
IV. THE IMPLEMENTATION PLAN

**OUR PLANS MISCARRY BECAUSE THEY
HAVE NO AIM. WHEN A MAN DOES NOT
KNOW WHAT HARBOR HE IS MAKING FOR,
NO WIND IS THE RIGHT WIND.**

SENECA (4BC - AD65)

The Key Implementation Steps

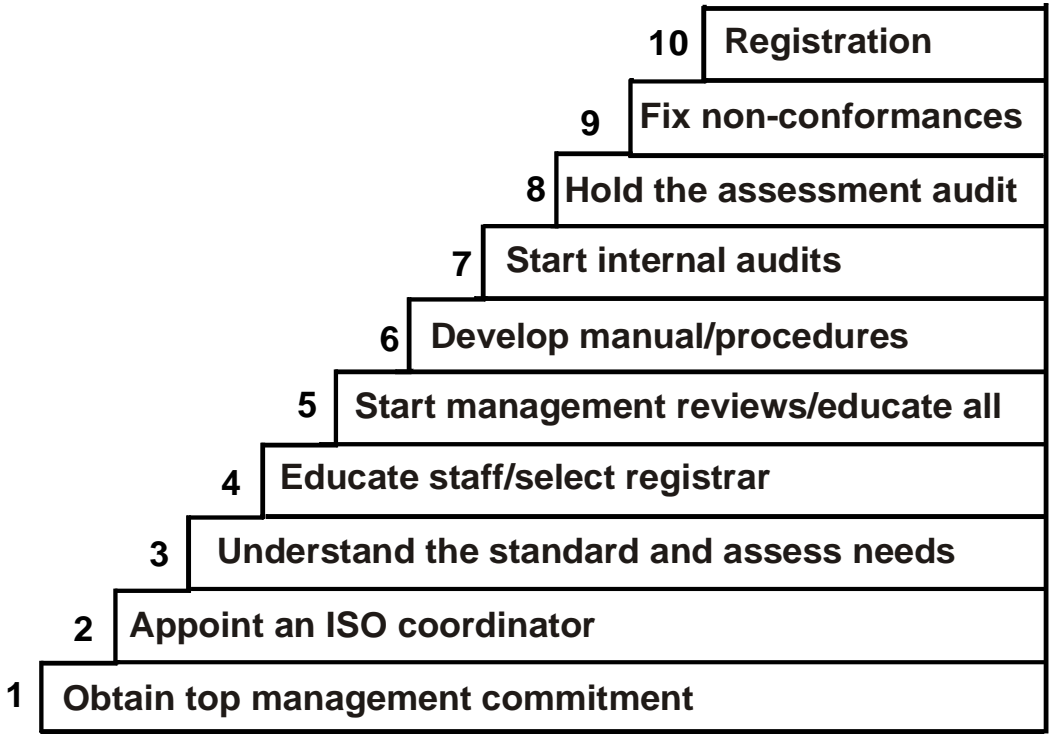


Figure 4.1 Ten Key Implementation Steps

All glory is fleeting. One must maintain the gains.

The Key Implementation Steps (Continued)

1. Obtain management commitment

Success in achieving ISO 9001 registration begins with top management. It is the general manager who will approve the resources and assign responsibility to achieve the ISO registration. Without this commitment, the registration process is going to take a lot longer than necessary.

2. Select an ISO coordinator(s)

The ISO coordinator is the clearing house for all ISO 9001 related matters. Some companies form an ISO implementation committee which functions as the ISO coordinator. The principal energies of either should be aimed at establishing a comprehensive ISO development program, and making sure it receives adequate resources and attention.

3. Understand the ISO 9001 Standard and assess current needs

Understanding ISO 9000 and its elements is central to the success of any registration road map. The members of the implementation committee should be from every area of the company's organization. It is vital to establish a body of functional experts operating by consensus.

The ISO coordinator or the implementation committee should be an information source and a good counselor. They will be required to answer questions and suggest strategies to correct quality non-conformances to ISO. Any questions should be directed to the ISO implementation team or ISO coordinator for resolution.

A needs assessment is required. Using the standard element checklist (which follows) a preliminary review of the system and procedures should be undertaken. The following schematic is useful to focus initial corrective action.

The Key Implementation Steps (Continued)

Procedures	System	
	In Conformance	Not in Conformance
Documented	Great!	Corrective action: If procedures are correct, follow them. If not, make them correct, then follow them.
Not Documented	Corrective action: Document what you are now doing.	Corrective action: Write procedures. Make sure they are correct and follow them.

Table 4.2 System versus Procedures Matrix

4. Educate the staff, evaluate and select a registrar

The department heads, managers, supervisors and team leaders will be strongly affected by the implementation of an ISO qualified system, so they must be fully educated about the subject and the changes that may be needed.

An important qualification for a registrar is its worldwide recognition status, especially within the European Community. The U.S.A. registration accreditation organization is the Registrar Accreditation Board (RAB). However, most U.S.A. Registrars have accreditation with boards in Europe as well. Of course, the European Registrars have their accreditation in their home country and often in several other countries.

The selection of a registrar that understands your business is important. Many registrars are booked months in advance, so time lag may be a consideration. If your company is basically in compliance now, you could wait months for the auditing team to get to you. Supply the necessary time and attention in selecting a registrar. A few years from now there will be a large number of companies wishing they had done the job right at the start.

The Key Implementation Steps (Continued)

5. Start management reviews and educate everyone

The general manager should delegate quality responsibility throughout the company organization. The general manager should appoint the management representative which is usually the quality manager. Management reviews should be started, focusing on the selected ISO 9000 standard and what must be done to comply with all the elements.

As the management reviews are building the quality system or fine tuning the compliance of an existing one, educate everyone in the company regarding ISO fundamentals. This means EVERYONE! Registering a company to ISO 9001 requires full participation from all employees. Education reduces resistance to change and gains the confidence of the entire work force.

6. Write the quality system manual and operational procedures

That's how the *ISO Primer* can help. The top quality system tier of documentation is the area of concentration of this effort. The Manual On a Disk will help you write your own Quality System Manual. Use the "text" to construct a shell of a manual which you can polish to meet the specific needs of your company. Each functional manager or department head should write the section of the manual that applies to their function or department. Hold management reviews to determine the suitability of the sections in the quality manual.

Some companies write the quality manual first, then procedures, and then work instructions. A more logical approach is to document the necessary procedures first, then the required work instructions, followed by the quality manual. Regardless of the approach, an initial quality management system is an iterative process.

Develop vehicles to disseminate information about documentation and the standards that will assist employees in executing their job so the key elements of the quality program can be met.

The Key Implementation Steps (Continued)

7. Start internal quality audits

Several people from different parts of the Company, should be trained as auditors. They must be knowledgeable of the ISO 9001 and ISO 19011 requirements.

These internal audit teams will do the work of ferreting out the nonconforming manual sections, procedures, and activities. Correct the manual, upgrade the procedures, correct any non-conformance then re-audit. The system is not conforming until it has passed at least one audit. Refer to the internal audit portion of the text.

8. The assessment visit or registration audit

The assessment takes from 2 to 5 days to complete. Set aside a designated space for the auditors. Have available copies of all documents needed for the assessment. The ISO Coordinator should escort and assist the auditors, (if asked and usually they will be asked). Daily meetings should be held during the audit to review the previous day's results. Often, non-conformances can be corrected on the spot which should advance the audit process considerably. It is important to promote an open, friendly atmosphere. Plan to pass.

9. Correct non-conformances

Promptly fix the observations that the assessment team has found.

10. Registration

Hang the registration certificate in a conspicuous place, you earned it. Give the event recognition in the internal newsletter or local paper.

Quality Documentation and Records

The quality system manual is the means to require the identification, collection, indexing, filing, storage, maintenance, retrieval, and disposition of pertinent quality documentation and records. The availability and access of records to customers and suppliers is established by policy and procedures. Policies and procedures also provide for changes and modifications in various types of documents.

Quality Documentation

Sufficient documentation must be available to follow the achievement of the required product quality and the effective operation of the quality management system. Appropriate sub-contractor documentation should be included. All documentation must be legible, dated (including revision dates), clear, readily identifiable, and maintained in an orderly manner. Data may be in hard copy or stored in a computer.

The number of necessary procedures and work instructions is affected by the size and complexity of the organization. A small company (< 100 people) may have 6 procedures and 10 work instructions. A large company (> 500 people) may require 40 procedures and 120 work instructions.

The quality management system should provide a method for removing and/or disposing of documentation used in the manufacture of products when that documentation has become out-of-date. Section V of this Primer contains a list of documents required by ISO 9001.

Quality Records

The system should require that sufficient records be maintained to demonstrate achievement of the required quality and verify effective operation of the quality management system. Section V of this Primer contains a list of records required by ISO 9001.

Quality records should be retained, for a specified period, in such a manner as to be retrievable for analysis in order to identify quality trends and the need for, and effectiveness of, corrective action. While in storage, quality records should be protected from damage, loss, and deterioration due to environmental conditions.

ISO Management Review Process

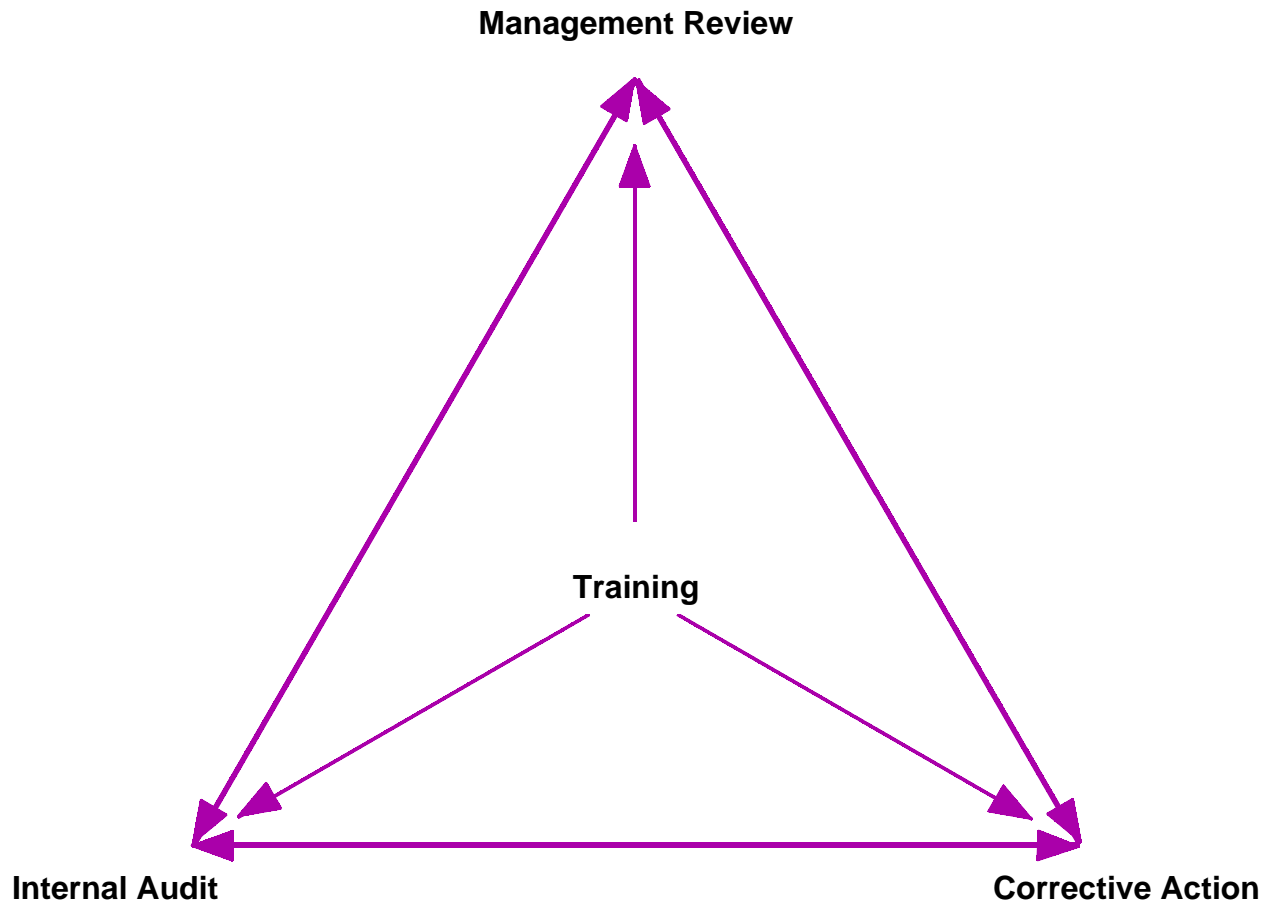


Figure 4.3 The Three Key Engines of ISO 9001 Compliance

The three engines of ISO 9001 compliance are the management review process, the internal audit, and corrective action. Effective education of all concerned parties is the fuel that drives these key factors.

IV. THE IMPLEMENTATION PLAN
C. MANAGEMENT REVIEW (ISO 9001:2008)

Quality Management System

The company must meet the requirements of ISO 9001:2008 with an established, documented, implemented, maintained and continually improved quality management system. Listed below are key questions.

STANDARD ELEMENT	COMMENTS/EVIDENCE
<p>SECTION 4 QUALITY MANAGEMENT SYSTEM</p>	
<p>SECTION 4.1 GENERAL REQUIREMENTS</p> <p>Does the quality management system:</p> <ol style="list-style-type: none"> 1. Describe and control the processes needed for the quality management system? 2. Establish and control the sequence and interaction of these processes? 3. Specify the criteria and methods required to ensure the effective operation and control of these processes? 4. Ensure the availability of information necessary to support the operation and monitoring of these processes? 5. Measure, monitor and analyze these processes, and implement action necessary to achieve planned results and continual improvement? 	
<p>SECTION 4.2 DOCUMENTATION REQUIREMENTS</p>	
<p>SECTION 4.2.1 GENERAL</p> <p>Does the Quality Management System documentation include:</p> <ol style="list-style-type: none"> 1. A quality system manual? 2. Documented procedures? 3. Documents required by the organization to ensure the effective operation and control of its processes? records? 4. Are the master documented procedures and master documents in hard copy or electronic form? 	
<p>SECTION 4.2.2 QUALITY MANUAL</p> <ol style="list-style-type: none"> 1. Where is the scope of the quality management system described? 2. Are the details and justification for exclusions made? 3. Are relevant documented procedures referred to in each section of the manual? 4. Does the Quality Management System apply to all processes associated or effected by the quality of the product or customer satisfaction? 	

IV. THE IMPLEMENTATION PLAN
C. MANAGEMENT REVIEW (ISO 9001:2008)

Quality Management System (Continued)

STANDARD ELEMENT	COMMENTS/EVIDENCE
<p>SECTION 4.2.3 CONTROL OF DOCUMENTS</p> <p>Are documents required by the quality management system controlled by documented procedures? Do they provide for the:</p> <ol style="list-style-type: none"> 1. Approval of documents for adequacy prior to being issued? 2. Review, update and re-approval as necessary? 3. Assurance that changes and the current revision status of documents are identified? 4. Assurance that relevant versions of applicable documents are available at points of use? 5. Assurance that documents remain legible and ready identifiable? 6. Assurance that documents of external origin are identified and their distribution is controlled? 7. Prevention of the unintended use of obsolete documents and suitable identification of them if they are detained for any purpose? 	
<p>SECTION 4.2.4 CONTROL OF RECORDS</p> <p>Are the records:</p> <ol style="list-style-type: none"> 1. Retained? 2. Legible? 3. Readily identifiable and retrievable? 4. Is there control by documented procedures for: <ol style="list-style-type: none"> a. identification? b. storage? c. protection? d. retention time? e. disposal? <p>Do the records show evidence of the effective operation of the quality management system?</p>	
<p>SECTION 5 MANAGEMENT RESPONSIBILITY</p>	
<p>SECTION 5.1 MANAGEMENT COMMITMENT</p> <ol style="list-style-type: none"> 1. Does the management group show a commitment to the development and continual improvement of the effectiveness of the quality management system? 2. Is there evidenced of the following: <ol style="list-style-type: none"> a. Importance of meeting customers as well as regulatory and legal requirements is communicated to all personnel in the company? b. Company's quality policy and quality objectives are defined by the quality management system? c. Published understandable quality objectives? d. Management reviews conducted at pre-determined intervals? e. Needed resources are supplied? 	