



TenStep Supplemental Paper

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Nine Important Aspects of ISO 9000

Thousands of organizations strive to gain ISO 9000 certification through standardized quality systems. This certification can improve the way an organization is managed as well as the quality of its processes, products, and services. There are twenty ISO 9000 Standards. Each standard describes how an area of the company should document written policies, procedures, and work instructions so that employees know exactly how to be successful. The standards also dictate how to record the results of work being performed. This system can lead to better product and service quality since detailed documentation, and proper training on how to use these documents, provides a reliable and consistent method of teaching employees how to do quality work.

The ISO 9000 standard was adopted by the European Economic Community over ten years ago and has since spread to almost 100 countries throughout the world. Today, it is the biggest standardization force in quality assurance. Many customers actually require this certification since they believe it leads to good business practices, better documentation and lower internal costs.

For the most part, employees will not have to change the way in which they work. The effectiveness of the ISO 9000 system is based on an increased awareness of specific areas in each person's work routine. Every employee needs to be familiar with four levels of ISO 9000 documentation that help define every area of the company that affects product or service quality. All documents must be current and have correct data, including titles, dates, revision letters and authorizing signatures).

1. **Policies** explain WHY things are done the way they are. Managers need to be familiar with them.
2. **Procedures** explain WHO does WHAT. These authorize an employee to do his or her job, so it is important to be familiar with them.
3. **Work Instructions** explain HOW the job must be done.
4. **Records** document the results of the work.

Training and Qualification

ISO 9000 requires everyone who affects product or service quality to be trained and have his or her own training record. Training must include the following

- Where all the paperwork and material comes from before it is routed
- What to do with incorrect paperwork or the wrong material
- How to identify, report, or segregate defective material

Nine Important ISO 9000 Areas

The following paragraphs cover nine of the most important ISO standards.



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1. **Quality policy.** Every ISO 9000 certified company has an established quality policy that incorporates the company's mission statement and often lists specific actions for achieving the mission. The employees should know and understand it. They should all be able to state the quality policy in their own words and be familiar with the actions that allow the company to achieve the policy.
2. **Procedures and Work Instructions.** Employees may or may not be doing a few things differently under ISO 9000. However, all work processes should be documented in written procedures and work instructions. Each employee's responsibilities will be defined in the procedures manual that has been developed by the company. It is important that everyone understands and follows these procedures. If an employee wants to change the way he or she is performing the work, he or she will have to make the appropriate changes in the procedures manual.
3. **Document control.** Under ISO9000, all documents relating to work will be controlled documents. This means that they will be reviewed and approved before issuing them to employees, and the documents will be distributed under a formal system of control. Employees can no longer assume that procedures and work instructions are correct or complete. Before using any of these documents, they should look at the header information that identifies the document name, document number, revision date, and authorization signature. These must be verified as correct. Finally, ensure that you have the correct revision of the document either through the "CONTROL COPY" stamp or through reference to the Master Document Index.
4. **Calibration.** All instrumentation used to measure critical characteristics of the product must be calibrated. A calibrated instrument is identified by a calibration sticker listing its date of calibration and the date when that calibration expires. Do not use an instrument to measure any critical product characteristics unless you are certain that the instrument is calibrated. To do this, you must know which measurements are critical product characteristics.
5. **Internal quality audits.** The ISO 9000 quality system requires an internal audit program. From time to time, employees from different departments will audit the effectiveness of the ISO 9000 system to ensure that personnel have received good training and are complying with the approved procedures and instructions. When there are problems within a department, it will be audited more often. Fewer problems mean it will be audited less often. Different employees should perform the audits so that different viewpoints are considered. The internal auditors will be specially trained and will schedule all audits in advance. The auditor will be looking for three types of problems:
 - Observation: This may be a problem, so keep an eye on it.
 - A Minor Non-Conformance: This is a small problem that needs corrective action.
 - A Major Non-Conformance: This is a large problem that needs corrective action.

There is nothing negative about these audits. They serve to identify improvements that can be made in the system, not to identify poor employee performance. Names



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are not recorded, but situations are. Audit reports lead to corrective action and additional training if necessary.

6. **Training.** Employees will probably receive more training than in the past, and it will be recorded on a training record. These records will assure that employees are given full credit for any training completed during the course of work. It is important to be aware of who has your training record and whether it is up to date.
7. **Corrective Action.** There will be an emphasis on corrective action in this quality system. Whenever a significant problem in the process is found, it is corrected and documented in a Corrective Action Request. These forms will go to the quality systems group, where they will be reviewed and analyzed for further preventive actions. A problem in the system should be considered an opportunity to correct and improve the system.
8. **Non-conforming Product** Employees should always know when the process or product is within specifications and when it is not. Additionally, when the process or product is out of specification, it is up to all employees to make every effort to isolate or re-direct the nonconforming product and initiate corrective action. It is also important to recognize the difference between a product or process that is out of a defined control range and one that is out of specification.
9. **Quality Records.** Throughout the process, there will be records to fill out and file. All required entries on a record form must be completed legibly. If an entry cannot be made because a part of the process was broken or inoperable, then a small note to that effect should be made in the entry block. All records are filed when they are no longer necessary. The fling system is organized to facilitate record retrieval when necessary.