CHAPTER 1

INTRODUCTION

1.1 INTRODUCTION

Since its introduction in 1987, ISO 9001 has been the target of criticism and considerable debate. Much of this is due to a misunderstanding and misapplication of the requirements. Some practitioners of quality disciplines view the requirements as too generic to be of any significant value. Some organizations view certification as simply the “ticket” for doing business. Purists state that it is physically impossible to manufacture products or deliver services defect free on a continuous basis. And some organizations view certification to be just one more mandated cost, a cost for which there is no return on investment.

In 1979, Phil Crosby created quite a stir in business when his book Quality is Free1 was published. What Mr. Crosby was saying is that “quality,” that is, a product or service that conforms to requirements, is the natural outcome of a well-planned and implemented manufacturing or service business. It is “non-quality” that results in the extra, profit limiting, cost to business. Simply said, if you plan correctly, make product or deliver service correctly, provide on-time delivery, you will make money – assuming your pricing is correct and affordable.

With the introduction of ISO 9001:2000, the business world now has a generic model for a quality management system that, when designed, developed and implemented, will provide the framework for assuring that customer requirements are defined, quality product or service is made or delivered on time, and that product/service and the management system are improved on a continuing basis. However, with the emphasis on the terms “system” and “process,” many readers
of ISO 9001:2000 miss the linkage or tie-in between the specific requirements and product or service quality. This paper will provide this linkage, sometimes as an overview, sometimes with specific links. The reader will also be provided with a view of the dynamics and interactions of various processes, and hints at what to audit for when assessing the quality management system.

1.2 HISTORICAL

**DURING WWII**, there were quality problems in many British high-tech industries such as munitions, where bombs were going off in factories. The adopted solution was to require factories to document their manufacturing procedures and to prove by record-keeping that the procedures were being followed. The name of the standard was BS 5750, and it was known as a management standard because it did not specify what to manufacture, but how to manage the manufacturing process. According to Seddon, "In 1987, the British Government persuaded the International Organization for Standardization to adopt BS 5750 as an international standard. BS 5750 became ISO 9000."

ISO 9000:1987 was also influenced by existing U.S. and other Defense Standards ("MIL SPECS"), and so was well-suited to manufacturing. The emphasis tended to be placed on conformance with procedures rather than the overall process of management — which was likely the actual intent.

ISO 9000:1994 emphasized quality assurance via preventative actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures. As with the first edition, the downside was that companies tended to implement its requirements by creating shelf-loads of procedure manuals, and becoming burdened with an ISO bureaucracy. In some companies, adapting and improving processes could actually be impeded by the quality system.

ISO 9001:2000 combines the three standards 9001, 9002, and 9003 into one, now called 9001. Design and development procedures are required only if a company does in fact engage in the creation of new products. The 2000 version sought to make a
radical change in thinking by actually placing the concept of process management front and center. ("Process management" was the monitoring and optimizing of a company's tasks and activities, instead of just inspecting the final product.) The 2000 version also demands involvement by upper executives, in order to integrate quality into the business system and avoid delegation of quality functions to junior administrators. Another goal is to improve effectiveness via process performance metrics — numerical measurement of the effectiveness of tasks and activities. Expectations of continual process improvement and tracking customer satisfaction were made explicit.

**Future Version: 2008.** The ISO 9001 technical committee has started its review on the next version of ISO 9001, which will in all likelihood be termed the ISO 9001:2008 standard, assuming its planned release date of 2008 is met. Early reports are that the standard will not be substantially changed from its 2000 version.

As with the release of previous versions, organizations registered to ISO 9001 will be given a substantial period to transition to the new version of the standard, assuming changes are needed; organizations registered to 9001:1994 had until December of 2003 to undergo upgrade audits.

The applying organization is assessed based on an extensive sample of its sites, functions, products, services and processes; a list of problems ("action requests" or "non-compliance’s ") is made known to the management. If there are no major problems on this list, the certification body will issue an ISO 9001 certificate for each geographical site it has visited, once it receives a satisfactory improvement plan from the management showing how any problems will be resolved.

An ISO certificate is not a once-and-for-all award, but must be renewed at regular intervals. In contrast to the Capability Maturity Model there are no grades of competence within ISO 9001.

1.3 **OBJECTIVE OF THE RESEARCH**