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A comparison between two Standards: ISO 9001-2000 and ISO 17025

Selecting the correct quality system standard is as important as implementing the standard correctly. ISO 17025 only applies to companies performing a testing or calibration service, while ISO 9001-2000 applies to companies designing, manufacturing, servicing, calibrating and testing.

Both standards have similar system requirements. They both require systems and processes for communicating with customers, handling of complaints, document control, control of records, corrective and preventive actions, internal audits, management reviews, and adequate resources and training.

The difference with the two standards is that all the above requirements for ISO 17025 apply only to the testing portion of the company, leaving the rest of the company exempt from all of the additional systems, controls and improvements that assist companies in achieving a good product with maximized efficiencies and minimized mistakes and problems. Quality cannot be tested into a product; Quality must be designed and manufactured, or built into the product.

Instruments manufactured under ISO 9001-2000 receive superior inspection, testing and scrutiny than instruments only tested under ISO 17025. Under ISO 17025, a good final test may be achieved; but under ISO 9001-2000, the testing and acceptance process is superior and far more expansive. The testing and acceptance process under ISO 9001-2000, begins with required design verification and continues with design validation. Materials and services going into the units are inspected and tested, product characteristics are monitored and measured throughout the design, manufacturing and assembly processes. Only after these controls, inspections and tests have occurred is the ISO 9001 manufacturer concerned about a final inspection and test to prove that the product meets defined design and/or customer requirements. All of these inspections and tests are performed with calibrated, NIST traceable equipment.

After the product ships, another real difference occurs between the 9001-2000 Standard vs. the 17025 Standard. With the new revisions to 9001 that occurred in the year 2000, a company is not allowed to continue to ship defective, less than satisfactory units or product. ISO 9001 requires a customer focus; it requires feedback from customers and

requires complaints to be evaluated for corrective action. This requires continual improvement to the design, manufacture, inspection, test and service of the units. ISO 9001-2000 also requires improvements to the management of the entire company for efficiency, customer satisfaction and defect prevention. ISO 9001-2000 also requires the use of other company data to be proactive in making these improvements and changes. The ISO 17025 Standard focuses a manufacturer only on controlling the testing the product. For a manufacturer today to only implement ISO 17025, is reminiscent of the 1980s and 1990s where an ISO 9003 standard existed. This ISO 9003 standard was applicable to Inspection and Test facilities only. But manufacturers, eager to be “ISO approved”, who also wanted to avoid the work that would have made a difference to their company and product, used ISO 9003 as their ISO standard instead of ISO 9001. Because of this widespread misapplication of ISO 9003 by manufacturers, ISO 9003 was canceled.

Manufacturers must first be concerned with constructing a quality product, paying attention to excellence in design and manufacture, before being concerned about having an excellent test. ISO 17025 could be added on top of ISO 9001-2000. But ISO 17025 is not a satisfactory substitute for ISO 9001-2000.