

9000/2000

**The
Memory
Jogger™**

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**A Pocket Guide to
Implementing the ISO 9001
Quality Systems Standard
Based on ANSI/ISO/ASQ Q9001-2000**



GOAL QPC

IMPROVING THE WAY ORGANIZATIONS RUN

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Memory
Jogger™
9000/2000

A Pocket Guide to
Implementing the ISO 9001
Quality Systems Standard
Based on ANSI/ISO/ASQ Q9001-2000

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GOAL/QPC

Contents

Acknowledgments	iii
Editor's and Authors' Note	iv
How to Use <i>The Memory Jogger™ 9000/2000</i>	vi

- 1. Introduction to ISO 9000* 1
It is important to first understand the what, why, and how of ISO 9000. This chapter covers the ISO 9000 series, explains why your organization should adopt the standard, and provides an overview to the steps in achieving registration.
- 2. Getting Ready for ISO 9000* 15
This chapter covers the fundamentals of ISO 9000. It consists of three main sections: Documentation, Improving Work Processes, and Getting Ready for Registration.
- 3. The ISO 9001:2000 Standard* 53
The clauses of the ISO 9001 standard are paraphrased, and organized by sections: •Why do it? •What is it? •What's new in ISO 9001:2000? •How do I do it? •Examples of quality documents •Examples of quality records •Pitfalls •Checklists, notes, illustrations, and examples, as they apply.
- 4. ISO 9000 & Continual Improvement Efforts* .. 147
Achieving ISO 9000 registration is but a milestone toward a comprehensive quality management system. Use this chapter to check out various options for continued improvement.
- 5. Additional Resources* 165
Find out where to call or write to get copies of the ISO 9000 standard/QS-9000 Requirements and supplemental references. Also: a short history and detailed list of the standard; a reading list of related and supplemental books; and definitions of key terms and acronyms.

Refer to the blue-edged pages for detailed contents.

How to Use The Memory Jogger™ 9000/2000

The Memory Jogger™ 9000/2000 is a convenient and quick reference guide to use on the job. It is intended to serve as a reminder of the things you have already learned through training, reading, or experience.

- To get an overview of what's in each chapter, check the "Contents" on page v.
- If you have a specific topic you're interested in, go to the chapter title pages for a detailed list of the contents. Each chapter title page has a blue edge.

Who Should Use This Book?

Much has been written to describe how to make use of the ISO 9000 Quality Systems Standard. Almost all of those resources were written for *the few people* in an organization who are responsible for guiding the implementation effort; however, in the end, *every member of the company will be affected*.

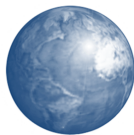
Unlike those other resources, *The Memory Jogger™ 9000/2000* was written for a broad audience, including managers, implementation teams, supervisors, staff, and all others who need to understand what **they** must do to actively contribute to the implementation and registration effort of ISO 9000.

A Note to QS-9000 Users

The Memory Jogger™ 9000/2000 is based on ISO 9001:2000. At the time of publication, no plans had been announced to modify the automotive industry QS-9000 Requirements to correspond to the revised ISO 9001:2000 clause structure; therefore, they could not be included in this edition. Users of QS-9000 are referred to the second edition of *The Memory Jogger™ 9000*, which is based on ISO 9001:1994 and remains available from GOAL/QPC.

Chapter 1

Introduction to ISO 9000



Customers and global competitiveness are changing the way organizations around the world are doing business. Quality is leading that change, providing quality products and services to keep your customers coming back. However, quality doesn't happen just because you talk about it.

To achieve quality you must work at it by understanding your processes—the work you do every day—and continually improving them.

Standardizing your work into an organized and documented system can provide the foundation for a comprehensive quality management program. ISO 9000 standards are helping organizations do just that!

<i>What does ISO mean?</i>	2
<i>What is ISO 9000?</i>	2
<i>The ISO 9000 Core Standards</i>	3
<i>Clauses in the ISO 9001:2000</i>	
<i>Quality Systems Standard</i>	4
<i>Why are we adopting ISO 9000?</i>	8
<i>Key terms</i>	9
<i>Quality Management Principles</i>	10
<i>Preparing for ISO 9001 registration</i>	11
<i>Steps to registration</i>	12

Why are we adopting ISO 9000?

Organizations adopt ISO 9000 standards for different reasons. Your organization's decision to do so may include:

- To comply with customers who require ISO 9000
- To sell in the European Union (EU) markets
- To compete in domestic and worldwide markets
- To improve your quality system
- To minimize repetitive auditing by similar and different customers
- To improve suppliers' performance

Global benefits include:

- A widening acceptance of the standards
- A worldwide availability of the standards in many languages, which enhances communication between multinational customers and suppliers

Both you and your organization benefit because use of ISO 9000 serves as a basis to:

- Achieve better understanding and consistency of all quality practices throughout the organization
- Ensure continued use of the required quality system year after year
- Improve documentation
- Improve quality awareness
- Strengthen organization/customer confidence and relationships
- Yield cost savings and improve profitability
- Form a foundation and discipline for improvement activities within the quality management system

Of course, these benefits are achieved only with good planning, hard work, and continuous improvement.

Quality Management Principles

The following eight principles have been identified by the ISO quality standards writing committee to facilitate achievement of quality objectives.

a) Customer focus

- Understanding current customer needs
- Understanding future customer needs
- Meeting customer requirements
- Striving to exceed customer expectations

b) Leadership

- Establishing unity of purpose and direction for the organization
- Establishing the organization's internal environment

c) Involvement of people

- Developing abilities fully
- Using abilities to maximum benefit

d) Process approach

- Managing resources as a process
- Achieving desired results more efficiently

e) Systems approach to management

- Identifying,
- Understanding, and
- Managing the interrelated processes of a system to effectively and efficiently attain objectives

f) Continual improvement

- Making improvement a permanent objective

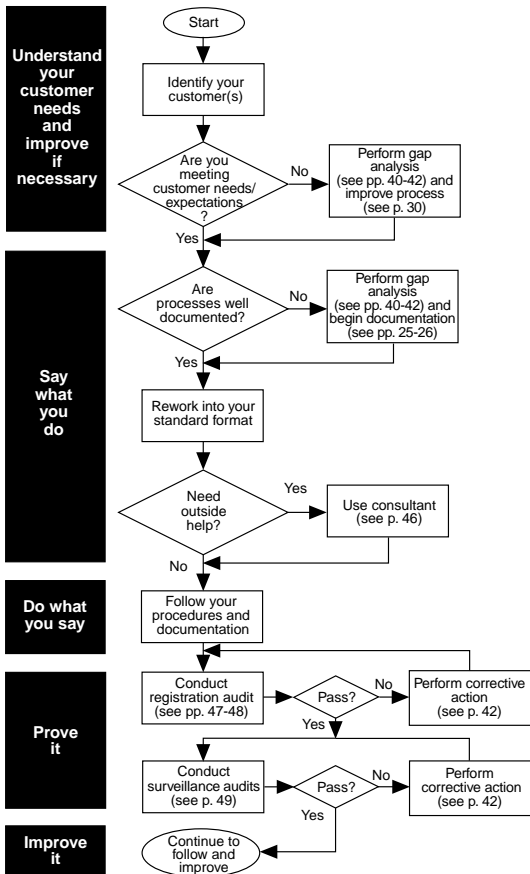
g) Factual approach to decision making

- Analyzing data and information logically

h) Mutually beneficial supplier relationships

- Creating value through mutually beneficial, interdependent relationships

ISO 9001 Process Flowchart



Suggestions for Writing Documentation

Procedures, Work/Job Instructions, and Other Documentation

- Keep it short and simple. Don't "over-document."
- Flowchart a process, if appropriate (see pp. 32–34). Make extensive use of charts and tables.
- Use a standardized format.
- Keep the audience in mind:
 - Make the meaning very clear; have someone else read it and explain back what you said.
 - Make the text grammatically correct.
 - Search out errors in spelling and punctuation.
 - Avoid jargon.
 - Separate ideas into individual sentences or paragraphs.
 - Write to the task, not an individual. Documents are written to help workers perform their tasks more efficiently and consistently.
 - Ask the user to help write the documentation, where possible.
- For every task, identify:
 - Who is responsible for ensuring that it is done
 - Standards to be met/completion criteria
 - What resources are needed
 - What records are kept
 - What to do if it doesn't work
- Pre-test procedures. Have those who will use the procedures try them and provide feedback.

Sample Work/Job Instruction

Tank Car Wash Rack and Inspection	
Document no.: TKWR02	Description: Tank car wash and inspection
Revision no.: 0	Sheet: 1 of 3
Prepared by: Paul Brown	Approved by: T. Jones
Issued by: Cleaning Section	Issue Date: May 31, 1991

1.0 Introduction

Prior to loading, most tank cars are washed and internally and externally inspected. Cars that are recycled for specified products are not washed. These recycled tanks are controlled by the shipping services supervisor.

2.0 Preparation

1. Switching crew selects tank car.
2. Secure tank car by chock and hand brakes.
3. Connect ground cables to each car.
4. Attach safety appliances to each car.
5. Depressurize all pressurized tanks.
6. Manway bottom outlet valves.
7. Open: Secondary valves
Vent valves
Induction valves.
8. Remove cap from bottom outlet valve nozzle.

Reprinted from ISO 9000: Preparing for Registration, James L. Lamprecht, by courtesy of Marcel Dekker, NY, 1992, p. 95

A "controlled document" will have:

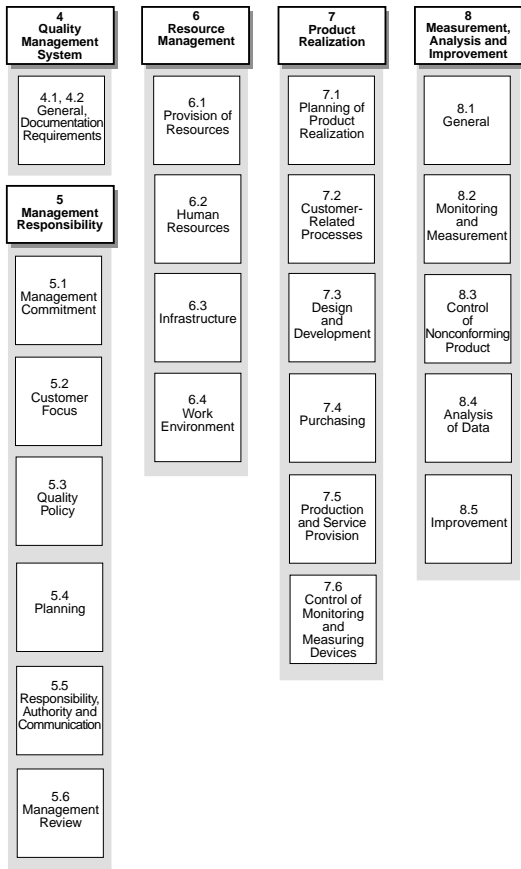
- (a) Title**
- (b) Document number** (a unique identifier)
- (c) Revision indicator** (e.g., Rev. A, -001, B)
- (d) Page number** (e.g., Page 1 of 3, Page 1.2, 1-2.3)
- (e) Date issued/revised** (e.g., April 6, 1996, 4/6/96)
- (f) Approval** (the approving authority by signature and perhaps also position title)
- (g) Prepared by/Issued by** (name, position, and/or department)

ISO 9000 Preparation Checklist

Area of Preparation	✓	Questions/ Tasks
Quality Manual	<input type="checkbox"/>	Is it complete?
	<input type="checkbox"/>	Does it contain all elements that you want to be registered? Are there other standards in addition to the ISO 9001 standard?
Application for Registration	<input type="checkbox"/>	Have you selected your registrar?
	<input type="checkbox"/>	Have you completed the application for registration and assessment?
	<input type="checkbox"/>	Does this company provide the long-term relationship you are seeking?
Internal Audits	<input type="checkbox"/>	Have you reviewed all recent (last two years) internal audits to ensure that all items are closed?
	<input type="checkbox"/>	Were there any systems issues that should be re-reviewed at this time?
Audit Agenda	<input type="checkbox"/>	Has this been finalized? Are all areas that you consider important scheduled to be assessed (so you get the most out of the assessment)?
Procedures	<input type="checkbox"/>	Are all standard operating procedures current with the quality manual policies and requirements?
	<input type="checkbox"/>	Do procedures in all areas correspond to the current revision status? Is the control of procedure revisions well understood by all personnel (and adhered to)?

Continued on next page

ISO 9001:2000 Process Model for Quality Management



Index

- American National Standards Institute, 2, 166
- ASQ Quality Press, 166
- audit
 - for registration, 47-48
 - internal, 129-131
 - preparation checklist, 50-51
 - steps involved, 13
 - surveillance, 13, 49
- auditors, working with, 46
- AIAG, 167
- Baldrige award criteria, 155-158
 - compared with ISO 9001, 157
- Canadian standards association, 166
- capability indices, 37
- certification, definition of, 9
- common cause, 35
- comparison of clause structure, 61-64
- consultant, role of, 46-47
- continuous improvement
 - after ISO 9000 registration, 148
 - and ISO 9001, 149-150
 - basic principles of, 159
 - See also* Plan-Do-Check-Act Cycle; process improvement
- contract review process, 95-96
- control chart, 36
- control of monitoring and measuring devices, 122-124
- corrective and preventive action, 142-146
 - problem-solving model, 146
- customer focus, 74-83
- customer property, 116-117
- customer-related processes, 93-96
- customer satisfaction, 18, 127-128
- data analysis, 140-141
- data collection, 38
- design and/or development, 97-102
- design validation versus verification, 102
- document and data control, 29, 74-83
- documentation for ISO 9000, 20-29
 - sample documents, 26, 28
 - writing suggestions, 25
- environmental management, 163-164
- flowcharting a process, 32-34
- gap analysis, 40-42
- improvement, 142-146
 - See also* continuous improvement; process improvement
- internal standard. *See* ISO 9004
- International Organization for Standardization, 2, 166
- ISO 9000, 20-29
 - description of series, 3
 - history, 168
 - process in flowchart form, 17
 - registration. *See* registration
- ISO 9000 standards, 169-170
 - basic requirements, 11
 - compliance with, 3
 - how individuals help implement, 16
 - reasons for adopting, 8
- ISO 9001
 - compared with Baldrige, 157
 - lessons learned, 52
 - list of clauses, 4-7
 - process model for quality management model, 60
 - quality assurance model, 59
 - use after registration, 131
 - See also* continuous improvement

- ISO 9004
 - as a guideline, 3
 - as a tool for improvement, 151
- management responsibility, 74-83
- management review, 77
- monitoring and measurement,
 - 122-124
 - of processes, 132-133
 - of product, 134-136
- nonconformity, 137-139
- organization, 9
- Plan-Do-Check-Act Cycle, 19, 31
- preservation of product, 118-121
- preventive action. *See* corrective and preventive action
- procedure. *See* quality procedures
- process
 - capability, 37; *See also* variation
 - how to flowchart, 32-34
- process control system, 35-37
- process improvement, 30-34
 - model for, 31
- product identification and traceability, 113-117
- purchasing, 103-107
- QS-9000, *vi*
 - and quality improvement, 152-153
 - customer reference manuals, 154, 167
- quality audit. *See* audit
- quality management principles, 10
- quality manual, preparing,
 - 22, 74-83
 - See also* quality procedures
- quality plan, example, 82, 83
- quality policy, 75, 79
- quality procedures
 - preparing, 23
 - sample format, 26, 71
 - writing process, 24-25
- quality records, 67
- quality systems standard,
 - composition of, 2
 - See also* ISO 9001
- registrar, 45-46
- registration
 - how attained, 2
 - preparation for, 11-14
 - See also* documentation for ISO 9000
 - roles and duties, 43-44
 - use of term, 9
- registration audit. *See* audit
- resource management, 84-88
- second party, 2
- servicing, 109-110
- special cause, 35
- statistical techniques,
 - 133, 140-141
- subcontractor, 9
- supplier, 9, 103-106
- surveillance audit. *See* audit
- third party, 2
- tool and data chart, 39-40
- tools for quality improvement,
 - 160-162. *See also* process improvement
- training, 85, 87
- variation, 35-37
- verification versus validation, 102
- work/job instructions
 - documentation, 25
 - preparing, 27
 - sample document, 28
- work procedure. *See* quality procedures