ISO 9001: 2000 In Brief

Ray Tricker

ISO 9001:2000 in Brief

About the Authors

Ray Tricker (MSc, IEng, FIIE (elec), FInstM, MIQA, MIRSE) as well as being the Principal Consultant and Managing Director of Herne European Consultancy Ltd – an organisation specialising in Quality, Environment and Safety Management Systems – is also an established Butterworth-Heinemann author (see Reference section). He served with the Royal Corps of Signals (for a total of 37 years) during which time he held various managerial posts culminating in being appointed as the Chief Engineer of NATO ACE COMSEC.

Most of Ray's work since joining Herne has centred on the European Railways. He has held a number of posts with the Union International des Chemins de fer (UIC) [e.g. Quality Manager of the European Train Control System (ETCS), European Union (EU) T500 Review Team Leader, European Rail Traffic Management System (ERTMS) Users Group Project Co-ordinator, HEROE Project Co-ordinator, ERRI Quality Consultant] and currently (as well as writing books for Butterworth-Heinemann!) he is busy assisting small businesses from around the world (usually on a no cost basis) produce their own auditable Quality Management System to meet the requirements of ISO 9001:2000. He has also recently been appointed as UKAS Technical Specialist for the assessment of Notified Bodies for the harmonisation of the trans European high-speed railway system.

For this book Bruce Sherring-Lucas (MIQA) joins Ray. Bruce was, for many years, employed by British Rail and held many managerial positions (e.g. West Coast Main Line Special Structures Manager, Project Manager for the Eurostar Track, Platforms and Overhead Catenary realignment and WCML Infrastructure Database population).

As a consultant Bruce worked with Ray at Herne European Consultancy Ltd and was instrumental in writing the ERTMS Environmental Specification for the European Railways, producing a generic Quality Management System for the UK dental technology profession and Railway Safety Specifications (for a German organisation specialising in train control systems). He has also been a member of the ERTMS Users Group Reliability, Availability, Maintainability and Safety (RAMS) Team.

Since returning to the railways, as the Network Rail West Coast Main Line Quality Development Manager, Bruce has been responsible for the successful certification of the West Coast Route Modernisation Project to the exacting standards of ISO 9001:2000. This achievement, completed within a multi-billion pound construction project, is believed to be a first within the railways.

> To Lynne and the Boys
> (Michael, Andrew and Luke)

ISO 9001:2000 in Brief

Second edition

Ray Tricker

and

Bruce Sherring-Lucas

Routledge
Taylor & Francis Group

LONDON AND NEW YORK

Contents

This page intentionally left blank

Foreword

There has never been a time when the demand for quality has been so high! We long ago stopped settling for 'second best' and now expect and demand consistently reliable products or the efficient dependable delivery of services. Out of this demand has come the necessity for manufacturers and suppliers to have some form of auditable Quality Management System. But how can this be achieved?

The aim of *ISO 9001:2000 in Brief* is to provide the reader not only with an explanation of the background, the requirements and the benefits of the new ISO 9000:2000 family of standards but also, at very little expense, to assist organisations (large or small) to set up an ISO 9001:2000 compliant Quality Management System for themselves.

Explanations are kept as simple as possible so as to appeal to students, newcomers to Quality Assurance or the beleaguered executive with little time to come to terms with the subject.

This page intentionally left blank

Preface

The ISO 9000:2000 family is an all-encompassing series of standards that lay down requirements for incorporating the management of quality into the design, manufacture and delivery of products, services and software. The family consists of three standards. These are:

- **ISO 9000:2000 Quality Management Systems – Fundamentals and vocabulary** (superseding ISO 8402:1995 and ISO 9000–1:1994). Describes fundamentals of Quality Management Systems and specifies their terminology.
- **ISO 9001:2000 Quality Management Systems – Requirements** (superseding ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994). Specifies the requirements for Quality Management Systems for use where an organisation's capability to provide products that meet customer and applicable regulatory requirements needs to be demonstrated.
- **ISO 9004:2000 Quality Management Systems – Guidelines for performance improvement** (superseding ISO 9004–1:1994 and ISO 9000–2:1993). Provides guidance on Quality Management Systems, including the processes for continual improvement that will contribute to the satisfaction of an organisation's customers and other interested parties.

To achieve its main objectives, ISO 9001:2000 requires the manufacturer, or supplier, to possess a **fully auditable Quality Management System** consisting of Quality Policies, Quality Processes, Quality Procedures and Work Instructions. It is this Quality Management System that will provide the auditable proof that the requirements of ISO 9001:2000 have been and are still being met.

The main parts of the book are as follows:

- What is Quality?
- What is a Quality Management System?
- The history of Quality Standards
- Who produces Quality Standards?
- What is ISO 9001:2000?
- How Quality helps during a product/service life cycle

- Who controls Quality in an organisation?
- What are the purchasers' responsibilities?
- What are the suppliers' responsibilities?
- What to do once the Quality Management System is established
- How computer technology can be used to improve a QMS.

For convenience (and in order to reduce the number of equivalent or similar terms) the following, unless otherwise stated, are considered interchangeable terms within this book:

- product – hardware, software, service or processed material;
- organisation – manufacturer and/or supplier.

The first edition of *ISO 9001:2000 in Brief* was written during the transition between the 1994 version of the standard and the all new 2000 edition. Consequently, the book was based substantially on the authors' interpretation of the new standard.

Nearly four years have passed since the introduction of the new standard and theoretical interpretation has been replaced with a sound understanding and experience in the actual implementation of the requirements. Whilst the requirements of ISO 9001:2000 have not changed, *ISO 9001:2000 in Brief* has been revised to reflect experiences gained over the last four years.

The revisions to the second edition of the book include:

- Reordering the quality management system structure to give process maps precedence over quality procedures
- Assistance on how to develop mission statements and policy statements
- Guidance on the mandatory written procedures required by the standard
- A method of setting Quality Objectives
- Amplification on the various components which comprise a process
- Compatibility with other Management Systems
- A summary of the Eight Principles of Management which are applied within the standard
- A synopsis of the 21 responsibilities that senior management must adopt to ensure the successful implementation of the standard
- An entirely new chapter on what to do once you have installed your quality management system, detailing:
  - The principles of continual improvement
  - How to measure processes
  - Utilising Six-Sigma methodology to improve your processes

- Auditing
- How to progress towards certification
- Another new chapter on the use of computer technology in Quality Management, including the benefits of using company intranets to control quality documentation
- A new Annex giving a comprehensive summary of the ISO 9001:2000 requirements and the intent of each clause
- Updated references and contact lists.

We have also taken the opportunity to remove a large amount of cross reference to the 1994 version of the standard, as this should now be confined to the history books.

This page intentionally left blank

Introduction

As a challenge we were once set the task of explaining ISO 9001:2000 in less than 500 words. It was this single action that resulted in the creation of this book. So, by way of an introduction we can think of no better way than reprinting our explanation, which could be titled *'ISO 9001:2000 in Extreme Brevity'*!

The principle of Quality Management

A comprehensive and fundamental rule or belief, for leading and operating an organisation, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all interested parties.

ISO/TC 176

ISO 9001:2000 is the internationally recognised standard for Quality Management Systems. It provides the benchmark against which companies are measured and if found to be adequate, certified as compliant.

ISO 9001 was first released in 1987 and comprised of 20 elements. It was relatively easy for companies to meet these requirements without actually embracing the intent of the standard. In many cases compliance simply meant a badge on the wall and nothing more. The 2000 version of the standard sought to address this issue and many other deficiencies found in the previous standard.

The current standard is much more business focused, aimed as it is at improving an organisation's management system through the application of eight principles:

1. **Customer focus** – Seeking to satisfy the demands and expectations of the purchaser.
2. **Leadership** – Provision of purpose and direction, such that everyone can achieve the organisation's goals.

3. **Process approach** – The logical sequencing of activities to efficiently achieve a desired result.
4. **System approach** – Managing inter-related processes as a system.
5. **Factual approach** – Decision making based on the analysis of data.
6. **Involvement of people** – The proactive participation of all people in promoting the quality ethos.
7. **Mutually beneficial supplier relationships** – The mutual support of an organisation and its suppliers adds value.
8. **Continual improvement** – Constantly refining processes enables an organisation to become more efficient.

These principles are reflected in the requirements of the 2000 version of ISO 9001, which, in addition to general requirements is structured into four main sections:

1. Management responsibility
2. Resource management
3. Product realisation
4. Measurement, analysis and improvement

The model shown below indicates how each of these sections inter-relates and how continual improvement impacts on all aspects of business management.
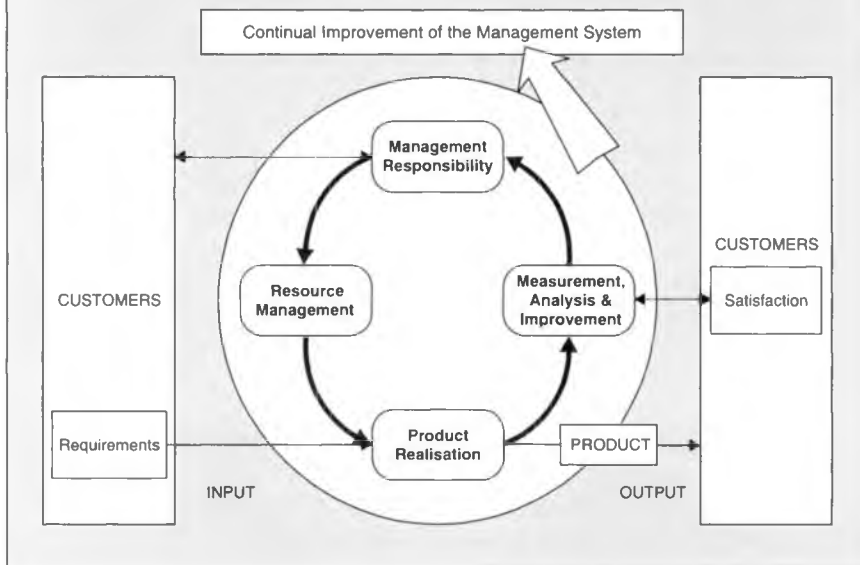
- **Management responsibility**
  The standard requires senior management to *provide evidence of its commitment to the development and implementation of the Quality Management System.*
- **Resource management**
  This part of the standard requires an organisation to *determine and provide the resources needed to implement and maintain the Quality Management System.*
- **Product realisation**
  Probably the most important part of the standard in which an organisation is mandated to *plan and develop the processes needed for product realisation.*
- **Measurement, analysis and improvement**
  No Management System can be effective without a suitable means of measuring its performance. The standard calls for an organisation to *plan and implement the monitoring, measuring, analysis and improvement processes needed* to prove the effectiveness of the Management System and its deliverables.

This short paper provides a very brief overview of the standard and, if that is all you bought the book for, it has served its purpose. However, the rest of this book is well worth a read as it expands upon and explains each of these principles in greater depth.

This page intentionally left blank

1 WHAT IS QUALITY?

Why is the word 'Quality' (although an everyday word), often misused, misquoted and misunderstood? Probably this is because when most people talk about the quality of an object, or service, they are normally talking about its excellence, perfection or its value. In reality, of course, they should be talking about how much it meets its designed purpose and satisfies the original requirements.

Take for example a £50,000 Mercedes and a £15,000 Ford. It would be very unfair to suggest that the Mercedes is a better quality car simply because it costs more! Being realistic, both cars meet their predetermined quality requirements because they have been built to exacting standards and are, therefore, equally acceptable as 'quality' vehicles. It is simply that the design purpose and original quality requirements (i.e. the level of quality) differ.

So what exactly is **meant** by the word quality? There are many definitions but the most commonly accepted definition of quality is '*The degree to which a set of inherent characteristics fulfils requirements*' (ISO 9000:2000).

In other words, quality is based upon customer satisfaction. So in the case of the Mercedes and the Ford, a purchaser of a Mercedes will be satisfied only if they get leather seats and cruise control, whereas the Ford driver is happy with crushed velour and a CD player. Their required level of quality differs but each is equally satisfied with their purchase. The characteristics of each car satisfy the customer's requirements.

Consumers, however, are not just interested in the level of quality 'intended' by the designer, manufacturer or supplier, they are far more interested in the delivery of a product (i.e. hardware, software, service or processed material) which is **consistently** of the same quality. They also want an assurance that the product that they are buying truly meets the quality standard that was initially offered and/or recommended.
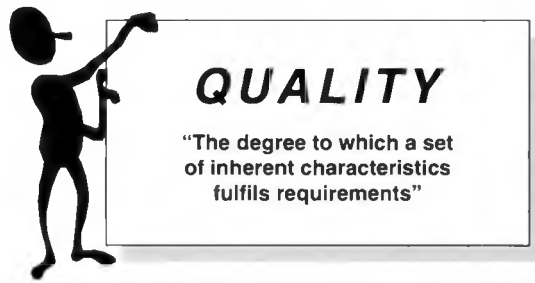
Figure 1.1 Definition of quality

Products of a consistent quality mean that repeat purchases are more likely; something which any car driver appreciates when considering whether to stay with a preferred make and model.

This consumer requirement has meant that manufacturers and suppliers (especially the larger organisations) have now had to pay far more attention to the quality of their product than was previously necessary. Organisations have had to set up proper Quality Management Systems in order to control and monitor all stages of the production process and they have had to provide proof to the potential customer that their product has the guaranteed – and in some cases certified – quality required by the customer. In other words, the manufacturer or supplier has had to work within a Quality Management System (see Figure 1.2 for details) to produce their product or deliver their service.

Unfortunately, with the current trend towards micro-miniaturisation and the use of advanced materials and technology, most modern day products have become extremely complex assemblies compared to those that were available just a few years ago. This has meant that many more people are now involved in the manufacture and/or supply of a relatively simple object and this has increased the likelihood of a production or design fault occurring.

Similarly, the responsibility for the quality of a product has also been spread over an increasing amount of people, which has meant that the manufacturer's and/or supplier's guarantee of quality has, unfortunately, become less precise.

The growing demand for an assurance of quality before a contract is awarded has reinforced the already accepted adage that quality products play an important role in securing new markets as well as retaining those markets that already exist. Without doubt, in these days of competitive world markets, quality assurance has never been more relevant. No longer can suppliers rely on their reputation alone!

Thus the drive towards quality-led production now means that today's purchasers are not just expecting a quality product but are also demanding proof that an organisation is constantly capable of producing quality products or providing quality services. The provision of this proof is normally
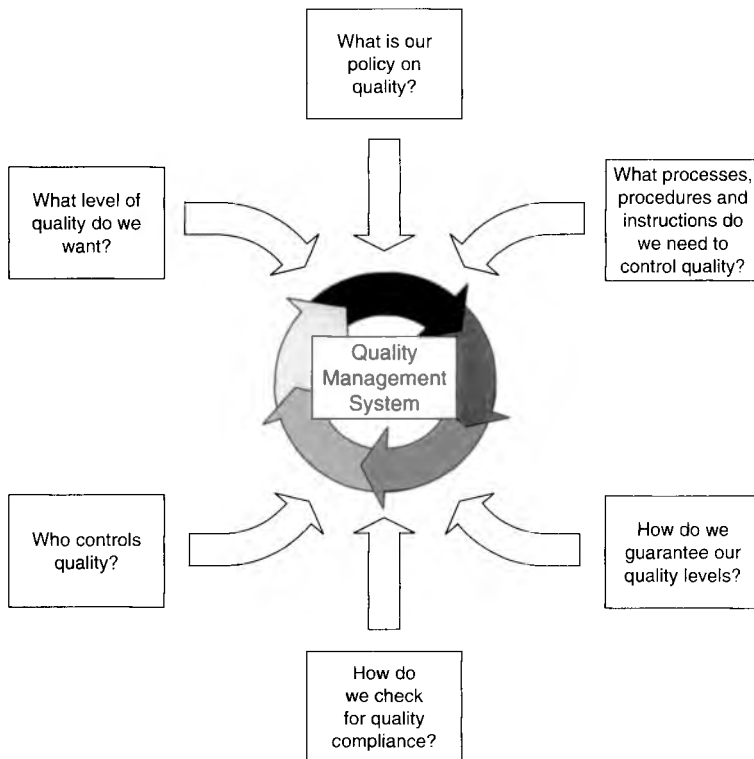
Figure 1.2 Some of the questions answered by a Quality Management System

in the form of an independent third party certification and this is possibly the single most important requirement for a manufacturer, organisation or supplier.

Up until a few years ago, however, there were no viable third party certification schemes available. But with an increased demand for quality assurance during all stages of the manufacturing processes, came the requirement for manufacturers to work to recognised standards, and this is why ISO 9000 was first introduced.

So in summary, 'Quality' **is**:

- giving complete satisfaction to the customer;
- a standard which can be accepted by both the supplier **and** the customer;
- complying consistently to an agreed level of specification;
- providing an acceptable product at an acceptable cost;
- providing a product which is 'fit for the purpose';
- the totality of features or characteristics of a product that bear on its ability to satisfy a given need.

Quality **is not** about:

- complying with a specification (as it is possible that the specification may be wrong);
- being the best (since achieving this ideal may be very costly and could exceed the price that the customer is prepared to pay);
- only producing a product that is 'fit for the purpose' (as that purpose may be completely different to the customer's actual needs).

Quality is all about customer satisfaction!