptance". If any flat measuring surface is also used for measurement it must be calibrated and verified, or it also must be marked as "For Reference Only - Verify Before Use - Not for Product Acceptance".

2.05 Controlling the Calibration Records

The Calibration Technician shall:

1. Group the calibration records into three categories:
    a. company owned measuring and test equipment;
    b. employee owned measuring and test equipment;
    c. customer and/or loaned measuring and test equipment;
2. *(Where is the document kept? How? Do you place the document in a sheet protector and then place in in a binder? What is the title on the binder? How are they organized?)*
3. Maintain document order within your established filing system at all times.

2.06 Inspection, Measuring, and Test Equipment Release

Release any measuring and test equipment as required by the process owners.

Quality Operating Procedure (QOP) 008

Inspection and Test Status

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Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

Section I

1.0 Purpose

Maintain control over inspection and testing indication through physical and electronic means.

2.0 References

Job Traveler – *A-013*

3.0 Procedure

Test indication shall be applied to products during the processing cycle. Products awaiting further processing are required to have inspection and testing clearly indicated on the Job Traveler *(form name ie:A-013)*.

Explanation of The Control of Inspection Stamps

This section should discuss the stamps used for quality control. The quality engineer, or representative that is in charge of said position needs to (as per previous QOP sections) inspect parts as part of his/her job. When the inspection is complete then that segment of work (either that process or the final product) receives a 'Stamp'. This can be seen on some other products, some as a sticker that might say "QC, OK" or something along those lines. 3.01 defines WHERE the list of stamp owners is located and who is responsible for maintaining that list of stamp owners. Further, it reassures that security over the stamps must be maintained by the quality engineer. It is also noted that at given times the quality engineer can give his/her own signature to replace the stamp.

3.01 The Control of Inspection Stamps

The Quality Engineer shall:

Explanation of the Control of Electronic Passwords and Content Access

This section should discuss the distribution of a "Communication Directive" which should detail basic information about requirements and conduct. It should further reinforce password ownership and the responsibility of that ownership. This section should slightly mirror the control of inspection stamps. It should note WHERE the list of password owners and their passwords are, the location that the passwords unlock and the importance of the information accessible. This section also should address the maintenance of the computer system with respect to the following information: virus protection, information backup, and file management.

3.02 The Control of Electronic Passwords and Content Access

The Quality Engineer shall:

Quality Operating Procedure (QOP) 009
Control of Non-conforming Products

Contents **Page**

Revision History

Rev Date	Rev Number	Description of Change	Signature
12/12/2013	0	Initiation of this Section	RK

1.0 Purpose

Keep control over non-conforming products, documents, and actions that have an affect on product quality.

2.0 Procedure

Apply to handling, reporting, and documentation of non-conforming products, documents, and actions affecting product quality.

General Requirements

Are the non-conformance in products verified? Are they documented? Documented evidence is needed to prove the indication of non-conformance. (Form A-018 and A-009).

The Materials Review Board (MRB) should have a unanimous decision on non-conformance. If conflict arises, the management makes the final decision.
A minimum of two members of the reviewing authority (MRB) shall be required to make a decision binding. One member shall always be a quality representative.
The customer has final authority over non-rework products.

Section I

1.0 Purpose

The purpose is to keep control of continuous reporting of non-conformance and maintaining records.

2.0 References

QOPs: 002, 004, 009
Forms: A-006, A-007, A-009

3.0 Procedure

This section applies to the process of reporting non-conformance

1. Internally
2. To customers
3. To subcontractor

3.01 Internal Reporting

Explanation of Internal Reporting

Overview

In this section the problem or defect with a product is looked into further. The idea is to identify what the underlying cause of non-conformance is in a given product.

Key Points and Important steps

Maintain documentation and reporting of non-conformance products is important to finding root causes. Non-conformance mainly comes from error in documenting procedures and rejected materials but there are other causes outlined below.

Example of Internal Reporting

The Reporting Authority shall:

1. Determine whether the non-conformance is:
   - Error in documented procedures
   - Rejected materials (used collectively)
   - Other

a. Correct the error in documented procedures in accordance with QOP 002, Section 2, paragraph 3.03.1 by the application of Amendment to Procedures (Form A-009)
b. Process the rejected materials in accordance with this QOP 009 section 2 or 3 by the application of Non-conforming Materials Report (Form A-006)
   Note: Notification of non-conformance to the affected parties shall be a requirement for Aerospace application (SAE AS9000 par. 4.13.1)
c. When there is an error in documentation and rejected materials, follow step b above.
d. When corrective action is needed from lack of compliance with written procedures, or with audit results, or any other major violation, process it by the application of Non-conforming Materials Report (NCMR; form A006)

3.02 Customer Supplied Products

The Reporting Authority shall:
Follow instructions of QOP 004, (Product Rejection)

3.03 Reporting Non-conformance to Subcontractors

Explanation of Reporting Non-conformance to Subcontractor

Overview

If the product shows non-conformance due to the work of the subcontractor, a report is ordered and the product is sent back to the vendor.

Key Points and Important Steps

A Return to Vendor form may be used by the "Reporting Agent" to send back the product. This process takes time and must be done as non-conformance products are found.

Example of Reporting Non-conformance to Subcontractor

The Reporting Agent shall:
Refer to QOP 009 Section 2, paragraph 2.01.4.4 Return to Vendor (RTV), regarding subcontractor rejects.

3.04 Non-conforming Material Report Issuance Control

Explanation of Non-conforming Material Report Issuance Control

Overview

This section is about the organization of any NCMR forms.

Key Points and Important Steps

Maintaining organization of these forms is important for repeat non-conformance and it can also be used to reduce time to filling out new forms.

Example of Non-conforming Material Report Issuance Control

The Reporting Agent Shall:

Enter the NCMR serial number on the Non-conforming Materials Report Form (A-007) before issuing an NCMR then follow instructions in QOP 009, Section 2, paragraph 3.01.1 in regards to the processing of NCMRs.

Section II

1.0 Purpose

The purpose is to control process reporting, determining the cause, disposition, come up with corrective/preventative action, follow-up of non-conforming products and process. Section 2 is an application of NCMR. This is a process to submit the NCMR forms.

2.0 References

QOP's: 002, 005, 006
Forms: A-003, A-006, A-007, A-018, A-024, A-028, A-037, A-039

3.0 Procedure

Evaluate the Problem
Apply the process of Non-conforming Materials Report (Form A-006) to determine the above purpose statement.

3.01 Performance Requirements

Explanation of Performance Requirements

Overview

This section is extensive and detailed because all processes must be documented and organized appropriately.

Key Points and Important Steps

Maintaining organization of documents and processes is key to adhering to the Performance Requirements.

Example of Performance Requirements Process

3.01.1 Processing Non-conforming Material Reports Through Form A-006

The Reporting Authority shall:

1. Obtain blank Non-conforming material report form (A-006)
2. Assign the document the next sequential serial number for organization and easy location when needed

3. Transfer the product data from the Inspection Report (Form A-018) onto the NCMR. Sign and date under "inspector" and turn over to the supervisor for approval.

3.01.2 Cause Determination (Section three of Form A-006)

The Supervisor shall:

1. Review the reported non-conformance and identify the causes to why the problem happened
2. Describe the contributing reasons for the non-conformance
3. Sign and date under "supervisor" and send the form A-006 and all related documents with the product to the Material Review Board.

3.01.3 Material Review Board (MRB) Disposition (Section four of Form A-006)

Material Review Board shall:

1. Review and evaluate inspection results and the causes of non-conformance.
2. Identify the appropriate actions to correct the problem and indicate it. Add comments and instructions with the affected item.
3. Decide whether the corrective/preventative action is required and note it. Sign and date.
4. Describe in detail what the corrective action should be and who, where, and what should enforce it. Enter the "required by" date so that there is a deadline to be followed.
5. Distribute copies of the NCMR to the affected parties.

3.01.4 Compliance Activities Regarding Disposition(s)

3.01.4.1 Rework (RWK)

The Responsible Department or Individual shall:

1. Rework the product, as required:
    a. if process is still in progress, use job traveler to isolate batch
    b. if it is an isolated unit, start rework on the unit or batch and setup process so that the problem is fixed
    c. if the rework is a document change requirement, carry it out in accordance with QOP 002, Section 2.

3.01.4.3 Accept (ACC)

The Process and Quality Engineer shall:
Compare purchase order of customers request to the acceptance of non-conforming products.

3.01.4.4 Return to Vendor (RTV)

The Quality Engineer shall:
1. Inform the Purchasing and Planning Departments with a copy of the NCMR.
2. Request Packing Slip (Form A-028)
3. Keep together all documentation; Packing Slip, Inspection Report (Form A-018), a copy of the NCMR (Form A-006), and the completed Supplier Corrective Action Request (SCAR, Form A-037)
4. Send product to the Shipping Department for return to subcontractor
5. Maintain the Supplier and Inspection Product Folders regarding documentation
6. Check with the subcontractor's "SCAR" response and follow up with the Management representative regarding corrective action responses.

3.01.4.5 Scrap (SCR)

The Quality and Process Engineers shall:
Dispose of scrap product as instructed by the customer

3.01.4.6 Waiver

The Quality Engineer shall:
Issue Waiver Request (Form A-024) to the customer and fill out according to the instructions under paragraph 3.01.4.2.1

3.01.4.7 Regrading Material

The Quality Engineer shall:
1. Identify the products traceability and documentation requirements. Follow customers instructions that fall in line with what is described in QOP 005, paragraph 3.02.

3.01.5 Handling Corrective and Preventative Action

1. Figure out the extent of the corrective action requirements so that there is an estimated time for response on the SCARs from suppliers.

2. Summarize the implementation plan on a new Form A-003 and send it to the responsible agent and keep a copy.
3. Determine if the corrective action will involve change to the Quality Systems Documents. If so, refer to QOP 002 for implementing.
4. After any corrective action, training requirements should be considered and then refer to the Training Metrics. Evaluation of training results should be documented on Form A-039. A score of less than 70% means there should be retraining. Maintain a Training Log.

3.01.6 Follow-up of Corrective/Preventative Action Implementation (on NCMR)

The Management Representative shall:

1. Locate the original NCMR according to the scheduled follow up for implementation of corrective action.
2. Review the C/A implementation summary previously issued by you on Form A-003 to the responsible individual.
3. Confirm the effective implementation of the required C/A.
4. Indicate unsatisfactory implementation under "no" and note action taken.
5. If satisfactory, indicate "yes." Sign and Date.
6. Return completed NCMR to its binder under sequential serial number.

3.01.7 NCMR Close-out

The Management Representative shall:

1. Open latest NCMR and locate the NCMR register (Form A-007)
2. The right side of the page should say "CLOSEOUT" if all NCMRs that were issued and registered under sequential serial number listing. This will show the effective compliance with the MRB.
3. Apply the correct NCMR serial number and close it out after the corrective action implementation is satisfactory. Note: do not close out any NCMR without effective follow-up.

3.01.8 Document Retention

The Management Representative and Quality Engineer shall:
Follow QOP 002, Section 3 for correct document retention.

Section III

1.0 Purpose

Keep documented reporting of customer complaints, product returns, and customer satisfaction.

2.0 References

Document and Data Control – QOP 002
Inspection and Test Control – QOP 006
Job Traveler – *A-008*
Rejected Material Ticket – *A-018*
Customer Complaint and Evaluation Report – *A-038*

3.0 Procedure

The process should address each section of customer interaction;

- Customer Complaints
- Product Returns
- Customer satisfaction reporting

3.01 Customer Complaints

Explanation of Customer Complaints

Overview

The Quality Assurance Manager should mainly carry out this section and all problems should be documented and treated with the same importance/urgency. All inquiries of customer complaints should be directed toward the Quality Assurance Manager. It is an important business practice to remember, "the customer is always right."

Key Points and Important Steps

At first, all customer complaints should be reported to the Quality Assurance Manager where any problem gets documented. Steps are then taken to reach a solution to the problem so that the customer is not dissatisfied.

Example of Customer Complaints

3.01.1 Reporting, Documentation, and Resolution

The Quality Manager shall:

1. Record the customer and product information in the Form A-038 under the first section. Note: The second section of this form is for reporting investigation and corrective action into the matter of the customer complaint.
2. Start Investigation:
    a. Go over the Product Folder to determine processing and final inspection. Review NCMR and Supplier Product Folders for additional information.
    b. Decide on the course of action to take. If necessary, recall the defective product to resolve the issue. Use sections 1 and 2 of QOP 009 because the NCMR process applies to non-conforming products found in the field.
3. Fill out the second half of Form A-038 by identifying "cause of the problem" and "corrective action taken." Then sign and date. Send a copy to the customer for an update.
4. Create a folder of "Customer Complaints" and leave relevant documents in them.

3.02 Product Return

Explanation of Product Return

Overview

The Product Return Process is straightforward in that the product is received by the "Receiver" and documented then sent to the Quality Engineer for further evaluation of the non-conformance of the product. It is then decided if the product should be returned or reworked.

Key Points and Important Steps

It is important to document the Product Return and why it was returned in order to avoid future returns. Remember, a returned product means it is a defect and the ultimate goal is to eliminate defects in products.

Example of Product Return

3.02.1 Receiving

The Receiver shall:

1. Sign shipping document to accept the returned product

2. Fill out Rejected Material Ticket (Form A-012) and keep it with the returned product.
3. Take all documents and send them to the Engineering Department
4. Place returned product in incoming shipments and wait for Receiving Inspection

3.02.2 Identification, Verification, and Resolution

The Quality Engineer shall:

1. Review customer NCMR, or other documentation.
2. Identify returned product through the final inspection records
3. Inspect product for packaging and/or handling damage.
4. Record what is seen on an Inspection Report (Form A-018)
5. Conduct an evaluation of the verification against the customer's Rejection Report.
6. Decide the next action to take from the results. Including engineering and GM.
   Note: The NCMR process also applies to non-conforming products identified in the field including all returned products.
7. Decide to return or replace product and follow the "Product Delivery" instructions from QOP 006, Section 4 if need to return.
8. Maintain control over the document retention using QOP 002, Section 3.

3.03 Cause/Corrective Action Request by the Customer (SCAR)

Explanation of Cause/Corrective Action Request by the Customer (SCAR)

Overview

SCAR stands for Supplier Corrective Action Request or Report. This document is used to address any non-conformance that a product may have. It also gives specific instructions on what needs to be fixed.

Key Points and Important Steps

The SCAR comes from the customer. Generally a recall of the product is needed to assess the problem and the customer is refunded or given a new product.

Example of Cause/Corrective Action Request by the Customer (SCAR)

The Quality Engineer shall:

1. Review the SCAR sent by the customer and determine the correct action to take that complies with the document.
   a. Use the Product Folder and find the customers file.
   b. Review contents such as the Job Traveler (Form A-008) and the Final Inspection Report (Form A-018)
2. Address the SCAR according to what was found in the records. Respond to the SCAR or recall the product or skip to step 3.
   *Note: Do not respond to SCAR before all the internal cause/corrective actions have been done from section 2 of QOP 009
3. Decide on appropriate corrective action that corresponds to the answer in the SCAR.
4. Send the completed SCAR to the customer
5. Keep control over the documents that are related to the product following QOP 002, section 3 using Form A-037.
6.

3.04 Customer Satisfaction Reporting

Explanation of Customer Satisfaction Reporting

Overview

Customer satisfaction is vitally important to any company that is dealing with repeat customers. Customer Complaint and Evaluation Reports are used only when the customer asks for it. It is useful to ultimately ensure customer satisfaction by documenting more than what is asked in the customer purchase order. The supplier should set up quality provisions so the customer is not responsible for coming up with the standards.

Key Points and Important Steps

The main document used is the Form A-038. This document is used to handle customer complaints reported outside the SCAR provisions of the customer's Purchase Order. It is also designed to process the customer's product evaluation when they receive a product.

Example of Customer Satisfaction Reporting

3.04.1 Handling and Controlling Customer Evaluation Reports (Form A-038)

3.04.1.1 The Final Inspector shall:

1. After final inspection, obtain a new Form A-038

2. Add in the shipping documents to the "Documents Enclosed" envelop for the customer

3.04.1.2 The Management Representative shall:

1. Review customer responded Evaluation Report (Form A-038)
2. Decide the importance of quality of the product
3. Start corrective action as stated earlier in QOP 009, section 2.
4. Report the "Customer Satisfaction Measurement" at the Management Review
5. Update and control the documents in the Customer Complaint Folder.

Quality Operating Procedure (QOP) 010

Internal Quality Audit

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12/12/2013	0	Initiation of this Section	RK

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Management Review

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12/12/2013	0	Initiation of this Section	RK

Section I

Quality Operating Procedure (QOP) 012
Performance Standard, Processing Control

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Section I

Processing Control

This section requires documenting the methods used to determine what the process steps are to create a quality part. What sources are drawn from? As an example, who plans the layout? What operations come first, second, third etc. Example:

1.0 Purpose

Evaluate "Request for Quote" (RFQ) in order to determine cost and capability.

2.0 References

Maintenance Record – *A-002*
Contract Review – QOP 001
Control of Purchases (Internal) – QOP 003
Inspection and Test Control – QOP 006
Control of Non-conforming Products – QOP 009

3.0 Procedure

3.01 The Administrative Secretary shall:

Sends copy of the customer's Purchase Order and Product Specifications to Engineering, Planning, and Quality. **Requirement:** QOP 001, Section Two

3.01.1 The Quality Engineer shall:

Reviews the customer's Purchase Order and Product Specification to determine the product quality requirements for the whole production cycle. Fills out Form A-001 (Purchase Order Review Sheet). Distributes Form A-001. **Requirement:** QOP 1, Section Two

3.01.2 Engineering shall:

Reviews the customer's Purchase Order, the Product Specifications and Form A-001 (sent by the Quality Engineer) in order to plan the production layout and the technical and equipment requirements. **Requirement:** QOP 001, Section two

3.01.2 The General Manager shall:

Holds contract review meeting in order to determine process evolution and direction. Issues summary of commitments, action items, and target dates on *Form A-003*. Distributes to the attendees. **Requirement:** QOP 001, Section Two

3.02 Enacting the Planning Provisions for the Product Realization Processes

3.02.1 The Process Engineer shall:

Prepares, reviews, approves releases the Job Traveler with overview drawings, including (if applicable) overlay film, membrane film, etc. to the Production Manager.

3.02.2 The Purchasing Agent shall:

Carries out the procurement activities.
Requirement: QOP 003, Sections One and Two

3.02.3 The Production Manager

Interacts regularly with all departments to maintain schedule. **Requirement:** QOP 001, Section Two

3.03 The Product Realization Process

3.03.1 The Production Manager shall:

Issue the Job Traveler. **Requirement:** QOP 001, Section two

3.03.2 The Production Manager shall:

Review the Job Traveler and production scheduling and carry out process controls before setting up operations.
Requirements:
a) Material identification as per QOP 006, Section Five
b) Tooling, fixture, special gages as per QOP 001, Section Two
c) Equipment maintenance on *Form A-002*
d) Availability of standard gages as per QOP 007

3.03.3 The Operator shall:

Sets up the job as required. Make first production piece. **Requirement:** QOP 006, Section One

3.03.4 The Production Manager, Engineering, or the General Manager shall:

Determines production continuation. Reviews product completion on Job Traveler and signs *Form A-033* under "Audited". **Requirement:** QOP 006, Section One

3.03.5 The Quality Inspector does:

Verifies and approves the first production piece. **Requirement:** QOP 006, Section One

3.04 Final Inspection, Product Release and Delivery

3.04.1 The Quality Engineer shall:

Carry out final inspection and controls product release and delivery. **Requirement:** 1. QOP 006, Section Four, QOP 009, Section Two

Section II

Handling Non-conformities in the Process Cycle

Example:

1.0 Purpose

Integrate the handling and control of non-conformities as part of process control during the product's overall processing cycle.

2.0 References

Non-conforming Material Report – *A-006*
Inspection Report – *A-018*
Rejected Material Ticket – *A-012*
Customer Complaint and Evaluation Report – *A-038*
Contract Review – QOP 001
Document and Data Control – QOP 002
Inspection and Test Control – QOP 006
Control of Non-conforming Products – QOP 009

3.0 Procedure

3.01 Hardware related nonconforming products identified during production

3.01.1 The Operators shall:

Notify supervisors if product is nonconforming.
Requirement: QOP 006, Section One

3.01.2 The supervisor shall:

Review the Operator has properly verified the product nonconformance. Take the necessary corrective action to continue production. Process NCMR through the Quality Engineer. **Requirement:** QOP 006, Section One

3.01.3 The Quality Engineer shall:

a) Verify the product nonconformance and document it on the Inspection Report *(ie: Form A-018)* **Requirement:** QOP 006, Section One;
b) Process Nonconforming Material Report *(ie: Form A-006)* **Requirement:** QOP 009, Section Two.

3.02 Hardware related nonconforming products identified at any point during the processing cycle of a product.

3.02.1 The Quality Engineer shall:

a) Document the nonconforming product's results onto Form A-018. Tag the nonconforming product with Rejected Material Ticket *(ie: Form A-012)* and segregate it.
b) Fill out Form A-006, Non-conforming Material Report. **Requirement:** QOP 009, Section Two

3.02.2 The Quality Engineer/Supervisor shall:

Review NCMR for completeness and accuracy. Sign and dates NCMR. **Requirement:** QOP 009, Section Two

3.02.3 The Production Manager shall:

Determines the cause of the nonconformance. **Requirement:** QOP 009, Section Two

3.03 Handling Corrective Action

3.03.1 The Management Representative shall:

Carry out corrective preventive action planning and determine an action plan with the individual responsible. Document the planning results**. Requirement:** QOP 009, Section Two

3.03.2 The Management Representative shall:

Follow up the corrective preventive actions effective implementation.

3.04 Production related document change requirement identified by process owners throughout the product's life cycle

3.04.1 The Process Owners shall:

If any errors, mistakes, or misleading instructions are found in any document by the process owner, they must report the problem immediately to their immediate supervisor. **Requirement:** QOP 002, Section Two

3.04.2 The Supervisor shall:

Review the document. If quality is impacted, stop production. If not, continue production. Regardless, call over the Quality Engineer to point out the documented problem. **Requirement:** QOP 002, Section Two

3.04.3 The Supervisor and Quality Engineer shall:

a) carry out the "immediate and provisional" change requirements.
Requirement: QOP 002, Section Two
b) carry out the "standard document changes" when the process is not immediately impacted.
Requirement: QOP 002, Section Two
c) carry out "software changes".
Requirement: QOP 002, Section Two

3.05 Document change requirements affecting the Quality System Manual and the Quality Operating Procedures.

3.05.1 The Management Representative shall:

a) review the type of change requirements.
Requirement: QOP 002, Section Two, 4.0
b) carry out the indirect changes to the procedures.
Requirement: QOP 002, Section Two, 4.01.1
c) carry out the direct changes to the procedures
Requirement: QOP 002, Section Two, 4.02
d) carry out the revision indication changes to the Quality System Manual.
Requirement: QOP 002, Section Two, 5.01
e) carry out the revision indication changes to the Quality Operating Procedures.
Requirement: QOP 002, Section Two, 5.02

3.06 Handling non-conforming products resulting from document changes

3.07 Customer initiated contract (PO) amendments:

3.07.1 The Contract Administrator shall:

Handle the amendment related documents to maintain administrative control.

3.07.2 The Contract Administrator shall:

Determine the impact the customer's amendment has on the current contract and takes action **Requirement:** QOP 001, Section Four

3.07.3 Engineering shall:

Implement, internally, the processing related document changes through form A-009, Amendment to Procedures Revision Change Log.

3.07.4 Engineering shall:

Implement the customer's amendment. **Requirement:** QOP 001, Section Four

3.08 Customer complaints, product returns, and customer evaluation (satisfaction) reporting.

3.08.1 Customer Complaints

3.08.1.1 The Complaint Receiver shall:

Direct the complaint reporter to the Quality Manager. **Requirement:** QOP 009, Section Three.

3.08.1.2 The Quality Manager shall:

Investigate the complaint to resolve the problem. **Requirement:** QOP 009, Section Three.

3.08.2 Product Return

3.08.2.1 The Receiver of the Product shall:

Receive the customer returned products and alerts the Quality Engineer. **Requirement:** QOP 009, Section Three, 3.02.1

3.08.2.2 The Quality Engineer shall:

Investigate the customer returned product, finds out cause determination and follow up with corrective action. **Requirement:** QOP 009, Section Three, 3.02.2.

3.08.3 Customer Satisfaction Reporting

3.08.3.1 Everyone shall:

Understand Sigma 6 Electronics' stance on customer satisfaction reporting. **Requirement:** QOP 009, Section Three, 3.04

3.08.3.2 The Final Inspector shall:

Initiate the customer evaluation and satisfaction report (Form A-038) **Requirement:** QOP 009, Section Three, 3.04

3.08.3.3 Management shall:

Handle the filled-out Form A-038 and files it. **Requirement:** QOP 009, Section Three, 3.04

Section III

Processing Control for New Jobs

Following the guidelines from the previous two sections construct a similar flow for the same processing control (as section I) but for new jobs.