

Office to the Factory Floor

TAKING CARE OF BUSINESS



How to Become
More Efficient and Effective
Using ISO 9000

GREG HUTCHINS

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and Effective Using ISO 9000

Greg Hutchins

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PREFACE

The title of this book, *Taking Care of Business*, was chosen because increasingly businesses are focusing on internal operations, systems, and processes to improve the bottom line. In this constrained economy, all elements of an organization's competitiveness are being examined and improved.

Traditionally, the external elements of marketing and selling often received the lion's share of your attention. The customer was king. The first product on the market or the one with the highest quality often won over customers. As long as there was high customer demand and only a small number of companies could satisfy the demand, profits were guaranteed. Now times have changed. Most companies compete and excel using similar mechanisms and processes. The critical issue is to discover and develop new ways of staying competitive, and to provide the customer value through high-quality products and services at a low cost.

The critical question for you and many others is "How do you provide value at a low cost?" The answer is to tighten up and improve internal operations. More top-management focus is being centered internally, where it can focus on what can be done to enhance productivity, to produce and deliver more with the existing or fewer resources. This is one of the major reasons for the attention and growth in ISO 9000 and the rationale for the title of this book. ISO 9000 encourages the development of organizational operational systems and processes that improve internal operations.

In the last decade, U.S. industries have lost international and domestic market share to foreign competitors in consumer electronics, steel, autos, and a host of other commodities. Basic assumptions on how to run a business have been challenged. Many solutions have been offered. The only enduring solution that has been proposed, Total Quality Management (TQM), is still around and widely used, and ISO 9000 represents the most accessible, understandable, and accepted structure for TQM.

OUR OBJECTIVE

Quite frankly, ISO 9001/9002/9003 standards are boring to read. They are technical quality standards, full of breathtaking requirements such as “Organizational and technical interfaces between different groups shall be identified and the necessary information documented, transmitted, and regularly reviewed.”¹ This dense information does not lend itself to easy implementation.

Taking Care of Business goes beyond the rigorous details of the quality standards to address the broader issues of good business. If you read beyond the dense quality requirements and specifications of the ISO standards, you’ll see that there are a set of commonsense business values, directions, techniques, and ideas inherent in the standards that are valuable for all businesses.

In this book, we’ve attempted to look at how the requirements can be used by you, the reader, in your attempts to create a better business. *Better* can be defined as operating more efficiently, providing better customer service, or producing defect-free products.

The ISO standards offer generally accepted and approved methods for operating a business. While the emphasis and examples of *Taking Care of Business* are particularly manufacturing oriented, they can be used by almost any type of organization, be it a small metal fabricator, a hospital, even a school. The standards are based on simple and sound business principles, systems, and processes. Each business and organization is structured in terms of similar and common systems that produce different products.

The products may be a pencil, happy customers, or educated students. The overlying systems in ISO 9000 are common to each operation.

ORGANIZATION OF THE BOOK

The first part of this book describes the strategic benefits of using ISO 9000 to “take care of business.” Three broad categories of benefits are accrued-customer/marketing, and internal and customer-supplier partnering benefits.

The first part of this book follows a simple outline:

- *Taking Care of Business.* Chapter 1 is an overview of the critical benefits of implementing ISO 9000.
- *What Are the ISO 9000 Standards?* Chapter 2 explains the structure, purpose, and objectives of ISO 9000.
- *Customer/Marketing Benefits.* Chapter 3 describes the customer and marketing benefits of implementing ISO 9000.
- *Internal Benefits.* Chapter 4 describes the internal—organizational and operational—benefits of implementing ISO 9000.
- *Customer-Supplier Benefits.* Chapter 5 describes the supplier-benefits of implementing ISO 9000.
- *Getting Started.* Chapter 6 describes how to get started implementing and registering to ISO 9000.

The second part of this book emphasizes the “what is” and “how to” implement the 20 quality system elements of ISO 9001. The 20 quality system requirements of ISO 9001 are:

4.1 Management Responsibility

4.2 Quality Systems

- 4.3 Contract Review
- 4.4 Design Control
- 4.5 Document Control
- 4.6 Purchasing Quality
- 4.7 Purchaser-Supplied Product
- 4.8 Product Identification and Traceability
- 4.9 Process Control
- 4.10 Inspection and Testing
- 4.11 Inspection, Measuring, and Test Equipment
- 4.12 Inspection and Test Status
- 4.13 Control of Nonconforming Product
- 4.14 Corrective Action
- 4.15 Handling, Storage, Packaging, and Delivery
- 4.16 Quality Records
- 4.17 Internal Quality Audits
- 4.18 Training
- 4.19 Servicing
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PART I

An Introduction to ISO 9000

CHAPTER

1

Taking Care of Business

Business assumptions are being rethought in all organizations. Restructuring may mean downsizing, partnering, reengineering, or outsourcing. Companies have discovered that the old ways of doing business don't necessarily work anymore and that new approaches are required. The goal of these approaches is to become world class and to have the best quality, service, and delivery systems.

A major element of the restructuring effort is to use quality standards such as ISO 9000 both externally and internally. Externally, companies are adopting new systems of management, such as ISO 9000, as a means to enter new markets or to satisfy international customers. They are also using ISO 9000 as a way to link up with companies in order to develop, manufacture, and deliver products and services quickly. Internally, companies are using ISO 9000 to understand, monitor, and improve their fundamental systems and processes.

The critical question, then, becomes: How can ISO 9000 help you to "take care of your business"? The complete list of benefits is covered in the first half of this book but the following are among the most important:

- Involves top management in operations.
- Proceduralizes operations.
- Facilitates operational control.

- Encourages management by exception.
- Encourages customer-supplier partnering.

INVOLVES TOP MANAGEMENT IN OPERATIONS

A revolution has erupted in corporate America. The old ways of doing business have been tossed aside and new ways are taking over. Those who spout, “If it ain’t broke, don’t fix it” are corporate dinosaurs. The new spirit is “If it ain’t improved, then we won’t have to worry about being around to fix it.”

Traditionally, organizations have been set up in departments divided into functional or professional areas. Each organizational unit developed its mandate and defended itself from intruders. Protection, inertia, conformity, and risk-averse behaviors prevailed in these organizational silos. Departments played games such as stealing ideas from other departments; avoiding ideas not invented in one’s department; shooting down requests or ideas that do not conform to prevailing attitudes; guarding information that may help the overall organization; and building bureaucracies that hold people to unrealistic rules and regulations. Issues critical to competitiveness and survival were forgotten as the issues of turf and protection took over. Departmental turf wars, political posturing, or insider games are being replaced by a cooperative, team-oriented, and partnering spirit.¹

The changes can be seen in the following areas:

- Top management is actively involved in the quality vision.
- Organizational culture, values, and ethics are changing to reflect the new quality environment.
- Quality strategy is aligned with the organization’s business strategy.
- Policies, procedures, and operational instructions are vertically and horizontally aligned and harmonized with the quality business strategy.

PROCEDURALIZES OPERATIONS

By adopting ISO 9000, each process step from designing to delivering a product is done correctly the first time. If a nonconformance should arise, the monitoring and correcting quality systems will catch and correct the deficiency. For example, internal auditing is a quality system used to ensure that processes are periodically monitored. Corrective action quality systems eliminate system deficiencies.

Quality process and systems thinking complements the goals of reengineering. Proceduralization ensures that processes are smooth, continuous, and uninterrupted. Design development and other projects are performed simultaneously. And highest value is added when interruptions are minimized and proceduralized.

Proceduralization also implies that a company is willing to spend the time and effort necessary to analyze work operations and ask additional tough questions. Policies, procedures, and work instructions are analyzed. Quality systems and processes are made flexible to satisfy changing market demands.

FACILITATES OPERATIONAL CONTROL

Fundamental to ISO 9001/9002/9003 is the concept of control. What is control? Webster defines *control* as: "to check or verify; to regulate; to verify by comparison with a standard; and to exercise authority over." The last element, "to exercise authority over," is what many people object to, especially if control is being exercised over them. In the workplace, this often implies that management or a supervisor is looking over one's shoulder, telling the person how and when to do something. This is disempowering.

With the extreme downsizing and flattening of organizations taking place today, the concept of control has changed. Control is not used anymore in the authoritarian sense of controlling

people but rather in having people control their operations. Control means defining standards of operation, keeping processes at the defined target, and controlling variation around the target. The goal implicit in ISO 9000 is to empower employees to control processes, to take responsibility for their area of operations, and to have the authority to change processes if necessary.

The fundamental goal of establishing and maintaining quality systems is to guarantee consistency. This is the basic principle behind monitoring and controlling processes. While these principles have their major application in manufacturing, they apply to all business operations, systems, and processes.

Consistency Is the Ability to Control Variation

Quality is the ability to develop consistent operations. Consistent or uniform products are obtained through controlling variation. The rationale for controlling variation is as follows:

- *Quality is conformance to requirements.* Customer requirements are spelled out in specifications, engineering prints, contracts, standards, and other documents. On a production line, conformance to a specification is assured by identifying a product's critical quality characteristics, monitoring them, and comparing them against the specification target. If there is any abnormal deviation, then the process producing the part is adjusted back to the nominal dimension.
- *Products and process vary.* Some say the study of quality is the study of variation—of a process producing products, for example, or of someone answering a phone. The more variation from what is prescribed in a policy, procedure, or work instruction, the higher the possibility of