The Reality of ISO 9000

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BACKGROUND

ISO 9000 mania has taken the electronics industry by storm. Industry periodicals have sections listing manufacturers who have recently been certified to the standard. Advertisements from distributors and manufacturers boldly feature ISO 9000 compliance. Many component vendors have received "When will you be ISO 9000 certified?" questionnaires from customers seeking their own ISO certification. The process is an endless spiral forcing a quality standard onto each level in the manufacturing chain. Great sums of money have been spent on ISO consultants. Entire companies devote many years to becoming certified. Why?

The ISO 9000 ball started rolling with the harmonization of European standards, a program originally called EC '92. The intent of EC '92 was to harmonize standards for product safety, EMI control and quality assurance. The goal was to lower non-tariff trade barriers between EC member countries. Member countries agreed on safety, EMC, and quality standards to encourage the smooth flow of products between countries. As a result, the alphabet soup of multiple country agency approval and testing should end, making it easier for manufacturers to sell their goods.

ISO 9000 is the basis for the harmonized quality standard EN 29 000. It defines a quality system and explains guidelines for selecting and applying the applicable sections of the ISO 9000 standard. If an organization decides to seek certification, a competent national body of the home country usually performs the audit of the QA system.

A series of internationally accepted quality assurance standards covers all aspects of design, production, installation and service.

ISO 9000 FORMAT

The ISO 9000 standard comprises three parts. ISO 9001 (EN 29 001) is a model for quality assurance in design/development, production, installation and service. This is the most comprehensive of the ISO standards since it covers all aspects of a product. Most manufacturers seek qualification under this standard. Distributors seek qualification under 9002 (EN 29 002), which focuses on production and installation. Equipment installers concentrate on 9003 (EN 29 003), which focuses on final inspection and test phases.

ISO 9001 APPLICATIONS

The ISO 9001 standard covers all aspects of a quality system for a company. Section I defines the role of management in supporting the quality system. The basic message of this section and most of the subsequent sections is that a plan must be devised to prevent production of nonconforming electronics. If nonconformity results, it must be thoroughly documented. A solution must be provided through the organization structure. The necessary changes must be verified and a procedural follow-up must confirm that a change has corrected the problem. The standard emphasizes the human aspects of the system. It specifically states that the people responsible for the outcome must have the freedom and authority to act.

The quality system section requires manufacturers to identify what is a good product, and which test equipment and standards are needed in manufacturing, test procedures and documentation. Relationships with suppliers are part of the contract section. ISO 9001 even addresses aspects of purchase order accuracy, fulfillment of contractual obligations, and conflict resolution. Again, there are no specific rules, just proof that a method of dealing with potential problems has been established.

The middle section of ISO 9001 covers manufacturing aspects. All parts of the design process including design verification are covered. Changes and documentation control are specified. Purchasing plays an important role in supplier assessment.

Orders placed with external or internal vendors must be accompanied by complete documentation and must be traceable. Process controls and inspection must be documented and appropriate procedures for dealing with deviations must be instituted. Metrology equipment must be calibrated and maintained. Procedures must exist for dealing with nonconforming products. How products are handled, stored, and delivered must be documented. Records must be kept. Regular internal quality audits must be conducted. Personnel must be trained. Last, an appropriate statistical process control should be established.

This laundry list is daunting but before any action is taken the manufacturer should review the standard. Most companies are already performing the tasks listed above. Through audits by customers, deficiencies in the QA system have probably been corrected. Procedures for nonconforming material have been established. Staffs have been trained in their jobs. What is the big deal with ISO 9001? Quite simply, documentation.

ISO 9001 forces documentation for everything, from purchasing to shipping, according to a known and accepted international standard. The choices of what and how are up to you. Many sections in the standard begin, "Where appropriate . . .. " Who decides what is appropriate? The OEM and the ISO investigator make these decisions. A current joke among industry analysts is that if a procedure which includes throwing the product against the wall until it works is properly documented, the product can be certified for ISO 9001. Surely this reflects very cynically on the standard. What the ISO seeks is logical documentation of reasonable and accepted industry practice. Most of the time spent in the certification process is ensuring that current documentation and practices meet the standard.

ISO 9001 AND VENDORS

Is certification worth the effort involved? Most experts say yes but representatives of several companies sharply disagree. Scores of stories portray companies which have been almost paralyzed by their certification efforts. Ultimately, decisions to apply for certification must be based on customer expectations, the state of existing documentation, and what, if anything, certification will provide.

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In this industry, certification to ISO 9001 is strongly recommended if a manufacturer wants to self-certify products for shipment. Part of being self-certified is having a quality system which meets international standards. Under the new rules, self-certification is possible without a certified quality system. This is a dangerous practice. There are severe penalties for EMC noncompliance in the EC after 1996. Punitive fines and criminal penalties are on the books for noncompliant products. If a noncompliant product is shipped from a noncertified QA system, the manufacturer will have a very hard time defending the action in the EC. If self-certification is selected for EMC, ISO 9001 certification is almost mandatory.

In supplier evaluations, the following questions may be helpful. Has the supplier been through a re-certification? ISO certificates are good for three years. Supplier re-certification indicates that they have maintained the standard instead of relying on a one-shot approval. If the company has not been re-certified, an investigation should be made as to whether they have been audited by another ISO-certified customer. Many large companies have ISO audit teams to evaluate the quality of their ISO certified suppliers.

CONCLUSION

In theory, ISO 9001 certification should guarantee that vendors supply good products. ISO-certified suppliers reduce the need for intense vendor surveillance. In effect, the vendor's ISO certification is tantamount to OEM ISO certification. As a practical consideration, manufacturers must also remember that they are dealing with people of different countries, cultures and certifying bodies. Interpretive standards like ISO 9000 leave room for different opinions. The key is documentation.

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