



*Centre for Advanced Engineering*  
University of Canterbury

# **Quality Assurance Systems for Smaller Manufacturers**

**INTRODUCTORY GUIDE**

**by A.I. Shaw**



Centre for Advanced Engineering

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QUALITY ASSURANCE  
SYSTEMS FOR SMALLER  
MANUFACTURERS

**INTRODUCTORY GUIDE**

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**by A I Shaw**



**University of Canterbury  
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# Centre for Advanced Engineering

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## Establishment

The Centre for Advanced Engineering was founded in May 1987 to mark the centenary of the School of Engineering at the University of Canterbury. It was established by means of an appeal fund launched in conjunction with the centennial celebrations. To date, approximately \$2.24 million has been raised, contributed by 144 corporate donors and 660 individual donors. The earnings from this capital sum are used to run the Centre and fund its activities.

## Objective

The objective of the Centre is to enhance engineering knowledge within New Zealand in identified areas judged to be of national importance, and to engage in technology transfer of the latest research information available from overseas. The Centre is not concerned with basic engineering research, but more with the application of research findings to engineering problems.

This objective is achieved for each major project by bringing together a selected group of practising and research engineers and experts in the particular field from both within New Zealand and overseas to:

- consolidate existing knowledge
- study advanced techniques
- develop approaches to particular problems in engineering and technology
- promote excellence in engineering
- disseminate findings through documentation and public seminars.

The Centre thus creates for each project a unique forum that facilitates co-operation among industry, the engineering profession and university research engineers.

## Function

The Centre is controlled by a Board of Directors comprising representatives from industry, the engineering profession and the University of Canterbury. The present Chairman of the Board is Mr Gavin Cormack of Auckland.

The Board selects the title of each project undertaken by the Centre and approves the level of funding. A Steering Committee is appointed, initially to carry out detailed planning for the project and then to provide overall direction. The Steering Committee then appoints Task Group Leaders and a Project Manager.

Detailed work on the project is carried out on a voluntary basis by the members appointed to each Task Group. The Centre arranges to bring to New Zealand, at the appropriate time, several Visiting Fellows who work with Task Group members and contribute to the project the latest available information from overseas.

The Centre also undertakes smaller projects such as the one described in this report on subjects of current concern to engineers, and arranges lectures and seminars on appropriate topics as the occasion arises.

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# **Setting the Scene : the Growing Need for Quality Assurance Systems**

## **A Layman's Guide to ISO 9000 Certification**

**(A summary prepared from the Country Saturday programme broadcast on National Radio, 7.05 am, 27 February 1993)**

ISO stands for the International Standards Organisation, which is based in Geneva, and 9000 is the numerical system it uses for describing its series of quality management standards.

ISO 9000's origins are military, coming out of the post-Second World War aerospace and nuclear industries and the ever-increasing reliance on sub-contractors. The American military developed the first official quality system standard for procuring defence equipment in 1963.

Australia was the first country to produce a standard for non-military purposes in 1975. Other countries, such as Britain and Canada, followed with their own set of national quality standards, none of which was totally compatible with the others. This became a hindrance to international trade as manufacturers found they had to comply with more than one set of standards. To overcome this, the International Standards Organisation began a project in the 1980s to develop one internationally accepted standard for quality management systems. It published the ISO 9000 series in 1987. Since then, more than 50 countries, including New Zealand, have adopted the ISO series, although some have different names for it.

In New Zealand, it is known as NZS 9000. In Australia, it is known as AS 3900. In Britain it is still known as BS 5750. In America it is Q 90. However, it doesn't matter what it is called locally, as all are taken from the original Geneva ISO document.

What ISO 9000 does is to provide a series of model quality management systems that companies can aspire to.

Many people are familiar with product standards. The ISO 9000 standards are similar, but instead of applying to a product they apply to quality management systems. They describe basic quality management systems that could be applied to any kind of organisation. They are a generic framework, a model that can be adopted by any kind of company.

The core documents used within industry are ISO 9001, 9002 and 9003. ISO 9003 is the simplest in the series. It is a standard which is all about sorting the good from the bad at the back door. That may be fine from the customer's point of view, but it doesn't do anything for the manufacturer. The manufacturer is still making defective product and somebody has to pay for it.

ISO 9002 then comes along and builds on 9003, adds in a few more clauses to try and get it right the first time. It is the standard that brings the discipline to the manufacturing of the products to try and avoid the mistakes in the first place.

ISO 9001 goes one step further and introduces formal quality management of the design process. In this context, design is used in its widest possible sense to mean design developments or formulation of a product. The top of the line programme is one that aims to ensure that the customer's needs are understood, the product is designed to meet those needs and that the product is manufactured without mistakes. At the end of the day, the final inspections of 9003 are still done just to catch any mistakes which have been made.

There are now seven agencies in New Zealand that audit and certify quality management systems. They include Standards New Zealand, formerly the Standards Association; Telarc, a user-funded quasi-government agency that began life as a laboratory auditing body; and a number of private organisations.

ISO 9000 certification has become an enormous growth industry in New Zealand. The number of companies that Telarc alone has signed up for ISO 9000 has risen from about 50 in early 1989 to 650, with about 25 new applications each month.

In continental Europe, the demand is growing, essentially for market reasons rather than regulatory reasons. There is certainly an indication as to how the EC as a body is moving in that there is a draft directive on food hygiene which states that ISO 9000 certification is recommended as the minimum quality standard, but this is by no means mandatory. However, the three reasons for the market demand in Europe are that:

- the customer is demanding quality;
- companies selling transnationally are seeking products of uniform quality; and
- there is increasing attention being paid to the EC product liability directive of 1985, which puts the onus of responsibility for a malfunctioning product on the manufacturer. In the case of the importer of foreign products, this puts the onus of responsibility on the importer, who in turn is going to be demanding of a foreign supplier that they provide some form of quality assurance and certification to the ISO standard.

The trend is definitely gaining momentum in Europe. In the UK for example 16,500 companies have been certified to the ISO standard, 500 of which belong to the food and beverage industry. In France, the figure is about 200 companies certified, 170 of which have been certified in the last twelve months. In the USA, the government bodies are looking very critically at the ISO standards and looking at building in the standard in many respects to regulations.

ISO 9000 defines a set of basic disciplines, basic structures and systems and procedures that just about any kind of company can put in place. Total Quality Management, or TQM as it is known, goes one step further and involves almost a philosophy in the way of doing business, a commitment to the customer, a commitment to ongoing improvements and a commitment to a certain level of statistical control of processes to optimise them.

Once companies have developed their ISO 9000 system, they should then be moving on to formal TQM systems. ISO 9000 systems are regarded as being the foundation on which TQM programmes are built. An analogy often used is that of a large communication tower with a revolving restaurant on top. This can be called the "TQM tower" or the "quality improvement tower". In order to keep the tower upright there is an enormous block of concrete underneath as a solid foundation. That is the ISO 9000 quality system. It is this foundation of basic quality management disciplines on which a quality improvement programme is then built.

# CONTENTS

<b>Foreword</b>	<b>iii</b>
<b>Executive Summary</b>	<b>v</b>
<b>Glossary</b>	<b>vii</b>
<b>1 Introduction</b>	<b>1</b>
1.1 Background to the Study	1
1.2 History and Purpose of Quality Systems	1
<b>2 Quality Systems</b>	<b>3</b>
2.1 Quality Systems	3
2.2 National Quality Standards	3
2.3 Selection and Use of Quality Systems	4
<b>3 ISO 9002 : 1987 — An Overview</b>	<b>5</b>
3.1 Management Responsibility	5
3.2 Quality System	6
3.3 Contract Review	9
3.4 Document Control	9
3.5 Purchasing	10
3.6 Purchaser - Supplied Product	10
3.7 Identification and Traceability	10
3.8 Process Control	11
3.9 Inspection and Testing	12
3.10 Inspection, Measuring and Test Equipment	13
3.11 Inspection and Test Status	14
3.12 Control of Non-conforming Product	15
3.13 Corrective Action	15
3.14 Maintaining Post-production Quality	16
3.15 Quality Records	16
3.16 Internal Quality Audits	17
3.17 Training	17
3.18 Statistical Techniques	17
<b>4 Certification of Quality Assurance Systems</b>	<b>18</b>
4.1 Certification	18
4.2 Accredited Certification Bodies	18
4.3 Certification Process	19
4.4 Certification Benefits	20
<b>5 Certification Bodies, Training and Grants</b>	<b>21</b>
5.1 Certification Bodies	21
5.2 Professional Bodies	22

5.3	<i>Training Opportunities</i>	23
5.4	<i>Grants and Prizes</i>	24
5.5	<i>Consultants</i>	26

<b><i>Appendix 1</i></b>	<b>27</b>
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*Summary of Part One: Pilot Study on Quality Assurance Systems for  
Smaller Manufacturers in Canterbury*

# FOREWORD

In August 1991 the Board of Directors of the Centre for Advanced Engineering agreed to fund a Pilot Study with the aim of producing a document outlining quality assurance procedures suitable for smaller manufacturers. It was observed that there was an increasing demand for such companies to adopt quality assurance systems.

Mr Andrew Shaw who completed his postgraduate studies in the Department of Mechanical Engineering at the University of Canterbury in 1991 with a thesis on the introduction of quality assurance systems was engaged to undertake the initial work. Mr Shaw had also completed two years working with a manufacturing engineering company on the design and implementation of a quality assurance system within the company, before becoming a consultant.

Part One of the project was commenced in late 1991 and completed in October 1992, with a report detailing the results of a survey of manufacturing firms in Canterbury in regard to their current needs in the implementation of quality assurance systems.

Part Two of the project was then undertaken to produce this introductory guide to the implementation of quality assurance systems for smaller manufacturers.

At regular intervals the work on the project has been reviewed by a panel including the writer and Dr P Venkateswarlu, Lecturer in Management and Dr P G Hodgson, Lecturer in Mechanical Engineering, both of the University of Canterbury.

It is hoped that this report will provide useful information to many smaller manufacturing companies who are at present contemplating the implementation of a quality assurance system with their organisation.

**J P BLAKELEY  
EXECUTIVE DIRECTOR  
CENTRE FOR ADVANCED ENGINEERING  
UNIVERSITY OF CANTERBURY**



# EXECUTIVE SUMMARY

During the last 10 years, the increasing implementation of Quality Systems in the manufacturing industry has gained momentum. Smaller manufacturers are now coming more into contact with organisations that operate Quality Systems and are now themselves having to consider the relevance of Quality Systems and management principles within their own organisations.

There are now approximately 600 organisations in New Zealand that have Quality Assurance Systems registered to a recognised standard. This number is increasing rapidly. The main reasons driving the introduction of such systems are:

- use of systems to strengthen competitiveness and achieve product quality; and
- satisfaction of contractual requirements demanding the existence of quality system elements.

This guide gives an introduction to Quality Systems. It emphasises that the introduction of such systems should be company-wide and that the responsibility for quality involves all those personnel within the organisation.

This introductory guide is aimed primarily at providing information to company managers who wish to know more about Quality Assurance Systems currently being implemented in New Zealand and the requirements of such systems.

The guide is further aimed at those smaller manufacturing companies who are currently considering options with regard to the implementation of Quality Systems. The guide is split into three broad areas:

- History and development of QA Systems and associated standards. This includes a description of these standards and their content and a short guide to the selection and use of these standards.
- The requirements associated with the introduction and registration of a Quality System to be employed in a contractual situation. This includes a review of ISO 9002 and discussion of the certification procedure.
- An information section detailing training, grants and organisations associated with the Quality Assurance field.

The guide does not detail the cost of the implementation of such systems, as the amount of work required is dependent upon the extent to which elements of the systems are already employed by the company. The explanation of the requirements of ISO 9002 should help managers identify the amount of work they need to undertake to introduce a system. The following general observations can be made for smaller organisations:

1. Sufficient resources are required to enable trained personnel to plan and implement the introduction of the Quality Assurance System. If an external consultant is employed for this task, costs would be in the vicinity of \$10,000 to \$20,000.
2. Sufficient time and resources must be set aside for the documentation of the Quality System. This will involve the planning and writing of a Quality Manual and procedures.
3. External auditing of QA Systems for smaller manufacturers will cost approximately \$6000 to \$8000, depending on the organisation's size and range of activities.



# GLOSSARY

## Introduction

This guide has been written to appeal to company managers and senior management considering the implementation of Quality Systems in their organisations. Where possible, the terms and definitions used in the guide are explained. However, there are some terms which have specific meanings and applications when used in the quality field. These are listed below. Section 3 of NZS 5604:1987/ISO 8402 1986 may be viewed for a more comprehensive vocabulary.

<b>Certification Body</b>	An independent agency or body that provides a third party audit of a quality system to a standard or specification.
<b>Conformance</b>	The fulfilment of quality characteristics or quality system elements to specified requirements.
<b>Corrective Action</b>	Those activities necessary to investigate, analyse, initiate and audit changes to the quality system in order to eliminate potential causes of non-conformance.
<b>Non-conformity</b>	The failure of a product or service to meet specified requirements.
<b>Quality</b>	The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs (NZS 5604:1987).
<b>Quality Assurance</b>	All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (NZS 5604:1987).
<b>Quality Audit</b>	A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (NZS 5604:1987).
<b>Quality Management</b>	That aspect of overall management function that determines and implements the quality policy (NZS 5604:1987).
<b>Quality Policy</b>	The overall quality intentions and directions of an organisation as regards quality as formally expressed by top management (NZS 5604:1987).
<b>Quality System</b>	The organisational structure, responsibilities, procedures, processes and resources for implementing Quality Management (NZS 5604:1987).
<b>Traceability</b>	The ability to trace the history, application or location of an item or activity, or similar items or activities, by means of recorded identification.



# CHAPTER ONE

## INTRODUCTION

### 1.1 BACKGROUND TO THE STUDY

This guide is Part Two of a two-stage project completed for the Centre for Advanced Engineering of the University of Canterbury entitled *“Pilot Study on Quality Assurance Systems for Smaller Manufacturers in Canterbury”*. Part One was completed in October 1992, and the report detailed the results of a survey of manufacturing firms in Canterbury with regard to their current needs in the implementation of Quality Assurance (QA) Systems. The report is summarised in Appendix 1 of this guide.

The guide has been created to provide a reference for smaller manufacturers who require an overview of the purpose of having a Quality system, why ISO 9000 was created, how the ISO 9000 standards relate to each other and direction on the choice of a system. Whilst the guide is aimed primarily at smaller manufacturers, the information contained in it is relevant to other organisations seeking information on the content and implementation of Quality Systems.

This guide has the following objectives in mind:

1. To provide an overview of quality systems, their history, intent, evolution and current use (Chapter 1);
2. To discuss the various quality systems used in New Zealand and their application to local manufacturers (Chapter 2);
3. To explain the quality system elements contained in one of the most common standards, ISO 9002:1987 (NZS 9002:1990) (Chapter 3);
4. To provide details of quality practitioners, trainers, auditing bodies and information organisations currently operating in New Zealand (Chapters 4 and 5); and
5. To describe assistance available, in the form of grants or training, for the introduction of quality systems for manufacturers (Chapter 5).

This guide seeks to provide basic information to the smaller manufacturer so that he/she can make an informed decision on the implementation of a quality system.

### 1.2 HISTORY AND PURPOSE OF QUALITY SYSTEMS

**Quality assurance: All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality. (ISO 9000:1987 Section 3.5)**

When looking at the current scope and intent of Quality Assurance Systems, as defined by the ISO 9000 series of standards (equivalent to NZS 9000 series), it is often helpful to look at the evolution and increasing importance of quality systems from the period following the Second World War.

During the War, the emphasis on the production floor was on the numbers of items produced. Production staff were often given quotas specifying a quantity of items to be produced each day, week or month. The quality (adherence to specifications) of the product manufactured was often poor due to the processes, material and technology used in their manufacture, though this was by no means the only reason for product nonconformance. Consequently, large “armies” of inspectors were employed at the completion of the production process to identify those products that did not meet specifications and then scrap them before they left the workplace.

In the period following the War, the emphasis changed from assuring the quality of the product on the

basis of final inspection to assuring quality through the use of systems to identify and correct quality problems during manufacture — Quality Control. Consequently, the responsibility for the control of quality passed from the production floor to middle management, whose task involved the design and implementation of systems to control manufacturing quality.

Quality assurance of products became more important as the expected lifetime and complexity of products increased, and manufacturers were expected not only to provide products that complied with customer specifications but also proof that they conformed.

It was shown that controlling the quality of the product is not only a matter of controlling the manufacturing process but is also dependent on controlling those elements which affected the quality of the final product. These elements include:

- contract review
- design control
- purchasing
- process control
- product identification
- inspection status
- inspection and testing activities
- inspection equipment
- control of non-conforming product
- handling, storage, packaging and delivery
- document control
- records
- training

A system must be set up to control these elements within an organisation with regard to quality; such a system is called a Quality System.

**Quality system: The organisational structure, responsibilities, procedures, processes and resources for implementing quality management (ISO 9000:1987 Section 3.3).**

In order to successfully control these elements within an organisation they must be properly *managed*. “Top management” are the only personnel within the organisation who are capable of achieving this management. These are the personnel who have the authority to control the direction the company takes and the allocation of resources to achieve set goals. Quality systems developed by a middle management function may be ineffectual if they do not have the authority to perform activities which include:

- Determination of quality policies;
- Strategic planning to satisfy quality objectives;
- Allocation of resources to achieve quality objectives; and
- Evaluation of quality activities.

Only top management have the authority to ensure the implementation of systems. Direction of the Quality System must be co-ordinated by the management functions of companies. It is top management, and in particular Company Managers, that this handbook seeks to provide information for.

In the following chapters of this guide, quality system elements, the standards they are contained in and the certification of these standards will be explored in greater detail.

# CHAPTER TWO

## QUALITY SYSTEMS

In the previous chapter, the evolution and constituent elements of quality systems since World War II were discussed. It was demonstrated that many elements within a company's operations must be controlled with regard to quality to ensure the quality of the final product or service.

### 2.1 Quality Systems

Quality systems can be separated into two groups which are applied in different situations: quality systems for contractual situations and quality systems for non-contractual situations.

In both situations, the organisation wishes to adopt and use a system that will benefit the company and achieve product quality. Furthermore, in the contractual situation the organisation's purchaser may require that certain elements are present in the organisation's system to assure themselves that the organisation will be able to consistently provide a product or service that meets customers' requirements.

Individual countries have appointed national bodies to provide clear guidance on Quality Assurance/Management Systems. These guidelines are in the form of standards that detail the elements (or requirements) needed to ensure the technical, administrative and human factors affecting the quality of its products and services are under control.

### 2.2 National Quality Standards

Standards are published by the Standards organisations of individual countries. In New Zealand, this body is Standards New Zealand (SNZ). SNZ is the New Zealand national authority responsible for the production of standards. It is governed by the Standards Council, as established under the Standards Act 1988.

Examples of national standards on quality assurance are:

- NZS 9000:1990 series (New Zealand);
- AS 3900:1987 series (Australia); and
- BS 5750:1987 series (United Kingdom).

The NZS 9000:1990 series were prepared by SNZ and were previously numbered in the NZS 5600 series. The series were renumbered without change and are **identical** to the ISO 9000-4 series.

The NZS 9000 (ISO 9000) series of standards consist of the following individual standards, which are published jointly by the SNZ and Standards Australia.

- |  |   |
|--|---|
| • NZS 9000/AS 3900<br>(ISO 9000)       | Quality Systems — Guide to Selection and Use                                      |
| • NZS 9001/AS 3901<br>(ISO 9001)       | Quality Systems for Design/Development, Production,<br>Installation and Servicing |
| • NZS 9002/AS 3902<br>(ISO 9002)       | Quality Systems for Production and Installation                                   |
| • NZS 9003/AS 3903<br>(ISO 9003)       | Quality Systems for Final Inspection and Test                                     |
| • NZS 9004.1/AS 3904.1<br>(ISO 9004.1) | Quality Management and Quality System Elements —<br>Guidelines                    |

- NZS 9004.2/AS 3904.2 (ISO 9004.2) Quality Management and Quality System Elements — Guidelines for Services
- NZS 5604 (ISO 8402) Quality Vocabulary

Henceforth in this guide, the term ISO 9000 will represent ISO 9000/NZS 9000/AS 3900 series of standards. This similarly applies to the other standards in the series.

## 2.3 SELECTION AND USE OF QUALITY SYSTEMS

# NZS 9000/AS 9000 (ISO 9000): Quality Systems — Guide to Selection and Use

This standard's scope is to:

- a) Clarify the distinctions and interrelationships among the principle quality concepts...
- b) To provide guidelines for the selection and use of a series of international standards on quality systems."

This standard identifies the two situations where quality systems are to be used, contractual and non-contractual, and then directs the reader to the appropriate standards in the series corresponding to their situation.

Companies should determine the objectives that they wish to meet through the development of the Quality System programme:

- Quality Management
- Quality Assurance in contractual situations

ISO 9004 (together with ISO 9000) gives organisations guidance on **quality management purposes**:

*“ISO 9004 provides guidance on the technical, administrative and human factors affecting the quality of products and services at all stages . . . from detection of needs to customer satisfaction.”*

ISO 9001, ISO 9002, ISO 9003 are used for ***external quality assurance purposes in contractual situations:***

*"The selection and application of a model for quality assurance appropriate to a given situation should provide benefits to both producer and supplier. Examining the risks, costs and benefits for both parties will determine the extent and nature of reciprocal information and the measures each party must take to provide adequate confidence that the intended quality will be achieved."*

The main demands currently being placed on manufacturers are compliance with ISO 9002:1987, *Quality Systems for Production and Installation*. ISO 9003:1987, *Quality Systems for Final Inspection and Test*, is viewed as too restrictive and, if companies are to implement a quality system, inspection and testing is insufficient because the system does not include production quality elements. Similarly, companies viewed ISO 9001:1987, which includes design quality elements, as a ***standard to achieve at a later date***.

Thus, from the survey it emerges that ***current market emphasis is for the introduction of Quality Assurance Systems for contractual purposes***. These concentrate on production and installation.

This guide will address ISO 9002:1987, as it is the most likely standard to be adopted by smaller manufacturers in the near future. For this reason, Chapter Three will address those quality system elements which make up ISO 9002:1987, *Quality Systems for Production and Installation*.

# CHAPTER THREE

## ISO 9002 : 1987 — AN OVERVIEW

Smaller manufacturing businesses in Canterbury developing Quality Systems for contractual purposes have selected ISO 9002:1987 as a system being sufficient to meeting their company objectives for quality assurance.

This chapter will address each element of the Standard and will attempt to explain the requirements of the Standard with respect to documentation and company work methods.

This chapter will deal with Section 4 of ISO 9002:1987 — “Quality System Requirements”. This section can be divided into two broad areas:

1. Definition and documentation of the quality system and responsibility for its implementation and co-ordination (Sections 4.1 and 4.2); and
2. Specifications of those areas in a company which must be addressed to ensure quality, and the manner in which quality is achieved.

### 3.1 Management Responsibility

Section 4.1 of the Standard consists of three parts: Quality Policy, Organisation and Management Review.

These areas will be addressed in turn. It is the function of senior management to determine these quality system requirements.

#### 3.1.1 Quality Policy

Management is required to *“define and document its policy and objectives for and commitment to Quality”*. Furthermore the policy must be *“understood, implemented and maintained at all levels of the organisation”*.

As suggested, each company must develop a specific policy (or policies) for their organisation that states their objectives and commitment to quality. This is sometimes known as a Company Quality Policy.

This policy is documented in the *Company Quality Assurance Manual* (see Section 3.2.2 of this guide) and is a statement to staff and customers of the importance of quality in the organisation. The policy states objectives that the company wishes to pursue to ensure quality.

The Standard calls for the policy’s implementation at all levels of the organisation; thus the policies must be introduced to staff (see Section 3.17, Training) and are an indication of senior management’s commitment to quality.

#### 3.1.2 Organisation

The Standard requires that management define *“the responsibility, authority and interrelation of all personnel who manage, perform and verify work affecting quality”*.

This section of the Standard pays particular attention to those activities that prevent nonconformities and initiate corrective action for quality problems.

The Standard requires that management define the responsibilities of personnel that are part of the QA System. In reality, this means that for each activity someone will be responsible for ensuring it is completed and someone will have the authority to complete the activity (they may not necessarily be the same person).

The interrelation of responsibilities for major activities or areas of the company are usually represented on a “tree” diagram. This diagram may represent a “chain of command” and ultimate responsibility as well as the interrelationship between areas.<sup>1</sup> Individual responsibilities or personnel are recorded in company procedures (see Section 3.2.2 of this guide) and job descriptions.

The Standard requires that a company identifies in-house verification activities (listed in ISO 9002:1987 Section 4.1.2.2 ) and provides resources and trained personnel to carry them out. These activities are addressed later in this chapter and are implemented to ensure product quality and the integrity of the system. They are not activities carried out by a company which does not have a QA System, and the Standard requires that companies adopting these systems make provision of resources and training to ensure these new activities are carried out. They include production/process monitoring and quality system audits.

Management must appoint a representative who will have the responsibility for ensuring that the requirements of the Standard are implemented and maintained. This position is titled the *Quality Assurance Manager*. In smaller organisations this need not be the only job the incumbent holds. The *Company Quality Manual* should state that the QA Manager is responsible for the implementation and maintenance of the system.

### **3.1.3 Management Review**

The Standard requires that management review the “*continuing suitability and effectiveness of the Quality Assurance System*”. This is most easily achieved by having Periodic Management Review Meetings throughout the year. At these meetings, the system is reviewed by management (audit results are presented, quality reports accepted) and the system’s suitability and effectiveness are assessed. Decisions regarding the future and direction of the system are made. The records of these management decisions are retained in the form of minutes.

## **3.2 Quality System**

This section of the Standard defines the activities that the company must undertake to establish and maintain a documented Quality System. These activities fall into two areas: Documentation and Implementation.

### **3.2.1 Documentation**

Each company must prepare documentation that defines the quality system they operate. Quality System documentation falls into three different tiers, each of a differing complexity:

- Quality Assurance Manual;
- Quality Assurance Procedures; and
- Process or Work Instructions.

#### **3.2.1.1 Quality Assurance Manual**

This manual defines the structure and extent of the Quality System and contains:

- Company Quality Policies;

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<sup>1</sup> A copy of the company “tree” or structure should be included in the QA Manual.

- Responsibilities and authority of personnel; and
- Details of the company's quality assurance activities in each of the areas specified by the Standard.

The Quality Assurance Manual is the documented evidence of what activities the company performs to ensure quality. In addition, it defines the organisation's structure and responsibilities for carrying out these activities. It is the company's statement to customers and staff that quality is of primary importance in the organisation. This document is widely circulated, as it is the definitive description of the company's Quality System. Within the company, the manual details to all employees the Quality System that the company has adopted. Furthermore, as a document, it may be used to communicate to customers a description of the Quality System used to ensure product conforms to specified requirements.

The Quality Manual describes **what** is done by the company to ensure quality. The **method** by which the company achieves quality is addressed in in-house documents, called *Company Procedures*. These documents define individual in-house activities that are performed to ensure quality.

### 3.2.1.2 Quality Assurance Procedures

Quality assurance procedures detail **explicitly** how each area of the company works and the method of work which ensures quality. The procedures define for each activity:

1. *What is being done;*
2. *Who is responsible;*
3. *When it is done;*
4. *How it is to be performed (the method); and*
5. *What records are compiled.*

These procedures define the major areas of a company's activities and include:

- contract review
- document control
- purchasing
- product identification and traceability
- process control
- inspection and testing
- inspection and test equipment
- non-conforming product
- handling, storage, packaging and delivery
- quality records
- quality audits
- quality plans

The second half of Chapter Three will deal with each of these areas with respect to the requirements of NZS/ISO 9002:1987.

Specific procedures for each of these sections form the second tier of documentation.

A third tier of documentation exists in the form of work instructions.

### 3.2.1.3 Work Instructions

These instructions, usually of widely varying form and content, are the third tier of the documentation hierarchy. The method of use, timing, etc., are defined by a procedure but, due to the high variation, individual instructions are completed before use. They are, in effect, 'small procedures', but because

of their high variation, short shelf-life (days or weeks) or content, do not warrant the completion of a full procedure. These can also be referred to as “training instructions” if long-term use is required (e.g. repeated tasks).

For example, in a jobbing workshop a standard procedure cannot cover every eventuality required to meet a customer’s requirements. In this event, individual work instructions must be issued. These instructions form the third tier of the quality documentation and involve a standard method of work which is flexible enough to suit the different jobs involved.

### 3.2.2 Implementation

As can be seen from the scope of the Standard, the activities it addresses form a large part of a company’s day-to-day routine, the obvious exception being the administrative side of business (accountancy, debtors, creditors, etc.).

The Standard requires that the quality system is effectively implemented. This involves, amongst other things, the training of staff in the quality system and retraining of staff when the system is modified. The method of work and activities performed, as described in a company’s quality documentation, must reflect the actions performed on the shop floor. There is no point in documenting the system if it does not reflect company policy and actions.

The second part of Chapter Three will detail those areas and activities of the company that must be brought into the Quality Assurance System. ***Each of these areas must be addressed by a company implementing ISO 9002:1987.*** Each area would normally be covered by a separate procedure; however, it is not unknown for a single procedure to cover several areas.

The following steps should be addressed when preparing and implementing quality procedures:

#### ***Step One***

The procedure which the company presently uses and which an area of the Standard covers must be assessed. That is, it must be determined how the company specifies how this activity is carried out. The documentation used and the procedures followed must be ascertained.

#### ***Step Two***

An analysis of the requirements of the Standard must be made in relation to this area. The Standard may require particular actions and documentation in order to assure quality. It is usual to find at least some of the requirements of the Standard inherent in a company’s standard practices.

#### ***Step Three***

A review of current company practices and the Standard’s requirements must be made. A new procedure which satisfies company practices and the Standard’s requirements must be written. This will detail documents used and activities carried out.

#### ***Step Four***

The new procedure should be implemented in the organisation. All staff should be trained in the operation of procedures adopted. The systems should then be operated in accordance with documented procedures.

#### ***Step Five***

The system should be subject to an internal audit after an appropriate period of operation. The audit should review both the documentation and implementation of the procedure as well as the ability

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<sup>2</sup> Remember that the procedure is developed according to ***each individual*** company’s goals. The procedure ***must*** contain those elements specified by the Standard, but how compliance is achieved is the individual company’s decision.

of the procedure to fulfil company goals and Quality System requirements.<sup>2</sup>

### **Step Six**

In the case of contractual standards, the system should then be externally audited. This is discussed in Chapter Four.

## **3.3 Contract Review**

The Standard requires that companies establish and maintain a procedure for the review and co-ordination of contract reviews. Each contract should be reviewed to ensure that all requirements are adequately defined and documented, differences from the tender document are resolved and that the company is capable of meeting requirements.

This section of the Standard covers orders received by the company. These orders can be the result of a quote, tender or customer selection. If a tender or quotation is selected by a customer, the Standard requires that the company tender/quote documents are reviewed prior to acceptance to ensure the above requirements are met. Company procedures must state who carries out these activities, when they are done, in what manner each document is treated and what records and paperwork are to be used in completing this activity.

The Standard also notes that, where appropriate, these activities should be co-ordinated with the purchaser's organisation.

The Standard emphasises the importance of understanding what the customer requires and whether the company is able to achieve it.

## **3.4 Document Control**

The Standard requires that all documents and data related to the quality system are controlled with respect to approval and issue, and changes and modification.

Examples of documents are:

- Quality assurance manuals and procedures;
- Standards;
- Computer files;
- Drawings;
- Documents that convey instructions (e.g., worksheets); and
- Standard forms and documents used in the system (e.g., purchase orders).

### **3.4.1 Document Approval and Issue**

Company procedures must ensure that all documents created or introduced are reviewed for adequacy and approved (by a separate person) for use in the company's system. The procedure must also specify where documents are to be held to ensure they function effectively in the quality system. The procedure must also describe how obsolete documents are to be removed from the system.

The procedure must detail who is responsible for the preparation, review and issue of the documents used by the company.

### **3.4.2 Document Changes/Modifications**

When a company document is changed or modified, the Standard requires that these activities be performed by the same function or organisation that initially performed the review and approval. The procedure must reflect this fact, unless specifically designated otherwise.

The procedure must also state how these changes to the documents are to be recorded (e.g., reissue, amendment) and what changes are made.

A master list of documents and their revisions must be kept. All documents issued for use must be the same version as recorded on the master list.

### 3.5 Purchasing

*“The supplier shall ensure that purchased product conforms to specified requirements.”* The Standard identifies three areas of purchasing that must be addressed to ensure the quality of purchased product:

- Assessment of subcontractors;
- Purchasing data; and
- Verification of purchased products.

#### 3.5.1 Assessment of Subcontractors

The Standard requires subcontractors (and suppliers) be selected on their ability to meet requirements (including quality requirements). The selection of suppliers is dependent on the type of product and the subcontractor’s performance record and capability.

The Standard requires that the company establish and maintain records of all sub-contractors (suppliers). That is, before purchase orders are made the subcontractor must be assessed on the basis of their capability to meet contractual and quality requirements. All suppliers are recorded and preference should be given to those suppliers who can fulfil quality requirements. The procedure should specify how suppliers are selected and the requirements for selection.

#### 3.5.2 Purchasing data

The Standard specifies that all purchasing documents contain data describing the product ordered. This data includes:

1. *The type class, style grade or other precise identification;*
2. *Title or other positive identification; and*
3. *The title, number and issue of the quality system standard to be applied to the product.”*

The procedure should define the company’s purchasing procedure and include responsibilities, method for purchasing and method of review and approval of purchase documents prior to release.

#### 3.5.3 Verification of Purchased Products

This clause of the Standard, if specified contractually, allows the customer to verify, at source or upon receipt, that the purchased product conforms to specified requirements. If specified contractually, subcontractors **must** be made aware of this clause.

### 3.6 Purchaser - Supplied Product

The Standard requires that companies establish and maintain procedures to verify, store and maintain any product supplied by the customer for incorporation into goods supplied. Any non-conformities detected during storage and use must be reported to the customer.

### 3.7 Identification and Traceability

The Standard requires that organisations *“establish and maintain procedures for identifying the product from applicable drawings, specifications or other documents during all stages of production, delivery and installation”*. The procedures must specify how the product is to be identified throughout

production, through to delivery and final installation. Various methods exist for identifying products, depending on the method of manufacture.

Where traceability of product is a requirement of a contract it must ensure that individual products or batches have a unique identification. That is, the system must ensure all products are traceable or have a documentation system to attain this goal when required contractually.

### 3.8 Process Control

The Standard requires that suppliers *“identify and plan the production and, where applicable, installation processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions.”* (ISO 9002:1987 Section 4.8.1)

The Standard lists four controlled conditions that shall be included in this section. They are:

- Work instructions;
- Monitoring and control of process and product characteristics;
- Approval of processes and equipment; and
- Criteria for workmanship.

In this section of ISO 9002, the way in which products are manufactured and installed is addressed. The controlled conditions that are included in the Standard are specified to ensure that the processes are controlled to ensure quality.

#### 3.8.1 Work Instructions

Documented work instructions are required to define the manner in which a product is made and installed ***where the absence of instructions*** would adversely affect quality. Additionally, the Standard requires the use of suitable equipment, a suitable working environment and compliance with reference standards and quality plans where the absence would affect quality.

Here it is necessary to plan production and installation activities to ensure quality. Work instructions must suit the type of work. For example, in a mass production environment a single work instruction would cover the process, whereas in a jobbing shop, work instructions must be sufficiently flexible in their format to cover a multitude of work. Mass production techniques require a single procedure whereas jobbing work requires planning for each job.

#### 3.8.2 Monitoring and Control of Suitable Process and Product Characteristics

This section of the Standard addresses the control of process and product characteristics. The manufacturing process must be controlled to ensure the quality of product. This extends to machinery used and processes the product undergoes. The process and resultant characteristics of the products must be under control to ensure the same activity is performed for each job or item. The processes that directly affect quality must be monitored and controlled to such an extent that this quality is achieved.

#### 3.8.3 Approval of Processes and Equipment

If equipment or processes are to be used to achieve the manufacturing goals it must be ensured that those chosen are appropriate for the job being undertaken. A suitable process or equipment must be selected for the job that, where appropriate, will ensure processes are carried out under controlled conditions.

#### 3.8.4 Criteria for Workmanship

Some form of criteria must be stipulated *“to the greatest possible extent”* for the level of workmanship

that is wished to be achieved for each job or process. Methods used include representative samples and standards.

The approach in this section of the Standard is to specify a method for manufacture and installation that uses the appropriate processes or equipment and provides a criteria by which the finished product can be measured to determine that all goals of manufacture and installation have been met.

### **3.8.5 Special Processes**

The Standard identifies some processes as 'special'. These are *"processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use"*.

These type of processes are characterised by compliance to documented procedures and/or continuous monitoring which ensure the specified requirements are met. Examples of 'special' processes are:

- welding
- painting
- casting
- heat treatment

All must be performed under controlled conditions and to specified procedures.

The Standard requires that these processes are qualified and comply with Section 4.8.1 of ISO 9002:1987. The Standard further specifies that, where appropriate, records of processes, equipment and personnel must be maintained.

## **3.9 Inspection and Testing**

The Standard identifies three types of inspection and testing activities that are required in a quality system. They are:

- Receiving Inspection and Testing
- In-process Inspection and Testing
- Final Inspection and Testing

### **3.9.1 Receiving Inspection and Testing**

The Standard requires that a system be implemented to ensure that any incoming product is not used or processed until it has been inspected or verified as conforming to specified requirements.

This activity is outlined in Section 4.5.2 of the Standard, which notes, *"In determining the amount and nature of receiving inspection, consideration should be given to the control exercised at source and documented evidence of quality conformance provided"*.

That is, if the supplier chosen can provide evidence of quality performance, incoming inspection activities would be of a more general nature than, say, for a supplier who cannot provide such evidence. As a minimum, incoming inspection should consider the following points for all items:

- identification of product
- item count
- document verification
- visual inspection for damage

Suppliers who cannot provide evidence of quality performance would have to further qualify their product. Qualification may include product testing and provision of compliance certificates.

In Section 4.9.1.2, the Standard provides for the release of product from inwards inspection for ur-

gent production purposes. The procedure should state how this is achieved and how the product is identified. Records must be kept and the procedure should ensure that the product can be identified and recalled *“in the event of nonconformance to specified requirements”*. (See Section 3.7 of this guide: Identification and Traceability.)

### 3.9.2 In-process Inspection and Testing

The Standard requires that a system be implemented for in-process inspection activities and testing. The Standard identifies four areas of in-process inspection which should be documented. They are:

- Inspection, testing and identification of products where such activities have been specified in quality plans or documented procedures. That is, if such activities are required the procedure must detail how they are to be carried out.
- The use of process monitoring and control methods to establish product conformance. That is, documented procedures for the use of control charts and sampling methods to ensure conformance to specified requirements.
- A method which details how products are to be held until inspection is completed; that is, until inspections and tests are complete and reports have been completed and verified, the product may not be released for further production activities. This step ensures that value is not added to a product **before** it is certain that it complies with specified requirements. As in Receiving Inspection and Testing, the Standard allows for release of product for urgent production. The same activities for receiving inspection and testing must be addressed for in-process positive recall procedures.
- Non-conforming product must be identified. Once identified, such product must be dealt with in accordance with nonconformance procedures (see Section 3.12 of this guide).

### 3.9.3 Final Inspection and Testing

Quality plans or procedures are documented for final inspection and testing activities. They must ensure that all specified inspections and tests have been carried out according to procedure. This includes both inwards and in-process inspection activities. Furthermore, inspections performed must ascertain that the data obtained meets the required specifications. Final inspection procedures must provide evidence that the **finished product** is in compliance with specified requirements.

### 3.9.4 Inspection and Test Records

The Standard requires that records be established and maintained to *“give evidence that the product has passed inspection and/or test with defined acceptance criteria”*.

Records kept should document:

- who performed the activity;
- acceptance criteria;
- results obtained and whether passed/failed;
- instruments used for inspection/test; and
- identification of product.

## 3.10 Inspection, Measuring and Test Equipment

The Standard requires that suppliers *“control, calibrate and maintain inspection measuring and test equipment”* used to demonstrate conformance to specified requirements. This includes equipment:

- owned by the supplier;
- owned by employees;

- on loan; or
- provided by the purchaser.

The Standard requires that measurement uncertainty in equipment be known (and documented) and that all equipment used is accurate enough to be capable of providing the required measurements.

When using inspection, measuring and test equipment, suppliers are required to document a system which performs the following activities:

- Identifies measurements to be made, the accuracy required and the selection of appropriate equipment to perform the task.
- Ensures all measuring, inspection and test equipment “***that can affect product quality***” is identified, calibrated and adjusted against certified equipment that is traceable to nationally recognised standards. The calibration must be carried out at (specified) prescribed intervals or prior to use. In the event no standard exists, the basis for calibration must be documented.
- Documents and maintains a calibration system with details of:
  - equipment type
  - identification method
  - location of use
  - frequency of calibration
  - method of calibration
  - acceptance criteria

This system must also:

- Ensure that “*the inspection, measuring and test equipment is capable of the **accuracy and precision***” required for the inspectors and tests.
- Identify all inspection, measuring and test equipment in a manner which shows its identification number and the status of calibration (current or out-of-date).
- Ensure that all measurements made by equipment found to be out of calibration are identified and corrective action taken.
- Maintain records that record all the details of the calibration requirements of this standard.
- Specify the procedure by which measurements made with equipment subsequently found to be out of calibration are assessed and documented for validity.
- Ensure that measurements to calibrations, tests and inspections be carried out in an environment suitable for that purpose e.g., calibration of instruments is carried out at 20°C.
- Ensure that inspection, measuring and test equipment is handled, used and stored to ensure accuracy and fitness for use.
- Ensure that “*inspection, measuring and test facilities, including both test hardware and software*” are safeguarded against actions which would invalidate calibrations.

The Standard specifies that test hardware used for inspection purposes, including jigs, fixtures, templates and patterns, are to be checked to ensure they are capable of verifying the acceptability of product. Furthermore, such items should be checked at prescribed intervals and records of such checks are to be kept as evidence of control. The Standard further specifies that measurement design data is made available to the purchaser when required.

### 3.11 Inspection and Test Status

The inspection and test status of product must be identified with regard to inspection and tests performed and the resulting conformance or nonconformance. Identification methods include:

- markings
- stamps

- tags
- labels
- routing cards
- inspection records
- test software
- physical location

Identification should be maintained throughout production and installation to ensure that only product that has passed required inspections and tests is used, dispatched or installed.

The system should be able to verify the test status of product at any point during production.

Records of the person or inspection authority that releases conforming product must be kept. At this point, the **responsibility** for the quality of the product for release is recorded.

### 3.12 Control of Non-conforming Product

When products do not conform to specified requirements, as a result of inspection and testing activities or mishaps or accidents, the Standard requires that procedures to control non-conforming product are implemented. These activities are designed to prevent inadvertent use or installation and provide a method of review and disposition.

Non-conformance procedures must provide for the following activities when a non-conforming product is identified:

- identification of the item;
- documentation of the non-conformity;
- evaluation of the severity of the non-conformity;
- segregation (when practical);
- disposition of the non-conforming product; and
- notification of functions concerned.

The Standard requires that all non-conforming product be reviewed and categorised in accordance with documented procedures. Procedures should specify:

- reworking of non-conforming product to meet specified product;
- acceptance of product without repair;
- regrading of product for alternative applications; and
- rejection or scrapping of product.

When repairing product or supplying product that does not conform to specifications without repair, a process by which the customer is informed must be documented. This must ensure that the customer has documented records to identify the actual condition of the goods. In some cases this may be a contractual condition.

Reworked or repaired product must be inspected in accordance with documented procedures.

### 3.13 Corrective Action

This section of the Standard addresses actions to be implemented once non-conformity review and disposition has been completed. It is aimed at reviewing the reasons for the non-conformance and at modifying the system to preclude further non-conformities.

Procedures are documented and maintained for the following activities:

- investigating the cause and determining suitable corrective action to preclude further non-conformances;
- analysis of work processes, records, customer complaints, etc., to detect and eliminate potential

- causes of non-conforming product;
- ensuring that corrective actions taken are implemented and that they are effective; and
- changing the system documentation and actions when implementing changes resulting from corrective action.

### 3.14 Maintaining Post-production Quality

This section of the Standard details those actions that occur once production is complete. The Standard emphasises that the quality of the product can be altered once production is complete and, accordingly, seeks to maintain quality until receipt or installation at the customer's premises.

#### 3.14.1 Handling

The Standard requires that the supplier *“provide methods of handling that prevent damage or deterioration”*. This not only includes during production, but also delivery. Where certain methods of handling may be unacceptable, required methods should be stated.

#### 3.14.2 Storage

The Standard requires secure storage areas that prevent damage to stock during production or delivery. Procedures should state activities associated with the following areas:

- methods of receipt and dispatch;
- monitoring of stores to prevent deterioration;
- identification of stores; and
- access to stores.

#### 3.14.3 Packaging

Packaging must be controlled to ensure that product conforms to specified requirements. This includes:

- packing, preservation and marking processes
- identification

Furthermore, the Standard requires that such packaging identifies, preserves and segregates all items through to the point where supplier responsibility ends.

#### 3.14.4 Delivery

The Standard requires that suppliers *“arrange for the protection of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination”*.

It is worth noting that a courier or delivery agent is a subcontractor and thus records of their performance should be kept as per Section 3.5.1 of this guide. Records should be kept on delivery performance, damage in transit and lost goods to assess subcontractor performance.

### 3.15 Quality Records

This section of the Standard specifies that procedures must account for the following activities with

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<sup>3</sup> Note: Pertinent data from subcontractors is identified as part of these records.

respect to records<sup>3</sup>:

- identification, collection, indexing, filing, storage, maintenance and disposition;
- maintenance of records to demonstrate achievement of the required quality specifications; and
- maintenance of records to demonstrate the effective operation of the quality system.

All records must be kept in such a manner to ensure that:

- all documents are legible;
- damage or deterioration is minimised;
- documents are readily retrievable; and
- documents are disposed of after their retention period ends.

Procedures must specify retention periods for all records and any contractual agreements for purchaser access.

### **3.16 Internal Quality Audits**

The Standard requires that procedures for Internal Quality Audits be implemented. The purpose of these audits is to verify whether quality activities comply with planned activities and to determine the effectiveness of the system.

All audits shall be performed in accordance with a documented procedure. Activities will be audited on the basis of the status and importance of the activity. At any one time some areas may take preference over a prescheduled audit.

The company will identify these audit requirements, provide adequate resources and assign trained personnel for verification activities (Section 3.1.2).

The results of audits are documented and supplied to the personnel responsible for those areas. Corrective action taken after the results of the audit will also be documented (Section 3.13).

### **3.17 Training**

Training procedures will be implemented to provide training for staff in the following areas:

- activities affecting quality during production and installation; and
- use and purpose of the quality system.

Training procedures should identify training needs, provide training for identified needs and qualify personnel on the basis of education and experience.

Records of training must be maintained.

### **3.18 Statistical Techniques**

The use of statistical techniques to assure quality can include:

- Use of statistical sampling to test large batches of material. Test sample programmes may be employed during production or inwards inspections to inspect a portion of a batch to assure conformity.
- Use of statistical quality control techniques to maintain and control production processes.

Where such activities are carried out, suitable procedures must detail their use and application.

# CHAPTER FOUR

## CERTIFICATION OF QUALITY ASSURANCE SYSTEMS

As previous chapters have demonstrated, the demand for companies to adopt Quality Assurance Systems has become more pronounced in recent years. As larger companies have become aware of the benefits provided by the introduction of QA systems, market conformance to demands for these systems has increased. This chapter details how such systems are assessed or 'certified' by independent or 'third party' auditing bodies. It further details how such bodies are 'accredited', the national and international recognition of certification and the benefits it provides.

### 4.1 Certification

Whilst the introduction of a quality system within an organisation can provide increased assurance of the quality of the goods or service provided, the Part One survey has indicated that the majority of respondents are introducing systems to meet customer demands of quality assurance. There are two methods a customer may use to ascertain that their supplier's quality system is acceptable to their requirements:

- second party audit by the customer on the supplier; or
- third party audit by an independently-recognised body.

Where the customer has the time, inclination, money and resources to perform audits on their suppliers, this may be an acceptable proposition. However, more frequently companies are accepting registration by certification bodies who independently assess a customer's quality systems to recognised standards as proof of a company's commitment to and operation of Quality Assurance Systems.

Independent third party certification bodies provide confirmation (or proof) that a company's Quality Management System meets the requirements of the standard adopted.

Certification entails the assessment of the quality system and then provides **recognition** that the system complies to the standard selected.

In order for a system to be fully recognised nationally and internationally, it must be certified by an **Accredited Certification Body**. On occasions where customers indicate that a non-accredited third party is acceptable, it may be preferable to use them, but note that a recognised body may have more appeal to new customers.

### 4.2 Accredited Certification Bodies

Accredited certification bodies assess supplier's systems against the requirements of National or International standards and provide independent proof that the systems are in compliance at time of audit.

At present there are several accredited certification bodies providing these services in New Zealand. In addition to providing certification of QA Systems, they may also provide certification for some of the following activities:

- Auditor training
- Laboratories

- Products

Certification bodies in Australia and New Zealand are **accredited** by an inter-governmental self-funding organisation called JASANZ (the Joint Accreditation System of Australia and New Zealand). This organisation, managed by a council, has 14 Australian and 7 New Zealand members. These members are nominated from groups or organisations that are key stakeholders in the quality environment.

The JASANZ council authorises representatives to assess *“the independence, integrity and technical competence of certification bodies . . . which apply for accreditation against the appropriate criteria published by JASANZ”*.

This ensures the conformity of certification of Quality Management Systems by different certification bodies within Australia and New Zealand.

Certification of a quality system by an accredited certification body will provide national and international recognition of a supplier's quality system. Bodies similar to JASANZ are working in Europe to establish a European system, with which JASANZ is expected to achieve mutual recognition. Similar bodies are being established in other parts of the world.

When selecting certification bodies, companies should ascertain that they are accredited in the field of activity being certified.

Some of the certification bodies currently operating in New Zealand are:

- Telarc New Zealand
- Standards New Zealand (SNZ)
- KPMG Quality Certification International
- Lloyd's Australia
- SGS (Societe Generale de Surveillance)
- Bureau Veritas

### 4.3 Certification Process

Each certification body has its own procedure by which it certifies a company's systems. The following steps are a general overview of what the certification process involves, and this example only shows how the system is assessed. Certification bodies are contacted during the development of the system, and it is desirable to set up a working relationship prior to audit.

#### **Step One**

The certification body will provide details of the audit process they use and how they audit the requirements of the standard. Towards the end of the development phase, the company may opt for a pre-audit of the system to assess compliance.

#### **Step Two**

Some certification bodies perform a 'pre-audit' of a company's systems in order to assess the readiness of the system for the audit. This is a 'mini-audit' and is used to identify areas of the system that may need more development before a full audit can be contemplated. Some companies may benefit from this pre-audit as it may highlight some areas of the system which do not meet the requirements of the standard. It is also a good opportunity to meet the certification body representative and to provide a heightened awareness of Quality Assurance Systems within the organisation.

#### **Step Three**

Prior to the on-site audit of the Quality Assurance System, an assessment of the company's documented quality system is made. At this stage, the company's quality manuals and quality procedures are assessed against the requirements of the nominated standard. That is, the auditors are assessing whether the quality system documented complies with the appropriate section of the standard and that all of the standard's requirements are documented.

The document audit is usually carried out at the certification body's premises. The certification body provides a report on the document audit and may detail further development of the documentation system to reach compliance with the requirements of the standard.

#### ***Step Four***

Following on from the document audit by usually 2 to 3 weeks (although this varies), the on-site audit takes place. This may take from 1-5 days, depending on the size of the auditing team and company. Two days is quite common.

The purpose of this audit is to assess whether the Quality Assurance System documented in the manuals is being implemented in the company. Upon completion of the audit, the findings are recorded and presented in a report.

The certification body may then require further work to the system to comply with the standard or, following certification, that the system continues to comply with the standard.

#### ***Step Five***

At periodic intervals from the point of registration, the auditing body will perform surveillance audits of the company's documents and quality system to ensure compliance with the requirements of the standard.

Registration is only the first step in the assessment of a quality system. Surveillance audits by the certification body provide assurance to customers that the company's quality system are being maintained and that they are effective in meeting the company's quality objectives.

### **4.4 Certification Benefits**

Formal national and international recognition of a quality system through certification by an accredited certification body provides the following benefits:

- Listing as having a certified system in the certifying body's directory of registered suppliers;
- Access to new customers that demand proof of certification to national/international standards;
- Access to those overseas markets who demand certification as a prerequisite to supplying goods;
- Customers no longer need to assess a company if it can provide independent proof of compliance to standards;
- Benefits to a company's work practices, including reduced scrap and rework, reduced customer complaints and better communication; and
- Recognition of the achievement backed up by the credibility of the system.

# CHAPTER FIVE

## CERTIFICATION BODIES, TRAINING AND GRANTS

This chapter of the guide presents information on New Zealand organisations and institutions that provide services and information in the following areas:

- Certification bodies
- Training opportunities
- Grants and prizes
- Professional organisations
- Consultants

### 5.1 Certification Bodies

Section 4.2 of this guide listed some of the organisations currently providing certification of QA Systems in New Zealand. Further details of three of these organisations are given below. Details of the remaining organisations can be sourced through the telephone directory.

#### 5.1.1 Telarc New Zealand

Established by an Act of Parliament in 1972, Telarc is a “*not for profit, user-funded body*” which provides services, including laboratory accreditation, training and Quality System certification.

Telarc’s original function was the operation of the New Zealand National Testing Laboratory Accreditation Programme. In 1983, Telarc’s empowering legislation was amended to include quality assurance certification.

Day-to-day management of the Registered Supplier Programme (RSP) is the responsibility of the Group Manager, Quality Certification. The RSP provides certification of quality standards.

Telarc New Zealand is an accredited certification body. Telarc provides an information kit detailing its Registered Supplier Programme. This can be obtained from:

Telarc New Zealand 630 Great South Road Greenlane Private Bag 28901 AUCKLAND Phone (09) 525 0100 Fax (09) 525 1900	OR	Telarc New Zealand 53 Victoria Street P O Box 25065 CHRISTCHURCH Phone (03) 379 7358 Fax (03) 379 7368
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#### 5.1.2 KPMG Quality Certification (International) Ltd

KPMG Peat Marwick has established its certification body, KPMG QCI Ltd, in Auckland and Wellington.

KPMG-QCI’s certifications are recognised under the New Zealand Dairy Board (NZDB) Supplier Approval Programme. They are also registered as a participating certification body in the TRADENZ Quality Advancement Programme for Food and Beverage Exporters.

KPMG-QCI is an accredited certification body. KPMG-QCI offers certification to NZS/ISO 9000 in manufacturing and service sectors.

**Contact:** Ian Hendra  
Wellington  
Phone (04) 802 1222  
Fax (04) 802 1225

### 5.1.3 Standards New Zealand (SNZ)

SNZ operates a Quality Assured Supplier (QAS) scheme that examines and registers companies and organisations that can demonstrate compliance with recognised standards.

SNZ is a non-profit organisation whose income is generated from sales of standards, membership, subscriptions and the operation of their S Mark and QAS schemes.

SNZ QAS service is approved by the Standards Council (established by the Standards Act 1988) to examine and register companies that demonstrate compliance with recognised standards for quality systems.

SNZ QAS service is operated by the Quality Services Division.

**Contact:** Quality Services Division, SNZ  
6th floor, Wellington Trade Centre  
181-187 Victoria Street  
Private Bag  
WELLINGTON  
Phone (04) 384 2108  
Fax (04) 384 3938

SNZ is an accredited Certification Body.

## 5.2 Professional Bodies

### 5.2.1 New Zealand Organisation for Quality (NZOQ)

NZOQ is a non-partisan non-profit organisation dedicated to improving the quality of New Zealand's goods and service.

NZOQ has over 1000 members, both corporate and individual. The organisation is set up with divisions and branches that cater for members in their particular areas.

NZOQ has established training and educational programmes run in conjunction with local educational institutions as well as providing quality-related presentations and seminars covering a wide range of interests to cater for all members. NZOQ runs an annual conference dealing with quality-related issues.

**Contact:** New Zealand Organisation for Quality  
P O Box 622  
**PALMERSTON NORTH**  
Phone (06) 356 9099  
Fax (06) 355 5604  
Executive Officer: Bryan Wenmoth

### 5.2.2 Total Quality Management Institute (TQMI)

TQMI's mission is *"to provide the driving force for widespread adoption of TQM by enterprises for the benefit of the whole community"*.

TQMI's benefits of membership include:

- access to knowledge and networking with other organisations involved in TQM;
- participation in TQM quality forum activities;
- national and regional conferences;

- access to training and education in TQM; and
- provision of TQM resources.

**Contact:** Wayne Squires  
New Zealand Manager TQMI  
P O Box 90455  
**AUCKLAND**  
Phone (09) 302 0062  
Fax (09) 307 3831

## 5.3 Training Opportunities

### 5.3.1 Polytechnic Courses

Two training courses are offered at New Zealand polytechnics for those people wanting to improve their knowledge of quality assurance.

The New Zealand Organisation for Quality (NZOQ) Training Programme is provided at polytechnics and offers the following courses:

- Introduction to Quality Assurance
- Certificate in Quality Assurance

Both are run in conjunction with NZOQ, which provides course notes and supervises exams under the direction of the NZOQ Regional Educational Committee.

The ***Introduction to Quality Assurance*** course has the following aims:

- To demonstrate why quality assurance is essential in modern industry;
- To explain the principles of QA as part of the management system;
- To teach participants basic tools by which they can introduce or improve quality in their organisation; and
- To provide a forum for discussion and solution of participants and quality problems.

The ***Certificate in Quality Assurance*** covers different aspects of quality assurance and caters for the needs of the QA Supervisor as well as those with an interest in quality.

A Certificate in Quality Assurance is awarded following a pass in a 4-hour exam, which covers subjects taught in the course in addition to meeting other criteria set by the NZOQ Education Committee.

**Contact:** The Education Committee  
NZOQ  
P O Box 622  
**PALMERSTON NORTH**

**Or:** The local Polytechnic

### 5.3.2 University Courses

The Department of Production Technology at Massey University holds block or in-house courses on:

- Developing Quality Systems
- Quality Systems Auditing (with the NZOQ)
- Statistical Process Control

In-house programmes in TQM are also available.

**Contact:** Bryan Wenmoth  
Senior Lecturer  
Department of Production Technology  
Massey University  
**PALMERSTON NORTH**

Phone (06) 356 9099

Fax (06) 355 5604

In addition to those courses offered at Massey University, Canterbury University's Management department offers block courses on aspects of QA and TQM.

**Contact:** Mr Peter Leeming  
Department of Management  
University of Canterbury  
Private Bag 4800  
**CHRISTCHURCH**  
Phone (03) 366 7001  
Fax (03) 364 2020

### 5.3.3 Video Training Courses

Various types of training videos dealing with aspects of Quality Assurance and Quality Management are available for in-house use. There are companies operating in New Zealand that have videos on a wide range of topics which may be rented or bought. Most companies have preview facilities to help choose the video course most suited to your needs. Look under Training in the local yellow pages.

### 5.3.4 Further Reading

The Canterbury Public Library has a selection of books relating to Quality Assurance and associated topics. Copies of all standards are held in the library. See the technical section of the library.

Other sources of literature include:

- University of Canterbury libraries; and
- NZOQ provides a selection of books related to quality that are available for purchase.

### 5.3.5 New Zealand Quality College

The New Zealand Quality College is a division of Telarc New Zealand and offers a range of short courses covering preparation, development, implementation and management of Quality Systems as well as courses on internal auditing.

**Contact:** New Zealand Quality College  
Auckland — Private Bag 28901, Remuera, **AUCKLAND 5**  
Wellington — P O Box 12071, **WELLINGTON**  
Christchurch — P O Box 25605, **CHRISTCHURCH**

## 5.4 Grants and Prizes

### 5.4.1 Business Development Programmes

The Ministry of Commerce (Te Manatu Tauhokohoko) has developed a Business Development Programme, which is administered by 21 Business Development Boards located around the country.

These centres provide *“information, advice and referral services to people looking at business expansion and development and financial assistance for qualifying projects by way of grants through three targeted schemes”*.

Of the schemes offered by the Board, the two relating to Quality Systems are:

- EAGS: Expert Assistance Grant Scheme
- EGDS: Enterprise Growth Development Scheme

#### **EAGS**

The EAGS aims to assist existing businesses in increasing growth and profitability through the use of

outside assistance.

Component 5 of this scheme offers 50% of the cost of a qualifying consultancy project to a value of \$8000 (or \$20,000 when used in conjunction with the EGDS). The scheme may be used to provide assistance to review quality management strategy and systems.

Assistance can involve:

- Bringing the quality system up to the NZS/ISO 9000 series of standards;
- Strategies for introducing TQM; and
- TQM development.

### **EGDS**

The EGDS provides assistance to help businesses become more effective in the marketing of their goods and services. Component 7 of the scheme relates to providing grants to offset the costs of:

- obtaining QA certification; and
- undertaking quality audits as part of the certification process i.e., pre-audits, document audits and on-site audits.

For both these schemes, contact the local Business Development Board and request the appropriate literature and application forms. Note that applications for grants **MUST** be made prior to starting projects, as retrospective applications are not accepted.

#### **5.4.2 Business Development Quality Awards (BDQA)**

The BDQA is promoted by the Business Development Board. The objective is to foster commitment to quality principles by all New Zealand commercial enterprises and to recognise those companies which have implemented quality principles and benefited from them during the past three years.

Applicants for the BDQA are assessed region-by-region and each winner is invited to participate in a function to present the overall BDQA. Application forms are available from the local BDB.

#### **5.4.3 Quality Prizes Administered by the NZOQ**

These prizes are open to persons or groups of persons who are **members of NZOQ** or who work for NZOQ member companies. They include:

- Carter Holt Harvey Quality Prize
- BECA Prize
- NZOQ Prize

**Contact:** Bryan Wenmoth  
NZOQ  
P O Box 622  
**PALMERSTON NORTH**  
Phone (06) 356 9099  
Fax (06) 355 5604

#### **5.4.4 Railfreight Quality Awards**

The Railfreight Award for Excellence in manufacturing is based on the United States Malcolm Baldrige National Quality Award. There are two national awards and six regional awards.

The awards are promoted by the New Zealand Manufacturers Federation and Railfreight and are awarded in two categories:

- manufacturing; and
- small manufacturing (fewer than 50 employees).

**Contact:** The respective director of the Auckland, Wellington, Canterbury, Otago or Southland Manufacturers Association for more details

## 5.5 Consultants

Consultants can be contacted through the following avenues:

1. Trade literature advertising
2. Business Development Boards
3. Certification bodies

Avenues 2 and 3 would be more likely to recommend consultants that they are familiar with and whose work is known. The selection of a consultant should be discussed with the intended certification agency.

TELARC New Zealand publishes a Quality Services Directory that lists most of the quality consultants and training organisations operating in New Zealand.

# APPENDIX ONE

## Summary of Part One: Pilot Study on Quality Assurance Systems for Smaller Manufacturers in Canterbury

Part One of the project was initiated after it became evident that there was an increasing emphasis on the introduction of QA Systems in the manufacturing community. The two principle reasons for this heightened emphasis were:

- an increasing demand from customers for the documented existence of such systems before contracts are awarded; and
- the realisation by management that a reduction in the cost of problems arising from poor quality leads to greater productivity, market share and profit.

The report describes Part One of a two-stage Pilot Study on Quality Systems for Smaller Manufacturers. Part One details the survey of 25 manufacturing engineering companies in the Canterbury region.

The objectives of this survey were as follows:

- to gauge the extent of exposure and understanding of QA systems in Canterbury companies;
- to assess the extent of introduction of QA systems in the region; and
- to determine what resources companies are committing to the introduction of these systems and indicate what resources and information need to be provided to foster the introduction of these systems.

The report details the process by which companies were selected for the survey, the methodology of the survey itself, the results obtained and the conclusions drawn from the survey.

Twenty-five manufacturing engineering companies were included in the survey, with employee numbers ranging from four to more than 300. The majority of companies (23) employed less than 60 personnel. The companies surveyed were predominantly involved in batch production and/or jobbing work, the proportions of which varied from company to company. The results are contained in Section One of the report. Twenty-nine companies (including four additional companies) consented to being interviewed and these results are contained in Section Two of the report.

The main motivation behind the introduction of QA systems was customer or contractual requirements, due to two reasons:

**Firstly**, increasing numbers of larger companies with QA systems requiring Approved Suppliers (ISO 9002:1987 Section 4.5.2); and

**Secondly**, more contractual requirements specifying demonstration of a supplier's capability through the accreditation of their QA system.

An increase in product quality was cited as the next most popular reason for the introduction of a QA system.

Companies recognised the need for the introduction of QA systems (for whatever reason), but it was evident from responses that the scope and application of the Standard was not clear to those considering adopting a QA system, and concerns were expressed about the development of a 'paper war' to satisfy requirements of the Standard.

In-house design was performed to some extent by 22 of the 25 companies surveyed. Most companies indicated that the design function would not immediately become part of their QA system and that ISO 9002:1987 — *A Model for Quality Assurance in Production and Installation* was to be their initial starting point. The system would be expanded to encompass the design function at a later date.

One-third of companies surveyed had software-based manufacturing technology and two-thirds employed a special process (as defined by ISO 9002:1987 Section 4.8.2), such as welding or painting, in their manufacturing system. The preferred choice of standard by the companies, ISO 9002:1987, encompassed these activities and was seen as the foundation standard. ISO 9003 — *Model for Quality Assurance for Final Inspection and Test* was viewed as too restrictive, and if a QA system was to be implemented, then ISO 9002 was considered the standard to use.

The majority of companies had viewed ISO 9001-9003, but the supporting documents ISO 9000 and ISO 9004 were virtually unheard of by respondents. Choice of standard appeared to be by 'industry recommendation' rather than through use of the guidelines set out in ISO 9000. **Two-thirds of respondents envisaged accreditation to ISO 9002:1987 by the end of 1993.**

The majority of respondents were aware of the existence of consultants and accreditation agencies offering services, but **less than one-third** were aware of available grants and training opportunities offered by Government departments and educational institutions.

Companies were aware of the more obvious areas in their organisation that directly affected quality, but did not show awareness of the full scope and content of the ISO standards and how they would apply to their organisation. In implementing these systems two factors need to be considered:

1. The **high variance of work undertaken by these companies** suggests that QA systems being developed for this type of industry must be flexible enough to cope with the demands associated with the production lots; and
2. **Education of company management** in the scope and content of QA systems and their application.

These factors were highlighted in the survey by the companies intending to implement QA systems. They described their main concerns as:

- lack of knowledge;
- cost of implementation; and
- the commitment of time and resources needed to set up the system.

*The full 35-page document is available from the Centre for Advanced Engineering.*