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Development and Implementation of ISO 9000 : An Executive Overview

- ISO 9000의 전개와 적용 -

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요 지

본 연구는 우선 ISO 9000의 배경, 구조 및 인증에 따른 혜택과 전망에 대해 알아보고 MQA, IQS 등 13가지 ISO 9000 전개 방법을 조사한다. 끝으로 일본, 미국을 비롯한 6개국과 TickIT, 대학, 공공분야에서 적용된 다양한 사례를 소개한다.

1. Introduction

The world's business community is becoming a global economy. Many companies are now buying and selling products and services throughout the world. Even those companies with current domestic market limitations have plans for future worldwide competition with a potential worldwide marketplace, each company must aggressively assert its position by establishing and maintaining a quality-based strategy.

For assurance of market success, such strategies must also involve the company's customers and suppliers throughout the world. This type of outreach will eventually mean that any product or service will be equally capable of supporting the intended quality goals. This will be true no matter what country the affected proactive companies use as trading partners, whether the country is developed or still developing.

The ISO 9000 series of international quality standards was first published in 1987. Five basic quality system documents were released. Since their introduction to a somewhat questioning user base, these standards have become one of the most significant influences on the advance of the global quality movement. Now, most business organizations with international undertakings or intentions are well aware of these standards. Many organizations are learning more about these

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documents and their application[63].

With the 1994 versions of the ISO 9000 series, including its widespread adoption and implementation, these international standards continue to generate a lot of attention[60].

This paper provides a sound understanding of the background, development and implementation of ISO 9000 through an executive overview. Effective approaches to develop ISO 9000 model are introduced. In particular this paper considers various successful case studies for implementing a quality process in ISO 9000 and TQM

2. ISO 9000

2.1 Background and Structure

Input to the evolution of the ISO 9000 series are reflected in Figure 1, which portrays the historical and widespread influences in the development of ISO 9000[9].

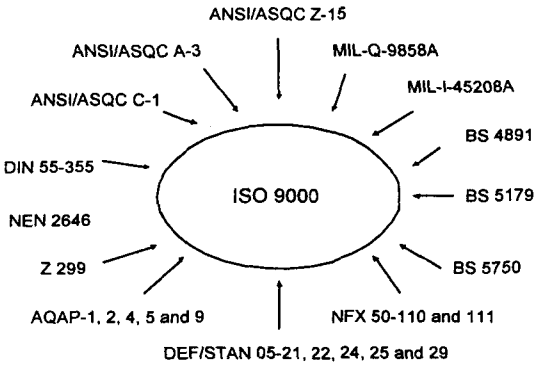

Figure 1. Historical Influences in ISO 9000

In terms of application, the ISO 9000 series of standards is well illustrated by the diagram shown in Figure 2[6, 11, 22, 24, 30, 34, 35, 37, 46, 53, 56, 72].

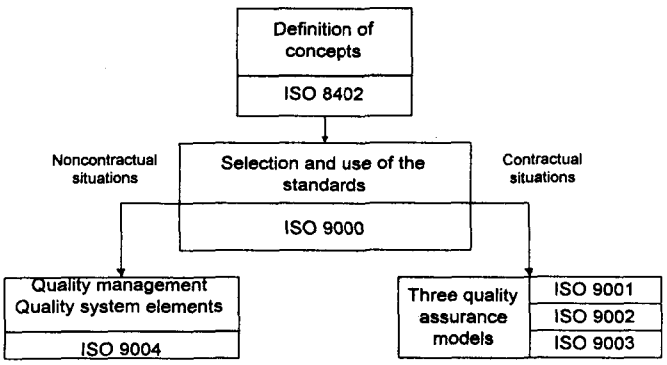

Figure 2. Structure of ISO 9000

On the positive side, the series lie in the structure that sets forth a uniform, consistent set of procedures, elements and requirements that can be applied universally, albeit within limitations of interpretation and individual implementation.

On the negative side, as for many standards passing through debate, review, negotiation and consensus, ISO 9000 represents a least common denominator in its coverage of the quality management/assurance/system disciplines. There is much emphasis on conformance rather than on adequacy and/or effectiveness. Meeting the requirements is the principal concern. Short-term corrective action is emphasized rather than long-term improvement[63].

2.2 Registration

The following ten simple tenets for successful registration [31, 57] are :

- Forget the ISO 9000 standard.
- Know the standard.
- You are smarter then any auditor.
- Keep it simple.
- Salvation is in the details.
- Set milestone and enforce them.
- Get help.
- Keep the project visible.

Figure 3 Shows road map to ISO 9000 registration. This map was reviewed and approved by the IIT at the first meeting [5].

2.3 Implementation and Benefits

The following 12 reasons to implement ISO 9000 are following[36].

- ISO 9000 standards are common sense on paper.
- A smart employees will love ISO 9000.
- ISO 9000 certification requires employee input to write practical, user-friendly procedures.
- ISO 9000 certification will have positive effect on union relations.
- ISO 9000 certification takes the emotion and subjectivity out of everyday decision making.
- ISO 9000 enables companies to achieve continuity of purpose.
- ISO 9000 certification provides for inherent personal responsibility among employees.
- ISO 9000 provides for standardized training tools.
- Customers will benefit substantially by involving your sales force properly in the certification process.
- Being certified helps many companies in the marketing arena initially.
- ISO 9000 reduces the cost of regular customer audits of systems.
- Certification will ensure more harmonious communication between customers and suppliers.

Alberti[1] recommended 10-step plan to avoid the common of ISO 9000 implementation :

- Keep your current documentation system at costs.
- Do not question the old way of doing things.
- Do not ask for input from your hourly employees.
- Document everything down to the tiniest detail.
- Hire the same company to do both your preassessment and your registration.
- Automatically assume that you need to be certified.

· Assign tour quality manager to the ISO 9000 implementation project.
· Blindly throw employees and money at ISO 9000 implementation.
· Do not follow your new system on "rush" jobs.
· Attempt to implement ISO 9000 requirements without any plan.

A successful ISO 9000 effort requires building an implementation framework[21] :

Step 0. Management understanding & commitment.
Step 1. Develop work description narrative.
Step 2. Define documentation structure & format.
Step 3. Generate responsibility matrix.
Step 4. Produce master plan
Step 5. Management approach periodic review.

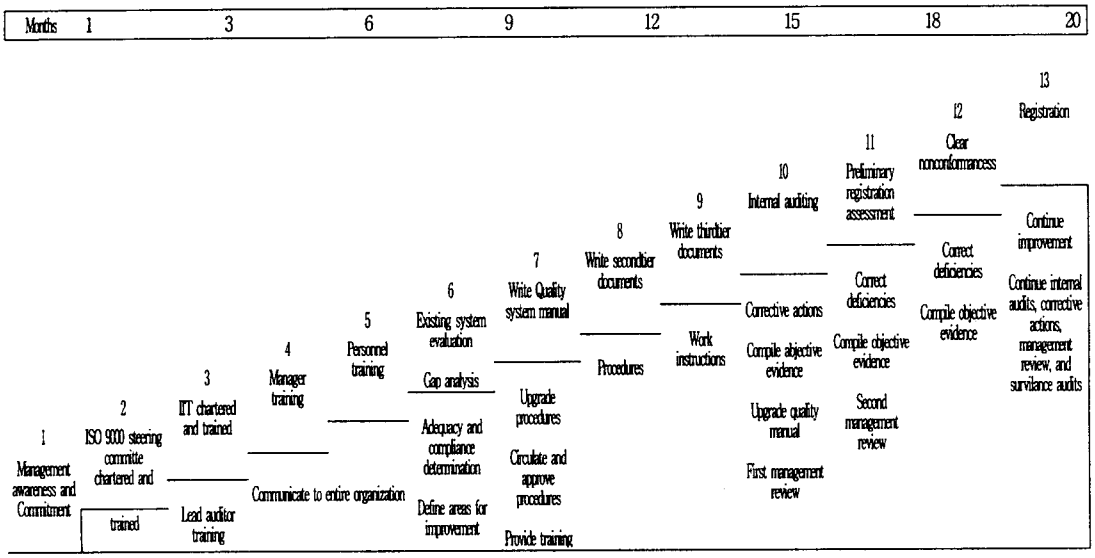

Figure 3. Road Map to ISO 9000 Registration

Many small to medium sized enterprises now see ISO 9000, i.e. as a licence to trade imposed on them by the dictates of the major purchasing agencies[17, 18, 19, 33].

Panton et al.[45] made a matrix listing nearly 200 consultants specializing in ISO 9000 and its automotive cousin, QS 9000 and a directory and matrix showcasing registrars[51].

Following misinformations about ISO 9000 are leading many companies down the wrong path[15] :

· It's a European standard.
· It's only good for large companies.
· It doesn't faster continuos improvement or improve product quality.
· It's outdated and meaningless.

Quality system audits require rigorous organization, methodology and capable auditors, both on the technical side and the behavioral side. The ISO 10011 series was completed in 1991 and covers three auditing areas(see Figure 4)[3, 4, 7, 16, 20, 38, 39, 41, 50, 52, 65, 71].

Wilson[73] proposed eight-setp process to successful ISO 9000 implementation :

· The first step provides a company with all of the considerations it must investigate in order to determine if ISO 9000 implementation is actually going to be beneficial.

· The setp 2 module assumes a go-ahead decision on ISO 9000 implementation.
· The shortfall analysis and its associate activities are accomplished in the setp 3 model.
· The ISO 9000 implementation plan is developed in the setp 4 model.
· Step 5 and 6, which can be worked in parallel, implement the plan. Step 5 resloves all compliance variances with those elements of the standard that are assoicated with the company's documented qualtiy system.
· The setp 6 covers all of the remaining ISO 9000 implementation activies, including related orientation training, management approaches, employee interfaces, and system related transitional concerns.

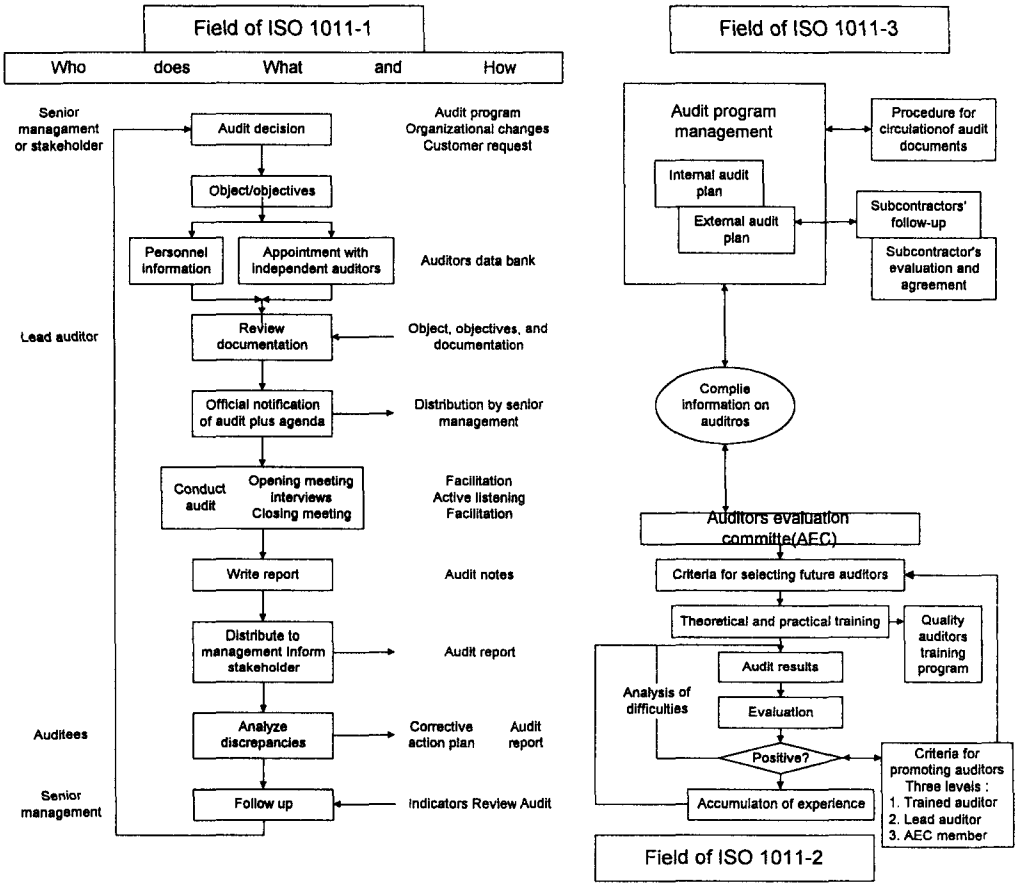

Figure 4. The ISO 10011 Series Standards

· The step 7 module provides guidance for the comapany to assure it has satisfactorily implemented its selected standard.
· The final module, step 8, provides information about the visit of the selected acceptance agency.

Companys should not go for ISO 9000 registration until they are certain they have the right means of control in the right places and that right place is usually in the hands of the workers[60].

Seven moneymaking areas, in order of prerequisite are :

· Positive management

- Management style change at all levels
- Process improvement
- Using the creative power of the work force
- Direct mangagement link to improvement efforts
- Maintaining machines and people
- Documentation shortcuts[59]

2.4 Future

The ISO 9000 family has now exceeded its usefulness because of the proliferation of guidance standards. These standards have become highly repetitive and in some areas are competitive giving different guidance on the same subject.

Table 1 shows the current list of guidance standards and those in the course of preparation[27, 29].

Table 1. Guidances Standards.

ISO 9000 : Quality management and quality assurance standards
ISO 9000-1 Guidelines for selection and use (formerly ISO 9000:1987)
ISO 9000-2 Guidelines for the application of ISO 9001/2/3 (under revision)
ISO 9000-3 Guidelines for the application of ISO 9001 to the development supply and maintenance of software (under revision)
ISO 9000-4 Guide to dependability management (IEC/TC 56)
ISO 9004 : Quality management and quality system elements
ISO 9004-1 Guidelines (formerly ISO 9004:1987) under revision
ISO 9004-2 Guidelines for services (to be incorporated in Phase II ISO 9004)
ISO 9004-3 Guidelines for porcessed materials (to be incorporated in Phase II ISO 9004)
ISO 9004-4 Guidelines for quality improvement
ISO 9004-5 Guidelines for quality assurance plans(waiting publication)
ISO 9004-6 Guidelines for quality in project management(committee draft)
ISO 9004-7 Guidelines for configuration management(waiting publication)
ISO 9004-8 Quality principles(new work item)(working draft)
ISO 10011 - Guidelines for auditing quality systems(under revision)
ISO 10011-1 Auditing
ISO 10011-2 Qualification criteria for quality systems auditors
ISO 10011-3 Management of audit programmes
ISO 10013 Guidelines for developing quality manuals(waiting publication)
ISO 10014 Economic effects of total quality management(committee draft)
ISO 10015 Continuing education and training guidelines(working draft)
ISO 10016 Inspection and test records-presentation of results(working draft)
N.B. Some of the titles and/or numbers may change on those standards that have not yet been published. New work items such as standards about product recall systems and disposition of returned product are currently being balloted.

Understandably, businesses want to ensure that the ISO 9000 certificate in which they have invested so much to obtain is acceptable to clients everywhere. ISO has been sensitive to the need of ISO 9000 users for 'one audit, one certificate-accepted everywhere.' with the International Electrotechnical commission(IEC), it is in the process of setting up a voluntary programme, known as ISO/IEC Quality System Assessment Recognition(QSAR), to encourage the worldwide recognition of ISO 9000 certificates so that certification represents a one-off investment by companies. Figure 5 shows ISO/IEC QSAR structure.

The success of ISO 9000 in the quality field has stimulated ISO's initiative on the standardization of environmental management systems(EMS). It is the phenomenal success of the ISO 9000 standards which has created an awareness that generic management standards could be applicable to other management objectives, in particular, to an organization's management of its environmental impact. The first draft international standards of the ISO 14000 series on EMS have been published. Looking to the future, ISO is also to consider whether occupational health and safety(OH&S) is an appropriate area for it to develop management system standards. Standards for the service sector represent an enormous future potential for ISO programmes. With the increasing emphasis on free and open international trade in the services, the need for international standards in such areas as insurance, finance, tourism and education is stronger than ever before. Possible new work on international standards for services is one of the areas on which ISO is liaising with the World Trade Organization(WTO)[49, 67].

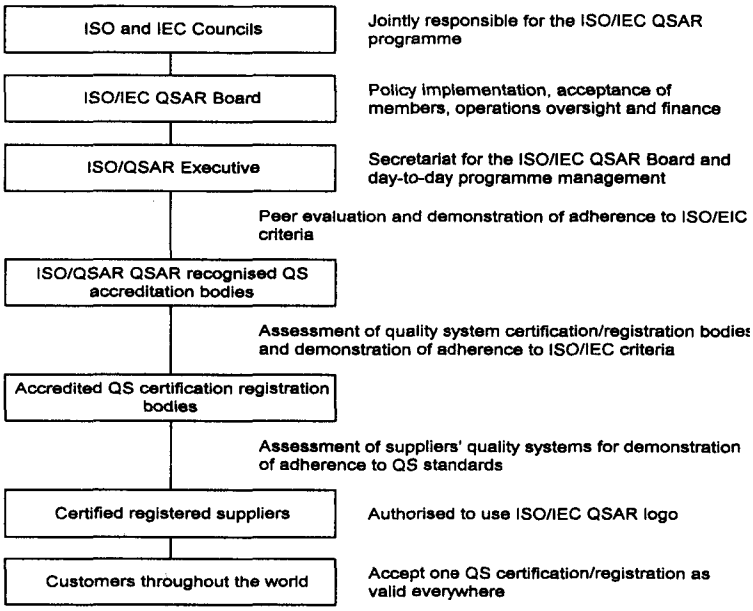

Figure 5. ISO/IEC QSAR Structure

2.5 Similarity between BS 7750 and ISO 9001

Various management system elements are shared by the two standards, such as document control, recordkeeping regimes and established organizational arrangements[23, 48].

3. Development of ISO 9000

3.1 Business Process Approach

Registration should be a secondary benefit to developing an effective quality system. The

companies that are forced into pursuing ISO 9000 registration may neglect the business process approach and take one of two approaches. They may either band-aid their present quality system trying to meet the ISO 9000 requirements(this is the normal approach taken by companies forced into implementation and given an unrealistic completion date) or try to develop a system based on the standard's 20 elements(standard approach).

Documenting the organization's business processes(core and supporting) that outline what they do to make money is an excellent place to start when developing a quality system(see Figure 6). After determining which processes exist, the next step is to put this down on paper. A flowchart is a good format for documenting process flow.

Four to five key top-level people within the organization should develop the business process. Each business process should contain less than 25 boxes, if possible. When there are more than 25 boxes for the core and supporting processes, the flowchart may be at too low of a level. Once the team has documented the business processes and top management has approved the document, a process owner should be designated for each step of the business process[62].

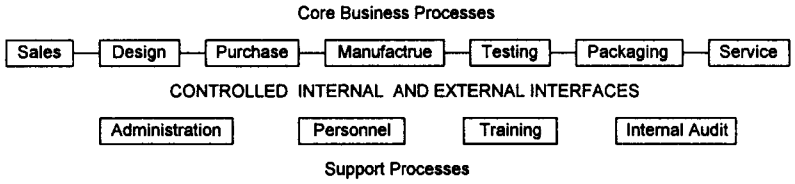

Figure 6. Busines Process Model

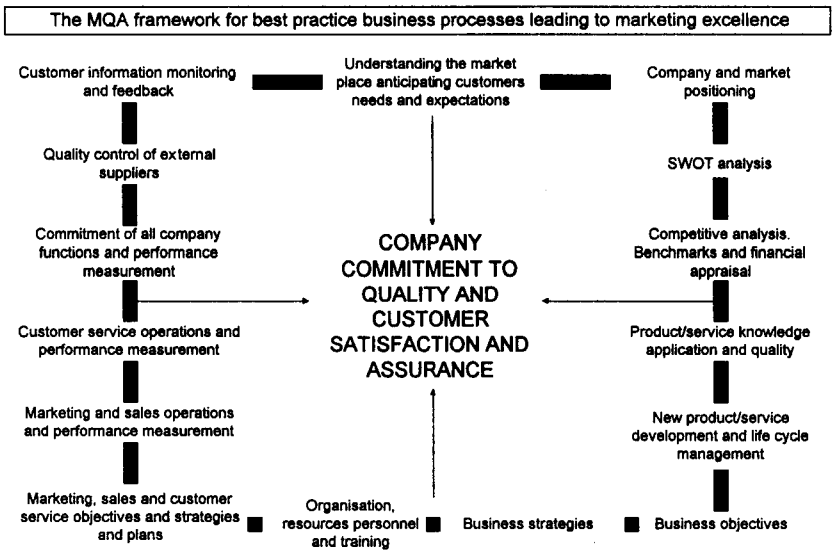

Figure 7. MQA Framework

3.2 MQA 01

If one of the business priorities is to look at how to improve the effectiveness of a company's marketing effort, there is help at hand. One option is the quality assurance specification(MQA 01),

published by Marketing Quality Assurance Ltd(MQA), as a best practice blueprint for marketing, sales and customer service.

First published in 1990 an increasing number of companies have used the MQA 01 specification to help them achieve ISO 9001 registration for their marketing, sales and customer service functions. A clear picture (see Figure 7) is now emerging as to the benefits which are to be derived from developing effective business processes around these key functions.

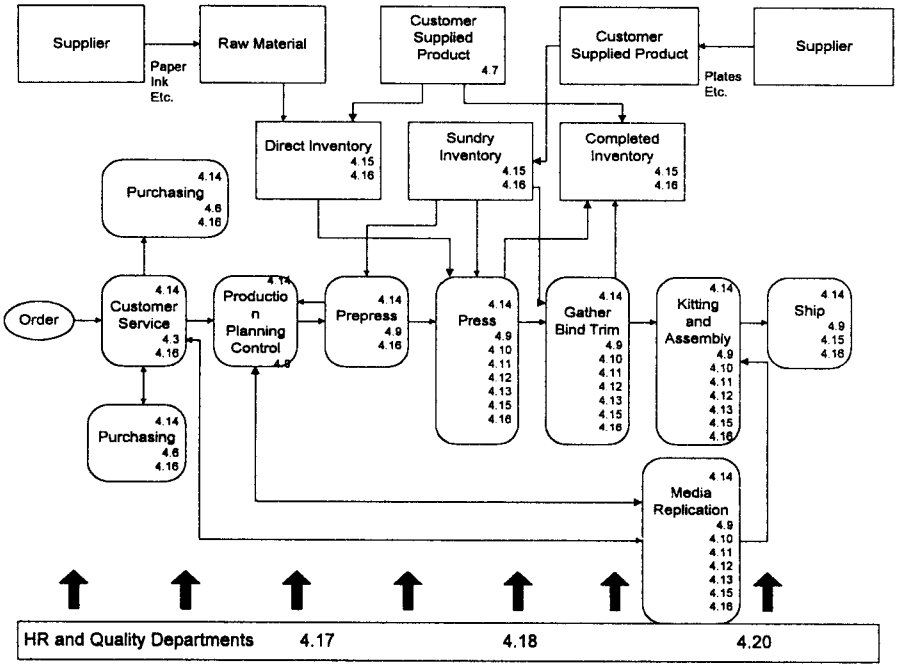

Figure 8. ISO Path

3.3 ISO Path

The Figure 8 representation mirrors the work flow at five major hub sites. Satellite locations, which are near our customers, stem from these hubs, providing additional fulfillment and packaging functions.

The lessons that we learned came from our experiences at the hub sites, We registered sites from East to West. Each site applied individually for registration, but we utilized a team approach in sharing information and process documentation, and making policy decisions[2].

Figure 9 shows ISO 9000 elements-a template view[15].

3.4 ISO 9001/PDCA/COQ

COQ, PDCA, ISO 9001 and other quality tools should not operate independently of each other. These tools should work in union and complement the ISO 9001 standard, The documentation should also be written in a format easily understood by employees and allow for a match between what is documented and what is performed.(see Figure 10, Figure 11)

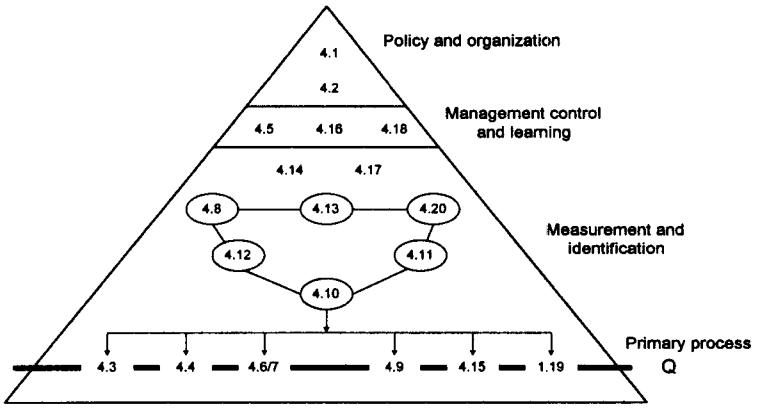

Figure 9. ISO 9000 Elements

PDCA	Cost of Quality	ISO 9001	
Plan	Prevention	Leadership Process 4.1 Management responsibility 4.2 Quality system	4.17 Internal quality audits 4.18 Training
Do	COQ Goal: Do right things right (customer - specific product / service processes)	Core Process 4.3 Contract review 4.4 Design control 4.6 Purchasing 4.7 Purchaser supplied product	4.8 Product ID and traceability 4.15 Handling storage, packaging and delivery 4.19 Servicing
Check	Inspection	Inspection/Test Process 4.10 Inspection and testing 4.11 Inspection, measuring and test equipment	4.12 Inspection and test status
Act	Failure	Correction Process 4.13 Nonconforming Product 4.14 Corrective action	
Controls		Control Process 4.5 Document control 4.9 Process control	4.16 Quality records 4.20 Statistical techniques

Figure 10. Comparison: ISO 9001, PDCA and COQ

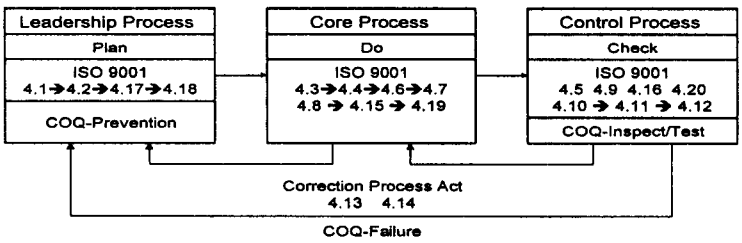

Figure 11. Process Flow : ISO 9001/PDCA/COQ

3.5 ISO 9000/TQ

Inputs to the evolution and development of quality systems are shown in Figure 12.

With consideration of additional resources, the resultant system should be better, more dynamic, more comprehensive, more effective, and more economical than that of ISO 9000 alone in its present

form. Illustrated by Figure 13, with ISO 9000 shown only as a basic foundation for a total quality system, which, for completeness, includes other techniques and procedures previously mentioned. Future revisions to the ISO 9000 series, within the framework of its intended purpose, will address many of its inherent weaknesses[63].

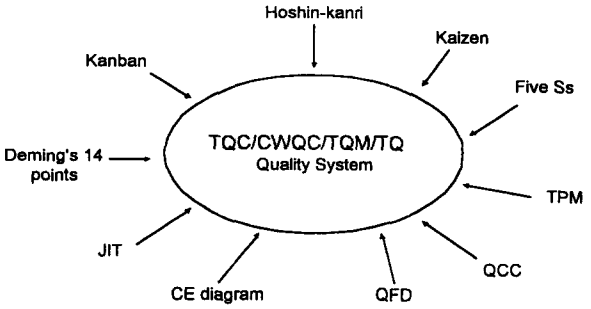

Figure 12. Inputs of Quality Systems

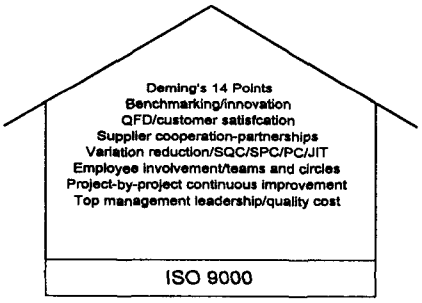

Figure 13. ISO 9000 and Total Quality System.

3.6 IQS

The Integrated Quality system is a management system which by using intelligence activity, and developing policies, encourages the evolution of integrated, motivated, and learning human activity in seeking continuous improvement and economic usage, of the selected and focused structures, integrated systems, technology, processes and resources required, to transform the creation, production and delivery of focused products and services, so that they are consistently distinctive in the quality characteristics(tangible and intangible). They provide, at their price, for the grater benefit of their customers, in comparison to competitive offering. This definition has been used to assemble the model shown in Figure 14[10].

3.7 R&D

The department director views R&D as providing certain services to customers, reflected by level 1 departmental model; middle managers oversee sections performing functions that result in delivered products and services, illustrated by level 2 functional model. The same concept applies for the Level 3 operational model; individual R&D members carry out processes an a day-to-day basis to accomplish their functions(see Figure 15). Level 3 models show much more detail including errors, rework loops, and links to management and administrative support processes that enable

accomplishment of business processes[66].

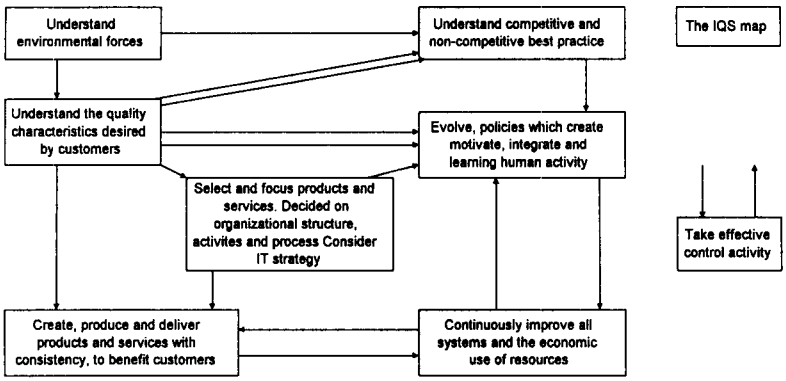

Figure 14. IQS

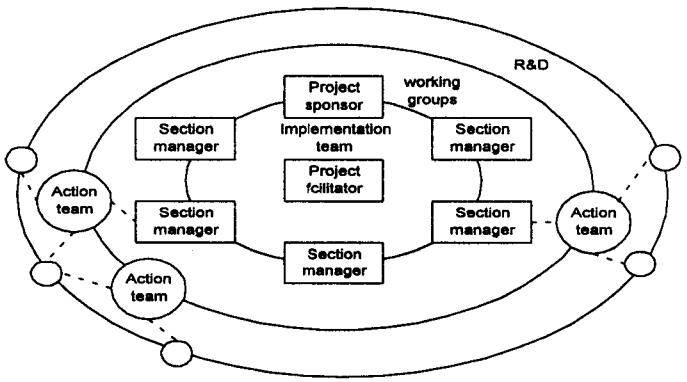

Figure 15. Quality Process Organization

3.8 DR

Wayman[69] presented the following guidelines for conducting design reviews :

- Product design steps
- Design reviews
- Scheduling
- Attendees
- Documentation package
- Agenda
- Report

3.9 Statistical Technique

The radius of the circle is given by the following formular :

$$R=\sqrt{\chi^2}\ \frac{S_p}{\sqrt{n}}$$

in which

R=the radius of the circle

n = sample size

χ^2 = chi square for two degrees of freedom

S_p = average standard deviation of the samples

The center of the circle is located on (S_p, M_p) when $M_p = 0$. Draft your circle with a radius R_1, R_2, R_3, etc. Determine the intersection of the circle with the vertical going through S_p. Draft the straight line going through (0, 0) and the point. The intersection of that straigh line with the n-scale determines n[44].

3.10 Work Instruction

Stewart[60] presented ISO 9000 standard work instruction for "fun". He described activities to maximize the likelihood of creation of a fun work environment and suggested that fun is a critical factor in employee productivity.

3.11 Quality Management Software

Quality management software can help you reach ISO 9000 certification and much more actions as well as proper adaptive actions.[43, 61].

3.12 Root Cause Analysis

The pieces depicted in Figure 16 are shown completing the TQM picture. It could be argued that if a TQM program were totally effective, some of the elements which focus on problems are not necessary. However, if "doing the right thing right the second time" seems the next best thing. Root cause analysis can help identify the more obvious and needed improvements to current operations, since if focuses on present obstacles. Therefore, root cause analysis techniques can be used to identify these likely opportunities for improvement, as well as provide the road map for their attainment. Figure 16 shows elements of total guality management. Table 2 shows comparison of analysis techniques. Figure 17 shows selection of analysis technique[74].

<table>
<tr><td colspan="4">Customer Focus/Satisfaction</td></tr>
<tr><td colspan="4">Management Support/Direction/Commitment</td></tr>
<tr><td>Defining Realistic Expectations</td><td>Continual Improvements</td><td>Trend Analysis</td><td>External, Internal, and Self Assessments</td></tr>
<tr><td>Human Resources Utilization/Development</td><td>Project /Process Management</td><td>Root Cause Analysis</td><td>Corrective, Adaptive, and Preventive Actions</td></tr>
</table>

Figure 16. Elements of TQM

3.13 Metrology System

Figure 18 reflects the steps that lead to the application of required calibration procedures. There are three main sources of calibration procedures :

- Procedures compiled by the product manufacturer
- Published standards
- Instrument manufacturer's recommended calibration procedures[47].

Table 2. Root Cause Analysis

Problem Nature	Change Analysis	Barrier Analysis	Event and Causal Factors Analysis	Tree Diagrams
Organizational	Good	Best	——	Better
Activity or Process	Good	Best	Good	Better
Reorganization	Best	Good	——	Better
New or Changed Activity	Best	Better	——	Good
Personnel	Good	Best	Better	——
Accident or Incident	Good	Better	Best	Good

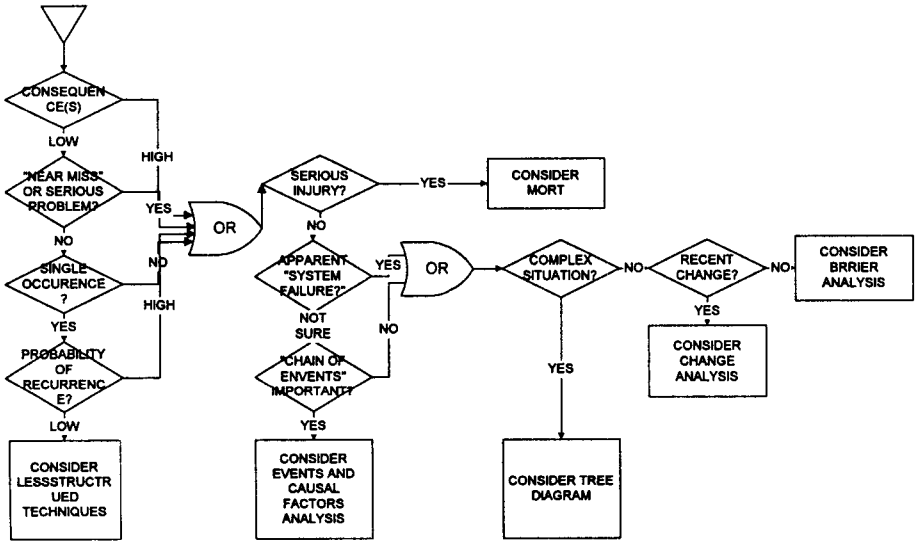

Figure 17. Selection of Analysis Techniques

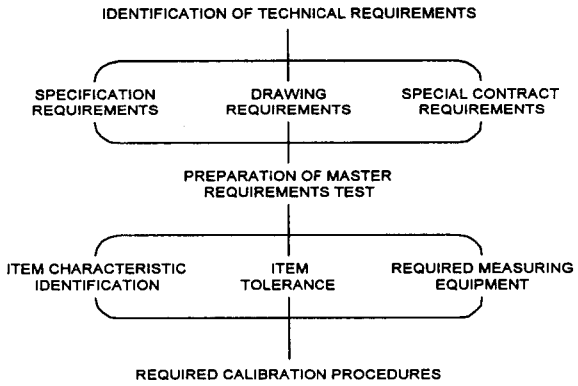

Figure 18. Calibration Procedures

4. Implementation of ISO 9000

4.1 Japan

On the whole, Japanese quality management sits rather uneasily with a certification system based on ISO standards. This is because, whereas the certification system is constructed from the purchaser's standpoint, the main stream of Japanese quality activities is from the supplier's standpoint. However, the ISO system has many advantages also for suppliers, and reassessing Japanese quality management in comparison with ISO standards and reconstructing it on the firm foundation which these standards provide, Japanese quality management will be raised to even higher levels internationally[32].

4.2 Australia

The aim of the questionnaire survey is to examine the effect of factors influencing ISO 9000 certification on small manufacturers.

Seven sections of the questionnaire are :

- How do the customers evaluate the product and/or service quality of the respondent's organization?
- Awareness of ISO 9000 certification.
- The status of the respondent's organization in the ISO 9000 certification process.
- Reasons for the respondent's organization to start the ISO 9000 certification process.
- Reasons hindering the respondent's organization to start the ISO 9000 certification process.
- Number of employees of the repondent's organization.
- The industry of the respondent's organization[42].

4.3 USA

This study, which is part of a series of quality-related studies on manufacturing firms in Colorado, sought to discern links between the ISO 9000 registration process, total quality management(TQM), and the Malcom Baldrige National Quality Award.

Twelve sections of the survey are :

- Most important reasons for seeking ISO 9000 registraion.
- Extent that foreign trade(particularly with Europe) was a factor in seeking ISO 9000 registration.
- Top management involvement in the ISO 9000 registration process
- Length of time to achieve ISO 9000 registration
- Period when ISO 9000 registration was achieved.
- Obstacles to achieving ISO 9000 registration.
- Comments concerning resistance to ISO 9000 registration.
- Benefits of ISO 9000 registration.
- Perceived positive benefits of ISO 9000 registration at the shop-floor level.
- Lessons learned
- Actions that would be done differently
- Current focus on quality[67]

4.4 Belgium

To learn more about ISO 9000 implementation, a written survey was conducted with ISO 9000 certified organizations in Belgium. Eight sections of survey are:

- Motivation for implementing ISO 9000
- Satisfaction with ISO 9000
- Elements that have a positive effect on ISO 9000 implementation.
- Elements that have a negative effect on ISO 9000 implementation.
- Quality problems
- Internal changes associated with ISO 9000
- External changes associated with ISO 9000
- Disadvantages of the ISO 9000 Quality Manual [68].

4.5 Malaysia

This paper considered the extent to which ISO 9000 and total quality management(TQM) were being successfully implemented in Malaysian manufacturing companies.

A survey on Malaysian companies was conducted in 1995 and produced 247 positive responses.

Ten sections of survey are :

- Organizations with certified standards
- Reasons for certified standards
- Years of TQM involvement
- Breakdown of sizes and types of industries involved
- Quality activities before quality system registration
- Quality activities after quality system registration
- Quality activities to be adopted in the next three years
- The most beneficial activities to the organization
- The main benefits of TQM
- Main difficulties for TQM[25].

4.6 China

While China boasts the world's third largest economy, it's implementation of TQM strategies and ISO 9000 standards remains embryonic and woefully inadequate.

4.7 TickIT

The procedures manual had the following ten sections :

- Introduction and overview
- Organization
- Control of quality, audit and measurement
- Product design
- Drawing office procedures
- Purchasing
- Materials control
- Manufacturing
- Dispatch and delivery

· After sales

It was proposed to prepare a quality manual containing ten principal documents to match the ten sections of the procedures manual. This approach has worked extremely well. The BSI checks that quality manual conforms to ISO 9001 and must approve any changes to it. Changes to the procedures manual are subject to approvals control at primagraphics. They are also audited by the BSI's auditors during surveillance visits[28, 58, 72].

4.8 Education in QA

Over the last five years, quality assurance(QA) has become one of the focal issues. Almost everyone has heard about it, but, in comparative terms, very few are being educated in its concepts. This paper outlined those considerations necessary in providing a model through which education in quality assurance could be provided in higher education[55].

4.9 Public Sector

The forest service is charged with managing 191 million acres of America's forests and grasslands. Uses have traditionally run from wilderness and restricted natural resource areas, to fully developed campground facilities, timber production, and forage for livestock. Management for these multiple uses has always been a tenuous balancing act. Forest service leaders concentrated on building a creative and innovative work culture, relying on the good judgment of their people, cultivating partnership, and listening to customers.[13] Eighteen months ago, the U.S. Army Corps of Engineers, New Orleans District, took the first steps down the total quality management road. It may be several years before the paradigms and business skills characteristic of a mature TQM program will be common throughout the district. However, early efforts have achieved some dramatic improvements in both the quality and cost effectiveness of services provided to our customers. Diffley et al.[14]. described the framework for quality improvement program and illustrate how they obtained substantive, measurable quality improvements in their navigation lock maintenance.

New Orleans District is responsible for federal participation in water resource projects - navigation, flood control and environmental - in control and coastal Louisiana The district has a budget of about $400 million and employs 1,300 people. The activities of the district are evenly split between the operation, maintenance and improvement of existing water resource projects, and the planning, design and construction of new projects.

Figure 19 conceptually illustrates their relationships for project operations business.

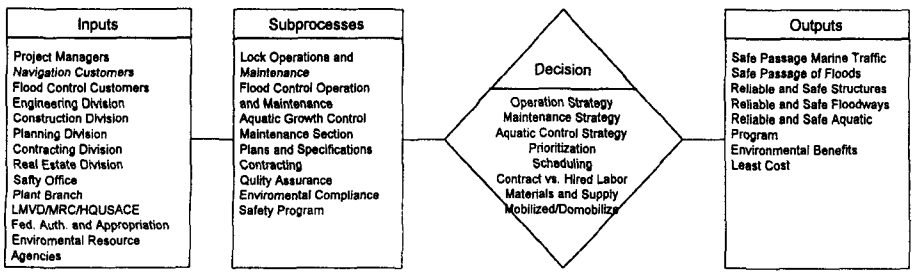

Figure 19. Project Operation Process

5. Summary

The ISO 9000 series is a uniform, consistent set of procedures, elements and requirements for quality assurance that can be applied universally to any total quality system. Its widespread adoption by companies and nations has brought about harmonization on an international scale and has supported the growing impact of quality as a strategic factor in international trade.

This paper has shown that many benefits can be obtained by any company from implementing the ISO 9000 standard as a step on the way towards total quality.

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