THE APPLICATION OF ISO 9000 TO A SMALL BUSINESS

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ABSTRACT

Quality of products, services and processes has become a crucial factor in the performance of an organization in today's global market. As a result of a worldwide trend to ensure consistent and standardized processes that will produce products and services meeting and surpassing customers needs, the International Organization for Standardization has developed a series of quality system standards named ISO 9000. The standards have been drafted by a number of quality professionals, originating mainly from large manufacturing organizations. Small-sized businesses that have encountered the application of ISO 9000 have reported a number of concerns that lead to the question of whether small businesses need separate ISO 9000 standards. This thesis examines the applicability of the current ISO 9000 standards in a small business.

Using a small-sized textile manufacturer as a case study, the application process has been initiated by the selection of the appropriate ISO 9000 model. A model for small business quality system assessments (SBQSAM), featuring the requirements of ISO 10011-1 Quality System Audit Standard and the recommendations from literature, has been adapted. The model has been implemented in the case study for the purpose of the initial assessments against the requirements of the ISO 9001 standard. It proved to be manageable, cost-effective and useful, with an increased auditee participation. A project plan for the application of ISO 9001 has been developed.

Subsequently, the ISO 9000 quality system documentation and implementation aspects have been focused. Quality loop flowcharting technique in a small business has

been introduced, with rules and symbols for integrated flowcharts provided. The technique has been applied for the following:

- to analyze the processes having an impact on quality
- to cluster operations requiring work instructions
- to provide flowcharts that will become an integral part of procedures in a company

Two procedures: for writing procedures and work instructions have been darfted. These procedures have been applied to format ten work instructions and a production process control procedure, that completely covered the production process in the company. The two procedures, together with flowcharting rules and symbols, form a package for standardized documentation design. The approach used to facilitate the process of ISO 9000 application in a small business has been designated as "Do it Yourself With a Boost" approach.

Issues related to the ISO 9000 application to large and small-sized businesses have been investigated by comparing the experience in a large steel enterprise with the case study company.

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1.0 INTRODUCTION

1.1 ISO 9000 Quality Systems

In today's global market, customers require their expectations and needs to be continually met. Quality of products, services and processes has therefore become a crucial factor in the performance of an organization. As a result of the worldwide trend to ensure consistent and standardized processes that will produce products and services that meet and/or surpass customer's implied or stated needs, The International Organization for Standardization (ISO) has developed a series of quality standards named ISO 9000 standards. The standards present three models (ISO 9001, 9002 and 9003), which stipulate a number of requirements on which an organization's quality system can be assessed by an external party (registrar) according to ISO 10011 quality system audits standard. Quality system involves organizational structure, processes and documented procedures constituted towards achieving quality objectives. If these minimum requirements are met, a registrar accredited by a national accreditation institution issues a certificate of compliance and the organization's quality system becomes ISO 9001, 9002 or 9003 registered.

1.2 Small Business

Numerous studies (ISO /TC 176 NZ, 1994, Brasier, 1994A, Placek, 1987) have shown that roughly 80% of all business, regardless of the country of origin, can be considered as small to medium enterprises (SMEs). SME is an acronym referred to firms that are independently owned and operated by a personal type of management,

not dominant in their field of operation. Moreover, SMEs account for about half of a country's work force (White, 1989). They have long been identified as the primary source of innovation and entrepreunership. These facts clearly illustrate the importance of small business in global economy. However, small businesses face a number of problems, including (White, 1989):

- lack of organizational and management skills
- lack of strategic planning and documentation
- inconsistent record keeping for evaluation
- shortages of working capital and credit (undercapitalization)

In their quest for quality of processes, products and services, SMEs have recently begun to encounter the standards a lot of large companies already had to comply with - ISO 9000. The aforementioned problems are moreover increasing in magnitude as they confront the standards.

1.3 ISO 9000 in Small Business

ISO 9000 standards have been designed by a number of quality professionals, originating mainly from the industry and large business sector. However, in the course of standards implementation in a small business environment, it has become apparent that SMEs have encountered a number of serious difficulties (Willborn and Cheng, 1994, Standards Australia, 1994). The most frequently reported problem is a lack of a documented quality system in place (Willborn and Cheng, 1994). Other difficulties accounting for a relatively large number of SMEs' failures to introduce an ISO 9000 quality system include:

- Minimal available resources (Standards Australia, 1994)
- Applying the standard (British Standards Institute, 1994)
- Time and money consuming. (Willborn and Cheng, 1994).

British Standards Institution, 1994. emphasizes that applying ISO 9000 standards in small firms is likely to be five times more expensive per employee than in a large business. However, the number of small businesses facing increasing customer requirements for a quality system conforming to ISO 9000 requirements is constantly growing. Considering the importance of the sector that accounts for 80-90 % of all businesses by number of companies, in order to help SMEs overcome aforementioned problems, national organizations for standardization have recently focused their activities on developing special aids for small businesses. The aids include developing ISO 9000 handbooks for SMEs, organizing seminars and meetings with reputed experts, combined with greater participation of the small businesses representatives in the future development of the standards. In spite of the considered efforts, research conducted up to now has not provided necessary tools and methods to control small business problems with ISO 9000.

The difficulties are typically encountered when addressing the following aspects of applying the ISO 9000 quality system:

1. Quality System Conceptualization, including selecting the appropriate model, conducting initial assessment and developing the project plan

2. Quality System Documentation and Implementation,

3. Quality System Registration

The following sections will address the first two aspects.

1.3.1 Conceptualization

The process of applying ISO 9000 quality system commences with the management decision to develop the system, followed by a selection of the appropriate model. If a specific model is not requested by the customer, enterprises performing design of their products and processes select, more often then not, ISO 9001 model. Otherwise, ISO 9002, covering production, installation and servicing, or ISO 9003, encompassing final inspection and test activities is selected. Subsequently, the company must assess the current status of its quality system against the requirements stipulated in the standard. This is ensured by the initial assessment or audit of the system. Using the results of the assessment, a project plan is created. Therefore a new, ISO 9000 quality system, conforming to the requirements of the selected model, is conceptualized. Consequently, it has to be documented and implemented.

1.3.2 Documentation and Implementation

ISO 9001 standard requires development and implementation of a documented quality system (QS). Furthermore, the standard requires the preparation of a quality manual and the preparation and effective implementation of documented quality system procedures. Documented procedures may take reference to work instructions that define how an activity is performed (ISO 9001-94). Other than above mentioned requirements and guidelines, the standard does not specify methods for developing QS

documentation, nor does it stipulate the required documentation structure. However, the following four-level structure is most commonly suggested in existing literature (Willborn & Cheng, 1994, Lamprecht, 1992).

(1) Quality Manual and Policy,

(2) Quality System Procedures,

(3) Work Instructions,

(4) Quality System Records.

The structure will be further discussed in chapter two.

Without subsequent implementation, documentation efforts are worthless. A number of serious difficulties have arisen in both large and small companies due to inadequate or missing implementation, in spite of existing documentation conforming to the requirements. Moreover, SMEs have encountered serious difficulties due to the fact that they had to apply the standard initially developed for and by large businesses in a small business environment. The following section will address these aspects.

1.4 Large and Small Business

A number of complaints from the small business sector regarding the excessiveness of standard requirements, non-understandable language and possibilities of misinterpretation from a non-expert have been recently reported (British Standard Institute, 1994). The difficulties have raised the question of a separate standard for a small business environment. Small companies differ from large ones in type of management, available resources and market share. An SME usually does not cover all

the twenty elements of the standard, nor does it always make a clear distinction between them. Small enterprises usually assign the same people with significantly different duties. These duties are clearly distinguished in the standards. British Standards Institute, 1994, however, concluded that a separate standard for small business is not at all necessary. Small business needs to transform the requirements of the standard according to its needs and possibilities, and to tailor its quality system so that the system meets the same requirements as large companies conform to.

1.5 Organization of the Thesis

Chapter Two deals with a survey of existing literature to develop a background for the problems addressed in this thesis.

In chapter Three, quality system conceptualization in a small business environment is discussed. A model for small business quality system assessments is given, followed by an example using a case study. Subsequently, a project plan for establishing an ISO 9000 quality system is presented.

Chapter Four discusses quality system documentation and implementation. The chapter introduces flowcharting as a tool for documentation and presents procedures for standardized documentation design. Finally, documentation and implementation issues in a manufacturing oriented SME are discussed.

Chapter Five further investigates issues related to the application of the current ISO 9000 standards to a small business environment by comparing two cases: a small and a large-sized company.

Chapter Six concludes the thesis with a summary of results and contributions of the work. The scope for further research is also discussed.

2.0 LITERATURE SURVEY

2.1 Introduction

A survey of existing literature has been conducted to oversee the following aspects of the application of ISO 9000 to a small business:

- The concept and importance of ISO 9000 quality systems, applying and registration motives, advantages and concerns related to this matter
- The definition, importance and general problems of a small business
- The phases of the application of ISO 9000, namely quality system conceptualization, documentation and implementation
- The similarities and differences between large and small-sized enterprises in applying the ISO 9000 standards.

2.2 ISO 9000 Quality Systems

A worldwide revolution in quality improvement bares its impact on businesses, regardless of the size. Companies can find that quality improvement is an excellent management strategy and provides the possibility of market breakthrough. Presenting results of the Gallup's survey, Bemowski, 1992, emphasizes that the fastest-growing organizations are concentrating on improving quality. As a part of thier efforts in quality improvement or customers expectations, a large number of companies have encountered a requirement to meet ISO 9000 standards. The process of applying the standards has shown to be treacherous, but fruitful for the ones that have successfully

implemented them. Subsequent sections will address the motives for developing an ISO 9000 quality system, followed by a discussion of its advantages and concerns.

2.2.1 Applying and Registration Motives

The motives for applying, and subsequently registering to ISO 9000 standards depend on the objective of application. A company can be forced into the process if its customers (other companies or the government) are requesting the quality system before a new contract will be awarded (Monty, 1985, Howell, 1994A). Some companies, especially small business ones, characterized by local or regional operations and no contact with multinationals or exporting may find little or no pressure to pursue ISO 9000 registration (Zuckerman, 1994). However, the motives that inspire such firms to pursue ISO 9000 registration are:

- The standards are an effective marketing and sales tool to procure new business or to expand to a new market (Howell, 1994A, Mathews, 1993,)
- Documentation and valid standard operating procedures (Wagner, 1994)
- Multinational recognition (Tarby, 1994)
- Competitive advantage for acquiring a contract (Garver & Pagliarulo, 1993).
- Credibility in the market (Eicher, 1994)
- ISO 9000 is a symbol of commitment to quality (Voehl et al, 1994)

2.2.2 Advantages

Experience of numerous companies has shown a set of benefits that emerge in the course of developing an ISO 9000 quality system. The results of the study conducted by Lloyd's Register Quality Assurance in 1994, highlighted that the ISO 9000 registration is beneficial for small companies - 83% reported an improvement in management control, and 64% reported an increased ability to contract for work. The following section will present the advantages in the area of economics of quality, marketing and improvement in management and production processes.

In terms of economics of quality, the following benefits have been reported by Hendricks, 1994, Wagner, 1994, Skrabec, 1995 and British Standards Institute, 1994:

- Increased sales
- Cost Reduction
- Improved profitability

The marketing benefits include (British Standards Institute, 1994):

- The ability to retain markets which might otherwise have been lost
- Opening up of new markets which would not otherwise have been available
- Identifying objectives and focus on customer expectations

Management processes have been improved through:

- Performance, coordination and productivity improvement

◆ Providing confidence to its own management that the intended quality is being achieved and maintained (Standards Australia, 1994)

◆ Coordination and productivity improvement (Standards Australia, 1994)

◆ Improved control of key processes (Sutherland, 1994)

◆ Reduced cost of training new personnel due to the availability of documented procedures and improved employee motivation due to clearer objectives (British Standards Institute, 1994)

◆ A better understanding of tasks and objectives (DeAngelis, 1991)

◆ A path to Total Quality Management (Corrigan, 1994)

◆ Transfer of technical knowledge offered by international standardization.

◆ Smaller companies benefit from the investment in standards made by larger ones (Eicher, 1994).

Improvements in production processes include:

◆ Reductions in justified complaints, reduced scrap materials and quality assurance specification reviews (Rockman et al., 1994, Sutherland, 1994)

◆ Improvements in the area of measurement and calibration (Skrabec, 1995)

◆ Reductions in process deviations due to increased consistency in the way production processes operate (Dzus, 1991).

2.2.3 Concerns

In spite of the advantages presented hereabove, several authors do not agree that ISO standards are beneficial. This section represents their views on the topic. It is stated that the quality assurance rules established in ISO 9000 have been used in the United States for more than 25 years with disastrous financial consequences and little, if any, improvement in quality and safety. These rules are so reliant on documentation and strict compliance that ensuring products compliance with specifications has become a secondary issue (Reedy, 1994).This is also underlined by Schaff, 1993, who states that the product produced by an ISO registered company will not, by definition, have quality superior to that of a product produced by a nonregistered company. In his "The Last Word" presentation, cited in Stratton, 1993. quality pioneer Joseph M. Juran expresses an opinion that the value of ISO 9000 is being oversold. While he praises the standards for being useful when creating control procedures and documentation, and reducing multiple assessments of production activities, the author emphasizes the standards' shortcomings in the area of continuous quality improvement, customer satisfaction, or employee participation.

It is also important to recognize that ISO 9000 ensures process, not product quality. A product or service has to comply with corresponding product or service standards, and ISO 9000 does not exclude these. The drawbacks underlined by Juran are emphasized to some extent by the 1994 version of the standards.

A feature of the standards has created much confusion and uncertainty in organizations that have considered the application. It is the existence of three different models to which a facility can be registered to: ISO 9001, 9002 and 9003. A typical company considers whether to embark on the most comprehensive one: ISO 9001 first, or to comply to ISO 9002 and subsequently expand it to ISO 9001 if required. Commonly, the main interest of small business' customers is to receive a quality product. Therefore, a small business may find that ISO 9003, a model for final inspection and test is just enough to comply to.

The ISO 9000 standards underwent a major revision in 1994, from its original version published in 1987. One of the features of the new edition is that the ISO 9001, 9002 and 9003 models are much closer to one another than they originally were. ISO 9002 is now almost identical to ISO 9001, except the two areas: Design Control and Servicing. ISO 9003 is still less comprehensive than ISO 9002, but several areas, including Statistical Techniques are now a requirement stipulated in this model as well. Other major changes include focusing on maintenance activities (4.9 Process Control, ISO 9001, 1994) and providing evidence of determining the need for the use of statistical techniques (4.20 Statistical Techniques, ISO 9001, 1994). This trend will eventually lead to an integrated ISO 9001 model (combining ISO 9001, 9002 and 9003 in one). With an anticipated integration of guidelines in ISO 9000 (selection and use), and ISO 9004 (quality management and quality system elements), beyond the year 2000 we anticipate to have three standards only: ISO 9000, ISO 9001 and ISO 9004.

2.3 Small Business

2.3.1 Definition

In spite of recent awareness of the outstanding role played by small and medium sized enterprises in a global market, a generally accepted definition still does not exist. Definitions given in literature vary from author to author and depend on the purpose for which the definition is used. It is even argued that there is no point in attempting to produce a universally open or even a nationally acceptable standard of defining small business (Harper, 1984.), since it is "really a frame of mind" (Wolak, 1987.). However, existing definitions can be grouped into two categories : qualitative and quantitative ones.

Qualitative definitions emphasize the following characteristics of small business (D'Amboise, 1991., Sutherland, 1994., Ganguly, 1985.):

- Local or regional operations. Influence on the conditions of sale is weak.
- Independently owned and operated. A small firm is usually run by one manager, who is often the owner.
- Personal type of management. The manager knows and communicates with each member of the staff personally.

Quantitative criteria are based on:

- concrete measurements, such as number of employees and quantities produced;
- financial measurements, such as total annual sales, added value, assets and capital stock. (Ganguly, 1985.)

For the purpose of excluding larger enterprises from preferential assistance programmes which are designed to help small ones, national governmental institutions stipulate their own definitions. They are summarized in table 2.1.

Country	Definition	Institution	Source
United States	- independently owned and operated - not dominant in its field of operation - up to 500 employees - up to $50 million in assets or sales	Federal Small Business Administration	Storey, 1983.
United States	- less then 500 full-time employees	Malcolm Baldridge Award	
Japan	- fewer than 299 employees - less then 100 million yen in capital		Storey, 1983.
United Kingdom	- manufacturing small business has up to 200 employees		
Canada	- gross revenues under $10 million - fewer than 100 employees	Canadian governmental agencies	White, 1989. Monty, 1985.

Table 2.1 : Definition of a Small-Sized Business in Various Industrialized Countries

The following practical definition of a small to medium enterprise (SME) is used in this thesis (adapted from Ganguly, 1985).:

" An SME is any firm which fulfills all the following conditions:

- The firm is independently owned and operated by personal management.
- The firm has an annual sales figure of less than $20 million and employs less than 500 people

♦ It does not dominate its economic sector of activities; its turnover is less than that of market leaders."

2.3.2 Importance

Small business is a vital part of a global economy. This fact can be demonstrated by citing Statistics Canada reports from 1987-88, where small businesses (with sales of less than $2 million), accounted for:

♦ 97% of all businesses in the country by number

♦ 24% of all sales

♦ 45% of total employment in all sectors (White, 1989.)

In 1991, there were more than 925,000 SMEs in Canada. They employed 6.6 million Canadians, accounting for about half of Canada's work force (Brasier, 1994A - according to Statistics Canada). Statistics in United States shows approximately the same features. SMEs have a share of 40% of the gross national product, and employ close to half the nations nonfarm workers in the USA. Manufacturing SMEs account for 85% of the nation's most innovative companies (Placek, 1987). There are more than 20 million small businesses in the United States (Bemowski, 1992). Generally. an estimated 80% of all companies can be considered as SMEs, regardless of the country observed (ISO/TC 176 NZ, 1994). In adition, small businesses are primary sources of innovation and risk-taking, provide a seed-bed for new entrepreneurial talent, create career opportunities and new jobs (White, 1987., Chamard and English, 1989, Placek, 1987).

2.3.3 General Problems

Although their importance is not disputed, SME are facing serious problems. The following are the most evident (White, 1989, Chamard and English, 1989):

- lack of organizational and management skills
- lack of strategic planning and documentation
- suscebility of their product to obsolescence and technological change
- inconsistent record keeping for evaluation
- shortages of working capital and credit (undercapitalization)

2.4 ISO 9000 in Small Business

Relevant surveys presented in the British Standards Institute, 1994. report indicate a very small percentage (3%) of small firms that had registered to BS 5750 (ISO 9000) and a further 26% considering registration. One of the main reasons for such a low percentage is that SMEs encounter numerous problems when embarking on ISO 9000. The problems reported in the literature (Standards Australia, 1994; ISO/TC 176/SC, 1995; Willborn and Cheng, 1994: Sutherland, 1994: Zorn, 1995 and British Standards Institute, 1994.) include:

- No documented and widely delegated line-staff organization
- Informal and orally communicated work assignments and responsibilities
- Lack of a formal quality policy, manuals, records or internal audits
- Personalized business relationship without formal contracts review
- No detailed control of suppliers and supplies

- Inadequate funding for and assistance by an external quality expert
- Difficulty in obtaining and understanding of quality system standards
- Time consuming in developing system
- Over bureaucratic system with consequent loss of flexibility
- Lengthy time scale to qualify and get certification
- Hard to maintain enthusiasm for the system
- Staff resistance to changes
- The problems mainly relate to the method in which standard is applied
- The cost may never be justified for many small businesses.
- Interruption of work processes from application of the standards
- Wrong advises to adopt large companies documentation

The endeavour to assist SMEs in applying ISO 9000 standards series has resulted in drafting special handbooks for small business. This approach is considered to be comprehensive and useful, and therefore used by several countries - Australia and New Zealand (Standards Australia, 1994.), Canada (ISO TC 176/SC, 1995), France (French task force for SME, 1994.), Italy (Italian Task Force for SME, 1994.) and United Kingdom (British Standards Institute, 1994). An 11-step approach for establishing an effective and suitable ISO 9000 quality system for a small business is provided by Willborn and Cheng, 1994. The approach underlines a concurrent quality system documentation and implementation, with corrective actions and reviews to ensure maintenance of the system effectiveness and continuous improvement.

However, the handbooks only provide explanations on the twenty elements of the ISO 9001 standard, without stipulating the methodology for use. There is also a need to expand the existing approach presented in Willborn and Cheng, 1994, and customize it with more detailed methodology for ISO 9000 quality system application in small business.

2.4.1 Quality System Conceptualization

2.4.1.1 Model Selection

The first step in conceptualizing the quality system is the appropriate model selection. An organization can select one of the three models : ISO 9001, 9002 or 9003. Guidelines for selection and use are provided in ISO 9000-1 standard, with supplementary guidelines found in Canadian CAN/CSA Q9000 standard. The emphasis in the thesis will be placed, however, on subsequent steps- assessment and project plan, rather than model selection, which is considered to be straight forward.

2.4.1.2 Assessments

Quality assessments (audits) are considered to be an effective tool in achieving quality improvements (Ossenberg, 1994.; Aquino, 1990.; Baer, 1993., Maday, 1992.; Kildahl, 1992.; Kuhn, 1993; Rosen, 1992, Rockman et al., 1994, Dzus, 1991, Dzus and Sykes, 1993, Girvin, 1992, Willborn, 1979, Wilborn, 1993). The current literature, including the quality auditing courses conducting throughout the world, provides audit (assessment) methodology. For instance, a six-step quality assurance system audit is provided by Willborn and Cheng, 1994. It encompasses the following steps:

(1) Initiation, (2) Planning, (3) Executing, (4) Reporting, (5) Follow-up and (6) Completion. Three techniques are available for execution (Dzus, 1991, Mathers et al, 1994.):

- Inquiry: asking questions, formally and informally
- Observation: collecting audit evidence through physical examination,
- Verification testing: following the audit trail, randomly selecting a sample and tracing it through the system.

However, currently used quality system audits posses weaknesses. Two of the weaknesses that can undermine their effectiveness are recognized by Bobbit, 1993:

- Subjectivity: Different auditors tend to interpret the same questions differently and tend to use different scoring system and criteria.
- Lack of participation by the auditee: The auditee often stands aside during the audit and is informed of the results at a post-audit meeting.

Attempts to decrease auditors subjectivity are being made towards using scoring systems, usually in the form of a checklist (Bobbit, 1993.; Johnson, 1993.) or a computer program (Rementeria et al, 1991). Allowing the auditee to participate in scoring during the audit (Bobbit, 1993.), or in the audit process itself by conducting periodic review meetings (Bishara and Wyrick, 1994.) are methods used to increase the auditee's participation. The latter is crucial due to possible conflicts in the company followed by an internal audit, reported by Rice, 1994. An audit cycle has been developed by Bishara and Wyrick, 1994, to facilitate the improved auditee/auditor partnership. The cycle consists of the following five steps: preparation, conduct, writing/documenting/review, reporting and follow-up. The authors

emphasize the importance of the educational change in which the auditors learn about the auditees' quality systems and auditees learn what areas require quality improvements. Other anticipated feature is that a methodology for conducting the audit considering the special features of the small business sector has not been found.

2.4.1.3 Project Plans

ISO 9000 project plans are, more often then not, presented in the form of a roadmap, with corresponding milestones and time scales. However, the roadmap given in literature can often be applied only in large companies where quality systems are practically in place and need minor changes in order to fully comply with the requirements of the standard. The example of this kind of the project plan is given in Batra et al., 1993.

An example of a roadmap for developing the ISO 9000 system from "scratches" is given in Rockman et al., 1994. Although the actual time required for attaining the registration depends on the initial status of the quality system, management commitment and the degree of involvement of every member of the organization, the authors estimate a time frame of 18 months for a medium sized company. The roadmap starts with a management decision and commitment to pursue the registration, establishment and training of a steering team and a management representative, followed by an internal audit, documentation design and implementation, preassessment and completes with a registrar's certification.

2.4.2 *Documentation and Implementation*

In order to establish an ISO 9000 quality system, manufacturing and service organizations are required to document practices that impact the quality of their products and services, and subsequently follow those documented procedures (Velury, 1995). Therefore, there are two aspects of developing the system that meets the standards requirements:

- Documentation, where "all the elements, requirements and provisions adopted by a company for the management of quality are documented in a systematic and orderly way in the form of written policies and procedures" (Dale and Oakland, 1991)
- Implementation, where a company follows documented practices.

In spite of the fact that ISO 9000 standards do not stipulate required documentation structure, the following is advised by a number of authors (Rothery, 1991, Rabbit, 1993, Hutchins, 1993, Lamprecht, 1993, Lamprecht, 1992, Hoyle, 1994, Puri, 1992):

(1) Quality Manual and Policy, describing an overall quality system of a small enterprise, quality objectives and policy. Guidelines for developing quality manuals are addressed by ISO 10013 standard.

(2) Quality System Procedures, covering all twenty elements of the standard. QS procedures describe the responsibilities, authorities and interrelationships of personnel who manage, perform, verify or review work affecting quality; how the different activities are to be performed, the documentation to be used and the controls to be applied (ISO 10013, 1991.)

(3) Work Instructions, defining the manner of the activities performed by an individual employee. Work instructions document only the operations that inadvertently affect quality.

(4) Quality System Records, bearing evidence on processes already executed.

A range of ISO 9000 documentation software packages are currently available on the market. They range from a toolkit providing a format for procedures and instructions that an interested user fills with concrete data from a company (Novack, 1994), to sophisticated (and expensive) packages that suppliers advertise as "panaceas for documentation problems". The advantage of software packages is that they accelerate the documentation process. A problem that can be anticipated if such packages are used in any environment, regardless of size, is that of a subsequent implementation of the documentation. The employees may feel intimidated by the lack of their participation in drafting the documentation.

Implementation is the process following documentation. A comprehensive outlook of the implementation process can be found in Lamprecht, 1993. However, the author does not distinguish large and small business and it is not clear whether the guidelines provided in the book can be used for both. The question that can be raised at this point is whether small businesses are required to document and implement processes and activities in the same manner as large companies or not. Velury, 1995., anticipates about twenty procedures, each covering one element separately. Several questions can

be raised at this point of time: "Does this apply to small businesses? Will this approach create an excessive documentation that an SME does not need for effective operation?

2.5 Large and Small Business

The fact that ISO 9000 standards have been created by the representatives from large businesses, and a number of problems that small companies have encountered in the course of applying the standards, have created the need to examine the relationship between small and large companies. Subsequent sections will address similarities and differences reported in literature.

2.5.1 Similarities

Several key-points for successful application, regardless of the company size, have been reported. The commitment from all levels in the company, especially the president and top management has been emphasized by a number of authors (Lynch, 1994., Placek, 1987., Wolak, 1987., Neblock, 1993.). The need for ongoing training, employee orientation and a focus on the improvement of the processes that create products and services is outlined by Lynch, 1994. A cultural shift throughout the organization, especially for informally organized companies, is a crucial condition for successful implementation (Neblock, 1993, Huyink, 1994). This, in turn can become an effective foundation for firms seeking Total Quality Management (Lynch, 1994).Company-wide team work can accelerate the fulfillment of this condition (Cirulli et al., 1994).

2.5.2 Differences

Several authors have reported that small companies have advantages over large ones when implementing quality initiatives. Citing the representatives of the small companies that won the Malcolm Baldridge National Quality Award and the George M. Low Trophy, Axland, 1994, emphasizes that the only disadvantage mentioned was financial constraints. However, not one company felt this sole disadvantage was enough to keep any company from successfully implementing quality. According to Placek, 1987, and Wolak, 1987, developing quality awareness in SMEs is easier than in large firms. Often the owner, president or CEO knows everybody in the company. He/she can more quickly spread the message about quality. A leader's change and actions can be observed by the employees instantaneously. Small firms also have the advantage in quality training, and are able to implement quality processes quicker because of less bureaucracy and politics. In addition to the views expressed beforehand, a small business owner or president usually knows the customers personally, and therefore, the communication and anticipation of a customer's needs is easier (Wolak, 1987.; Deming, 1993). Several major differences between small and large companies in terms of quality assurance are outlined by Wolak, 1987. They include communication barriers, formality of work, management-layers thresholds, and corporate control. There is a perception that big companies have the resources necessary to undergo quality changes and small companies do not. In most small companies, employees have lots of responsibilities and do not have idle time waiting

for a project or assignment. Changes require taking human resources away from their jobs, which is, hence very difficult to achieve (Ebel, 1991).

2.6 Motivation for the Proposed Research

The following conclusions of the British Standards Institute and ISO TC/176 New Zealand Committee (ISO TC/176/NZ, 1994.) illustrate the motivation for the proposed research:

- There is a high probability of a substantial increase of the number of small firms experiencing problems with the ISO 9000 in the next few years
- There is a serious lack of research data on the effects of the standard on small business.
- The extent to which the problems related with ISO 9000 application in a small business environment are significant can only be judged when the results of the research on the topic is available.
- The answers to the problems encountered by SME will be beneficial to every company, regardless of the size.
- A model for quality system assessments considering the special features of a small business environment
- A set of standardized guidelines for creating quality system documentation
- An explanation of the initiation, documentation and implementation processes
- Proposed methods for applying the standards in the small business.

2.7 Objectives of the Proposed Research

The following section describes the objectives of the proposed research:

♦ Adapt, expand or adopt a model for quality system assessments in a small business environment. Implement the model in a typical small business manufacturing company. Create a project plan for establishing ISO 9000 quality system model

♦ Develop a package for standardized quality system documentation applied to small business. The package should include:

- A set of rules and symbols for creating flowcharts
- A Procedure for Writing Procedures
- A Procedure for Writing Work Instructions

Using the package, cover the production process in the case company with appropriate procedures and work instructions. Implement the procedures and instructions.

♦ Compare an ISO 9000 quality system development in large and small business using case studies. The research should address the differences and similarities and answer the question whether small companies need a separate ISO 9000 standard.

3.0 CONCEPTUALIZATION

3.1 Introduction

This chapter addresses the conceptualization of a quality system (QS) conforming to ISO 9000 standards requirements in a Small to Medium Enterprise (SME). The conceptualization, as proposed in this research, includes the following three steps:

- Quality System Initiation.
- Conducting First Assessment
- ISO 9000 Project Plan Preparation

Subsequent paragraphs are dedicated to the discussing these steps, followed by an illustration using a case study.

3.2 Quality System Initiation

SMEs may ask themselves whether they need an ISO 9000 quality system, and if they do, which model they should select. One of the tools which can be used for the purpose of model selection is ISO 9000-94 International Standard, with supplementary guidance provided in Canadian CAN/CSA Q9000-92 standard. Q9000-92 presents a factor rating method and a quality system selection flowchart. An SME should develop the quality system according to the guidelines provided in ISO 9004-1 standard. The system should conform to the requirements of the selected model.

3.3 Small Business Quality System Assessment Model

The experiences of a number of companies that have been ISO 9000 registered, show that it is necessary to determine the organization's degree of compliance with the selected ISO 9000 model. This is demonstrated by the first quality system assessment. Its objective is to determine the current status of a quality system against the standard, and provide the company a list of areas where improvements are essential.

This section describes the quality system assessment model designed and implemented in the case study. The model, named SBQSAM (Small Business Quality System Assessment Model), is presented in figure 3.1 with detailed explanations demonstrated in tables 3.1 and 3.2. The model is graphically presented by the assessment flowchart (algorithm) for small business environment (figure 3.2). It is supported by the examples of assessment documentation, such as checklists (table 3.3 and Appendix IV), observation forms (figure 3.3) and questionnaires (figure 3.4 and Appendix III). The model has been developed considering the features of the ISO 10011-1, 1990 standard : Guidelines for Auditing Quality Systems, and the PLAN-DO-STUDY-ACT circle (Deming, 1993).

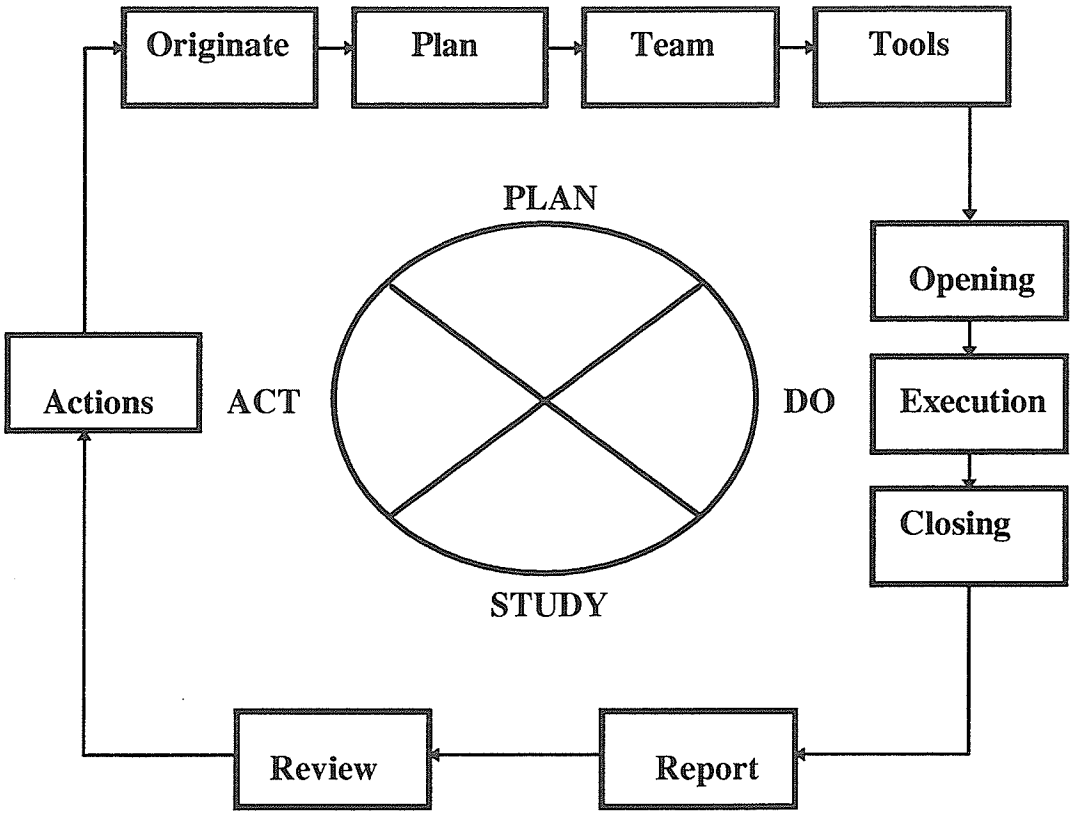


FIGURE 3.1 : SBQSAM

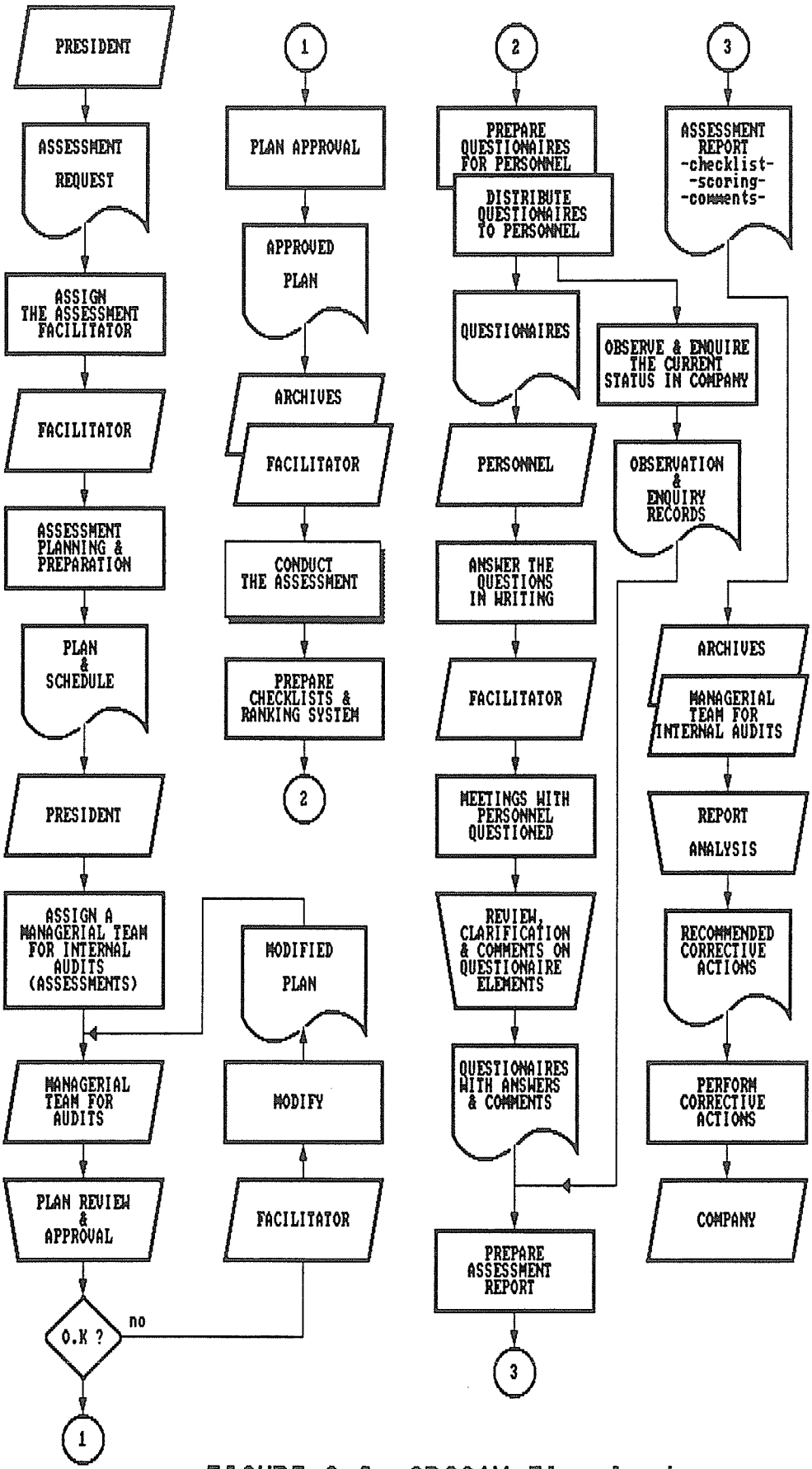


FIGURE 3.2: SBQSAM Flowchart

Cycle	No.	Step	Explanation	Related Sources
P	1.	Originate	An assessment is initiated by the president/owner. He/she assesses the need for and the purpose of the assessment and makes a formal request.	ISO 10011-1 4.2.2
			The president/owner assigns the assessment facilitator. Facilitator should be qualified for conducting quality system internal assessments, possess a thorough knowledge of the standards, and be free from bias and influences which could affect objectivity. (See Comment One)	ISO 10011-1 4.2.1.4.
L A	2.	Planning	The facilitator prepares an assessment plan that includes the following: ♦ purpose, objective and scope of assessment; ♦ reference standards ♦ language of the assessment; ♦ responsibility matrix; ♦ schedule of the assessment and meetings; ♦ assessment report distribution; ♦ description of assessments methods	ISO 10011-1 4.2.1.3; 5.2.1: Willborn & Cheng, 1994.
	3.	Team	The president assigns the managerial team for internal assessments. The team is comprised of second level managers (marketing and sales, design, production managers, vice-presidents) and the president. The team reviews, modifies and approves the assessment plan.	ISO 10011-1 5.2.1
N	4.	Tools	The facilitator prepares working documentation (tools) for the assessment. The tools include: ♦ **Checklists** with a space reserved for comments on each entry (see tables 3.3; 3.4; Appendix IV) ♦ **Questionnaires** to be distributed to personnel (see figure 3.4, Appendix III and Comment Two) ♦ **Observation forms** (see figure 3.3) ♦ **Other supporting documents** (evidence for conclusions, confidential information forms)	ISO 10001-1 5.2.3 Willborn & Cheng, 1994.
D O	5.	Opening	The facilitator initiates the assessment execution by conducting an opening meeting, with the participation of the managerial team. The availability of resources and facilities for the assessment is evaluated and confirmed. Any anticipated unclear details of the assessment plan are further clarified.	ISO 10011-1 5.3.1

TABLE 3.1: Small Business Quality System Assessment Model (Page 1 of 2)

Cycle	No.	Step	Explanation	Related Sources
D O	6.	Execution	The facilitator executes the assessment by: ♦ distributing questionnaires to personnel designated in the plan; ♦ observing the current quality system status; ♦ conducting questionnaire review meetings (See Comment Three) While the personnel answer the questions from questionnaires, the facilitator collects assessment evidence through physical examination and verification testing. He/she keeps observation records on observation forms and other supporting documents.	ISO 10011-1 5.3.2
	7.	Closing	A closing meeting with the participation of the managerial team is organized. Assessment report distribution date is confirmed, and the most significant findings are presented.	ISO 10011-1 5.3.3
S T U	8.	Report	The facilitator prepares and distributes the assessment report, consisted of the following: ♦ Checklist with corresponding rating system and comments ♦ General conclusions and recommendations for action ♦ Questionnaires, observation forms and other supporting documents are attached to the report. (See Comment Four, figure 3.4)	ISO 10011-1 5.4
D Y	10.	Review	The president conducts the report analysis meeting, with the participation of the managerial team and the facilitator. Importance weights are developed, areas of improvement identified, and priority is given to critical elements. The facilitator recommends and discusses corrective actions and improvements. (see Comment Five)	ISO 10011-1 5.4
A C T	11.	Actions	Actions for ensuring the compliance to standard requirements and/or planned arrangements resume. Critical elements that have been designated as priority are improved or designed and implemented immediately, with less crucial elements dealt with subsequently.	ISO 10011-1 7

TABLE 3.1 : Small Business Quality System Assessment Model (Page 2 of 2)

Comment (Detailed Explanation)	Model Step
ISO 9000 Representative may be assigned with the corresponding responsibility. However , if the president assigns an external facilitator, he/she may serve in both the documentation/implementation consultant and assessment facilitator role. This empowers the efficiency of an assessment, since its primary objective is to narrow and eliminate the gaps between the quality system and the selected model.	1.
Questionnaires are designed in a way that ensures clear understanding of questions. Questionnaire pages follow the standard format. Each page consists of one question, a space designated for the answer (half a page), and space designated for facilitator's remarks, explanations and comments.	5.
Questionnaire review meetings are held on the date and time stipulated by the facilitator on the questionnaire. After distributing the questionnaires, the facilitator allows two to three days to the auditee to answer the questions. Meetings are designed as personal interviews with two people participating: the facilitator and the auditee.	6.
The checklist is filled on the basis of questionnaires and observation findings. Each entry must have a corresponding textual comment. The purpose of comments is: ♦ to identify the areas of improvement; ♦ to assist the management in recognition of noncompliances ♦ to justify the score stipulated with the entry. The First Assessment rating system is designed primarily for the purpose of classification of the elements and activities described in the checklist according to their importance and priority for introduction or improvement. The total score demonstrates the extent of the company's compliance with the applicable quality system standard. A checklist example illustrated herein has been used as a tool for the gap analysis against section 4.9 Process Control of the ISO 9001 standard, 1994. edition. Elements designed by the author are followed by comments, derived from the case assessment. Subsequent assessment checklists use the same entries for the purpose of clear illustration of implemented improvements. However, assessment checklists do not have a rating system, but a checkmark on whether the element is "conforming" or "nonconforming".	8.

TABLE 3.2 : Detailed Explanation on SBQSAM Steps

ASSESSMENT OBSERVATIONS FORM No. 23	
WHAT:	Product C, Style No. 95972, Batch No. 18, 19 and 20 are not identified by the compulsory travel ticket. Traceability lost.
WHERE:	Assembly Room 2, Conveyor 3
WHEN:	August 16/1995, 13:45 h
HOW:	The tickets have been cut off and thrown away by the assembly operator.
WHO:	Assembly Operator John Smith
WHY:	The operator has been instructed to dispose of the tickets by the foreman, due to the tickets replacement in the following phase of assembly operation.

ASSESSMENT OBSERVATIONS FORM No. 24	
WHAT:	Product B, Style No. **95969**, Batch No. 2 are mixed with Product B, Style No. **95968,** Batch No. 2.
WHERE:	Pressing
WHEN:	August 16/1995, 14:00 h
HOW:	Operator did not identify the difference in style numbers.
WHO:	Operator John Surwillo
WHY:	Operator's mistake. Underlining style numbers to emphasize the difference suggested.

FIGURE 3.3 : Assessment Observations Form (Examples)

PRESIDENT'S QUESTIONNAIRE

-page 23 of 45-

Review Meeting on May 15th, 1995. at 11 am

QUESTION No. 23 : *Do you conduct regular meetings to ensure that the quality system is in place and to ensure its effectiveness ? If you do, are the records of the meetings kept and by whom ?*

ANSWER : *No. The managerial team for production , comprised of me, design and production preparation manager and vice-presidents, holds meetings daily to discuss and solve problems and to monitor progress. Meetings are not planned in advance. No records are kept.*

COMMENTS : *These are informal meetings, organized by the president. Production manager keeps records of conclusions and recommendations. Minutes of these meetings are not documented.*

FIGURE 3.4 : Assessment Questionnaire

4.9 Process Control		FIRST ASSESSMENT						ASSESSMENT	
	Checklist Elements	**Hi**	**Mo**	**Lo**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Company has defined and documented responsibility and authority for production, installation and servicing processes	10	5←	0		5	PC-1	√	
2	Processes directly affecting quality have been clearly defined	10	5←	0		5	PC-2	√	
3	Documented procedures defining each such process and ensuring the maintenance of controlled conditions are defined and are available to all affected personnel	10	5	0	NE		PC-3	√	
4	Company has defined, documented and implemented the use of suitable equipment and working environment for each such process	10	5	0←		0	PC-4	√	
5	Compliance with reference standards, quality plans and/or documented procedures is defined, documented, implemented and maintained	10	5	0	NE		PC-5	√	
6	Each such process is controlled and approved through monitoring and control of suitable process parameters, product characteristics and equipment	10	5←	0		5	PC-6	√	
7	Criteria for workmanship are stipulated in the clearest practical manner and are available to all affected personnel	10	5←	0		5	PC-7	√	
8	Suitable maintenance, including preventive maintenance is documented and implemented	10	5←	0		5	PC-8	√	
9	The requirements for any qualification of process operations, including associated equipment and personnel is documented	10	5	0←		0	PC-9		√
10	Records for qualified processes, equipment and personnel are maintained	10	5	0←		0	PC-10		√
TOTAL SCORE						25			

TABLE 3.3 : Process Control Checklist for SBQSAM

PROCESS CONTROL CHECKLIST ELEMENTS

PC-1 : The responsibility for production process has been defined and assigned to the production manager. The company does not perform an installation process, and servicing is limited to replacement or full refund of the returned product. Detailed responsibilities for the production process are defined informally, but are not documented.

PC-2 : The company's management considers that each process, from collecting customer's orders to shipping the final product to the customer affects quality. However, such processes are not clearly defined, nor is their list available. For instance, it is not defined whether the housekeeping process is considered to affect quality or not.

PC-3 : No. Such procedures do not exist.

PC-4 : No. The use of suitable equipment and working environment has been defined, but not documented.

PC-5 : No. There are no documented procedures, standards or quality plans to comply with.

PC-6 : Yes. Processes are controlled and approved, but a lack of documentation is apparent. Quality control records do not exist, although quality control is implemented throughout the production process to assure product quality.
Statistical quality control is applied, but no records on this matter have been found in the course of assessment.

PC-7 : Yes.

PC-8 : Maintenance of equipment, including preventive maintenance is applied. Records of regular preventive maintenance are in place. However, maintenance procedures have not been documented.

PC-9 : No.

PC-10: Production records exist at some extent, but the need for improvement is evident.

LEGEND:

Hi	:	High	NA	:	Non-Applicable
Mo	:	Moderate	NE	:	Non-Existing
Sc	:	Score	Lo	:	Low
Comm	:	Comments	CONF	:	Conforming
NONC	:	Nonconforming			

TABLE 3.4: Comments and Findings Corresponding to Process Control Checklist for SBQSAM

3.4 Project Plan : Establishing An ISO 9000 Quality System in an SME

The main objective of this Project Plan is to originate a process which will constitute an ISO 9000 quality system, put it to work and, if desired by the management, prepare the company to apply for formal ISO 9000 registration. The ensuing are to be followed:

(1) Management Commitment & ISO 9000 Representative

Management decision, commitment, leadership and involvement is essential for ISO 9000 QS establishment. Top management must assign its time and available resources to accomplish this endeavour. A formal commitment is embodied in a quality policy statement, signed by the President.

The Management Representative is the person who encompasses a genuine and passionate commitment to quality and the ISO 9000 system, detailed knowledge of quality methods and systems, ISO 9000 in particular, and power to influence employees at all levels of the company. For a manufacturing oriented SME, it is advised that the manager in charge of the production process be assigned specifically.

(2) Project Planning and Assignment of Responsibility

The plan details the objectives of the establishment process, resources required for the project, persons responsible for the Plan implementation, steps to be followed and estimated time for the completion of each step. It may include a GANTT chart, and should be reviewed and approved by the President.

(3) Standardize Documentation Design

(a) Adopt Rules and Symbols for Integrated Quality Loop Flowcharting

(b) Develop Procedures for Writing Procedures and Work Instructions.

(c) Train employees to understand and implement the rules and procedures.

(4) Quality Loop Flowcharting

(a) Collect data for drafting flowcharts.

(b) Illustrate the flow of processes, material and information using integrated quality loop flowcharting. Review the flowcharts.

(5) Identify, Document & Implement Work Instructions

(a) Assign the implementation teams for drafting procedures and instructions

(b) Identify operations requiring work instructions using integrated flowcharts.

(c) Document and implement them.

(d) Incorporate review comments.

(6) Document & Implement Production Process Control Procedure (PPCP)

(a) Document & implement PPCP using work instructions as reference

(b) Incorporate review comments.

(7) Document & Implement Required Procedures

Draft final copies of procedures. Obtain approval.

(8) Document & Implement Quality Manual

Draft a Quality Manual. Incorporate review comments. Approve the Manual.

(9) Assessments & On-Going Quality Training

Management should establish an on-going ISO 9000 implementation project review system. It includes quality system assessments, corrective actions etc.

(10) Start the Registration Process (Optional)

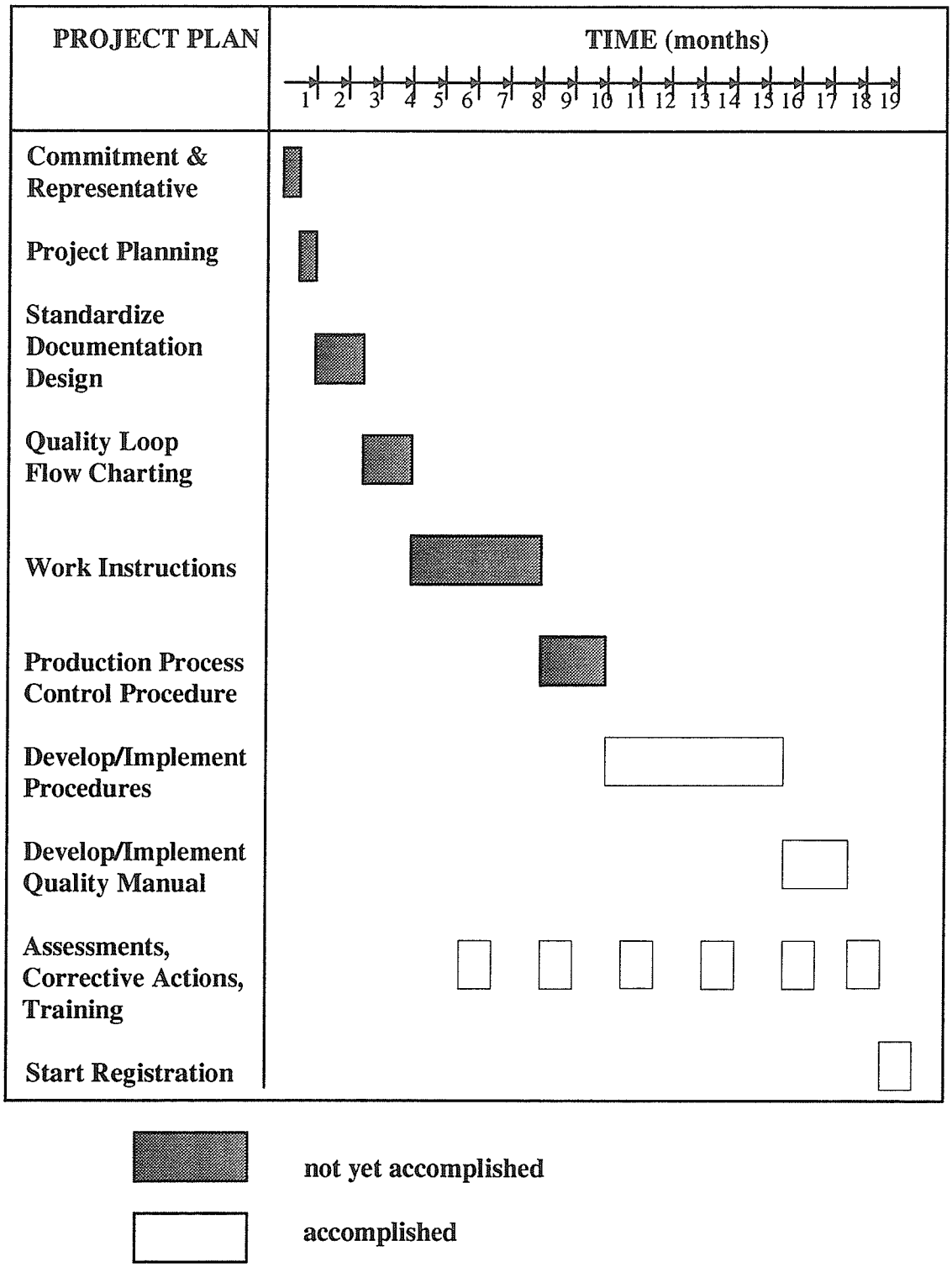


FIGURE 3.5 : Project Plan Gantt Chart

3.5 Small Business Case Study

Research work for the thesis has been conducted in a small, family business environment of a company based in Winnipeg, Canada. A detailed description of the company is provided in the fifth chapter of the thesis.

♦ Quality system initiation ⇒ "Do we need the system and if we do which standard model should we use?". Since the company designs it's products, the president has decided to develop a system complying to the ISO 9001 requirements.

♦ First Assessment ⇒ "Where do we stand ?": An assessment has been conducted to determine the degree of compliance with the ISO 9001 model. SBQSAM presented in the thesis has been used. The examples of SBQSAM documentation have been given in figures 3.1 and 3.2 respectively, whereas the complete checklist with comments is illustrated in Appendix IV. The list of questions supplied to the company's employees in questionnaires is given in Appendix III, while the steps are illustrated in table 3.5.

The case study showed the following:

- SBQSAM is a standardized model developed considering the features ISO 10011 standard and therefore in compliance with the current QS audit requirements.

- The model is designed specially for a small business environment, incorporating special features and characteristics of a SME in the frame of standardization written for large enterprises.

- The model is time and cost effective. For example, a simultaneous distribution of questionnaires and QS status observation save both the facilitator's and the auditees' time and financial resources.

- It is time efficient. Auditees can plan the time when they feel comfortable to answer the questions from questionnaires, and the facilitator can distribute his own time accordingly.

- Auditees participation and understanding is increased, and they feel less intimidated by the assessment (or audit).

◆ Project Plan ⇒ "How Do We Proceed ?" : The company has proceeded according to the Project Plan - Establishing ISO 9000 in SME. The plan, stipulated hereabove, can be used in any manufacturing oriented SME.

No.	Step	Date	Case Study
1.	**Originating**	Apr. 28	The President determines the need for the first assessment as: ♦ lack of information on the current quality system status is evident ♦ gaps between the system and model are unknown A formal request for the first assessment is written stating the intent to evaluate current QS against ISO 9001 model. The President assigns me as an external facilitator.
2.	**Plan**	Apr. 29	Facilitator prepares the first assessment plan. Plan follows the point form and includes: ♦ purpose and objective ⇔ as stated in the request ♦ scope ⇔ applies to all areas in the company ♦ reference sources ⇔ ISO 10011-1, SBQSAM ♦ language ⇔ English ♦ responsibility matrix ⇔ Appendix III-1 ♦ schedule ⇔ Appendix III-2 ♦ assessment report distribution ⇔ May 19th ♦ description of methods ⇔ Appendix III-3
3.	**Team**	May 1 9^{00} -9^{10} am	The president assigns the team for assessments, comprised of himself, vice-president for finance, marketing and sales/design/production managers and shipping supervisor. The team reviews the plan, and makes the following modifications and requests: ♦ scheduled times for interviews with the supervisor and vice-presidents are changed due to prescheduled obligations ♦ production manager requests simplified questions due to the lack of mastery in English language
4.	**Tools**	May 1	Facilitator prepares working documentation. It comprises of the following: ♦ checklist, slightly adapted from Johnson, 1994. ♦ individual questionnaires tailored for each member of the team (Appendix IV), including a list of terms to avoid misunderstandings and ambiguity ♦ observation forms
5.	**Opening Meeting**	May 2 9^{00}-9^{04} am	An opening meeting is conducted with all team members participating. The problem of the president's unavailability on the scheduled date of interview has been immediately solved by rescheduling it for the subsequent date. Availability of resources confirmed.

TABLE 3.5 : SBQSAM Case (Page 1 of 2)

No.	Step	Date	Case Study
6.	**Execution** •Distribution	May 2	At 9^{05} am, facilitator distributed questionnaires to team members. The questions were individually reviewed in the next ten minutes, and a few terms and questions clarified. Facilitator is available at any time for contact if any further clarification is needed. During the next three days, team members will be working on questionnaires.
	•Observation	May 2-5	Meanwhile, facilitator performs: ♦ physical examination, through continuous observation of QS elements in facility ♦ verification testing, through: -monitoring the flow of two products (sweaters) from raw material to the finished product shipping -tracing a specific sweater from packing to raw material stage
	•Interviews	May 5	Personal interviews are held. Review of answers and descriptions is performed, with corresponding explanations recorded in the comment section of questionnaires (figure 3.4).
7.	**Closing Meeting**	May 5 5^{00} pm	The date of assessment report distribution has been confirmed. The following significant findings are presented by the facilitator: ♦ Qs is well in place, but is not documented ♦ Discrepancies have been found in all requested QS elements, especially in: - Document Control - Identification and Traceability - Quality Records - Process Control
8.	**Report**	May 8-18	Facilitator prepares the report, consisting of: ♦ Checklist with comments and supporting documents (Appendix III) ♦ Conclusions and recommendations
9.	**Review**	May 18	Report analysis meeting is conducted, with the managerial team, president and facilitator participating. Documentation, process control and product identification and traceability have been designated as areas in need of improvement.
10.	**Corrective Actions**	May 18 -	Actions of ensuring the compliance to standard elements in areas designated in step 10 resumed (see the following chapter).

TABLE 3.5 : SBQSAM Case (Page 2 of 2)

4.0 DOCUMENTATION AND IMPLEMENTATION

4.1 Introduction

ISO 9001 standard requires development and implementation of a documented quality system (QS). Furthermore, the standard requires the preparation of a quality manual and the preparation and effective implementation of documented quality system procedures. Documented procedures may take reference to work instructions that define how an activity is performed (ISO 9001-94). Other than the above mentioned requirements and guidelines, the standard does not specify methods for developing QS documentation, nor does it stipulate the required documentation structure. However, the following four-level structure is most commonly suggested in existing literature (Willborn & Cheng, 1994, Lamprecht, 1992).

(1) Quality Manual and Policy, describing an overall quality system of a small enterprise, quality objectives and policy;

(2) Quality System Procedures, covering all twenty elements of the standard. QS procedures describe the responsibilities, authorities and interrelationships of personnel who manage, perform, verify or review work affecting quality; how the different activities are to be performed, the documentation to be used and the controls to be applied (ISO 10013, 1991.)

(3) Work Instructions, defining the manner of the activities performed by an individual employee. Work instructions document only the operations that affect quality.

(4) Quality System Records, bearing evidence on processes already executed.

This chapter describes ISO 9000 quality system documentation development and implementation for a manufacturing oriented small business. A convenient technique for outlining QS documentation is flowcharting. Several aspects of this technique are discussed, followed by the description of symbols and rules for effective QS flowcharting. The concept of quality loop flowcharting is introduced, followed by examples of flowcharts used for that purpose. Subsequently, design and implementation of the procedures for writing procedures and work instructions are addressed. A manufacturing oriented SME is focused on its production process. Establishing production process documentation can follow a treacherous path. Therefore, this aspect of documentation and implementation is discussed using a case study. Work instructions, process control procedure and quality records are focused.

4.2 Quality System Flowcharting

4.2.1 Overview of the Areas of Application

Flowcharts are used as a tool in quality improvement and for the purpose of QS documentation and auditing. They are known as one of the "seven old" quality tools (Evans & Lindsay, 1993; Besterfield, 1994). In terms of process improvement, according to Simic, 1993, flowcharts are used for the following:

1. Process description
2. New process design and implementation.
3. Process Improvement

If used for process description, flowcharts should answer the following questions:

- Where is the problem ?
- At what stage should we inspect the process ?
- Who should we assign to solve the specific problem ?
- How is one specific stage affecting the other ?
- What are the inputs and outputs of the process ?
- Does the information feedback exist and if it does, where ?
- What stages or basic processes are redundant ?

In terms of process improvement, flowcharts are used for::

- measuring the effectiveness of process improvements
- problem solving (Tomasek, 1992., Evans and Lindsay, 1993.)
- planning information systems (Pyzdek, 1989).

Flowcharts are also used in documenting a process, i.e. for writing QS procedures. A method for procedure writing using flowcharts is provided by Turnbull and Higby, 1985. Lamprecht, 1992. It emphasizes that a substantial advantage of flow charting, when used for this purpose, is that it forces a group of people to describe and brainstorm their conception of the process. Once a consensus has been reached on the process flow, opportunities to improve should be suggested. Documentation should not become a static event. It should rather be dynamic and allow for continuous improvement in process effectiveness.

4.2.2 Integrated Process/Material/Information Flowcharts

QS documentation covers all aspects of an organization's quality system. It describes the organizational structure, the processes, the flow of information and materials. For the purpose of effective illustration of these aspects, we need charts that can graphically represent the flow of processes, materials and information simultaneously. Therefore, we can call such charts - integrated flowcharts. Their quality is in integration of the most important business factors - processes, material and information. With these charts, one can perceive the flow of all three business factors using only one chart.

For the purpose of a simple and yet understandable presentation of flowcharts for documented procedures, standardized flowchart symbols should be used. We can find a variety of flowchart symbols in the existing literature, but we actually need only a few of them for creating an integrated flowchart. Integrated flowcharts can be illustrated with eight (8) symbols only, assuming the symbols are precisely defined. The symbols are illustrated in table 4.1.

Apart from standardized symbols, integrated flowcharting will be effective only if certain rules and principles are followed. If that is not the case, the experience illustrated in the fifth chapter has shown that an organization may encounter serious problems resulting in great loss of time and energy. Therefore, a set of ten rules, adapted for the use in SMEs from Karapetrovic, 1994b, is provided intTable 4.2.

4.2.2.1 Symbols

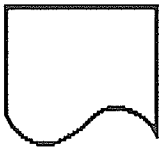
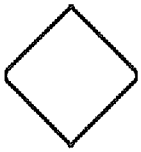
SYMBOL	SYMBOL DEFINED	SYMBOL	SYMBOL DEFINED
	INPUT/OUTPUT - SUPPLIER - - CUSTOMER - (Person/Dept.)		VALUE-ADDING ACTIVITY (Operation)
	DOCUMENT - Written Form -		NON-VALUE-ADDING ACTIVITY - Inspection - - Review -
	MATERIAL		DECISION POINT
	CONTINUE Flow Chart Continued On an Identical Symbol		REMARK

TABLE 4.1: Integrated Flowcharting Symbols

4.2.2.2 Rules

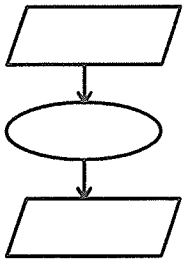
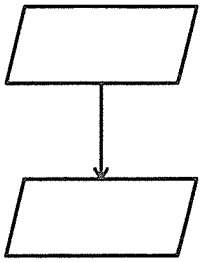
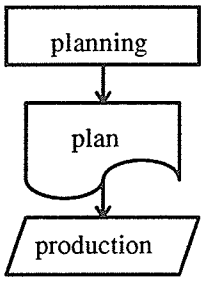
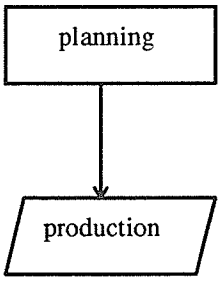
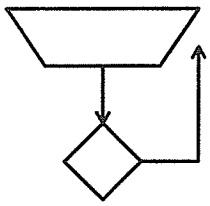
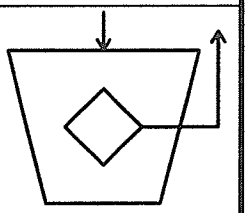
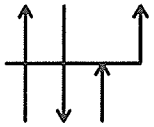
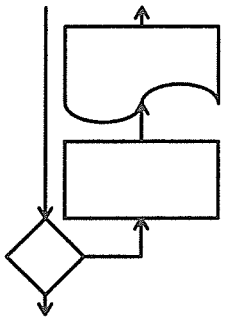
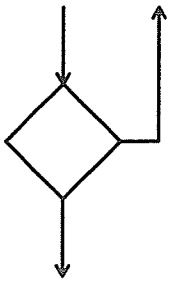
No.	Rule	Description	Yes	No
1.	Every process can be flowcharted			
2.	Never design two consecutive input/output symbols	There should always be a business factor and/or an activity between two consecutive symbols. If no business factors are transferred, use only one symbol.		
3.	If a business factor is created by an activity, draw the corresponding symbol after the activity symbol			
4.	Do not create hybrid symbols	Creating hybrid symbols makes the chart complicated and hard to understand		
5.	Simplify the flow of business factors as much as possible	Complicated flow hinders the possibility for easy understanding of the flow chart		
6.	If a business factor is created as a result of the feedback, assign an activity of creating it and a corresponding factor symbol	For instance, if a company wants to inform the customer of how his /her complaint has been processed, an activity of processing the report and a report symbol are included		

TABLE 4.2 : Integrated Flowcharting Rules (Page 1 of 2)

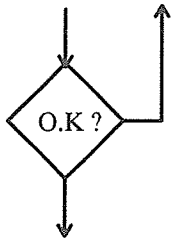
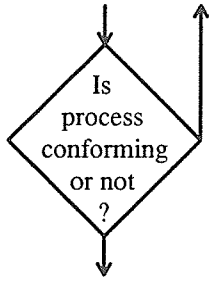
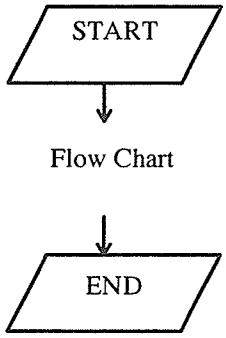
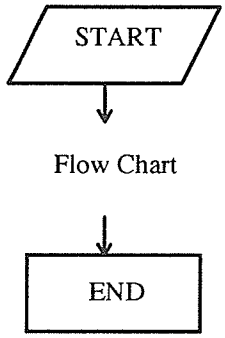
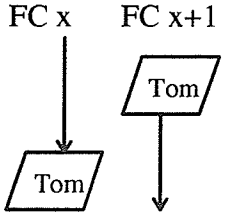
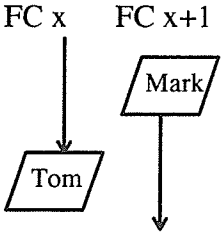
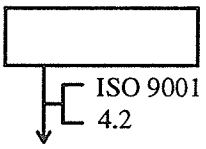
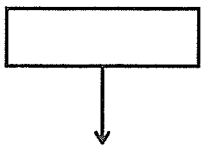
No.	Rule	Description	Yes	No
7.	Design a decision symbol as simple as possible	A decision symbol follows the review or inspection symbol and therefore should answer the question whether this activity had a positive or a negative outcome. For example, a simple question :"O.K ?" yields to two possible answers only : "yes" or "no".		
8.	The first and the last symbols of a flowchart is always an input/output symbol.	Every process starts with a certain input (materials, documents) and ends with a specified output (product, service, software). Therefore, there is always a corresponding symbol.		
9.	The output symbol of a flowchart is identical to the input symbol of the consecutive flowchart.	An output of a process is identical to the input of the subsequent process. The same applies to the flowcharts illustrating the two processes.		
10.	Standardized processes and activities are illustrated with a remark symbol.			

TABLE 4.2 : Integrated Flowcharting Rules (Page 2 of 2)

4.2.3 Quality Loop Integrated Flowcharting

In order to avoid unnecessary and extensive utilization of SME's limited resources, a most careful and precise planning on the scope of activities and processes being documented is crucial. Documented operational procedures should specify the objectives and performance of the various activities having an impact on quality (ISO 9004-1, 1994, section 5.2.5). This concept is known as "The Quality Loop", a model of interacting activities that influence the quality of a product in the various stages ranging from the identification of needs to the assessment of these needs have been satisfied (ISO 8402, 1986). In order to have a clear and unambiguous view on the processes and activities that have an impact on quality and therefore must be documented , an SME should illustrate the stages that comprise them. This can be done by using integrated flowcharts. The process , therefore called "Quality Loop Flowcharting" is portrayed hereunder. An outlook on the processes that should be flowcharted, as well as the tools used for that purpose are presented.

4.2.3.1 Processes

Quality loop flow charting process begins with identifying customer needs. This flowchart should indicate the sources of the identification of needs: customers, institutions, statistical agencies, governmental sources, marketing research surveys; and types of information they provide: market research results, statistical data, customer supplied information. This is followed by a description of activities that ensure communication of those needs within an SME, and approval of the capability to meet the needs. Specific customer and market needs and expectations should be

translated into a brief specification or outline, presenting an output from this process. A brief product specification is an input to the process of product design and development. This process is illustrated by a flowchart outlining in detail the activities of design planning, reviews, qualification and validation, and verification. After a new product has been developed, a process to materialize the product has to be planned and designed. The production process comprises of process development, planning, preparation, execution and verification. It is particularly useful to present charts showing the flow of material and information, as well as the process phases, for a number of reasons: (1) flow charts are subsequently used as a part of the production process control procedure, (2) used as a tool for quality improvement, production process flow chart may identify process bottlenecks and phases needing improvement, (3) process and product verification and inspections stages are clearly demonstrated, visualizing process control elements.

The purchasing process starts with an issue of specifications for purchasing and a selection of acceptable suppliers, followed by agreements with suppliers on quality assurance and verification methods. The purchasing process output is presented by input material to the production process. While after-production processes, such as packaging, storage, delivery, installation, and servicing are illustrated by integrated material / information / process flow charts, customer feedback flowcharts provides the information on company's performance to meet and/or exceed customers expectations.

4.2.3.2 Tools

Methods for designing an integrated flow chart include:

♦ Interviewing. Personnel possessing a comprehensive knowledge on processes are interviewed. Their remarks, comments, findings and experience are recorded on pre-drafted forms by a person assigned for drafting the process flow chart. An example of the form is illustrated in figure 4.1.

♦ Observation. Flow chart originator observes the process/material/information flow by tracking a specific product, document or a material from the first to the last stage of process. At decision points possible outcomes are followed and recorded.

♦ Self-flowchart drafting. Personnel who are able to provide a complete, but nevertheless detailed outlook of a part of, or even the whole process, draft flowchart themselves by following the flowcharting rules. Such flow charts are subsequently renewed and integrated by the flowchart originator.

Flowcharts are subsequently reviewed by a team comprised of the originator representatives of the top management. For instance, the production manager will participate on a review meeting on a production process flow chart, whereas the shipping supervisor participates in shipping process flowchart review.

INTERVIEW FORM FOR PROCESS FLOWCHARTING

Person interviewed : *Knitting Department Head* Date: *May 12/1995*

Process (Activity) name : *Knitting*

INPUT	
WHAT	FROM
1) *Production Order*	*Prepar. Technician*
2) *Yarn Voucher*	*Prepar. Technician*
3) *Yarn Cones*	*Receiving Dept.*

OUTPUT	
WHAT	TO
1) *Production Record*	*Prod. Manager*
2) *Yarn Voucher*	*Vice President*
3) *Bundles*	*Sewing Dept.*

PROCESS

STAGE ONE	WHAT / HOW
WHO : *Knitting Dept. Head*	*Knitting machine programming for specific*
WHERE : *Computer Room*	*style, size and colour. Program is installed*
WHEN : *After receiving Prod. Order*	*on the machine. Hard copy to operator.*

STAGE TWO	WHAT / HOW
WHO : *Knitting operator*	*Garment visual inspection.*
WHERE : *Knitting Department*	*repairs operator*
WHEN : *Every five minutes*	*O.K ?* / *yes* / *sewing*

FIGURE 4.1 : Flowcharting Interview Form (Example)

4.3 Procedures for Standardized Documentation Design

Experience in manufacturing oriented enterprises (Karapetrovic, 1994A) has shown that the process of developing QS documentation must follow standardized guidelines. The guidelines provide uniformity of the documentation and avoid ambiguity. However, since ISO 9000 standards do not provide such guidelines for developing procedures and work instructions, the first step in the documentation process is creating procedures for writing procedures and work instructions, respectively. The development of these procedures is addressed in the first step : "Documenting Procedures".

Implementation is a natural step following quality system documentation. Without proper implementation, documentation efforts are worthless. Therefore, procedures created in the first step must be adopted by all the personnel governed by them. This is ensured in the second step named "Implementing procedures".

4.3.1 First Step - Documenting the Procedures

(1) PLAN: The procedures for writing procedures and work instructions are prepared by the originator, assigned by the company's president. They must be adopted by all personnel participating in documentation design and implementation. In the initial memo, the president, along with the originator, stipulates a list of personnel affected by the procedures, a schedule of review meetings and the planned date of introduction.

(2) DO : The oiginator designs the procedures using the following approach:

- ♦ Procedures describe processes
- ♦ A process transforms input to output through a number of stages
- ♦ Processes are controlled by the resources responsible for process control
- ♦ A process consists of a number of sequential operations
- ♦ An operation is performed by an individual employee - operator
- ♦ A process is illustrated by the integrated flow chart
- ♦ Boundaries of an operation are shown in the flowchart by input/output symbols
- ♦ Operations that affect quality are defined by corresponding work instructions

The procedure format and table of contents, designed following the principles presented hereabove, is illustrated in figure 4.2.

(3) STUDY : After a draft version of the procedures is prepared, the originator distributes it to the personnel assigned by the president and/or the originator for their review and comments. Comments are drafted on a copy provided to the individual employee. The ISO 9000 Representative schedules a review meeting with the personnel addressed by the procedure. Recommendations for procedure changes are given to the Originator.

Company Name: PROSPERITY KNITWEAR	Title: PROCEDURE FOR WRITING PROCEDURES	Status & Issue Number: D1
		Date of Issue : July 17, 1995
		Page 1 of 6
CONTROLLED COPY		Procedure Code: PWW-1
DO NOT DUPLICATE	Compliance with ISO 9001: 4.5.1-3 Document Control	

A procedure is a controlled document.
The Originator maintains control over issued copies

Emphasizes compliance with appropriate section of the standard

1.0 Purpose

2.0 Scope

3.0 Application

Supports the procedure and explain the reasons for its existence

4.0 Definitions and Principles

5.0 Procedure

5.1 Input Elements

5.2 Output Elements

Demonstrates input and output elements of the process; its suppliers & customers

5.3 Flow Chart

5.4 Responsibility Matrix

Illustrates stages that constitute the process, material and information flow

Defines resources responsible for the process

6.0 Reference Documents — *Provides related cross-reference*

	Function	Name	Signature
Prepared by :	Originator	Stanislav Karapetrovic	
Revised by :	Vice-President		
Approved by :	President		

FIGURE 4.2 : Procedure Format

(4) ACT : The Originator subsequently modifies the document according to the conclusion from the review meeting. The procedure is supplied to the reviser, who revises the document. Revision is followed by document approval from the President.

4.3.2 Second Step - Implementing the Procedures

(1) PLAN : Before distributing the procedures, the originator assures that only approved copies are distributed to designated personnel. A note stating the availability of the originator for any comments and/or recommendations is enclosed with a copy.

(2) DO : Procedures are officially introduced when members of the team(s) assigned for documenting the system officially start their efforts towards creating procedures and work instructions.

(3) STUDY : In the course of creating the system procedures and work instructions, originator(s) perform a review of the procedures they follow, namely procedures for writing procedures and work instructions and rules for flow charting. This is an on-going review, an assessment of the quality and suitability of procedures.

(4) ACT : If procedure change(s) are required, modification(s) are performed by the originator, followed by the president's approval. The implementation process is continuous and improvement PDCA cycles are repeated on regular basis. The algorithm for procedures changes is presented in figure 4.4.

4.3.3 Procedure for Writing Procedures

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PROCEDURE FOR WRITING PROCEDURES	Status & Issue Number : A1
		Date of Issue: May 15, 1995
		Page 1 of 7
CONTROLLED COPY DO NOT DUPLICATE		Procedure Code : PWP-1
	Compliance with ISO 9001: 4.5 Document Control	

1.0 Purpose

The purpose of the procedure defines objective of procedure. It should be specific and clear.

The purpose of this procedure is to detail the requirements necessary for documenting procedures, and to assist the originator(s) attain uniformity in writing and implementing work instructions.

2.0 Scope

This section defines to what activities the procedure applies.

This procedure applies to all quality assurance activities in the company. The management shall support and approve procedure writing projects and resulting procedures. The personnel concerned with a specific procedure shall participate in its design, implementation, maintenance and review. Procedures are also maintained and reviewed through planned or requested audits.

3.0 Application

This section defines function of and persons addressed by the procedure; time and condition for its application, rules governing deviations and approvals, and assumptions made.

The procedure is to be adopted by the personnel assigned for procedure preparation, implementation and audit. It shall be applied to all written procedures. Any deviations are subject to approval of the Originator and/or the President.

The Originator of the procedure is in charge for adherence to the requirements of this procedure , with contributing responsibility from the ISO 9000 Representative and/or the President.

The responsibility for preparation, implementation and modification shall rest with the managers stipulated in section *5.3 Responsibility Matrix* of this procedure.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

4.0 Definitions and Terms

This section defines the terms, expressions, symbols and/or abbreviations that must be known and understood by all the personnel performing the work relative to the procedure. The purpose of this section is to provide a clear understanding of the procedure and to avoid any anticipated ambiguity in its design, implementation and evaluation. If no definitions are needed, it is mandatory to state "N/A".

Procedure: A formal and mandatory directive and guideline for work performance that provides all the necessary information and performance criteria. The procedure is a second level document in company's documentation tier.

Originator: The person formally assigned for the preparation and writing of a procedure.

N/A : Non Applicable (abbreviation)

5.0 Procedure

The general rules for procedures are the following:

(1) The writing of procedures is arranged as a project with an ISO 9000 Representative as a coordinator and/or Originator.

(2) The personnel addressed or planned to be addressed by the procedure participate in its planning, drafting, and implementation.

(3) Instructions are audited regularly every six months or upon request.

(4) All procedures must be prepared on a standard format paper. The format is illustrated in this procedure. It consists of the following elements:

a) Company Name or Logo

b) Title : Procedure name. If possible, the name should reflect an entry from the ISO 9001 standard.

c) Status & Issue Number : The procedure status must be signified on the form. The following symbols shall be used to identify the status:

D : for a draft procedure currently under review

AT: for a tentative procedure introduced for a trial period

A : for an approved procedure.

Procedures shall have an issue number attached to the symbol. Issue number depends on the number of reviews performed on the procedure.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

d) Date of Issue : If not stipulated otherwise, date of issue is the date of approval by the person responsible for instruction review and/or verification

e) Page _ of _ : Indicates page number and total pages.

f) Procedure Code : Consists of the letter "P", standing for "procedure", two-letter code indicating title initials and a number. There shall be no procedures with the same code.

g) Compliance with ISO 9001 : Indicates number(s) of paragraphs from ISO 9001 standard that the procedure complies with.

h) Prepared / Revised / Approved by : The procedure shall be prepared, reviewed and approved by the persons addressed in section *6.3 Responsibility Matrix* of this procedure. This entry illustrates their function, name and signature

(6) A procedure table of content consists of the following headings:

1.0 Purpose
2.0 Scope
3.0 Application
4.0 Definitions
5.0 Procedure
5.1 Input/Output Elements
5.2 Information/Material/Process Flow Charts
5.3 Responsibility Matrix
6.0 Reference Documents

Procedure elements under the headings shall be written according to principles described under the same headings in the "Procedure for Writing Procedures" in italic.

5.1 Input/Output Elements

Input element *is an information/material/document created as a result of the process preceding to the process described by the procedure.*

Output element *is a information/material/document created as a result of the process described by the procedure. This element is an input element of the subsequent process.*

Input and output elements are presented in a table form (Tables 1 and 2).

Input elements are identified with their name, code (if applicable), and a supplier.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

*The **supplier** is a person/department that supplies the input element to the process described by the procedure. A supplier is identified by a function and name.*

Output elements are identified with their name, code (if applicable), and a customer.

*The **customer** is a person/department that receives the output element of the process described by the procedure. Customers are defined by their function and name.*

5.1 Input Elements

INPUT ELEMENTS			SUPPLIERS		
No.	Name	Code	No.	Name	Function
1.	Proposal for a New Procedure	N/A	1. 2. 3.	Vice-Presidents Managers Supervisors	All
2.	Request for a Procedure Change				

5.2 Output Elements

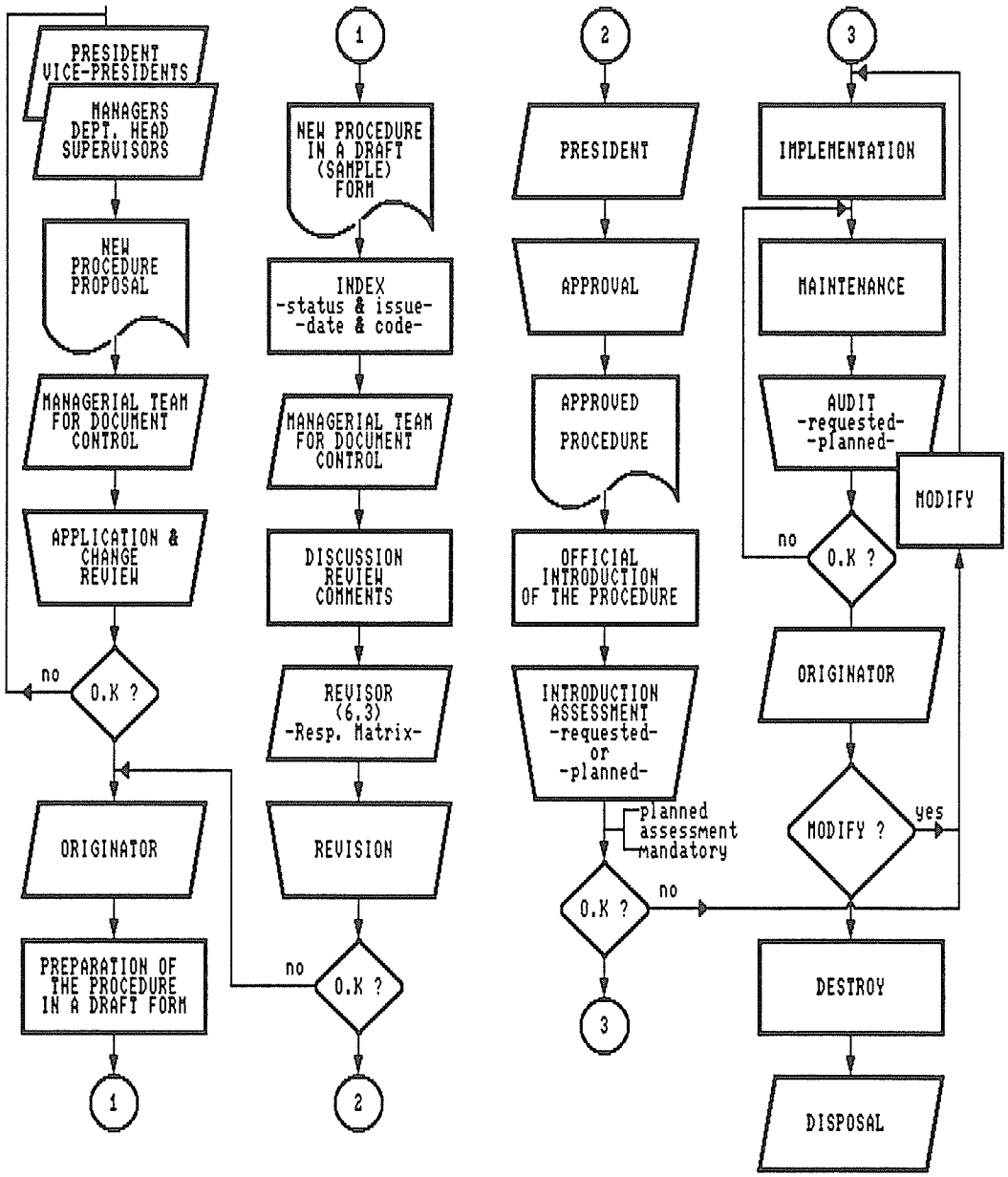
OUTPUT ELEMENTS			CUSTOMERS		
No.	Name	Code	No.	Name	Function
1.	Approved Procedure	PWP -1	1.	President	
			2.	Originator(s)	All
			3.	General Office	Archives

5.3 Information/Material/Process Flow Charts

*Information/Material/Process Flow Charts illustrate the sequence of operations/activities/phases in the process described by the procedure. Flow Charts are drafted according to the Internal Standard IS-1 **Rules and Symbols for Flow Charting.***

Operations documented by Work Instructions are coded and designated under the heading 7.0 Reference Documents.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	



	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.4 Responsibility Matrix

Responsibility Matrix defines specific authority and responsibilities for activities that consist the process covered by the procedure. It is given in a form of table (Table 3). Top row of the matrix illustrates the functions and/or the names of persons responsible for activities described in the procedure. Far left column illustrates activities which they are responsible for.

Responsibility can be defined as follows:

(a) in-charge : for persons with primary responsibility for the activity
(b) participate : for persons participating in activity
(c) supervise : for persons supervising the activity

FUNCTIONS RESPONSIBLE							
activities		President	Finances VP	General Manager	Production Manager	Shipping Supervisor	ISO 9000 Represent
Design Control	revise appr.	particip in charge		in charge	particip		particip
Handling, Storage, Packaging, & Delivery	revise appr.	particip in charge		particip		in charge	particip
Areas Covered by Sections 4.8 - 4.14 of ISO 9001	revise appr.	particip in charge	particip		in charge		particip
Areas not Covered Above	revise appr.	particip in charge	in charge				particip

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

6.0 Reference Documents

The references identify quality manual as a first level document, instructions and all the documents, such as external and internal standards, guidelines etc., referred to within the procedure, which are not part of the procedure itself. Instructions have designated codes for cross-reference.

NOTE: In the "Procedure for Writing Procedures", procedure written according to this procedure is referred to as **"the procedure"**, whilst the PWP-1 itself is refered to **"this procedure"**.

(1) Internal standard IS-1: Rules & Symbols for Flow Charting
(2) ISO 8402: Quality - Vocabulary
(3) ISO 9001: Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing
(4) Company's quality manual
(5) Willborn W., 1989, Quality Management System, Industrial Press Inc., NY

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

4.3.4 Procedure for Writing Work Instructions

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PROCEDURE FOR WRITING WORK INSTRUCTIONS	Status & Issue Number : A1
		Date of Issue: May 15, 1995
		Page 1 of 6
CONTROLLED COPY		Procedure Code : PWI-1
DO NOT DUPLICATE	Compliance with ISO 9001: 4.5 Document Control	

1.0 Purpose

The purpose of this procedure is to detail the requirements necessary for documenting work instructions, and to assist the originator(s) to attain uniformity in writing and implementing work instructions.

2.0 Scope

This procedure applies to activities leading towards drafting and implementation of work instructions in the company. The management shall support and approve work instruction implementation projects and resulting instructions.

3.0 Application

The procedure is to be adopted by the personnel assigned for drafting and implementation of work instructions. The procedure shall be applied to all work instructions. Any deviation are subject to approval of the Originator.

Primary responsibility for adherence to the requirements of this procedure shall rest with the Originator of the procedure, with contributing responsibility from the ISO 9000 Representative and/or the President.

The responsibility for preparation, implementation and modification of work instructions shall rest with the managers stipulated in section *6.3 Responsibility Matrix* of this procedure.

4.0 Definitions and Principles

Instruction: A formal and mandatory direction and guideline for work performance given in regard to what is to be done and how. A Work Instruction stipulates workmanship practices for performing the operation which it describes, identifies input and output material, equipment required and provides a layout of the workplace.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Originator: The person formally assigned for the preparation and writing of a procedure or a work instruction.

5.0 Procedure

The general rules for work instructions are the following:

(1) The writing of work instruction is arranged as a project with an ISO 9000 Representative as a coordinator and/or Originator.

(2) The personnel addressed by the instruction, i.e. operators and/or inspectors, participate in generating the necessary information for instructions, their planning, drafting and implementation.

(3) Instructions are evaluated regularly every six months or upon request.

(4) A change in elements addressed by the instruction, i.e. activities, workmanship practices, tests, material, workplace layout must be reported immediately to the ISO 9000 Representative and the Originator of the instruction.

(5) All work instructions must be prepared on a standard format paper. The format is illustrated by this procedure. It consists of the following elements:

a) Company Name

b) Title : For instance - " Knitting Operation Instruction"

c) Status & Issue Number : The instruction status must be stipulated on the instruction. The following symbols shall be used to identify the status:

D : for a draft work instruction currently under review

AT: for a tentative instruction introduced for a trial period

A : for an approved instruction.

Instructions shall have an issue number attached to the symbol. Issue number depends on the number of reviews performed on the procedure.

d) Date of Issue : If not stipulated otherwise, date of issue is the date of approval by the person responsible for instruction review and/or verification.

e) Page _ of _ : Indicates page number and total pages.

f) Prepared / Revised / Approved by : The instruction shall be prepared, reviewed and approved by the persons addressed in section *6.3 Responsibility Matrix* of this procedure. This entry illustrates their function, name and signature.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(6) An instruction table of contest consists of the following headings:

1.0 Purpose : Defines the purpose of an instruction, and the persons to whom it applies.

2.0 Responsibility : Describes detailed responsibilities of an employee performing the operation addressed by the instruction. Stipulates a name of the manager responsible for the operation.

3.0 Definitions : Explains the terms necessary for clear understanding of the instruction. If no definitions are necessary, it is mandatory to state N/A - Non Applicable under the heading.

4.0 Equipment : Provides a description of the equipment required for the operation. Explains where the equipment is located and/or who supplies it.

5.0 Instructions : Consists of the following entries:

5.1 Input Elements : Stipulates material(s) / document(s) / product(s) supplied to the operator, and their internal suppliers in a table form. Input elements and corresponding suppliers are designated with the name and number. If certain elements are attached together (a travel ticket and a batch, for instance), a rectangle covering the numbers of corresponding elements identifies such elements.

5.2 Output Elements : Stipulates material(s) / document(s) / product(s) supplied by the operator, and their internal customers in a table form. The rules described in 5.1 apply herein.

5.3 Work Instructions : Provide

5.3.1 Specific Instructions - step by step instructions for performing the operation addressed by the instruction, and

5.3.2 General Instructions - general instructions for the operation. May contain maintenance, inspection rules and/or activities performed less frequently then the ones described in 5.3.1.

5.4 Workplace Layout : Illustrates a layout of the workplace with a location of input and output elements, necessary equipment and documents, and a position of the operator while performing the operation.

6.0 Reference Documents : Contains reference second level (procedures) and fourth level (records) documents.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.1 Input Elements

INPUT ELEMENTS			INTERNAL SUPPLIERS		
No.	Name	Code	No.	Name	Function
1.	Proposal for a New Instruction	N/A	1.	Vice-Presidents	All
			2.	Managers	
			3.	Supervisors	
2.	Request for a Review	N/A	4.	Vice-Presidents	All
			5.	Managers	
			6.	Supervisors	
			7.	Operators	

5.2 Output Elements

OUTPUT ELEMENTS			INTERNAL CUSTOMERS		
No.	Name	Code	No.	Name	Function
1.	Approved Work Instruction	N/A	1.	Operator	
			2.	President	Archives

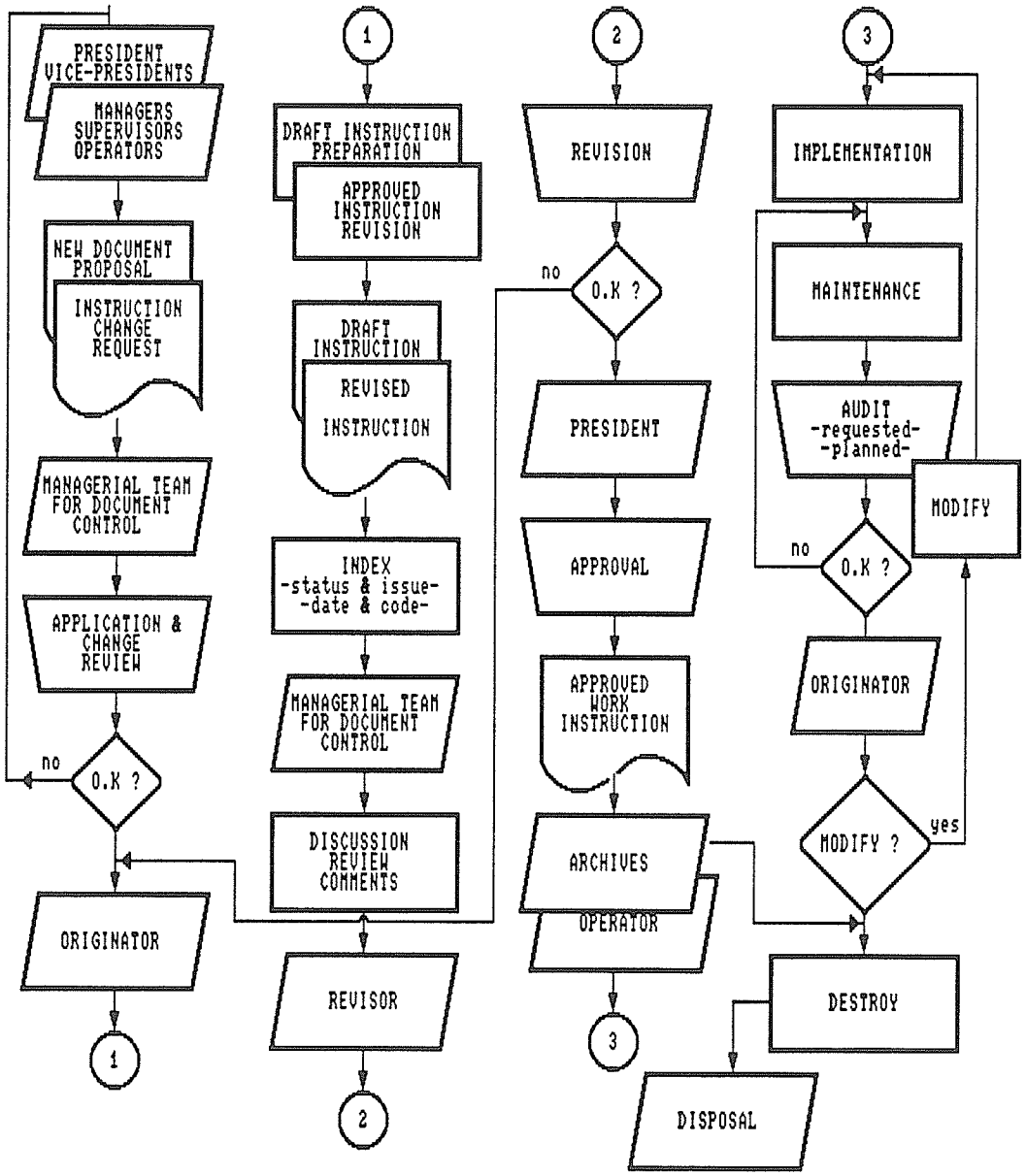
5.3 Work Instruction Implementation Flow Chart

Work Instruction Implementation Flow Chart illustrates the sequence of activities necessary for introduction and maintenance of work instructions.

It is drafted according to the Internal Standard IS-1 *Rules and Symbols for Flow Charting*.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PROCEDURE FOR WRITING WORK INSTRUCTIONS	Status & Issue Number : A1
		Date of Issue: May 15, 1995
		Page 5 of 6
CONTROLLED COPY DO NOT DUPLICATE		Procedure Code : PWI-1
	Compliance with ISO 9001: 4.5 Document Control	



	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.4 Responsibility Matrix

FUNCTIONS RESPONSIBLE							
activities		President	Finances VP	General Manager	Production Manager	Shipping Supervisor	ISO 9000 Represent
Production Process & Preparation	revise	particip			in charge		particip
	appr.	in charge					
Design & Marketing	revise	particip		in charge	particip		particip
	appr.	in charge					
Shipping & Receiving	revise	particip		particip		in charge	particip
	appr.	in charge					
Office & Areas not Covered Above	revise	particip	in charge				particip
	appr.	in charge					

7.0 Reference Documents

(1) PWP-1 : Procedure for Writing Procedures
(2) Internal standard IS-1: Rules & Symbols for Flow Charting
(3) PDC-1: Document Control Procedure
(4) ISO 8402: Quality - Vocabulary
(5) ISO 9001: Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

4.4 Production Process - Case Study

Having the rules for flowcharting and procedure for writing procedures and work instructions in place, a manufacturing oriented SME initiates the development of a documented quality system elements conforming to the twenty elements of the standard by documenting its production process. Firstly, necessary work instructions are designed. This is addressed in the first step - "Documenting Work Instructions". Next, they are implemented on the shopfloor. The implementation aspect is the focus of the second step called "Implementing Instructions". On the basis of production process work instructions, an SME creates a second level document addressing its production process: the Production Process Control Procedure. This procedure, covering sections 4.8 to 4.13 of the standard, along with the procedures for writing procedures and work instructions, encompassing section 4.5 Document Control, provides a sound foundation for the house of QS documentation. This concept will be addressed in detail in chapter five. An SME consequently continues the process of documentation/implementation, creating procedures covering the twenty elements, a quality manual, necessary work instructions and quality records. Activities proceed according to the project plan illustrated in chapter three.

4.4.1 Documenting Work Instructions

(1) PLAN : A meeting that would result in the decision of the necessary scope and application of production process work instructions is proposed. This meeting is attended by the ISO 9000 representative, production manager, supervisors in charge

of production, vice presidents and the president. The production process flowchart is analyzed. Using the principles given in section 4.3.1, we can determine the operations that need to be documented by work instructions. For example, the flowchart presented in figure 4.2 comprises of ten input symbols (assuming that the activity issuing the production order by the president is excluded). The symbols represent individual employees performing operations. Hence, knitting operator performs knitting operation, washing and drying operator performs the operation of washing, drying and separation, etc. Therefore, we have eleven operations comprising the production process. The standard requires that only the operations requiring inspection activities, or may be carried out in a way that would negatively affect quality must be documented (section 4.2.2, ISO 9001-94). In order to determine which operations ought to be documented, the question that should be asked at this point is "How does this activity affect the quality of our products?", and/or "If this operator does not follow prescribed practices, what could happen?".

After assessing the need for work instructions in a meeting attended by the production manager, production supervisors, vice-presidents, the president and originator, the following conclusions have been delivered:

- The knitting department head and sewing supervisor possess substantial training and experience to allow them to perform the scheduling operation without prescribed instructions.

- The repair operator follows the strict special instructions from the sewing supervisor, and the manner of his/her work depends heavily on the specific product style. Therefore, repair operation does not require a work instruction.
- All other operations could have a negative effect on quality if performed without prescribed practices, therefore needing work instructions.
- The production process will be covered by ten work instructions.: knitting, washing & drying, pressing, cutting, sewing, final visual inspection, final light inspection, sorting, pressing & blowing and packaging.

Each instruction is then assigned with a designated code, which is attached to the corresponding symbol on the flowchart. For example, knitting operation instruction is coded as IOK-1, and the code is attached to the knitting operation symbol. Subsequently, the president assigns me as a work instructions originator. The originator stipulates a schedule for a review meeting and the expected dates of work instructions introduction. Procedure for writing work instructions is strictly followed.

(2) DO : Data on activities planned to be documented by work instructions may be generated through similar steps, using the same tools as in the previous cycle. However, work instructions are more detailed and therefore require some modifications in data collection methods. An operator performing the activity to be documented usually possesses a most comprehensive and detailed knowledge of the operation. Therefore, his/her interview will significantly contribute to the originator's efforts. An operator interview form is used for this purpose (Figure 4.3).

OPERATOR INTERVIEW FORM

Operator interviewed : *Karla Staudzs* Date: *May 12/1995*

Operation name : *Cutting*

INPUT	
WHAT	FROM
1) *Production Order*	*Prod. Manager*
2) *Separated Bundles*	*Pressing Operator*
3) *Pattern Markers*	*Prod. Manager*

OUTPUT	
WHAT	TO
1) *Production Record*	*Prod. Manager*
2) *Bundles*	*Sewing Dept.*
3)	

EQUIPMENT

(1) Scissors

(2) Cutting machine

(3) Table

(4) Chalk

STEPS

(1) Put the sleeve and body bundles together

(2) Separate fronts and back

(3) Remove the threads

(4) Place the pattern marker on the bundle

(5) Mark with Chalk

(6) Cut with scissors or the machine

FIGURE 4.3 : Operator's Interview Form (Example)

(3) STUDY : Draft work instructions are given to the personnel addressed by the instruction for review and comments, for a period of ten days to two weeks. Work instructions are subsequently reviewed at regular meetings. The production manager is responsible for instruction revision.

(4) ACT : Modified and revised work instructions are approved by the president.

4.4.2 : Implementing Instructions

(1) PLAN : All personnel addressed by a specific instruction are informed of the instruction implementation. A copy of the instruction is placed on the workplace, where operators have easy access to it. The second copy of the instruction is kept by the production manager, whereas a third copy is archived in the president's office.

(2) DO : Operators perform their activities according to the instructions.

(3) STUDY : Operators, supervisors and the production manager evaluate the quality of the instructions, and suggest improvements. Instruction assessment is performed regularly or upon request.

(4) ACT : Corrective actions are undertaken according to the decision by the production manager.

4.4.3 Establishing A Production Process Control Procedure

On the basis of the documented work instructions, a production process control procedure is created and implemented. This procedure encompasses several sections (4.8 to 4.13) of ISO 9001 standard, and in SME, represents a model for other quality system procedures. After establishing the whole system, this procedure may be diffused to several more detailed procedures. The procedure is presented herein.

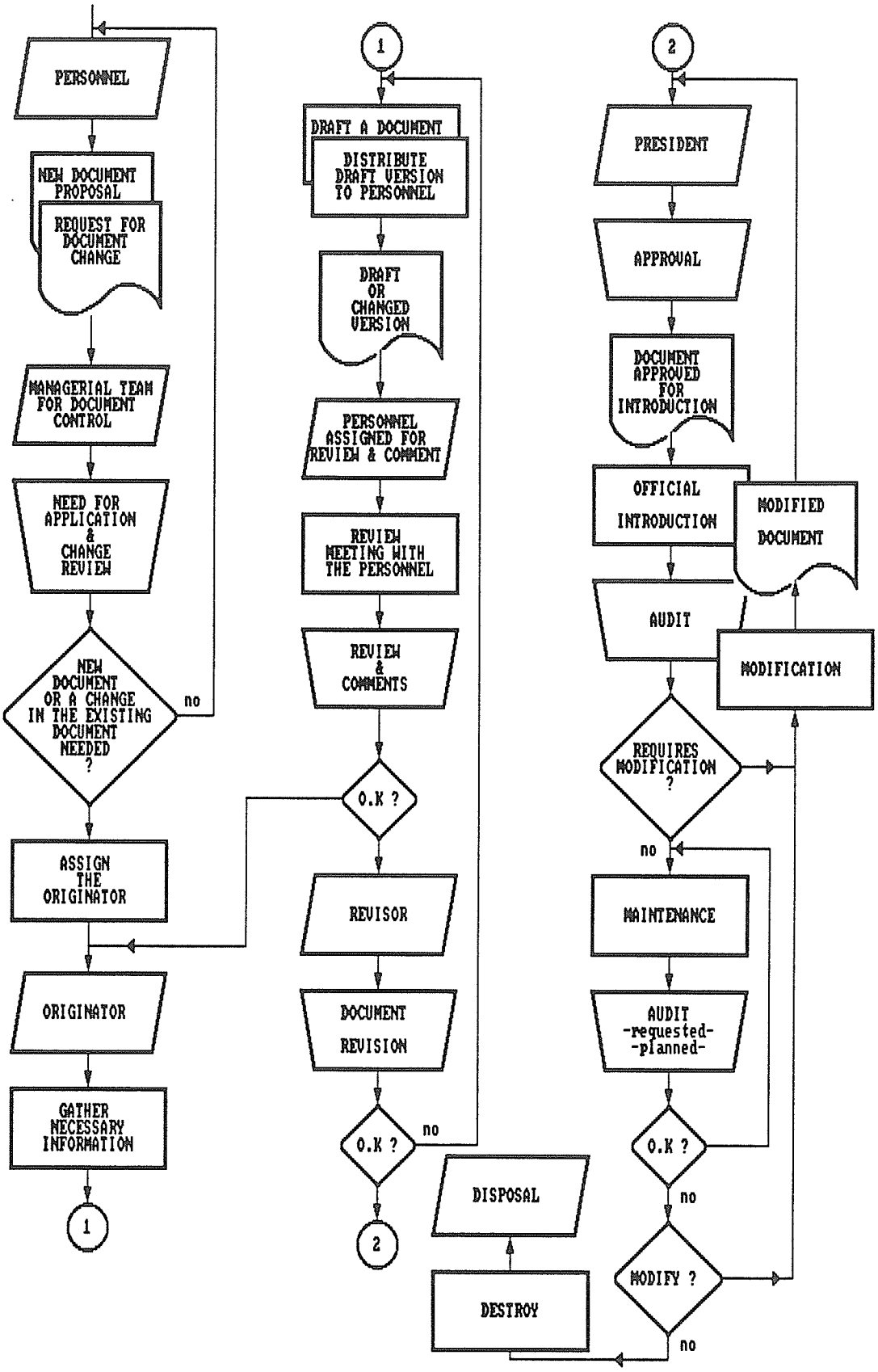


FIGURE 4.4: Documentation Design and Development Flowchart

4.4.4 Building Up the System

On the basis of the principles described hereabove, a quality system may be documented and implemented by continuously following the Shewhart cycle. All the necessary procedures and other documentation are created subsequently . An SME can expand the flowcharts created in the "Quality Loop Flowcharting" process to relevant procedures (flowcharts are integral parts of every procedure). It can also use its production process control procedure and work instructions to create other necessary documentation, thus covering the documentation pyramid (figure 4.5) .

The process, however, does not stop after registration. Quality improvement is an on-going process with no end. A perfect quality system does not exist and will never be created. We can only strive for better and better systems, knowing that the perfection we seek will never quite be achieved.

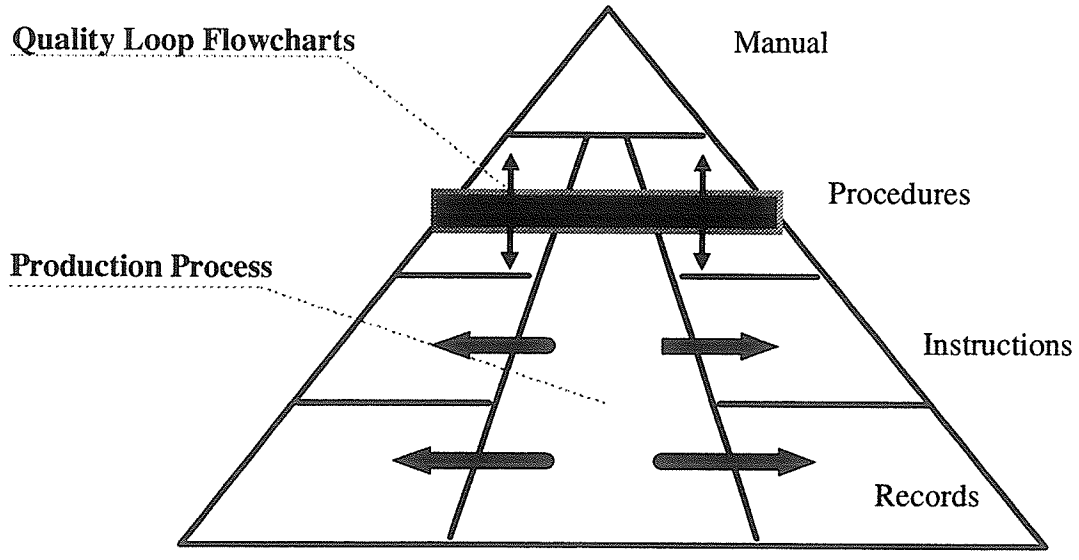


FIGURE 4.5: Building the System by Covering the Pyramid

5.0 LARGE AND SMALL BUSINESS: A TWO CASE COMPARISON

5.1 Introduction

During the last two years, the author of this thesis has had a unique opportunity to work on applying ISO 9000 standards in two very different companies. Although the companies were both manufacturing oriented and both decided to comply with ISO 9001 standard, they were distinctive in size, organizational structure and culture, field of manufacturing, ownership, processes, corporate goals, quality system levels and approach to markets. The first enterprise was a large steel company, specialized in production of tractors and farm industry machines. Located in Belgrade, Yugoslavia, it was a government owned giant that sold 70% of its products abroad, mostly to Asian, African and South American markets. The second firm was a privately owned SME - family business in textile industry, selling most of its products to North American markets.

ISO 9000 standards were created mainly by large industry representatives. The extent of difficulties that small businesses have encountered in the course of applying the standards raised the question of separate standards for SMEs. The objective of this chapter is to examine the adaptability of the standards to small business and relate the experience presented herein with that of large business using the two cases. Ultimately, the chapter should answer the question of whether the separate standards are necessary.

In order to provide a brief, but nevertheless comprehensive description of both companies' characteristics related to ISO 9000 standards, an illustration of their quality systems is provided. As defined in ISO 8402 Standard, a quality system comprises of the organizational structure, responsibilities, procedures , processes and resources for implementing quality management. An illustration includes some of the findings of ISO 9000 initial assessment conducted at the beginning of the efforts to pursue ISO 9001 registration.

5.2 CASE #1- Large Company

5.2.1 Organizational Structure

"Singidunum co." (SINco) is a large, government owned, steel manufacturer with about 12,000 employees. It is organized in a two dimensional matrix organizational structure, with four factories in a product dimension of the matrix (Tractors, Molding, Farm Machinery and Machines/Tools Factory) and nine sectors in the functional dimension. Quality Management (QM) is organized at a sector level (Quality Management Sector) and has more than 500 employees alone. QMS, with its human resources, processes, procedures and equipment performs the management of quality. It is comprised of quality assurance (QA) and quality control (QC) subsystems (Figure 5.1). The latter is characterized by a team organizational setting with two levels: self-inspection and process control inspection. Process control inspection comprises the quality control of equipment and phases, constituting the production process. Operators perform self-inspection and coordinate their work with the maintenance department, phase quality control teams, production supervisors and in-

process quality control manager (figure 5.1). QA subsystem consists of four bureaus: Continuous Improvement, Procedures Design (PD), Quality Management Information (QMI) and QA Cross-functional team. The latter encompasses representatives from QA teams in each functional sector. Apart from the QM sector, there is yet another level of quality management: the QM Steering Committee. It is a cross-functional management group responsible for managing quality related projects (ISO 9000, for instance), consisting of the CEO, sectors' and factories' heads.

5.2.2 Responsibilities

Quality authorities and responsibilities were generally defined by the organizational structure, but not clear to the extent the standard requires. An attempt to specially emphasize the authority and responsibility of the personnel who perform activities related to nonconformancies and verification activities has been successfully accomplished in the past, but no further actions to clarify management responsibilities have been made thereafter.

5.2.3 Resources

SIN's quality resources comprise of human resources, equipment, material and information resources. The following is an observation of the resources elements respectively:

◆ Human Resources : In QMS alone, about 20% of the employees were engineers, mostly mechanical and electrical, with 10-15 years of experience on

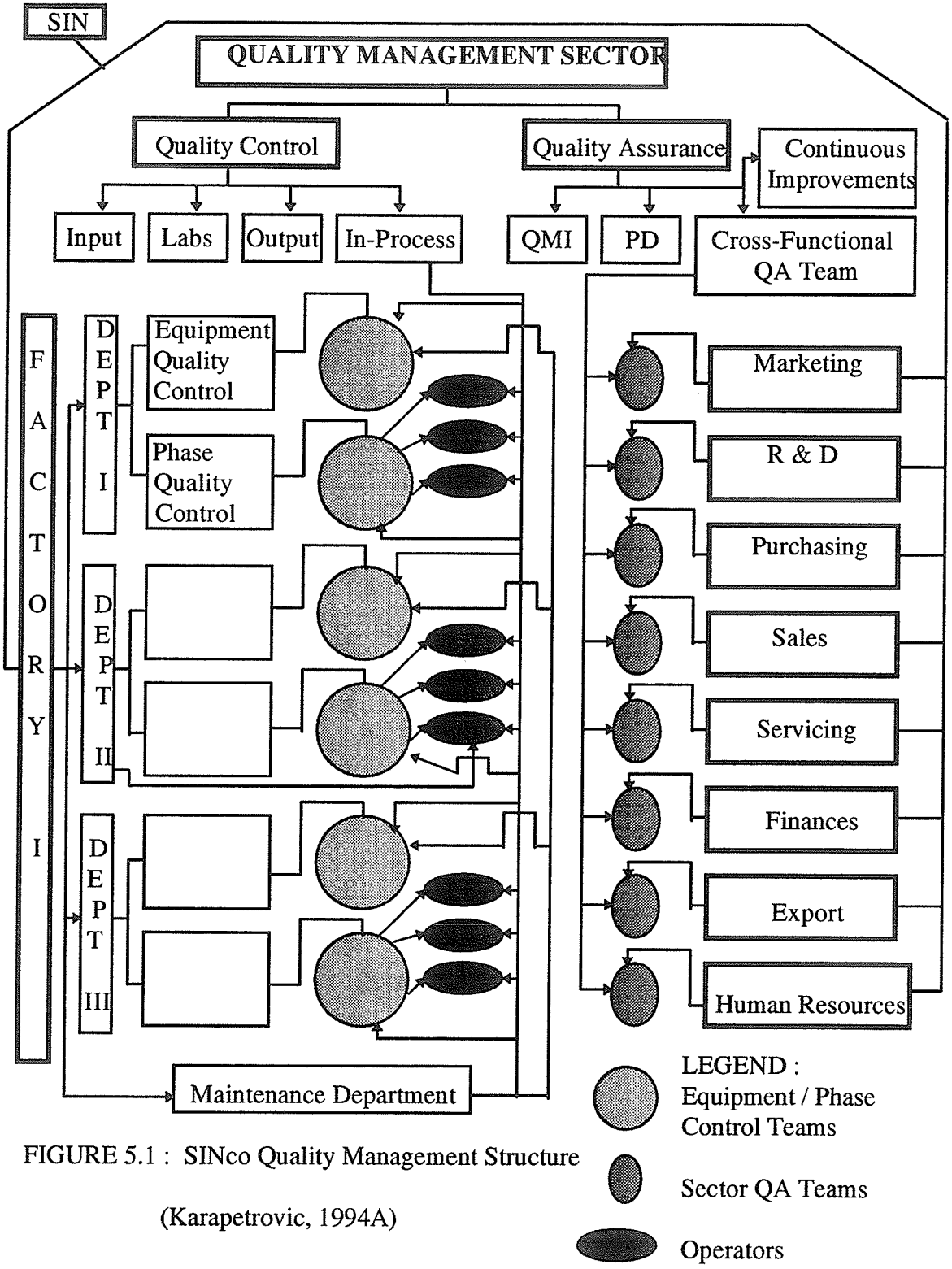


FIGURE 5.1 : SINco Quality Management Structure

(Karapetrovic, 1994A)

engineering in average. The majority of employees, about 50%, were technicians and technologists with a vocational secondary school or college and 15-20 years of experience in the field. Therefore, a general conclusion that the personnel had a ground training, qualifications and motivation for starting the process of implementation ISO 9000 standards was drawn.

♦ Equipment : Inspection, measuring and test equipment, as well as manufacturing systems are considered to be up to date and fit to comply with the standard requirements. Some of the most modern measuring and test equipment, including a three dimensional CNC measuring centre, was recently acquired, installed and is currently being used. The company has its own laboratories for inspection and testing, and even provides inspection, measuring and testing services to other companies.

♦ Material : Input material is supplied by long-term contractors with a well established history of supplies. However, due to the fact that a majority of sub-contractors are small businesses without ISO 9000 registration, SINco performs incoming inspection of all input materials and supplies. The fact that SINco's labs perform inspection of even water and air supplies speaks for itself.

♦ Information resources : Documentation was generally in place, but needed compliance to the standard. Due to the variety, volume and complexity of products being manufactured in the company, as well as the diversity in operations, processes and procedures performed, the overall amount of documentation was excessive and not easily controlled.

5.2.4 Procedures

The following are perceived features in terms of procedures :

- A clearly defined quality policy or quality manual did not exist
- Quality plans were being made related to the products and services performed
- A lack of sector or departmental quality assurance procedures was apparent, while documents such as operators instructions and quality control records were excessive in numbers and volume.
- Documentation in the company can be considered as comprehensive and provided overall coverage of the processes in the company.
- Document cross reference was non-existent, due to the fact that a list of either controlled or not controlled documents had not been in place.

In simple terms, no one in the company had control over, or knew exactly what documents were being used. This was obvious at sector's level, where different sectors would implement different procedures for control of the same documents. There was also an excessive number of different documents used for the same purpose (usually production and quality control records). Document and data control, therefore required documented procedures in order to meet the standard's requirements.

5.2.5 Processes

Due to specialization and departmentalization of the work processes in the company, processes other then production are covered by sectors, and the production process itself by the factories. Section 5.4 provides cross reference to the twenty

elements of the standards with respect to the processes and corresponding departments responsible, compared to the small business case.

5.3 CASE #2 - Small Company

5.3.1 Organizational Structure

Prosperity Knitwear Limited was established in 1984. as a family textile business. There were three employees: the owner, his spouse and sister. Gradually, the company grew and expanded to a firm that employs 65 people with annual sales of several million dollars. It is a privately owned company, a voting member of the Canadian Federation of Independent Business. The owner is the company's president, with three vice-presidents: for accounting and finance (owner's spouse), for production (owner's brother) and for preparation (president's sister). There are two departments: knitting and sewing. Production manager is in charge of production, and his spouse is responsible for the sewing department. Company's general manager is responsible for marketing and sales, and shipping supervisor manages shipping and receiving department. Quality management is executed by a managerial team, comprised of the president, vice-presidents, general and production managers and supervisors. However, a formal quality system organization is not defined.

5.3.2 Responsibilities

Vertical division of power exists, but not apparent and strict. Managers and department heads perform operator's roles, when the conditions require so. For instance, production manager will help operators by performing the operation they do,

actually becoming an operator himself, when it is perceived that the operation is becoming a bottleneck for production.

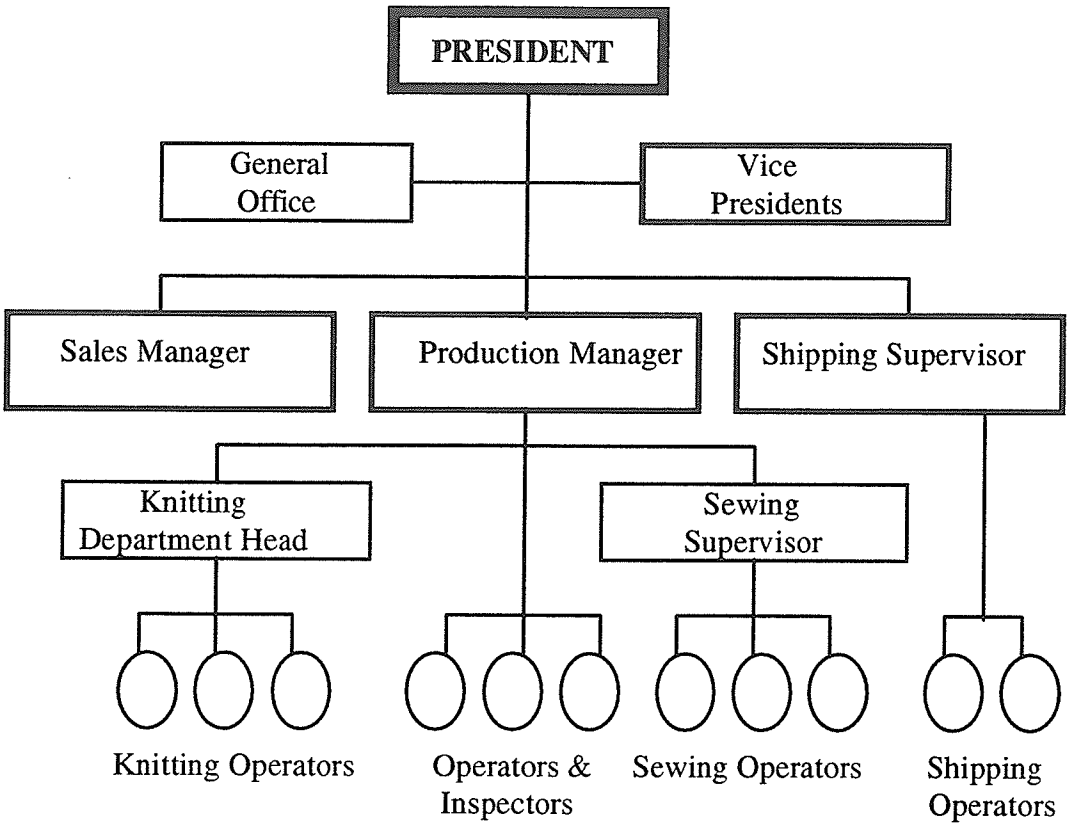


FIGURE 5.2 : Prosperity Knitwear Organizational Structure

5.3.3 Resources

◆ Human Resources : The majority of employees are skilled workers with a number of years of experience in the textile industry. For newly arrived unskilled operators, training is provided on site. The company's management possesses vast experience in the textile business and a high motivation for improving quality. Cultural homogeneity is another characteristic of this company. Nearly all employees are Chinese, as well as the president and managers. Employees in the general office all come from the

Philippines. Thus, the same conclusion as in a large business case (in regards to the human resources possibilities for applying ISO 900 standards) can be drawn.

- Equipment : The processes require relatively simple inspection, measuring and test equipment. Machines are all up to date, numerically controlled, and provide the possibility of autonomation (machines immediately stop if a thread is cut or broken)
- Material : Input material is supplied by long-term contractors with a well established history. However, systematized incoming inspection is not in place.
- Information resources : Lack of formal documentation is apparent. Existing documentation is 95% records. However, quality control records do not exist.

5.3.4 Procedures

The following are the company's perceived characteristics:

- Informal procedures. Quality assurance rests on the competence and experience of staff. Work assignments, instructions and procedures are orally and informally communicated. Informal relationship with customers is practiced.
- Personal touch. The operator will talk to the managers and the president himself about his problems. The president knows all his employees personally.
- Informal, but excellent communication between employees.

5.3.5 Processes

Major processes, entities responsible and characteristics related to ISO 9000 quality systems are presented in section 5.4.

5.4 *Quality Systems Comparison*

		Large Company		*Small Company*	
No.	**ISO 9001 Element (Process)**	**Entity Responsible**	**Features defined/ documented/ implemented (Yes or No)**	**Entity Responsible**	**Features (defined/ documented/ implemented)**
1.	Management Responsibility	CEO, QMS, sectors & factories management	Y/Y/Y	President, managers & supervisors	Y/N/N
2.	Quality System	QMS	Y/Y/Y	President	N/N/N
3.	Contract Review	Marketing	Y/Y/N		Y/N/N
4.	Design Control	R & D	Y/N/N	Team	Y/N/N
5.	Document & Data Control	QMS, factories & sectors	N/N/N	Vice-presidents	Y/N/N
6.	Purchasing	Purchasing	Y/N/N	President	Y/Y/Y
7.	Control of Customer - Supplied product	Purchasing & Factories	Y/N/N	Production manager	N/N/N
8.	Product Identification & Traceability	Factories	Y/Y/Y		Y/N/N
9.	Process Control		Y/Y/Y		Y/N/N
10.	Inspection and Testing	Factories & QMS	Y/Y/Y		Y/N/N
11.	Control of Inspection, Measuring and Test Equipment		Y/Y/Y		N/N/N
12.	Inspection and Test Status		Y/Y/Y		N/N/N
13.	Control of Nonconforming Product		Y/Y/Y		Y/N/N
14.	Corrective & Preventive Action	QMS	N/N/N	Team	N/N/N
15.	Handling, Storage, Packaging, Preservation & Delivery	Sales	Y/N/N	Shipping Supervisor	Y/Y/N
16.	Control of Quality Records	QMS	N/N/N	Nobody	N/N/N
17.	Internal Quality Audits		N/N/N	Nobody	N/N/N
18.	Training	QMS, Factories & Sectors	Y/N/N	Supervisors	Y/N/N
19.	Servicing	Servicing	Y/Y/Y	President	Y/N/N
20.	Statistical Techniques	QMS	Y/Y/Y	Nobody	N/N/N

5.5 *Establishing an ISO 9001 Quality System*

Although the management of both companies have decided to establish a quality system (QS) complying to ISO 9001 Model for quality assurance in design, development, production, installation and servicing, companies' quality systems, prior to the application process, both were at different levels. Applying ISO 9000 standards in a small company required a start from zero, whereas it appeared that the registration goal in a large company would be achieved without difficulties. Nevertheless, as the following section will show, plans do not always become reality.

5.5.1 Initial Knowledge of the Standards

A substantial number of employees in SINco's quality management sector were familiar with ISO 9000 standard series and its basic concepts. However, only the manager of the quality assurance department possessed a deep and clear knowledge of the standards. He was a mechanical engineer with over thirty years of experience in quality management. After the top management had decided to quest for ISO 9001 certification, he was appointed an ISO 9000 Representative.

In PKL, a vast majority of employees have never even heard of the standard before. The president and the production manager were familiar with the fact that the standard has to do with quality, but have never thought of it in depth.

5.5.2 Motives for Applying the Standards

The main reason for seeking registration in SINco was an apparent fact that only registered companies would be able to export their products and services to a broad market of European Union. The company considered ISO 9000 as an effective marketing and sales tool in other markets, as well as a path to Total Quality Management.

PKL's president and owner decided to concentrate the company's efforts towards improvements in quality control. It has been anticipated that the company will continue to grow, expanding its market share by "winning customers". Therefore, the president considered the establishment of ISO 9000 quality system beneficial, even if registration is not requested by the customers.

5.5.3 *Teams*

Due to the size of the company, it had become apparent that the ISO 9001 application process in SINco would require establishment of teams assigned with specific departmental tasks. Existing sectors' quality assurance teams were assigned to carry on all departmental tasks related to ISO 9000 project. The Steering Team was assigned to manage the project itself, and to develop a quality manual. The company's quality policy was drafted by the ISO 9000 Representative and signed by the CEO.

The approach practiced in PKL has been to employ an already existing managerial team for ISO 9000 activities. In a small business, teams specially engaged for the

project are not necessary. If several teams are created, the same people would be involved with different teams, because their responsibilities generally include more than one stage in the overall company's process. That would place unnecessary burden on their already busy schedule. Hence, in SMEs, the research suggests initial establishment of one team. Subsequently, if necessary, other teams can be created. In large businesses, in order to minimize the derangement of employees' daily activities, the use of existing formal teams is advised.

5.5.4 Initial Assessment

SINco organized an initial internal assessment by deploying audit teams. The teams were trained for internal auditing at a two day seminar held by an external consultant team hired by the company. They were independent of the area they assessed. The main conclusions of the assessment are presented in section 5.2.

PKL initial assessment has been executed by me, i.e. one person. The results are shown in the first chapter and Appendices II, III and IV of the thesis.

5.5.5 Project Planning

In spite of the obvious difference in quality systems status beforehand, both managements approved essentially similar project plans with corresponding milestones. This proves that companies seeking ISO 9000 registration, regardless of the size, in essence follow the same path.

Experience presented herein indicates that precise, well organized, clear and objective project planning is essential for success. Planning features include:

- ♦ Responsibilities and authorities of all employees involved in the project must be clearly and unambiguously defined
- ♦ The methods planned to be introduced by teams in terms of assessments, documentation and implementation must be clarified and documented.
- ♦ Standardization of the procedures they follow is necessary (see section 5.4.6)

If not, a company is likely to be facing a great loss in time, money, motivation and energy, due to the large number of employees working on a project and the tremendous extent of their efforts.

5.5.6 Standardized Documentation Design

Systematized documentation writing is amongst the areas where a comprehensive and clear plan is essential. The experience in a large company demonstrates that if a number of different people and/or teams were given a task without precisely stipulating the methods to be used in order to accomplish the task, it is likely that the methods and paths leading to fulfillment would be different. An example that proves this point follows. In the course of documentation design process in the large company, departmental teams were given a task to draft charts of information flow in each department using symbols stipulated in the national and European standard for flow charting. After a while, all the teams had completed their tasks, all flow charts had been ready and a review meeting was held. There were seventeen comprehensive flow charts, and all seventeen were different. The symbols used were the same, taken

from the standards. However, whereas some teams used only ten different symbols to flow chart their processes, some used as many as fifteen or sixteen.

One other major difference was apparent: flow charts were not consistent in the way they were presented. For instance, several teams used an approach where input/output symbols followed one another, others had a document or an activity between the two. It became indisputable that a tremendous effort had to be exerted to systematize the flow charts and enable possible users to understand them regardless of the process the chart is describing. The decision has been made to write Guidelines for Procedure Writing, that would explain in detail the methods, rules and symbols used for writing flow charts. As a result of that effort, it has been concluded that only a set of seven symbols can be used in order to illustrate an information flow. A set of rules has been derived and the results were published in a conference paper (Karapetrovic, 1994B). Departmental teams were obliged to follow the guidelines. A short time after the guidelines had been distributed to the teams, complete and systematized flow charts were drafted and ready for review.

Usefulness of such a document in a SME may be questioned, since it is perceived that only one team, even a single person can draft all the procedures and if necessary, instructions. However, both the findings of the New Zealand TC Committee (ISO/TC 176/NZ, 1994.), and the experience in our small business case study, have shown that writing a document that explains how to write a small company's documentation related to ISO 9000 standards is exceptionally useful for the following reasons:

- The document can be used as a tool for evaluating the effectiveness and efficiency of the documentation design process itself. Any written procedure can be compared with this procedure and subsequently evaluated.
- If operators themselves are involved in the instruction or procedure writing projects, this document is essential to avoid ambiguity.
- If a two step approach (see next paragraph) is used in documentation design and implementation, the document may be considered as a core document in the conceptualization phase. It may be used as a source for, and later as a part of the documentation control procedure.

5.5.7 Documentation Efforts

A quality system must be completely covered by relevant documentation regardless of the size of a company. As a British Handbook for SME (BSI, 1994.), demonstrates, it is a matter of writing down what you do, doing what you've written down and auditing that you do what you've written down. Slightly modified, it would be a PDCA circle: PLAN and write down what you do, DO what you've written down, STUDY it against the standard and audit that you do what you've written down on a repetitive basis, perform a corrective ACTION.

However, documentation process itself may follow different paths in a SME and LE. The method used in the small business case (PKL), was inductive in essence. At the very beginning, two second level documents were created : procedures for writing procedures (PWP) and work instructions (PWWI). Subsequently, the production

process has been completely covered by the process control procedure and instructions for each operation in the process, written strictly according to the corresponding writing procedures. Consequently, the production process and its documentation is used as a model for other processes. Manufacturing oriented small businesses owners are, more often than not, concentrated on a production process, and consider it to be the most important process in their business. It usually deploys experienced and knowledgeable personnel, improvements are being introduced in this process more often than in other processes and encompasses the largest portion of the company's overall business process. It is apparent that the production process encompasses a number of the standard's elements. After an all-encompassing production process control procedure (PPCP) had been created and possibly implemented, it can be broken down to a number of related procedures, covering each section of the standard separately, if requested. This method resembles the process of building a house (Figure 5.3), where the PWP, PWWI and PPCP represent the foundation, and all other procedures are "glued" like walls. Therefore, creating a quality system documentation is a process that may start from the middle levels of the documentation pyramid, and proceed towards the top level Quality Manual and Quality Plans (BOTTOM to TOP approach).

Large firm experience revealed that the company already had most of the lower level documentation, but a lack of a quality manual and procedures was evident. Accordingly, large businesses may develop a quality manual at the very beginning, and work towards low level documents consequently (TOP to BOTTOM approach).

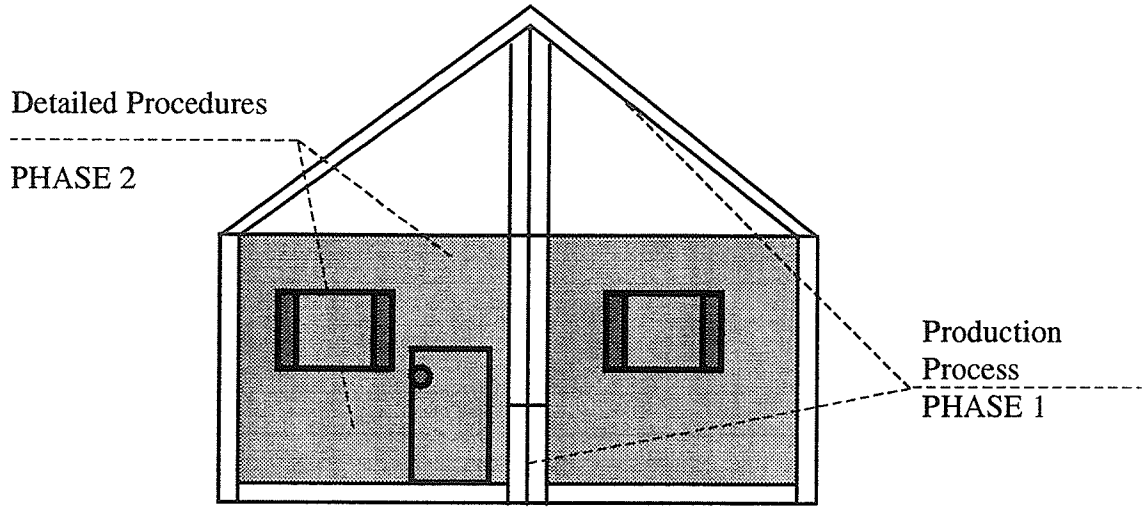


FIGURE 5.4: Small Business House of Quality System Documentation

5.5.8 Quality Training and Communication

Quality training is an essential process, which, if not carried out properly, may obstruct the efforts towards achieving ISO 9000 goals. A number of characteristics referring to quality training have been perceived in both the small and large company. The most significant difference between a large and a small enterprise, as perceived in this research, is not a number of employees or annual sales, but the management method. Whereas in the small company, the president, who is usually the owner, leads the company by personal involvement and participation, large companies have a number of hierarchical levels that make it difficult for the CEO to oversee all activities in the company. Therefore, as the company grows, "mediators" between the top management and operators are created, namely supervisors, foremen, managers etc.

As a result, vertical communication is slow, and the system tends to be more formal and bureaucratic.

In an SME, the ISO 9000 representative possesses the possibility of an easy access to virtually every employee in the company. Personnel becomes familiar with him/her, and initial hesitation and uncertainty towards the standard and its facilitator disappears rapidly. The experience of the author shows that immediate and informal communication supports quality training significantly. After only a month spent in PKL, essentially all employees knew me by my name, what I did and what I would ask them to do or study. The communication is immediate and open, and if a misunderstanding had occurred, it would have been solved without hesitation or delay.

This is impossible in a large company. There is a large number of employees, working on different tasks and projects. Communication lines have a number of "mediators", who transfer information to final users. However, basic theories of communication suggest that information can be distorted, and the more "mediators" that are placed between the transmitter and receiver, the more likely a distortion is.

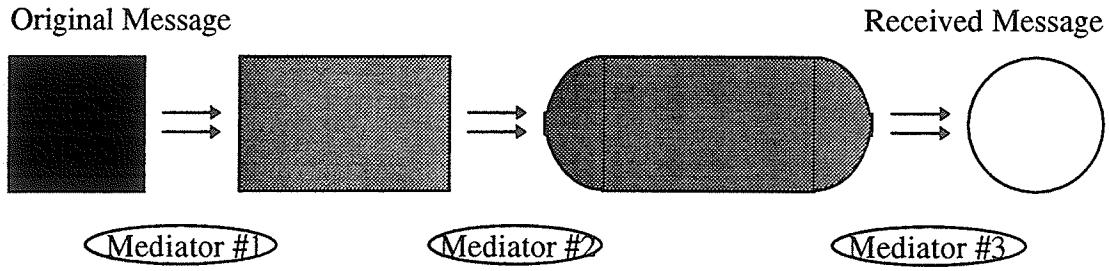


FIGURE 5.4: Impact of Communication Gaps on ISO 9000 Training

In SINco, there are five hierarchical levels, and at least that many mediators. An example of the impact of large company's communication problems on ISO 9000 project follows. An engineer working on procedures development projects prepares a weekly report on the status of procedures in one of the departments of the sales sector. Before the report reaches that particular department, the manager of the quality management sector has to verify it. Subsequently, it is delivered by the interdepartmental mail to the corresponding sales department. It was stipulated in the report that a feedback on the report should be sent back to the quality assurance department. However, after several months had passed without any feedback, it was determined that all the reports were neatly placed in the considered sales department, and had been read just briefly. None of the employees concerned were aware of the requested feedback!

The impact of communication gaps on quality training is a major issue in large enterprises. Even if a team of consultants on ISO 9000 is hired, limited time and financial resources do not allow them to convey their messages to every single employee in the company. The common method here is using presentations and seminars.

5.6 Summary

A summary of the main features addressed in the chapter are presented in the Table 5.4. The table compares the two businesses illustrating both the parameters with the same or opposite characteristics. Following explanations are provided:

- The Relative Index of QA/QC Human Resources is the number of personnel employed on quality assurance (QA) and/or quality control (QC) duties divided by a total number of employees. It indicates the intensity of personnel involvement in quality control and assurance issues.

- The relative number of employees working on a project is the number of people formally assigned to work on ISO 9000 project divided by a total number of employees. It indicates personnel involvement in ISO 9000 project.

- The Relative Consultant Index is the number of consultants hired by the company divided by a total number of employees. This index indicates the availability of consultants to the company and its employees. The study showed that although a large company hired a team of seven consultants, their role is significantly greater in a SME, with only one consultant. The relative index is 0.07 % for a large, and 2% for a SME.

PARAMETERS	LARGE ENTERPRISE	SMALL ENTERPRISE
Organizational Structure	Functional / Matrix. QM sector manages quality. QM manager reporting directly to CEO	Personal / Line. No formal quality management organization.
Responsibilities	Defined, not documented	Defined, not documented
Resources : Human	Qualifications exist	Qualifications exist
: Equipment	High technology, flexible	Low technology, simple
: Material	Incoming inspection	No incoming inspection
: Information	Needs compliance & procedures	Lack of documented procedures
Procedures	Formal, not documented	Informal
Processes	High variety & complexity	One simple process
Quality System Level Before ISO 9000	High	Low
Relative Index of QA/QC human resources	Higher	Low to Intermediate
Relative number of people working on the project	Lower	Higher
Relative Consultant Index	Low	High
Existing documentation level	Intermediate to High	Very Low
Initial knowledge of ISO 9000 standards	Intermediate. Needs basic training and education	No knowledge.
ISO 9000 Motives	Export	Concentrating on Quality
Teams	Specially assigned for each sector. Incorporated in the existing structure.	One team for all.
Initial Assessment carried out by	Teams	One person
ISO 9000 project planning	Important	Important
Standardized Procedures for documentation design	Important	Important
Documentation Design Method	Deductive Top to Bottom	Inductive ;Two-Step Bottom to Top
Communication :	Formal & Long, Large number of mediators	Informal & Short. Personal without mediators
- Lines		
- Misinterpretation	High	Low
- Coordination	Difficult	Between individuals only
- President's involvement	Relatively low	High
- Training Method	Indirect, Seminars	Direct
- Access to employees	Difficult	Easy

TABLE 5.1 : Large and Small Business - A Two Case Comparison

6.0 CONCLUSIONS

This chapter discusses the main contributions of the work presented in this thesis, followed by recommendations for future research.

6.1 Contributions of the Research

In chapter Three, quality system conceptualization in a small business environment was discussed. A model for small business quality system assessments is given, followed by the implementation of the model using a case study. It is an adapted model considering the requirements of ISO 10011-1 standard and the features of Willborn's and Cheng's, 1994 approach to quality system auditing and Deming's quality improvement philosophies. The model is designed specially for a small business environment, incorporating special features and characteristics of a SME in the frame of standardization written for large enterprises.

The application of the model showed the following:

- The model is time and cost effective. A simultaneous distribution of questionnaires and QS status observation saves both facilitator's and auditees' time and financial resources.
- It is information efficient. Auditees can plan the time when they feel comfortable to answer the questions from questionnaires, and the facilitator can distribute his own time accordingly.

- Auditees participation and understanding is increased, and they feel less intimidated by the assessment.

Subsequently, a project plan for applying ISO 9000 quality system was presented. The plan can be used as an example for a specific project plan developed by a SME.

Chapter Four focused on standardizing quality system documentation. A set of rules and symbols for integrated flow charting was presented first. Secondly, two procedures for standardized documentation design were given. Together with integrated flowchart rules, these procedures represented a useful ISO 9000 documentation toolkit for our small company case study. The methods used in designing the procedures, input/output elements and responsibility matrix for instance, provide opportunities for the development of TQM techniques and continuous quality improvement. Examples of QS documentation for a manufacturing oriented SME follows. These examples can be used to give an idea to SMEs managers of the scope and application of the production process documentation required by the standard, and possibly provide a source of useful methods for documentation design. However, the following has to be considered. Every company is an entity of its own. Like people, no two companies are identical in this world. A suit tailored for one person may not suit another, although they are very much alike. Therefore, any models presented herein should be tailored for use in a specific, individual case.

Chapter Five compared issues related to ISO 9000 application in small and large companies. The following conclusions were drawn:

◆ A separate set of ISO 9000 standards for small business is not necessary

◆ Although many SMEs have encountered problems, they posses numerous advantages over large companies when applying the standards. The sources of the advantages are in better communication, flexibility and innovation.

◆ The problems they encounter can generally be solved by better planning and organizing. Concepts such as team participation, continuous improvement through PDSA cycles and "Do it right the first time" can be of great assistance.

6.2 Scope for Further Research

The following are recommended issues for further research:

◆ Designing user-friendly, flexible computer models for applying ISO 9000 in small business

◆ Investigations aimed at relating ISO 9000 with Total Quality Management and programs of "Quality Gurus"

◆ Integrating quality costs into the models

◆ Creating a broader sample of SMEs that have encountered ISO 9000 for the statistical study of the impact of ISO 9000 to SMEs

◆ A study of the quality techniques and methods used in Japanese small businesses

REFERENCES:

- Aquino, M.A., 1990., Improvement Vs. Compliance, Quality Progress, ASQC Quality Press, Milwaukee, Wisconsin, v 23, n 10, p 47-49.

- Axland, S., 1992, Small Wonders, Quality Progress, ASQC Quality Press, Milwaukee, Wisconsin, v 25, n 11, p 29-34.

- Baer, J.L., 1993., What Is ISO 9000, Proceedings Of the 44th International Industrial Engineering Conference, Institute of Industrial Engineers, Norcross, Georgia, p 123-132.

- Batra, P.S., Singh, D. K., Willborg B.M., 1993, Roadmap To Successful ISO 9000 Registration, Industrial Engineering, Journal of the Institute of Industrial Engineers, October edition, p 54-55.

- Bemowski, K., 1992, Small in Size But Not in Stature, Quality Progress, v 25, n 11, p 17.

- Benson, R.S., Sherman, R.W., 1995., ISO 9000: A Practical Step-by-Step Approach, Quality Progress, v28, n 10, p 75-78.

- Bishara, R.H., Wyrick, M.L., 1994., A Systematic Approach to Quality Assurance Auditing, Quality Progress, v 27, n 12, p 67-72.

- Bobbit, C.E., 1993., Conduct More Effective Audits, Quality Progress, v 27, n 10, p 115-118.

- Brasier, S., 1994A, SMEs Move To the Forefront, Consensus, Winter 1994, Standards Council of Canada, Ottawa, Ontario.

- Brasier, S., 1994B, EC Does Not See ISO 9000 As Burden On Small Firms, Consensus, Winter 1994, Standards Council of Canada, Ottawa, Ontario.

- Brown, M., 1994, ISO 9000 Registration Opens Doors For Office Furniture Manufacturer, Consensus, Winter 1994, Standards Council of Canada.

- British Standard Institute, 1994., The Application of BS 5750 To Small Business, Initial Report by the BSI Policy Committee for Small Business, British Standards Institute (BSI), London, United Kingdom.

- Chamard, J., English J., 1989., How to Organize and Operate a Small Business in Canada, Allen & Unwin, Mississauga, Ontario.

- Cirruli, P.J., James B., Walker G.D., 1994, Accelerating the ISO Process Using Groupware and Teams, Proceedings of the ASQC 48th Annual Quality Congress Conference, Las Vegas, Nevada.

- Corrigan, J.P., 1994., Is ISO 9000 the Path to TQM, Quality Progress, v 27, n 5, p 33-38.

- Dale, B.G., Oakland, J.S., 1991, Quality Improvement Through Standards, Stanley Thornes Publishers, Cheltenham, United Kingdom.

- D'Amboise, G., 1991., The Canadian Small and Medium Sized Enterprise, The Institute for Research on Public Policy, Halifax.

- DeAngelis, C.A., 1991, ICI Advanced Materials Implements ISO 9000 Program, Quality Progress, v 24, n 11, p 49-53.

- Deming, W.E., 1993, Out Of the Crisis, Massachusetts Institute of Technology, Cambridge, Massachusetts.

- Dzus, G., 1991., Planning a Successful ISO 9000 Assessment, Quality Progress, v 24, n 11, p 43-48.

- Dzus, G., Sykes, E.J., 1993., How To Survive ISO 9000 Surveillance, Quality Progress, v 26, n 10, p 109-112.

- Ebel, K.E., 1991, Achieving Excellence in Business, ASQC Quality Press, Milwaukee, Wisconsin and Marcel Dekker, New York.

- Eicher, L. D., 1994, International Standardization Holds Many Benefits For SMEs, Consensus, Winter 1994, Standards Council of Canada, Ottawa, Ontario.

- French Task force for SME, 1994., Implementation Guidance for Small Business, AFAQ, Paris, France.

- Galver R.C., Pagliarulo, M.A., 1993, What Are The ISO 9000 Series Standards, Industrial Engineering, Journal of the Institute of Industrial Engineers, September, p 14-15.

- Ganguly, P., 1985., Small Business Statistics and International Comparisons, Harper & Row, London, England.

- Girvin, N.W., 1992., Writing Audit Findings : Be Reasonable, Annual Quality Congress Transactions, ASQC, Milwaukee, Wisconsin, v 46, p 855-862.

- Harper, M., 1984., Small Business In the Third World, John Wiley & Sons, New York

- Hendricks C., Cohn Z., Parker C., 1994, Fair-rite Implements TQM and ISO 9000, American Ceramic Society Bulletin, v 73, n 11, p 58-60

- Howell, V.W., 1994A, Quality Planning For the Future, , American Ceramic Society Bulletin, v 73, n 11, p 54-57

- Howell, V.W., 1994B, ISO 9000; Insight Into the Certification Process, Ceramic Engineering and Science Proceedings v 15, n 1, p 350-358

- Huyink, D.S., 1994., ISO 9000 Implementation; The Human Side Addressing Critical Sucess Factors of an ISO 9000 Registration Process Within a Corporate Culture, Proceedings of the ASQC 48th Annual Quality Congress Conference, Las Vegas, Nevada.

- Hutchnis, G., 1993., ISO 9000 : A Comprehensive Guide to Registration, Audit Guidelines and Successful Certification, Oliver Write, Essex Junction, Vermont.

- ISO/TC 176/SC, 1995., Quality Systems Explained - A Guide to the Interpretation and Application of the ISO 9000 Standards for Small Business - DRAFT, ISO/TC176/ Standards Canada Committee, 950526 Doc ID SBTG_HB.DR2, Charlottetown, N.B.

- ISO/TC 176/NZ, 1994., Difficulties in ISO 9000 Understanding and Certification for Small and Medium Business, ISO/TC176/ Standards New Zealand Committee, Doc 94106, New Zealand.

- Italian Task Force on SME, 1994., Sistemi Qualita - Linee Guida per L'Interpretazione delle Norme UNI-EN 29001 e UNI-EN 29002 con Particolare Riguardo alla Piccola e Media Industria, referenced in ISO/TC 176/NZ, 1994.

- Johnson, P.L., 1993., ISO 9000: Meeting the New International Standards, Mc Graw Hill, New York.

- Karapetrovic, S., 1994A, The Quality System Organization and Information Flow in a Large Steel Enterprise, graduation thesis, Faculty of Mechanical Engineering, University of Belgrade, Yugoslavia (in serbian).

- Karapetrovic, S., 1994B, An Approach to Information Flowcharting for Quality Improvement in a Steel Enterprise, proceedings of the Fourth Conference on Capacity Utilization, p 281-285, Faculty of Mechanical Engineering, Belgrade, Yugoslavia.

- Kildahl, D.D., 1992., ISO 9000 : Auditing the Conformance Process, Annual Quality Congress Transactions ASQC, Milwaukee, Wisconsin, v 46, p 1182-1187.

- Kuhn, R.R., 1993., ISO 9000 Impact Study, Proceedings of the 36th International Conference, American Production and Inventory Control Society, Falls Church, Virginia, p 42-45.

- Lamprecht, J.L., 1993., Implementing the ISO 9000 Series, Marcel Dekker, New York.

- Lamprecht, J.L., 1992., ISO 9000: Preparing for Registration, Marcel Dekker, New York.

- Lloyd's Register Quality Assurance, 1994., BS 5750/ISO 9000 - Setting Standards for Better Business, LRQA, Hoboken, New Jersey.

- Lynch, M., 1994., ISO 9001 Certification Impact on a Power and Environmental Engineering Firm, Proceedings of the ASME Joint International Power Generation Conference, Phoenix, Arizona.

- Maday, J.H., 1992., Audit onto others..., Annual Quality Congress Transactions ASQC, Milwaukee, Wisconsin, v 46, p 1170-1175.

- Mathews, M.V., 1993., Bottom Line Results From ISO 9000, International Industrial Engineering Conference Proceedings, Norcross, Georgia.

- Mathers, D.D., Marshall, R.T., Caillibot, P.F., Phipps, M.J., 1994, The ISO 9000 Essentials, Canadian Standards Association, Mississauga, Ontario.

- Monty, V., 1985., The Canadian Small Business Handbook, CCH Canadian Limited, Don Mills, Ontario.

- Neblock, P., 1993., ISO 9000: Lessons in International Competition, Annual International Conference Proceedings, American Production and Inventory Control Society, Falls Church, Virginia, p 76-78.

- Novack, J.L., 1994., The ISO 9000 Documnentation Toolkit, Prentice Hall, Englewood Cliffs, New Jersey.

- Ossenberg, H.W., 1994., Internal Auditing - An Instrument For Stepping Up the Pace Of Continuous Improvement, Technische Mitteilungen Krupp (English edition), Hamburg, Bundesrepublik Deutchland, n 2, p 87-92.

- Placek, C., 1987., Small Business - It's Big, Quality, August edition, Hitchcock Publishing Company, Wheaton, Illinois.

- Puri, S.C., 1992., ISO 9000 Certification and Total Quality Management, Quality Management Group, Ottawa, Ontario.

- Rabbit, J.T., 1993., The ISO 9000 Book : A Global Competitor's Guide to Compliance and Registration, Quality Resources, New York.

- Reedy, R.F., 1994, ISO 9000. Guidelines to Increased Costs and Reduced Product Quality, Cost Engineering, Morgantown, West Virginia, v 36, n 6, p 15-18.

- Rementeria, S., Gomez, A., Urrutia, J.A., Ruiz F.J., 1991., Smart Aid for Quality System Assessment - Diagnosis, 45th Annual Quality Congress Transactions, ASQC, Milwaukee, Wisconsin, v 45, p 823-834.

- Rice, C.M., 1994., How to Conduct an Internal Quality Audit and Still Have Friends, Quality Progress, v 27, n 6, p 39-42.

- Rockman, K.K., Grenville, R., Jackson, S., 1994., Road Map to ISO 9000 Registration, Quality Progress, v 27, n 5, p 39-44.

- Rosen, H., 1992., ISO 9000 : A Registrar's Perspective, Annual Quality Congress Transactions, ASQC, Milwaukee, Wisconsin, v 46, p 1156-1160.

- Rothery, B., 1991., ISO 9000, Aldershot, Hampshire, United Kingdom.

- Simic, J., 1993., Dijagrami Toka Procesa, Kvalitet, Poslovna Politika D.D., Belgrade, Yugoslavia, n 1, v 2, p 23-24.

- Sutherland, S., 1994., Quality Systems in the Small Firm : A Guide to the Use of the ISO 9000 Series (formerly BS 5750), Report of the ABCB/NACCB Small Firms Working Group - DRAFT, National Accreditation of Certification Bodies (NACCB), Association of British Certification Bodies (ABCB), London, United Kingdom.

- Schaff, D., 1993, Case Against ISO 9000, Materials Performance, Lakewood Publications, Minneapolis, Minnesota, v 32, n 12, p 35-39.

- Skrabec, Q.R., 1995, Maximizing The Benefits of Your ISO 9000 Campaign, Industrial Engineering, Journal of the Institute of Industrial Engineers, April edition, p 34-37.

- Shucavage, D., 1994, Cerdec Implements ISO 9000, American Ceramic Society Bulletin, v 73, n 11, p 60-63.

- Springings, H., 1994, Strategic Competitiveness: Standards/Technology and Small Business, Consensus, p 28-33, Winter 1994, Standards Council of Canada, Ottawa.

- Standards Australia, 1994., ISO 9000 ; Quality Systems Handbook For Small Business, HB66 (Int) - DRAFT, Standards Australia, Strathfiels, New South Wales.

- Storey, D., 1983., The Small Firm - An International Survey, St. Martin Press, New York.

- Stratton, 1993., A Few Words About The Last Word, Quality Progress, v 26, n 10, p 63-66.

- Tarby, M.K., 1994, ISO 9000 and its impact on the Metal Powder Industry, International Journal of Powder Metallurgy, v30, n2, p 185-196, Princeton, New Jersey.

- Velury, J., 1995, Integrating ISO 9000 in the Big Picture, Industrial Engineering Solutions, October issue, p 26-29.

- Voehl, F., Jackson, P., Ashton, D., 1994, ISO 9000: An Implementation Guide for Small to Mid-Sized Businesses, St. Lucie Press, Delray Beach, Florida.

- Wagner, R.G., 1994, Benchmarking the Quality Movement, American Ceramic Society Bulletin v 73, n 11, p 52-53 .

- White, J.S.,1989, The Art and Science of Small Business Management, Penguin Books, Toronto.

- Willborn, W.O., Cheng, E.T.C., 1994., Global Management of Quality Assurance Systems, Mc Graw Hill, New York.

- Willborn, W.O., 1989., Quality Management System: A Planning and Auditing Guide, Industrial Press, New York

- Willborn, W.O., 1979, Quality Audits in Support of Small Business, Quality Progress, v 12, n 4, p 34-37.

- Willborn, W.O., 1993., Audit Standards: A Comparative Analysis, ASQC, Milwaukee, Wisconsin.

- Wolak, J., 1987., It's Not What We Have, But What We Choose, Quality, August 1987, Hitchcock Publishing Company, Wheaton, Illinois.

- Zorn, J., 1995., QM-Systeme fur Kleine und Mittelstandische Unternehmen, QZ, Carl Hansen Verlag, Munchen, Bundesrepublik Deutchland, v 40, n 5, p 524-532.

- Zuckerman A., 1994, The Basics of ISO 9000, Industrial Engineering, Journal of the Institute of Industrial Engineers, June edition, p 13-15.

APPENDICES

APPENDIX I

Terminology

Definition of Terms

ISO 9000 standards provide terminology used in quality management and application of the standards. A specific international standard, ISO 8402 Quality Vocabulary, deals with quality management terminology. However, in the course of work on quality topics, the author has found that a significant number of terms are used in literature in different contexts, and therefore have different meanings. For instance, a generally accepted approach to whether a quality system is ISO 9000 "certified" or "registered" does not exist.

In order to avoid ambiguity and provide readers' clearer understanding of the research findings presented in this thesis, a list of terms with definitions and/or explanations is provided. Key points are the following:

♣ A product or a service is **certified**, a quality system is **registered**, and a registrar is **accredited**.

♣ QS assessments are performed when **a number of documented elements may or may not exist**. Subsequently, when **all the elements** required by the appropriate standard exist, an audit is executed.

Definitions cited from the standards or other relevant documentation are given in italics, whereas the definitions provided by the author are underlined.

♦ **Accreditation :** A process of verifying that an organization, agency, operational group or individual is allowed to perform activities specified by a duly recognized institution that issues accreditation. For instance, the Registrar Accreditation Board

accredits those organizations that register companies to the ISO 9000 series standards (Bemowski, 1992).

♦ **Certification :** A process of verifying that a product or a service is in compliance with the relevant product or service standard. A certificate to confirm compliance is issued.

♦ **Nonconformance :** *The nonfullfilment of specified requirements (ISO 8402)*

♦ **Quality Assessor :** A person who has the qualification to perform quality assessments. An assessor designated to manage and lead a quality assessment is called a "lead assessor".

♦ **Quality Audit :** *A systematic and independent examination,*(performed only when a documented quality system exists), *to determine whether quality activities and related results* (of the system) *comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (ISO 10011, 1990).* Thus, ISO 9000 quality system audit can be conducted only when all the required system elements exist. Quality audits can be conducted for **internal purposes**, carried out by staff not having direct responsibility in the areas being audited, or **external purposes**, carried out by the customer (second party audits) and/or third institution (third party audits).

♦ **Quality Auditor :** *A person who has the qualification to perform quality audits. An auditor designated to manage a quality audit is called a "lead auditor" (ISO 10011-1, 1990).*

♦ **Quality Management :** *The aspect of the overall management function that determines and implements the quality policy (ISO 8402, 1986).* If the quality policy

does not exist, or is not documented, a quality system, as defined herein, is not in place.

◆ **Quality Plan :** *A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, service, contract or project.(ISO 8402, 1986).*

◆ **Quality System :** *The organizational structure, responsibilities, procedures, processes and resources for implementing quality management (ISO 8402, 1986).* A quality system is a set of entities (QS elements) that interact towards achieving the goals set in quality policy. The boundary of a quality system is identical to the one of an organization which embraces the quality system.

◆ **Quality System Assessment :** A systematic and independent examination to determine whether quality system elements comply with the appropriate quality standard, and/or planned arrangements. QS Assessment does not represent a formal audit leading to registration. If an assessment or self-assessment is conducted as a rehearsal for the official audit aimed at QS registration, it is titled **Pre-Audit Assessment**.

◆ **Quality Surveillance :** *The continuous monitoring and verification of the status of procedures, methods, conditions, processes, products and services, and analysis of records in relation to stated references to ensure that specified requirements for quality are being met (ISO 8402, 1986).* Quality surveillance audit is carried out **after the registration exclusively**, by an accredited registrar to ensure that registered firms maintain compliance with the appropriate ISO 9000 standard. It may

also be carried out by or on behalf of the customer to ensure that contractual requirements are being met.

♦ **Registration :** A process of verifying that a quality system is in compliance with the relevant quality assurance standard. Registration is performed by an accredited registrar. After the compliance has been confirmed, the quality system is registered, and a certificate of registration is issued.

♦ **Specification :** *The document that prescribes the requirements with which the product or service has to conform (ISO 8402, 1986).*

APPENDIX II

SBQSAM Supplements

Appendix II-1 : Assessment Responsibility Matrix

Functions	President	Facilitator
Assigning the managerial team for assessments	In-charge	Participate
Preparation of the assessment documentation		In-charge
Scheduling	Participate	In-charge
Performing observations		In-charge
Interviewing		In-charge
Report distribution	Participate	In-charge

Appendix II-2 : Assessment Schedule

Date/Time	Activity
May 1st, 1995. / 9 am	Plan Review Meeting
May 2nd, 1995. / 9 am	Opening Meeting & Questionnaire Distribution
May 4th, 1995. / 4 pm	President's Interview
May 5th, 1995. / 9 am	Production Manager's Interview
May 5th, 1995. / 10 am	Vice-President's Interview
May 5th, 1995. / 11 am	Marketing/Sales Manager's Interview
May 5th, 1995. / 1 pm	Design Manager's Interview
May 5th, 1995. / 2 pm	Shipping Supervisor Interview
May 5th, 1995. / 5 pm	Closing Meeting
May 18th, 1995. / 9 am	Report Distribution and review

Appendix II-3 : Short Description of Assessment Methods

Method	Description
Questionnaires / Interviews	Each person designated in the schedule will get a questionnaire, containing questions in his area of competence. He/she is expected to answer them in three days. Subsequently, individual interviews will be held in order to better understand the current status of the firm.
Verification Testing	Facilitator will follow one or two products from raw material to the finished product and vice-versa.
Observations	The facilitator will make his observations of the company's quality system.

APPENDIX III

SBQSAM Questionnaires

III-1: President's Questions

1) How does the management verify the effectiveness of design, production and sales activities ? (Please, explain briefly)

2) Who is responsible for process and product verification ? (Verifying that the product or a process is conforming to requirements)

3) Do you conduct regular meetings to insure that your quality system is in place and to insure the system effectiveness ? If you do, how often do you conduct them ? Are the records of the meetings kept ?

4) Who has responsibility for securing resources sufficient to conduct your business activities ?

5) Please, briefly explain your system for selecting, monitoring and managing suppliers. Is this system documented ? What documents (procedures, records) do you have to support this system ?

6) Have the standards or rules of acceptability been identified and methods in place ? Please, explain them briefly for materials supplied by your suppliers.

7) How do you evaluate production process capability ? How do you keep your production process under control ? Is there any documentation (procedures, records) related to this matter ? Please, explain in detail.

8) Do the procedures for ensuring safe/secure identification, packaging and delivery of material/products ? Explain, if not, how is this matter being dealt with ?

9) What happens if a customer returns/ rejects your product ? Please, explain.

10) What quality control and inspection methods and principles do you use in the plant ? Do you use statistical quality control ?Who is in-charge of these matters ? Please, explain in detail.

11) How do you evaluate what kind of inspection, measuring and test equipment for quality control you need ? How do you acquire and manage the equipment ?

12) How do you deal with customer supplied products, if any ? Please, explain briefly.

13) Have the responsibilities and authorities for communication and interfaces with customers been defined ? Who is responsible ? What activities, in brief, are included ?

14) How do you ensure, before you offer customer a tender, that customer requirements are adequately defined and documented ? How do you ensure that the company is capable of meeting stated or implied requirements ? How do you solve inconsistencies between customer requirements and your own standards ? Please, explain in detail.

15) Are the records and detailed procedures for customer service available ? If yes, where and how ?

16) Please provide me with the list and examples of all existing documentation in the plant (Purchase Orders, Production Orders, Procedures, Records, etc...)

17) Have you ever conducted an assessment of your quality system (like this one) ? Please, explain briefly, if yes.

18) How do you set quality related employment qualifications, evaluate training needs (Brief explanation, please). Do the qualifications (education, training and experience) exist for each position in the plant? Are training programs, plans or records of training activities available ?

19) Is the responsibility and authority for servicing activities of the company defined ? If yes, who is responsible ? Are the procedures for performing these activities established and/or documented ? (For example, if a sweater rips apart after being sold, who is going to repair it ?

20) Has the management defined responsibility and authority for purchasing activities and quality of purchased products ? Who is responsible and what do the responsibilities include ? How do you document those activities ?

21) How do you ensure the quality of suppliers products ? Is there any documentation related to this matter ? If yes, please provide examples. If the suppliers do not provide what you've ordered, or if the quality/quantity does not conform to your specifications, how do you react ? What activities do you perform subsequently ? Please, answer in detail.

22) How do you choose your designers ? Are they contracted, or you design you r own products from scratch ? If you have a contracted designer, what happens if he/she does not supply the designs you've ordered ? How do you solve the problems, if any ?

23) How do you review your contracts ? Who is responsible ? Are these activities documented ?

24) How do you train operators ? How do you evaluate training needs ? If you find a problem with qualifications or training, what measures would you take ?

III-2: Design Manager's Questions

1) Does the company have defined responsibility and authority for the design process ? Explain briefly.

2) How is the design planning and development being handled ? Explain in detail, please.

3) Explain the design process briefly, with emphasis on inputs/outputs and documentation.

4) How is a product design verified ? Do you perform design reviews, tests, comparison with other, proven designs ? How do you handle design changes ? Who is responsible ?

III-3: Production Manager's Questions

1) How do you label your sweaters during production (knitting, sewing, packaging, etc.) ? Do you use labels, tags, travel tickets ? Explain in detail, please.

2) How do you label and separate a defected sweater? Who is responsible for inspection? When do you perform inspection ? (After knitting, sewing, etc.) ? Explain in detail.

3) Who is responsible for inspection and testing of :

a. raw materials: b. your own sweaters during production; c. final products

4) Do you have procedures (documents) that show how you produce, how you maintain your machines and equipment ? How do you control production ? What documents and records do you use (provide me with examples, please)?

5) How do you ensure that a defected product is seen, and thrown away or repaired ? What do you do then ? How do you inspect sweaters in early stages of production (knitting, washing, drying...)?

6) Please, explain your final inspection.

7) How do you control your machines ? Who is in charge of maintenance and control ? How do you choose inspection equipment ? What documents and records do you have?

8) How do you ensure that your inspection and testing equipment is in good shape ? Do you keep records when you repair it ?

9) How do you know the status of your work-in progress ? For example, if it's inspected or not, rejected or for repair ? Do you label this in any way ?

10) If a defected sweater has been found, what and who would inspect this, decide what is going to happen with the product ? If any documentation is in place, please provide me examples.

11) How do you find the cause of a defect ? How do you prevent this from happening again ?

12) Explain what quality control records are used ? Who is responsible ?

III-4: Shipping Supervisor's Questionnaire

1) Is the responsibility and authority for maintaining the quality of materials during storage and delivery defined ? Who is responsible ?

2) Do the procedures for handling, storage, shipping and receiving exist ? How do you control material flow during delivery ? Do you put tags on shipped boxes ? What kind of documentation you possess ?

APPENDIX IV

SBQSAM Checklists

4.1	Management Responsibility
4.2	Quality System
4.3	Contract Review
4.4	Design Control
4.5	Document & Data Control
4.6	Purchasing
4.7	Control of Customer-Supplied Product
4.8	Product Identification & Traceability
4.9	Process Control
4.10	Inspection & Testing
4.11	Inspection, Measuring & Test Equipment
4.12	Inspection & Test Status
4.13	Control of Nonconforming Product
4.14	Corrective & Preventive Action
4.15	Handling, Storage, Packaging & Delivery
4.16	Control of Quality Records
4.17	Internal Quality Audits
4.18	Training
4.19	Servicing
4.20	Statistical Techniques

4.1 Management Responsibility		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Management has defined and documented facility quality policy	10	5	0	***NE***	0	MR-1	√	
2	Specific quality responsibilities of all employees are defined and documented	10	5	***0***		0	MR-2		
3	An organization chart exists which shows management structure and responsibilities	10	5	0	***NE***	0	MR-3	√	
4	Management conducts activities to verify effectiveness of design, production and service activities	10	***5***	0		5	MR-4		
5	A management representative, with sufficient authority, has been designated to oversee conformance of quality system to the standard	10	5	0	***NE***	0	MR-5	√	
6	Management conduct regular review meetings to assess the quality system and ensure its continued effectiveness. Minutes of such reviews are documented and location of this documentation is specified	10	5	***0***		0	MR-6		
7	Procedures covering all activities specified by this section exist	10	5	0	***NE***	0	MR-7		

TOTAL SCORE	***5***

4.2 Quality system		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Management has specified who within the facility is responsible for the quality system, and who is subject to it	10	5	***0***		0	QS-1		
2	A system for selecting, monitoring and managing suppliers is established	10	5	***0***		0	QS-2		
3	Standards of acceptability have been identified and enforcement methods are in place	10	5	***0***		0	QS-3		
4	Procedures are in place to monitor process capability, affording sufficient lead time for implementation of improvement efforts when needed	10	5	0	***NE***	0	QS-4		
5	A system for conducting internal audits and reviews is in place	10	5	***0***		0	QS-5		
6	Procedures for safe/secure identification, packaging and delivery of products to customers are in place	10	5	***0***		0	QS-6		
7	A system for taking prompt and effective corrective actions in response to nonconformances is in force	10	5	***0***		0	QS-7		
8	A system for monitoring the need for inspection, measuring and test equipment , as well as for acquiring it and managing its use is in place	10	5	***0***		0	QS-8		
9	A system for monitoring customer complaints, and addressing them promptly and effectively is in place	10	***5***	0		5	QS-9		
10	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	QS-10		

TOTAL SCORE	***5***

4.3 Contract Review		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for contract review activities	10	5	***0***		0	CR-1		
2	Facility's contract review system ensures that customer requirements are adequately defined and documented	10	***5***	0		5	CR-2		
3	Facility's contract review system ensures that inconsistencies between customer requirements and facility standards are defected and resolved	10	***5***	0		5	CR-3		
4	Facility's contract review system ensures that facility has full capability to meet its obligations under the contract	10	***5***	0		5	CR-4		
5	Responsibility and authority for each step of facility's contract review system is specified by title and/or function	10	5	***0***		0	CR-5		
6	Records of contract review activities are maintained	10	***5***	0		5	CR-6		
7	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	CR-7		

TOTAL SCORE	***20***

4.4 Design Control		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for the design process	10	5	***0***		0	DC-1		
2	Facility has a system which defines the design planning and development process	10	5	0	***NE***		DC-2		
3	A document which displays the relationships and interfaces among functions involved in the design process, as well as interfaces between design process and other process elements	10	5	0	***NE***		DC-3	√	
4	Sources of design input are identified. Facility creates a particular document, resulting from input sources, that clarifies design requirements	10	5	0	***NE***		DC-4		
5	Facility has defined its types of design output-blueprints, design checklists, etc.	10	***5***	0		5	DC-5		
6	The facility system for verifying that designs meet input requirements is defined.	10	5	0	***NE***	0	DC-6		
7	The facility's design review system addresses, evaluates and implements design changes	10	5	***0***		0	DC-7		
8	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	DC-8		

TOTAL SCORE	5

4.5 Document Control		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**		
1	Facility has defined responsibility and authority for creation, distribution, revision and control of quality related documents	10	5	0	***NE***	0	DOC-1		
2	Types of quality related documents which are in use in the facility have been defined	10	5	0	***NE***	0	DOC-2		
3	A procedure which specifies how quality related documents are created and placed where employees who need them have access to them is available	10	5	0	***NE***	0	DOC-3		
4	A procedure which governs how quality related documents are modified and approved, and which specifies the ways obsolete editions are withdrawn and discarded. It also specifies a number of changes that can be made to a document before a complete reissue is required	10	5	0	***NE***	0	DOC-4		
5	A list of the current editions of all quality related documents is maintained	10	5	0	***NE***	0	DOC-5		
6	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	DOC-6		

TOTAL SCORE	0

4.6 Purchasing		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility for (a) purchasing activities and (b) quality of purchased products and services	10	5	***0***		0	PU-1		
2	Facility has a documented system for selecting suppliers that assures that authorized suppliers can meet specified requirements. Facility has a procedure which specifies how purchasing data is to be communicated to suppliers in a way that eliminates ambiguity or confusion	10	5	0	***NE***	0	PU-2		
3	Facility has a procedure for verifying conformity of purchased products and services either at facility or at source. Such verification does not absolve suppliers of responsibility of meeting specified requirements	10	5	0	***NE***	0	PU-3		
4	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	PU-4		

TOTAL SCORE	0

4.7 Purchaser Supplied Product		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**		
1	Facility has defined responsibility and authority for scheduling, handling and storage of purchaser supplied items	10	5	***0***		0	PSP-1		
2	Procedure for verification of incoming purchaser supplied product to determine conformance with respect to features, quantity and condition	10	5	0	***NE***	0	PSP-2		
3	Facility has a system for safeguarding purchaser supplier product	10	5	0	***NE***	0	PSP-3		
4	Facility has a program of regular communication with owners of purchaser supplied product to resolve any nonconformances	10	5	0	***NE***	0	PSP-4		
5	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	PSP-5		

TOTAL SCORE	0

4.8 Product Identification and Traceability		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**		
1	Facility has defined responsibility and authority for assessing the need for product identification and traceability: if deemed appropriate, facility has defined responsibility for managing these activities	10	5	***0***		0	PIT-1		
2	If appropriate, and/or if required by customer contract, procedures for identifying products are in place	10	5	0	***NE***	0	PIT-2		
3	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	PIT-3		

TOTAL SCORE	0

4.9 Process Control		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for process control activities	10	*5*	0		5	PC-1		
2	Process areas having an impact on quality have been clearly defined	10	5	*0*		0	PC-2		
3	Procedures for maintaining controlled conditions in each such process area are defined and are available to all affected personnel	10	5	0	*NE*	0	PC-3		
4	Procedures governing the rigorous measurement and monitoring of special processes are in place and available to all affected personnel	10	5	0	*NA*				

TOTAL SCORE	5

4.10 Inspection and Testing		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for receiving, in-process and final inspection and testing systems	10	***5***	0		5	IT-1		
2	Facility has a documented system for verifying that incoming products/services meet contractual requirements	10	5	0	***NE***	0	IT-2		
3	If facility system provides for release of supplied product subject to recall, system includes mechanism for identification, traceability, control and recall of such products, under defined responsibility and authority	10	5	***0***		0	IT-3		
4	Facility has system which assures early recognition of nonconforming product at various vital in-process stages, and provides for identification and disposition of such materials	10	5	***0***		0	IT-4		
5	Facility has system which assures that output meets specified characteristics prior to release. System includes means for clear identification of conforming versus nonconforming output	10	***5***	0		5	IT-5		
6	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	IT-6		

TOTAL SCORE	10

4.11 Inspection, Measuring and Test Equipment		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for inspection , measuring and test equipment	10	5	***0***		0	IMT-1		
2	Facility has procedure for selecting measurements, determing accuracy required, and acquiring equipment which meets these requirements	10	5	0	***NE***	0	IMT-2		
3	Facility has system for verifying equipment needed measurement accuracy, and for conforming that environmental conditions permit reliable use	10	5	0	***NA***		I IMT-3		
4	Facility has system for calibration and adjustment of equipment at prescribed intervals against (a) nationally recognized standards, or (b) documented benchmark, where no nationally recognized standards exist	10	5	0	***NA***		IMT-4		
5	Facility maintains full documentation of calibration procedures and results	10	5	0	***NA***		IMT-5		
6	Facility identifies all equipment with indicator or calibration status	10	5	0	***NE***	0	IMT-6		
7	Facility has system for re-verifying previous inspection, measuring and test results when equipment is found to be out of calibration	10	5	0	***NA***		IMT-7		
8	Facility has system for maintaining and storing equipment that assures that accuracy and fitness for use is preserved	10	5	***0***		0	IMT-8		
9	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	IMT-9		

TOTAL SCORE	0

4.12 Inspection and Test Status		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for identifying inspection and test status of raw materials, supplied items, work in progress and finished output	10	5	***0***		0	ITS-1		
2	Facility has system for showing at all stages whether such items have been inspected; been inspected and accepted; inspected and on hold awaiting resolution, or inspected and rejected	10	5	***0***		0	ITS-2		
3	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	ITS-3		

TOTAL SCORE	0

4.13 Control of Non-Conforming Product		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for identifying non-conforming product; its evaluation, segregation and disposal	10	5	***0***		0	NCP-1		
2	Procedures for identifying and evaluating non-conforming product are in place, including identifying its source	10	5	0	***NE***	0	NCP-2		
3	Facility has procedures for segregating the product to prevent inadvertent use in place	10	5	0	***NE***	0	NCP-3		
4	Procedures governing methods of disposal, including reworking to specified requirements, acceptance with or without repair by concession, modification for other use, or scraping are in place	10	5	***0***		0	NCP-4		
5	System includes specified means of documenting all above	10	5	0	***NE***	0	NCP-5		
6	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	NCP-6		

TOTAL SCORE	0

4.14 Corrective action		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for designing, implementing and documenting corrective actions	10	5	***0***		0	CA-1		
2	Facility has procedures for detecting causes of nonconformities; initiating corrective actions, controlling their implementation, verifying their effectiveness, and documenting procedural changes in order to prevent recurrence	10	5	0	***NE***	0	CA-2		
3	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	CA-3		

TOTAL SCORE	0

4.15 Handling, Storage , Packaging and Delivery		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for maintaining the quality of all materials during handling, storage, packaging and delivery	10	5	0		5	HSPD-1		
2	Procedures for damage and/or deterioration prevention during handling are in place	10	5	0	*NE*	0	HSPD-2		
3	Procedures which assure security of storage areas to avert environmental or human damage, deterioration or shrinkage exist	10	5	0	*NE*	0	HSPD-3		
4	Procedures governing audit and assessment methods and means of documentation are in place	10	5	0	*NE*	0	HSPD-4		
5	Procedures specify handling methods to preserve materials in a state that conforms with specified requirements	10	5	0	*NA*		HSPD-5		
6	Procedures for controlling the delivery process, assuring protection of the quality of materials during any type of transport, either in-process or after final output exist	10	5	0		5	HSPD-6		
7	Detailed procedures covering the systems herein are available	10	5	0	*NE*	0	HSPD-7		

TOTAL SCORE	10

4.16 Quality Records		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for creation, maintenance, retention and systematic disposal of quality records	10	5	***0***		0	QR-1		
2	Records exist which demonstrate effective operation of the quality system	10	5	***0***		0	QR-2		
3	Records document achievement of the required quality levels, and remedial actions taken in response to nonconformances	10	5	0	***NE***	0	QR-3		
4	Records are readily retrievable by all authorized to use them	10	5	***0***		0	QR-4		
5	Retention times which meet all customer and/or legal or regulatory requirements are documented	10	5	***0***		0	QR-5		
6	Records are discarded on an orderly and systematic basis when documented retention intervals have passed	10	5	***0***		0	QR-6		
7	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	QR-7		

TOTAL SCORE	0

4.17 Internal Quality Audits		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for planning, scheduling, conducting, documenting and benefiting from internal quality audits	10	5	***0***		0	IQA-1		
2	Procedures place emphasis upon auditing areas of critical importance to the quality system, or which have posted a history of nonconformances or other problems	10	5	0	***NE***		IQA-2		
3	Procedures specify the qualifications of the personnel assigned to perform internal audits (IA)	10	5	0	***NE***		IQA-3		
4	Procedures governing the conduct of IA, including safeguards against conflicts of interest and provision for follow-up actions	10	5	0	***NE***		IQA-4		
5	Results of internal audits are brought to the attention of the personnel responsible for the area audited	10	5	0	***NE***		IQA-5		
6	Management of audited areas are held accountable for taking corrective actions on or before specified dates	10	5	0	***NE***		IQA-6		
7	Detailed procedures covering the systems herein are available	10	5	0	***NE***		IQA-7		

TOTAL SCORE	0

4.18 Training		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for setting quality related employment qualifications, assessing training needs, providing training and maintaining records	10	5	***0***		0	T-1		
2	Qualifications, in terms of education, training and experience, exist for each position affecting quality	10	***5***	0		5	T-2		
3	Procedures which provide for evaluating training needs for all quality sensitive positions on a regular basis are in place	10	5	0		***NE***	T-3		
4	Training programs are conducted to correct identified nonconformances in qualifications	10	5	***0***		0	T-4		
5	Records, both individual and corporate, are maintained of all training activities	10	5	0		***NE***	T-5		
6	Detailed procedures covering the systems herein are available	10	5	0		***NE***	T-6		

TOTAL SCORE	***5***

4.19 Servicing		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined authority and responsibility for servicing activities	10	5	**0**		0	S-1		
2	Facility has established and maintained procedures for performing service	10	5	0	***NE***	0	S-2		
3	Facility has procedures for verifying that servicing meets established customer requirements	10	5	0	***NE***	0	S-3		
4	Detailed procedures covering the systems herein are available	10	5	0	***NE***	0	S-4		

TOTAL SCORE	0

4.20 Statistical techniques		FIRST ASSESSMENT						ASSESSMENT	
	Components	**St**	**Mo**	**We**	**NA**	**Sc**	**Comm.**	**CONF**	**NONC**
1	Facility has defined responsibility and authority for evaluating the use of statistical techniques (ST) throughout the facility and process	10	5	0	***NA***		ST-1		
2	Facility has procedures for assessing ST to verify product characteristics, assess process capability and other purposes	10	5	0	***NE***		ST-2		
3	Detailed procedures covering the systems herein are available	10	5	0	***NE***		ST-3		

TOTAL SCORE	

Self Assessment Conclusions

4.1 Management Responsibility

MR-1 Although there is an overwhelming understanding of company's strategic goals to produce quality products and expand market share, clearly defined and documented quality policy in terms of ISO 9000 standards requirements does not exist.

MR-2 Due to the small size of the family-run company, specific quality responsibilities of all employees are not clearly defined. The team approach for problem solving and decision making is widely used, with authority and responsibility distribution based on employees' experience and qualifications. Quality responsibilities are not documented.

MR-3 An organization chart showing management structure and relationship does not exist. The company is organized on the following levels:

1) Top level; president (the owner) has the ultimate responsibility for the company

2) High level; comprised of the president, vice presidents, design, sales and production managers. Team approach for company's management is used at this level. Team members have equal authority in terms of decision making, but the responsibility for problem solving and decision implementation in specific division is placed on the division managers. For example, production manager has the responsibility for decision implementation and problem solving in the field of production

3) Middle level; production and shipping supervisors

4) Low level: operators and technicians

MR-4 The ultimate responsibility is placed on the president. Division managers (Design, Production and Sales) participate in the process. Design manager is responsible for providing resources in product design - personnel and equipment. Production manager is responsible for providing raw material, machines and equipment and personnel for production. Responsibility for providing resources in terms of sales and delivery is placed on the sales manager.

MR-5 Verification activities include:

a) Design - Direct involvement of the president (top level management), team work (sales and production manager are involved in the design process and thus verify design activities) and pilot run

b) Production - organizational structure (knitting, washing and sewing supervisors report directly to the production manager, who verifies their activities. Production activities are ultimately verified by the president), continuous monitoring, coordination by the president and the vice-presidents

c) Sales - customer service coordination by sales, production and shipping divisions.

Due to the small size and flexibility of the company, employees at high management level have numerous responsibilities and authorities. Communication is informal and therefore, there is a lack of documentation covering the area of quality responsibilities. Hence, responsibilities for verification activities are not clearly defined.

MR-6 Production manager is responsible for verification activities in the production process. His responsibilities are clearly defined, but not documented. Sales and design managers are responsible for those activities in terms of sales, customer service and design. Finally, all processes and products are verified by the president. However, the ISO 9001 standard demands that the verification activities are carried out only by persons who do not have direct responsibility for the activities being verified. In order to comply with the standard, the company will have to rearrange these activities. No records of verification activities are kept.

MR-7 Nobody from the company has yet be designated to oversee conformance of the company's quality system to the standard.

MR-8 No such meetings have been conducted. Although some elements of the quality system as defined in ISO 8402 standard exist, company's quality system has not yet been defined as such. Regular meetings are held for decision support and coordination purposes. Production manager would sometimes keep notes, but the minutes of these meetings are not documented nor retrievable in any way.

MR-9 No procedures exist.

4.2 Quality system

QS-1 The management has not specified the responsibilities described in this entry.

QS-2 No documentation covering activities described in this entry exists. Informal selection of suppliers based on their past performance and the following criterion is being carried out. The criterion for suppliers selection described by the president is meeting the company's requirements in terms of quality, type, delivery time and price of raw material.

The president himself selects suppliers of the raw material he considers important, and production manager is responsible for selecting additional raw material (buttons, for example) suppliers. The system for monitoring suppliers performance practically does not exist.

QS-3 Acceptability standards have neither been identified, nor documented.

QS-4 The responsibility for production process control is placed on the production manager. No documentation related to this matter exists. Process capability is determined only in terms of productivity (comparison of the quantity ordered and produced). The

president expressed the wish to document the activities related to this matter before, but did not find sufficient resources and time to accomplish it.

QS-5 A system for conducting internal audits does not exist.

QS-6 Procedures described in this entry do not exist. A procedure for products delivery to customers has been written by the shipping supervisor, but not implemented at all.

QS-7 Procedures do not exist. Corrective actions are informal. A defined and documented system for corrective actions is not in place.

QS-8 Since the inspection equipment is already installed and the management feels there is no need to improve it for the time being due to low rate of product return, the system does not exist. The management decided that additional measuring and test equipment is not needed due to low complexity of inspection.

QS-9 100% final inspection is used. First piece (sample) inspection is also in use. It is performed before the line production is started. One sample piece is manufactured and then inspected for nonconformances to design specification. Input and in-process inspection practically does not exist. The system is not in place.

QS-10 Customer service deals with customer complaints with full money back guarantee, or repair policy. Records of such activities exist, but are not easily retrievable, if retrievable at all. Documented procedure covering feedback from customers does not exist.

4.3 Contract Review

CR-1 Specific responsibility for contract review activities has not been specified. The president is dealing with the major customers and has the responsibility for fulfilling the requirements defined in customer's order. Sales manager deals with sales representatives who are company's immediate customers.

CR-2 Customers requirements are defined and documented using the internal standard document - "Purchase Order" that sales representatives fill in. Purchase order was created to ensure customer's clear requirements and specifications.

Here, an analogy between the company and a supermarket can be drawn. Sales representatives come to the company and choose from variety of products (samples) company has to offer. They make an order (specification) and according to the order, the company runs production. Since the quantity of products ordered by a single customer (sales representative) is usually small, customer service department collects several orders, sorts them out and sends them to the president for review and approval.

Customer can also order a specific service or a product. In that case, customer would specify the requirements in writing and send it to the company's sales department.

CR-3 Inconsistencies between customer requirements and company standards are being solved by using the internal "Purchase Order". In the case of customer's specific requirements for a new product, company's sales manager and customer have a meeting where they identify and resolve all possible discrepancies. The company makes a sample product according to the customer's specifications, and after confirmation from the customer, runs the production.

The system described herein is not documented.

CR-4 The capability to meet customer requirements is evaluated by the president and the managerial team consisted of sales and production manager. This part of the order review system is not documented.

CR-5 No.

CR-6 No. Customers order records and reviews of specifications made in coordination with the customer exist, but are hardly retrievable. In fact, the president and sales manager did not even know about the book of records that production manager had kept for the past years. The first time they identified its existence was during the gap analysis the author of these lines has conducted.

CR-7 No. The procedures do not exist

.

4.4 Design Control

DC-1 Responsibility and authority for the internal design process is mainly placed on the design and sales manager. Most of the company's new product designs are bought from an external designer. Subsequently, these designs are being changed or adjusted according to customer specifications and feasibility study by the management team.

Records of the design changes are being kept by the production manager. The records are stored in a book, which is in possession of the production manager. In spite of the great importance of this book, there is only one (master) copy.
Production manager is responsible for the disposal of design related documents.

No documentation covering the requirements in this entry exists.

DC-2 No.

DC-3 The following procedures are used for new product design:

(a) External designer supplies the company with a design. The company might use the designs as it is, or change it according to the management decision.

(b) Design benchmarking. A representative of the company attends meetings with world-class knitwear manufacturers, textile fairs worldwide. The representative is supplying the company by the pictures of new designs, catalogues of the world leading companies in the field. On the basis of the information gathered, management team in charge of design, consisted of the president, vice-presidents, design, sales and production managers, selects appropriate designs and performs market research and feasibility study. Design changes are subsequently performed by the design manager according to the team's specifications and approved by the president for pilot (sample) production.

No documentation covering these procedures, except the design changes book kept by the production manager, exists.

DC-4 Sources of design input are identified in the way described in the DC-3
The document described in this entry does not exist.

DC-5 Design output is presented in a form of design list with the design drawing, specifications for production and different colour combinations of the same design pattern. Blue prints with specific instructions for production do not exist. The design document is kept by the production manager and is not easily retrievable. In fact, sales manager and the president himself were not aware of its existence before the quality system audit.

Hence, design output documentation has not been clearly defined.

DC-6 Design reviews are performed by the management design team. The system has not been clearly defined.

DC-7 The system illustrated herein is in power.

DC-8 No.

4.5 Document Control

DOC-1 No.

DOC-2 No. The only document existing in a plant that could be considered as a non-record document is the design list book and a prospective shipping/receiving procedure that is not being used in reality. Other documentation is in form of records covering production performance.

DOC-2,3,4,5 & 6 No.

4.6 Purchasing

P-1 Responsibility and authority for purchasing of the raw material that has a high impact on product quality and reliability is placed on the president. This material includes yarn and threads. Production manager is responsible for supplementary raw material purchase (buttons, chalks etc.). Contacts with suppliers are maintained by the president for yarn and by customer service for additional material. However, the responsibility and authority for purchasing activities should be defined and documented more clearly.

P-2,3,4 No.

4.7 Purchaser Supplied Product

PSP 1,2,3,4,5 Purchaser supplied products are very rarely used by the company. This can only be a sweater that the customer wants the company to copy with minor changes, defined in the customer specification letter that accompanies the sweater. No documentation covering this entry is available.

4.8 Product Identification and Traceability

PIT-1 The company is running a batch production. Therefore, batches (bundles) are identified with a "Knitting Ticket", that follows the batch all the way to the final inspection. There, the ticket is removed and disposed of. Individual products are marked with an individual label, subsequently.

In a case of a defective product identification, a sticker is placed on the knitting ticket to mark that the batch is not completed. Defective product is removed from the batch and identified with a wooden clipper. After it has been repaired, the defective product is returned to the original batch. If repair is not possible, defective product is placed in a box with no signs or marks on it. Batch size correction is provided by the red sticker placed on the ticket, illustrating that the batch has not been completed.

A number of nonconformaties to the standard has been found during the gap analysis, in terms of product identification and traceability. They are the following:

(1) Knitting tickets do not record the operations already performed on the product. Although the current "Knitting Ticket" contains entries for operations performed on the product, they are not in use. Operations that follow knitting, such as washing and pressing, are not recorded on the ticket. Production area layout enables product mixing between two operations, and since there is no record of product status, product misidentification is highly likely.

(2) The majority of knitting tickets currently being used were printed by the computer. However, old tickets are being used together with the new ones which might result in confusion and misidentification.

(3) The location of the defect is being identified by the clipper. However, the cause or nature of the defect can not be determined in this way - different defects are marked with the same clipper.

For example, yarn breakage can not be differed from the holes in the sweater. Since different operators repair defects that are different in nature, there is an excessive loss of time in inspecting the nature of the defects due to improper identification.

(4) Defective parts that can not be repaired are being placed in a box with no labels, marks or tags on it.

(5) Knitting tickets identify style, size, colour and other product characteristics. After they are removed, individual product labels are placed. However, the labels do not contain information on the garment colour combination. Therefore, misidentification due to colour similarities is possible.

(6) Raw material (yarn cones) is kept in the boxes labeled by the raw material supplier. No additional labeling of the individual cones is provided in the company. The audit has shown that there are numerous yarn cones not labeled at all. Since the yarn is being kept in the suppliers' original boxes, and due to high variety of yarn used for production, there is a high risk of raw material misidentification and displacement.

(7) Boxes where defective products for repair are placed are not labeled. The box with nonrepairable products (for disposal) is placed between two knitting machines. Since neither the box, nor the individual defective products are marked or labeled, there is a high risk of displacement of these products with conforming ones.

(8) There is a high possibility of batches misidentification during washing & drying operation. In order to maximize washers' and dryers' utilization, several bundles of the same style and size are placed together into the machines. Since the corresponding tickets are placed outside the machines, it is likely that the bundles are being identified with wrong tickets after the operation.

PIT-2 Customers do not require procedures for product identification. There are no procedures available.

PIT-3 The same as above. No procedures available.

PIT-3 No.

4.9 Process Control

PC-1 The production process consists of the following stages:

(a) Knitting
(b) Washing and drying
(c) Cutting
(d) Sewing
(e) Pressing

The process is controlled "a-posteriori" (after the event has occurred). For example, knitting process is stopped if the yarn is broken or when the whole bundle is

knitted. Only then, the operator can visualize nonconformance (defective products) and report it to the production manager for verification and corrective actions. Production manager is primarily responsible for the process control. Secondary responsibility is placed on the knitting supervisor for the first three stages and the sewing supervisor for the last two stages in the manufacturing process.

PC-2 No. They have neither been defined nor documented.

PC-3 Only documentation available is in form of productivity records, that are written down after the production (a-posteriori). No procedures that would show the method, or step by step approach for process control (a-priori) exist.

PC-4 There are no special processes in the facility. Therefore, this entry is not applicable.

4.10 Inspection and testing

IT-1 Only the final, 100% inspection has been performed in the facility. Input (raw material) inspection does not exist. Visual in-process inspection is performed after the knitting stage, but is not efficient, since most of the defects created in this stage are not identified until the final inspection is performed. Knitting operators do not have clearly defined responsibility for inspection. Sewing supervisor is in charge of the final inspection performed in two stages:

(a) visual inspection and mending
(b) light inspection
Inspection is performed on a sample (first piece inspection). Refer to

IT-2 No. System is neither documented, nor does it exist.

IT-3 No. The company does not recall its products unless it has been returned by the customer. The ticket that identifies the products during production stages is being thrown away after sewing, and replaced by the individual product label.

IT-4 No. Since only the final inspection is performed on the product, system for early recognition of nonconforming product does not exist. The following facts have been recognized in the course of the self-assessment (initial audit):

(a) Defective peaces are labeled with a wooden clip placed on a defect location. The clip does not identify the cause or nature of a defect.

(b) "Knitting Ticket" does not identify product status (i.e. operations that have been performed on the product).

(c) There are no quality control records in the facility. Therefore, recognition of possible causes of defects occurred is not possible at this point of time.

IT-5 This is ensured by the final inspection. Nevertheless, the system does not include clear identification of conforming versus nonconforming output product. Defective output products are not properly discarded from the nondefective ones. Boxes for nonconforming products are not labeled.

IT-6 No procedures covering final inspection and testing are available.

4.11 Inspection, Measuring and Test Equipment

IMT-1 In addition to IT-1, sewing supervisor is primarily responsible for final inspection and therefore, for inspection equipment. Workers who perform light inspection are responsible for light inspection equipment maintenance and operation. The responsibilities are not documented.

IMT-2 No. Management considers the existing inspection equipment sufficient for final inspection of products.

IMT-3 No. The only equipment used for inspection is light cones and cylinders. It is not a measurement or testing equipment.

IMT-4 No. Since the equipment consists of a light bulb and a plastic cone or cylinder, and therefore is not complex for maintenance, calibration of the equipment is not performed.
Testing of the inspection equipment has not been done since the equipment was bought. Records addressing inspection equipment do not exist.

IMT-5 N/A.

IMT-6 No. Testing equipment is not calibrated, and therefore not identified with a label.

IMT-7 N/A

IMT-8 The system described in this entry does not exist.

IMT-9 Procedures for inspection are informal and not in a written form.

4.12 Inspection and Test Status

ITS-1 Production manager has the responsibility for identifying inspection and test status of supplied raw material, work in progress and finished products.

ITS-2 Raw material is placed in boxes that are originally labeled by suppliers. Additional labeling is not provided in the company. Work in progress pieces are labeled by the "Knitting Ticket". However, the ticket does not show at any stages whether items have or have not been inspected, rejected or accepted, nor whether they have been inspected and awaiting resolution. In other words, inspection and test status of items is not identified at any production stage.

In the course of the final inspection of the items, a sticker illustrating that an item has been inspected is placed on the product. However, the sticker does not show the status of the item inspected (rejected, awaiting resolution, or accepted).
Inspection status identification relies on workers' experience and training - "Workers know whether the bundle is accepted or rejected".

Hence, the status of products can not be observed and recorded by the existing labeling system.

ITS-3 Written procedures covering inspection and test status of a product do not exist.

4.13 Control of Non-Conforming Product

NCP-1 Non-conforming product is identified by final inspection. Knitting operators have the responsibility of identifying a non-conforming knitted item. Production manager is responsible for its evaluation and segregation. Rejected items are placed in a non-labeled box. The disposal of non-conforming item is the responsibility of a factory helper, after the disposal has been ordered by the production manager.

NCP-2,3,4 Written procedures covering non-conforming product identification, evaluation and segregation do not exist. Defective product is not traced in order to identify its source. Procedures and instructions for identifying, segregating and reworking of a non-conforming product are given orally to operators and inspectors by means of training before they start working.

NCP-5,6 No documentation covering control of nonconforming product exists. The facility does not have any quality control records. The number, sources or characteristics of nonconforming products have not been recorded at any time since the company was established.

4.14 Corrective Action

CA-1 The responsibility for designing and implementing corrective actions (CA) is mainly placed on the production manager. The managerial team for production is authorized to design and implement CA in manufacturing areas of the facility. CA which identify a need for changes to documentation are usually addresses by vice-president responsible for production planning. Means of documenting CA do not exist.

CA-2 Procedures described under this entry are not in place. In terms of non-conforming (defective) items, sewing supervisor who is responsible for final inspection, identifies the cause of defect (raw material, operator's error or machine irregularity). However, since procedures addressing corrective actions to be taken do not exist, these causes are not eliminated, and continue to be a major problem for a controlled manufacturing process.

CA-3 No.

4.15 Handling, Storage, Packaging and Delivery

HSPD-1 Responsibility for handling and storage of raw materials and work in progress is placed on the production supervisors, namely the knitting and sewing supervisors. Production manager and sewing supervisor share the responsibility for finished products packaging. Shipping and receiving supervisor is responsible for maintaining the quality of finished products during packing the products in boxes to be shipped to the customer and delivery. The responsibility of the shipping supervisor is mainly to keep the finished garment in proper order by specified characteristics (sizes, color etc.). The responsibilities and authority have not been documented.

HSPD-2 No.

HSPD-3 Procedures described in this entry are not in place. Facility does not posses a designated storage area for work in progress. Items in progress are placed in boxes located wherever there is space available, namely between the knitting and sewing machines, in the cutting area, etc. This is due to the small space available for production.

HSPD-4 Audit and assessment methods have not been established in the facility. No procedures exist.

HASP-5 A procedure partially meeting the requirement exists. It was written by the shipping/receiving supervisor some time ago, but has not been implemented. The procedure states that "the packing of the garments must be presented in an orderly fashion

and must follow the packing slip". As far as marking processes are concerned, the garments (finished products) are tagged with a five digit number that indicates the year of the design and style. Colour combination is not included in the tag. The procedure was designed to back up the computer system for packaging and delivery. However, the system has not yet been introduced, and the procedure is not in use at the time.

HSPD-6 A procedure described in the previous entry partially covers the requirements described. However, it is still not in use.

HSPD-7 No. Only the procedure described in HSPD-5 exists.

4.16 Quality Records

QR-1 Quality control is primarily the responsibility of the production manager. Secondary responsibility is placed on the knitting and sewing supervisors, who monitor the inspection processes used in the plant. However, quality control records do not exist. Only the productivity of the inspectors is recorded. Namely, the number of inspected parts by each inspector is recorded. The number or the source of defects is not recorded. The defects are tagged by a wooden clipper and placed in a box for repairs.

QR-2 Only the records showing productivity at each stage exist. Quality control records do not exist.

QR-3 No. Records described in this entry are not in place.

QR-4 Productivity records are kept for a certain period of time (usually three years). Production manager is responsible for storage of these records. They are retrievable by the vice-presidents and the president of the company. The purpose of these records is to provide a basis for workers motivation (employees who are paid by piece work), and to provide an overall record of the system's performance in terms of productivity. Quality records do not exist.

QR-5 Customers do not require the keeping of quality records by the company.

QR-6 Productivity records are usually discarded after three years. Purchasing and accounting records are kept for seven years, according to legal and regulatory requirements. Quality control records do not exist, and hence, can not be discarded.

QR-7 No.

4.17 Internal Quality Audits

IQA-1 Internal quality audits as described in ISO 9001, ISO 9004 and ISO 10011 standards have never been conducted in the facility. The managerial team conducts regular meetings where a general review of the company's performance is done. The president conducts daily visits to the manufacturing area for assuring that the process is performed and controlled according to his specifications. Internal quality audit against the ISO 9001 standard conducted by the author of this thesis is the first one in this facility.

IQA-2 Procedures as described in this entry are not in place.

IQA-3 Same as above (IQA-2).

IQA-4 Same as above.

IQA-5 Results of the managerial team review meetings are brought to the attention of the employees in the company.

IQA-6 Review meetings are attended by the managers in the plant.

IQA-7 No.

4.18 Training

T-1 The primary responsibility and authority for setting quality related employment qualifications is placed on the president of the company. Responsibility for assessment of the training needs and providing training is placed on the division managers and supervisors.

Namely, knitting operators are trained by the knitting supervisor, sewers and inspectors in the final inspection are trained by the sewing supervisor. Cutters and operators who perform washing and drying are trained by the production manager, shippers are trained by the shipping supervisor. Office workers who deal with customers are trained by the sales manager. Accountants are trained by the vice president for finance and accounting.

Training records are not kept or maintained. Records that illustrate training provided do not exist.

T-2 Qualifications, in terms of education, training and experience, exist for employees. Employees have the skills needed to perform their tasks in a way that is consistent with informal quality policy and presidents specifications. However, in order to fully meet the

requirements of the standard described under section 4.18, positions affecting quality, quality policy and quality system have to be defined.

T-3 Training needs are evaluated by the supervisors and/or division managers. However, procedures described in this entry do not exist.

T-4 Formal training programs or procedures for training programs do not exist. Training is provided by the employees mentioned in T-1.

T-5 No records of training activities exist.

T-6 No.

4.19 Servicing

S-1 Servicing activities are related to customers complaints. If a customer returns a finished product for non-complying to the requirements, the company evaluates the complaint. Accordingly, the company would offer to repair it or a new product to replace the returned one. If the customer complaint is not justified, the company returns the product. Responsibility for these activities is not clearly defined, since the management concerns their return rate to be minor.

S-2 No.

S-3 Procedures described in this entry do not exist.

S-4 Same as above (S-3).

4.20 Statistical Techniques

ST-1 100% final inspection is used. Accordingly, the company does not evaluate the use of statistical techniques throughout the facility and process. In-process or incoming inspection is not used.

ST-2 No.

ST-3 No.

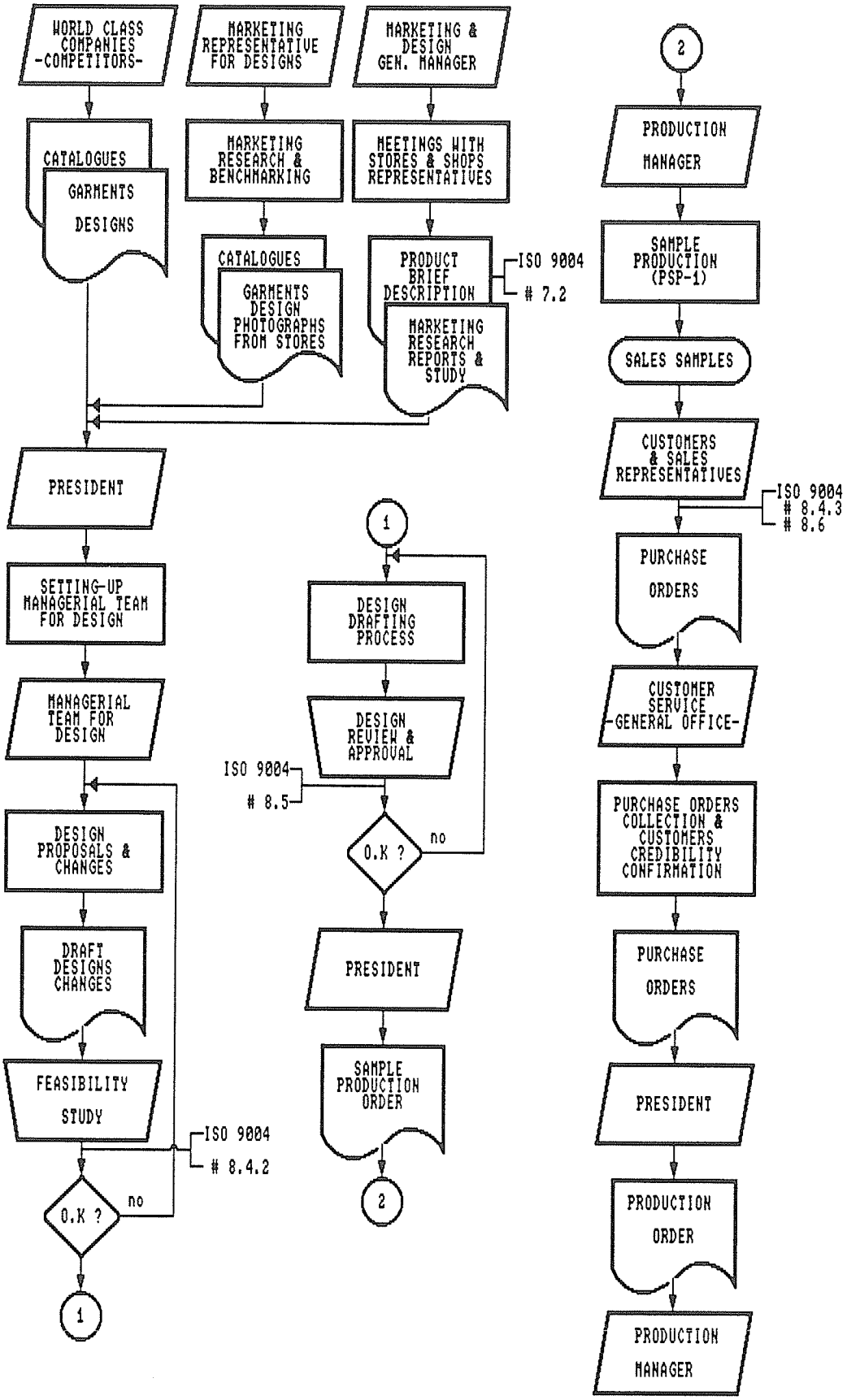
TOTAL SCORE - 70.

APPENDIX V

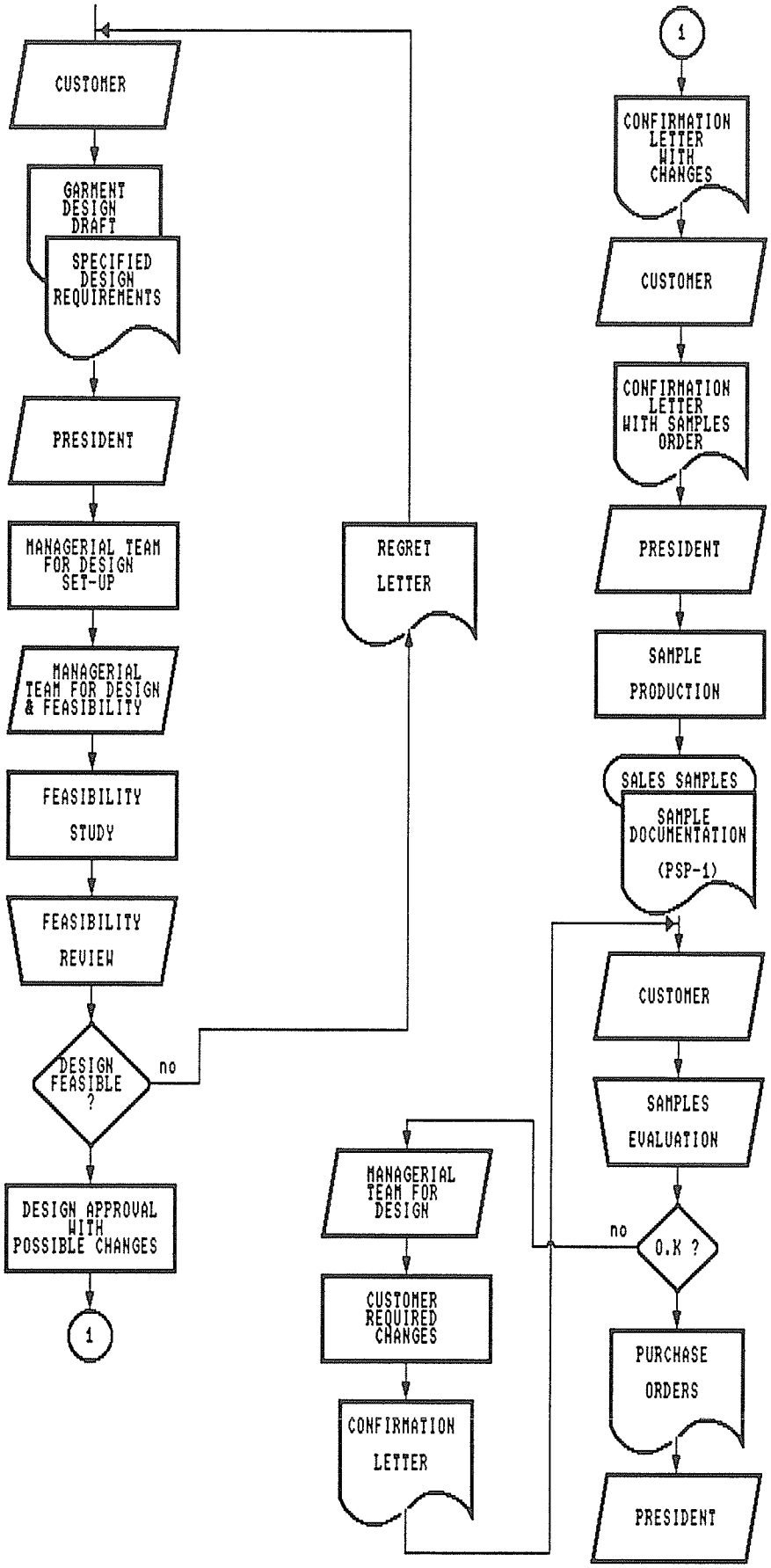
Quality Loop Integrated Flowcharts

1. Marketing Research & Internal Design
2. Customer Specified Internal Design
3. External Design
4. Sample Preparation
5. Purchasing
6. Production Preparation
7. Production
8. Shipping & Receiving
9. Training
10. Human Resources

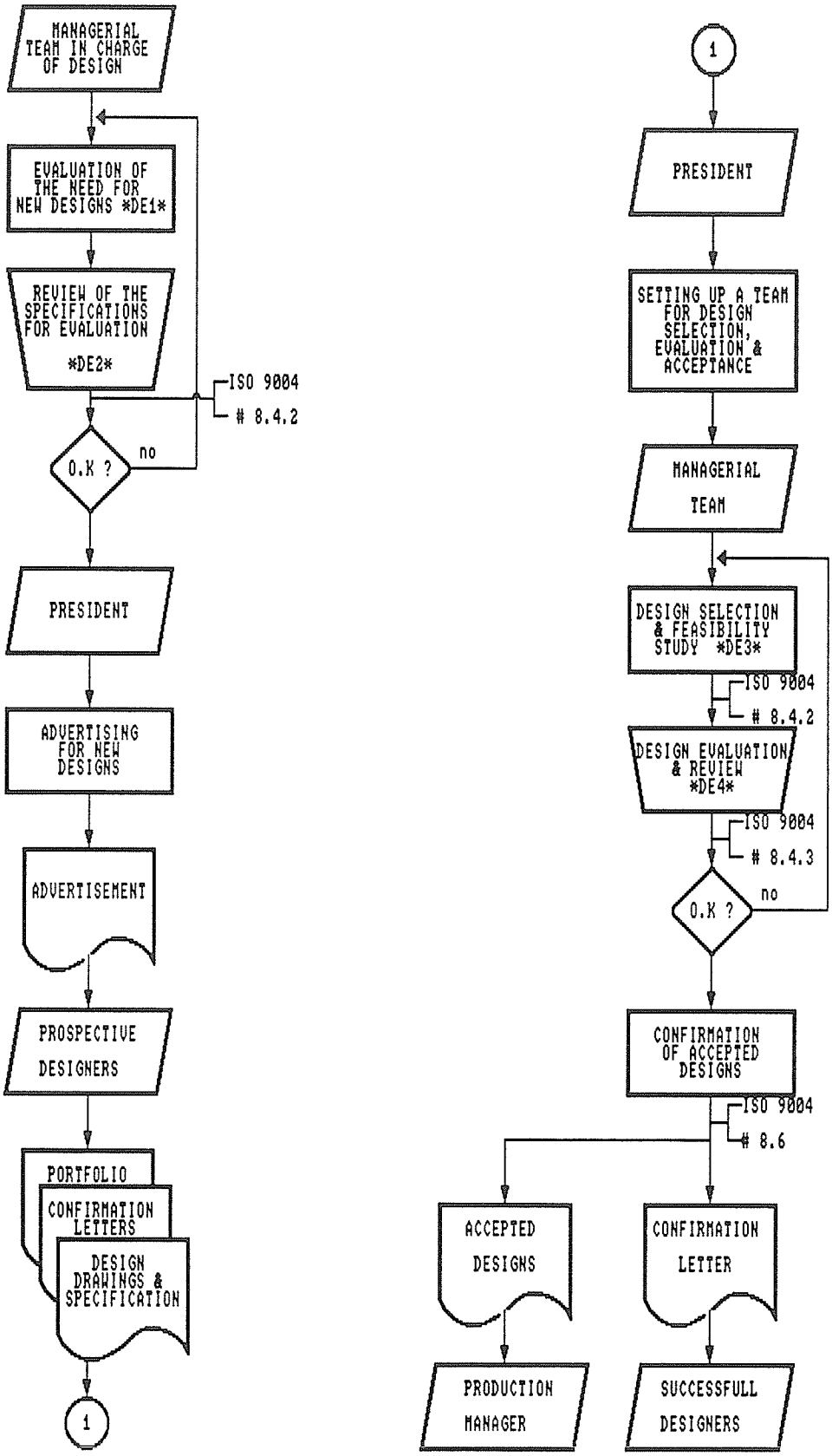
Marketing Research & Internal Design



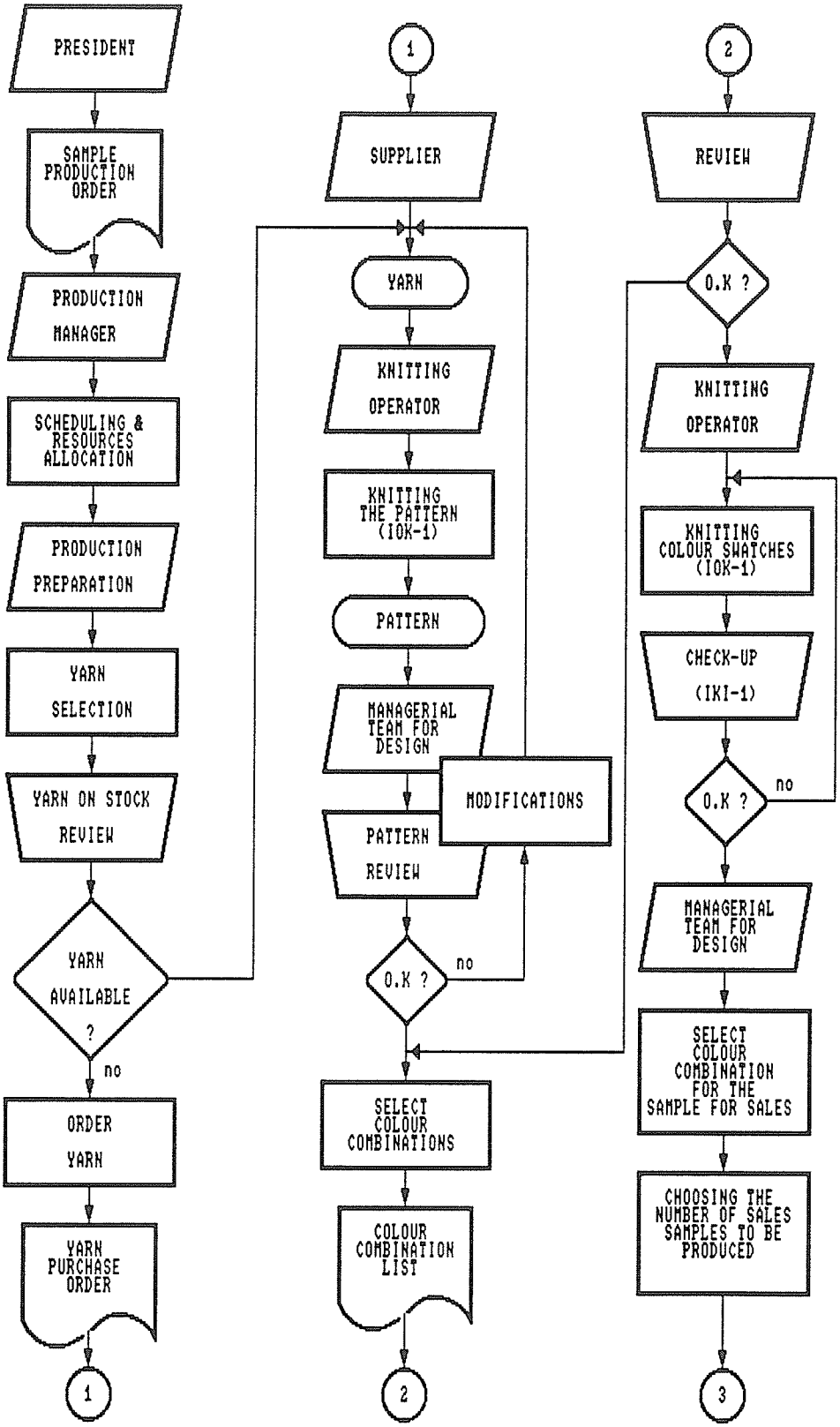
Customer Specified Internal Design



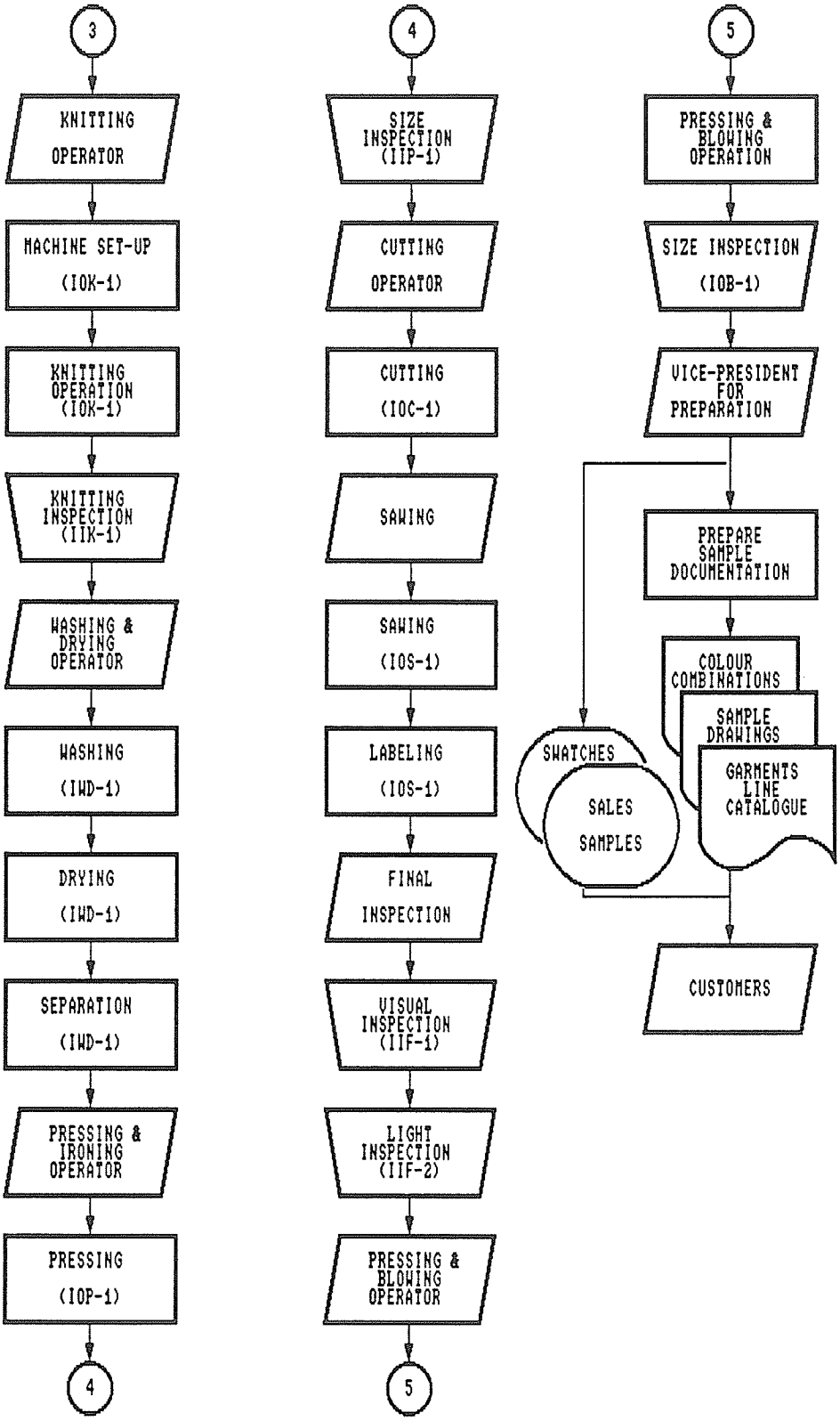
External Design



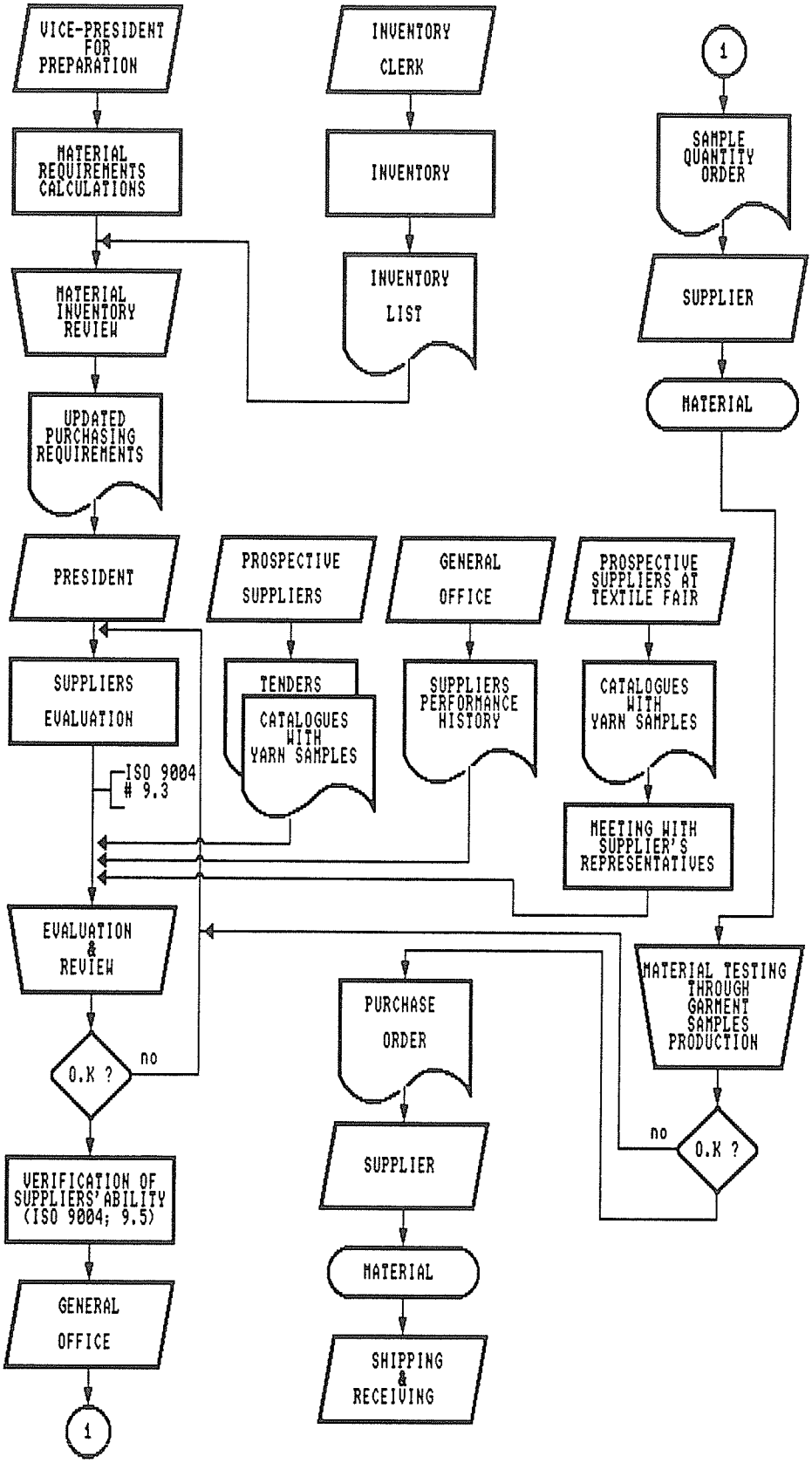
Sample Preparation



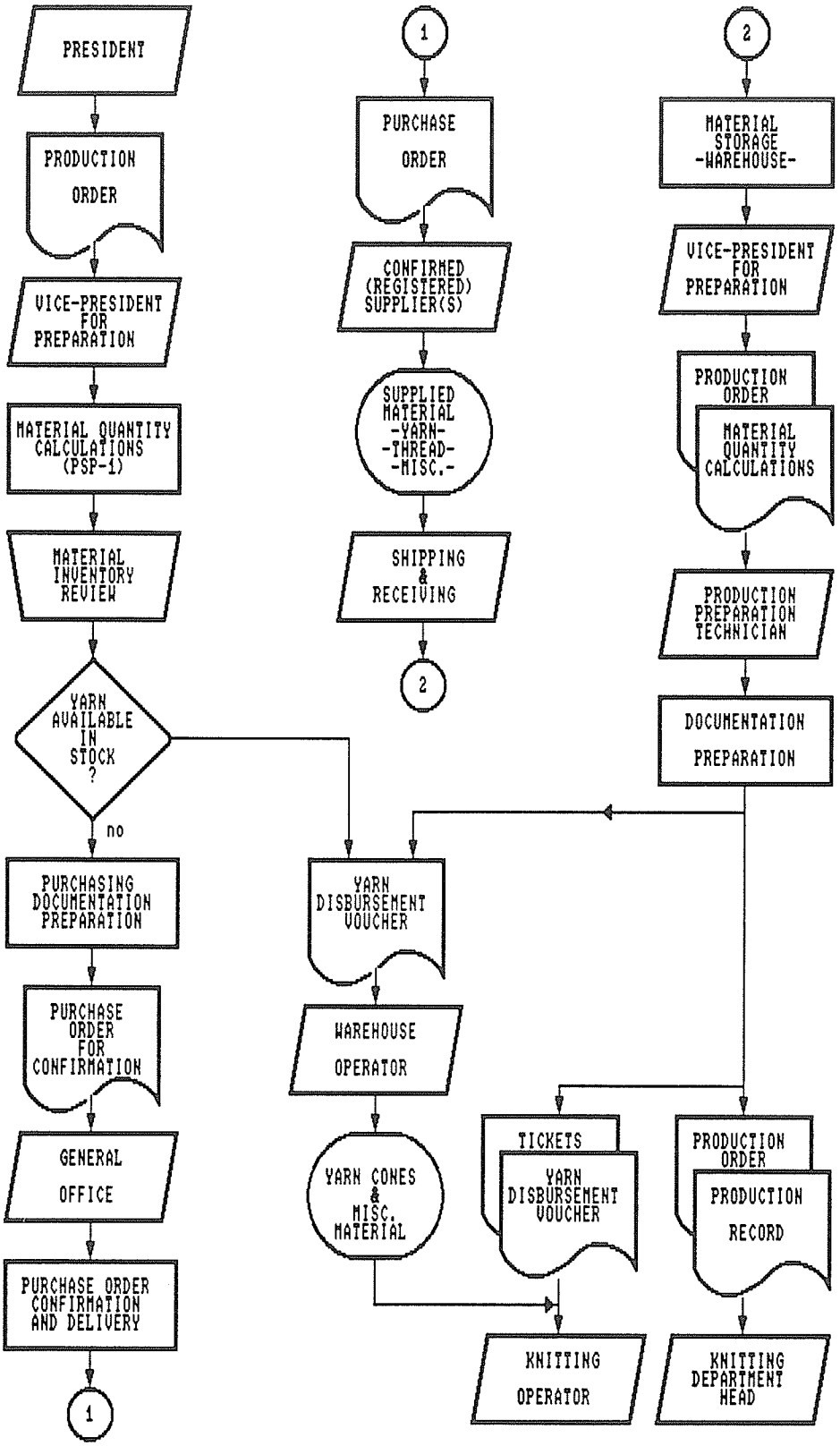
Sample Preparation (Page 2)



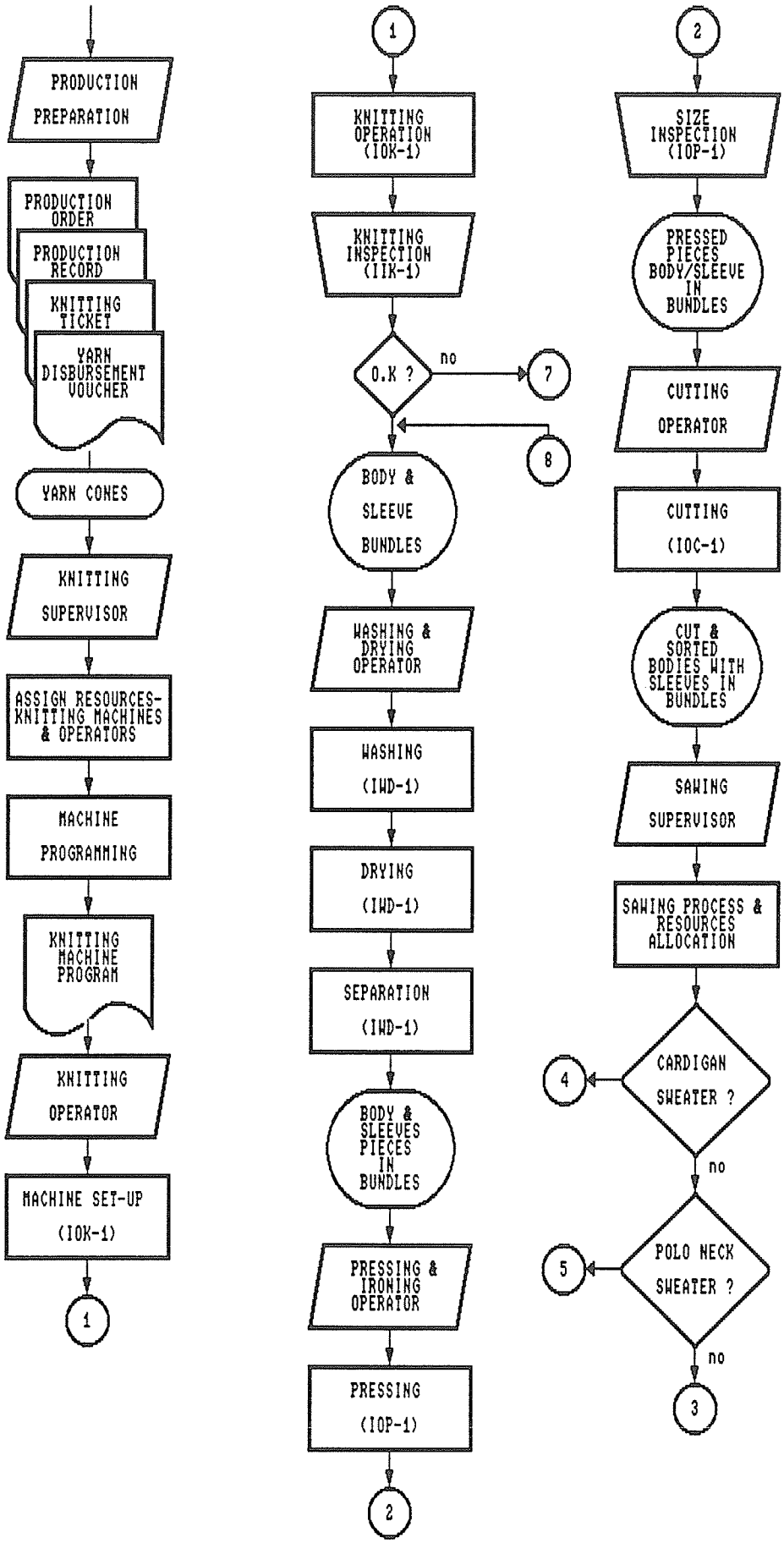
Purchasing


VICE-PRESIDENT FOR PREPARATION
MATERIAL REQUIREMENTS CALCULATIONS
MATERIAL INVENTORY REVIEW
UPDATED PURCHASING REQUIREMENTS
PRESIDENT
SUPPLIERS EVALUATION
ISO 9004 # 9.3
EVALUATION & REVIEW
O.K ?
no
VERIFICATION OF SUPPLIERS' ABILITY (ISO 9004; 9.5)
GENERAL OFFICE
1
INVENTORY CLERK
INVENTORY
INVENTORY LIST
PROSPECTIVE SUPPLIERS
TENDERS
CATALOGUES WITH YARN SAMPLES
GENERAL OFFICE
SUPPLIERS PERFORMANCE HISTORY
PROSPECTIVE SUPPLIERS AT TEXTILE FAIR
CATALOGUES WITH YARN SAMPLES
MEETING WITH SUPPLIER'S REPRESENTATIVES
PURCHASE ORDER
SUPPLIER
MATERIAL
SHIPPING & RECEIVING
1
SAMPLE QUANTITY ORDER
SUPPLIER
MATERIAL
MATERIAL TESTING THROUGH GARMENT SAMPLES PRODUCTION
no
O.K ?

Production Preparation



Production (Page 1 of 3)



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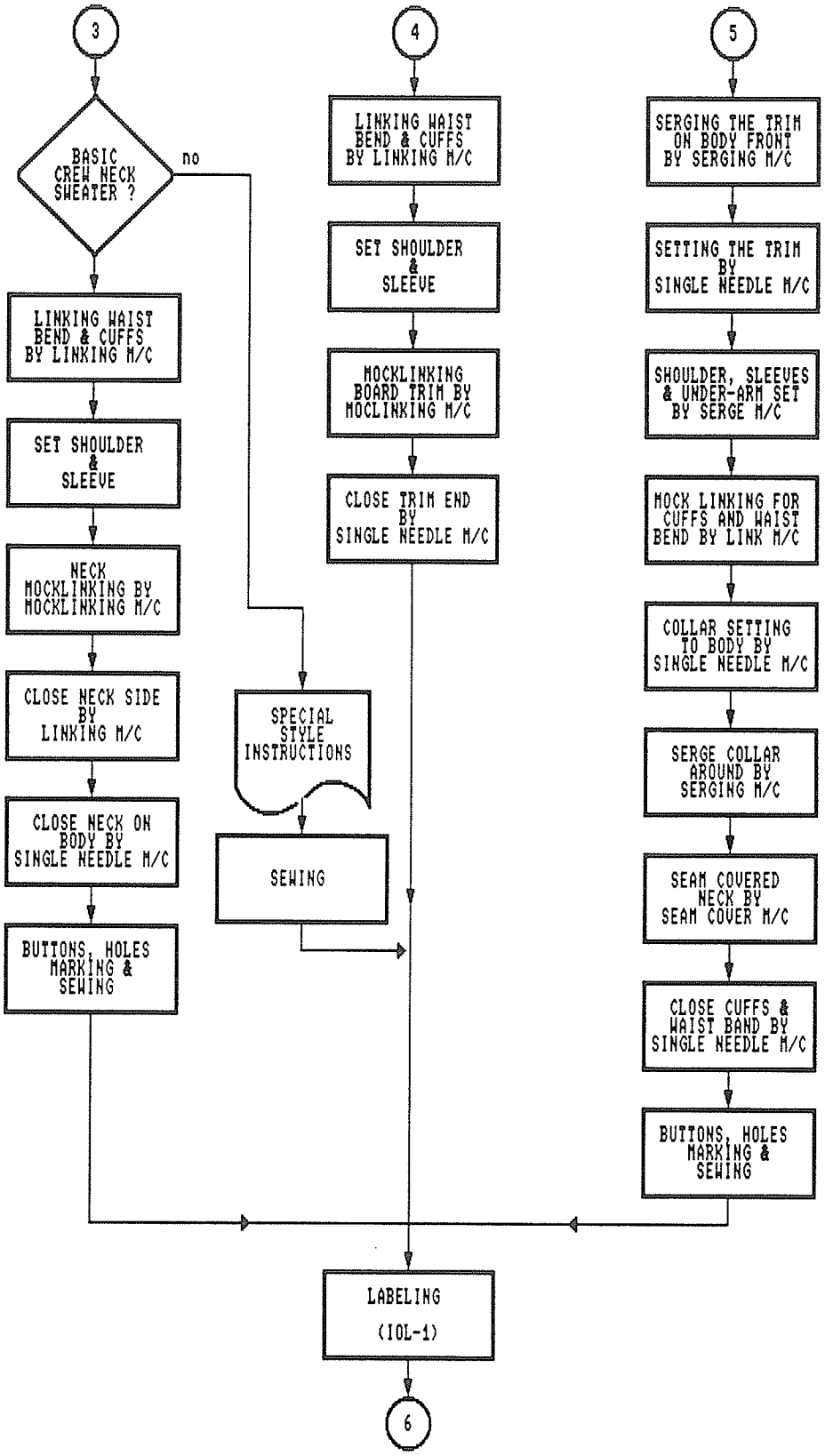
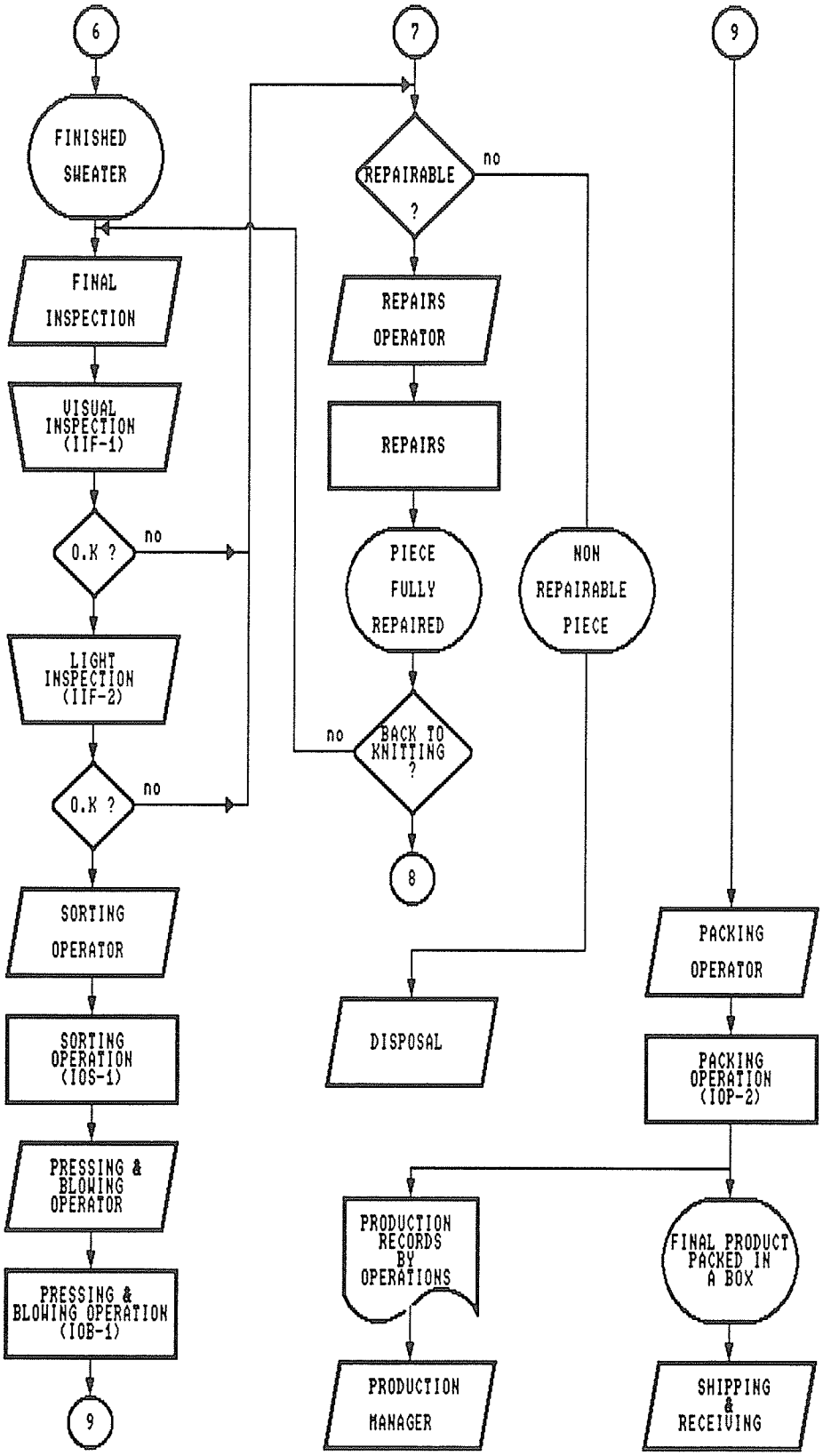


Production (Page 3 of 3)



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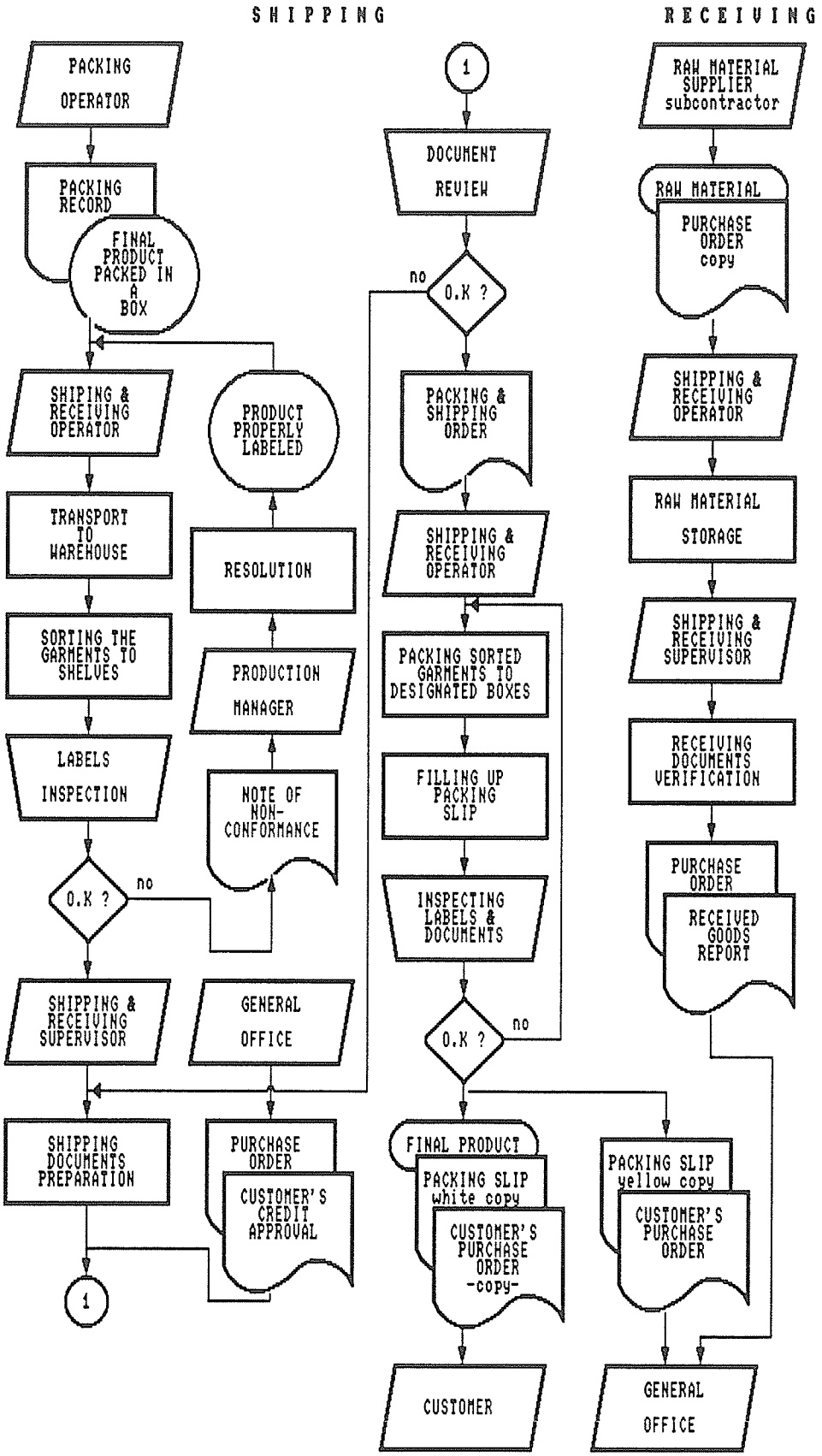
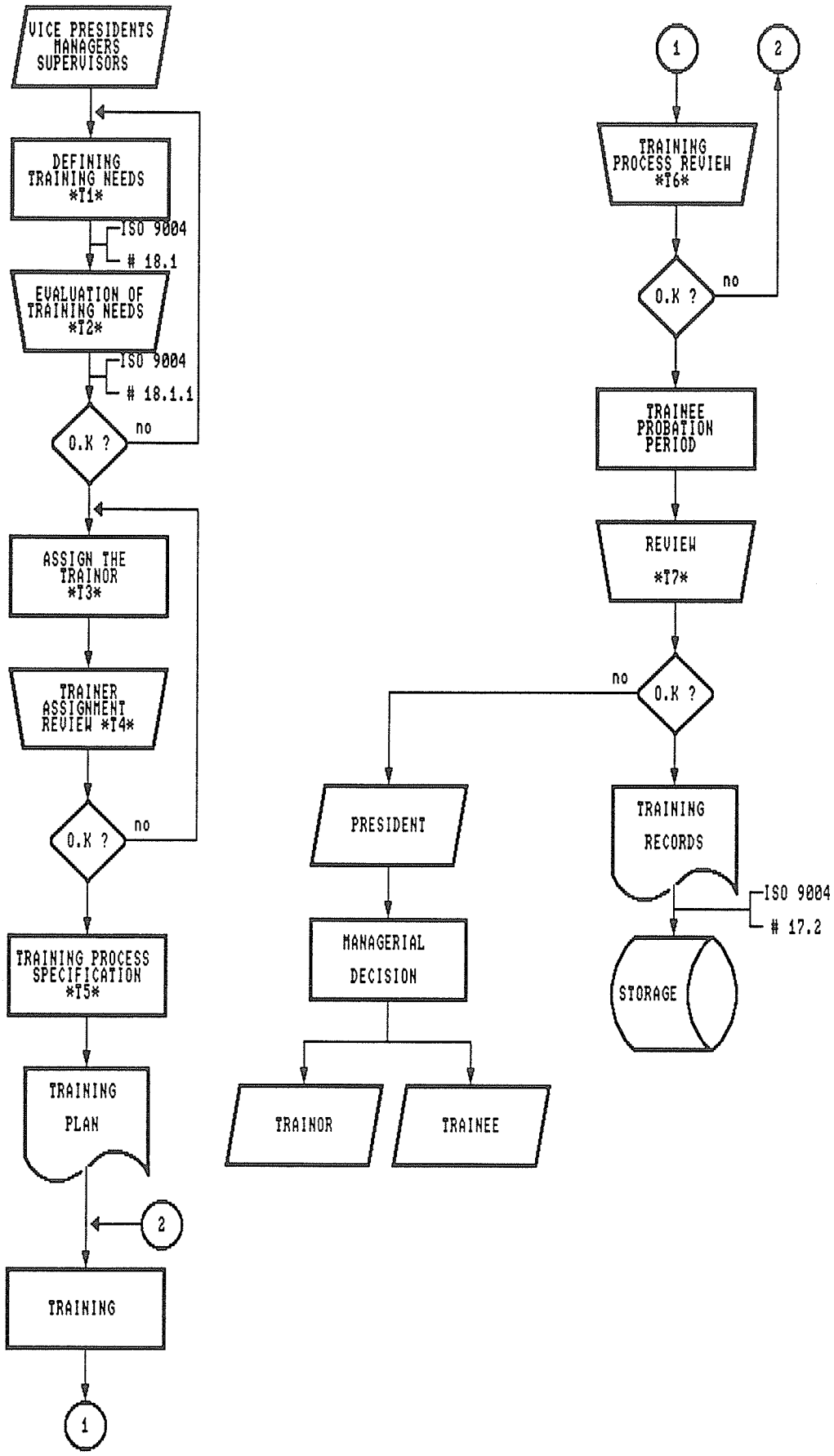
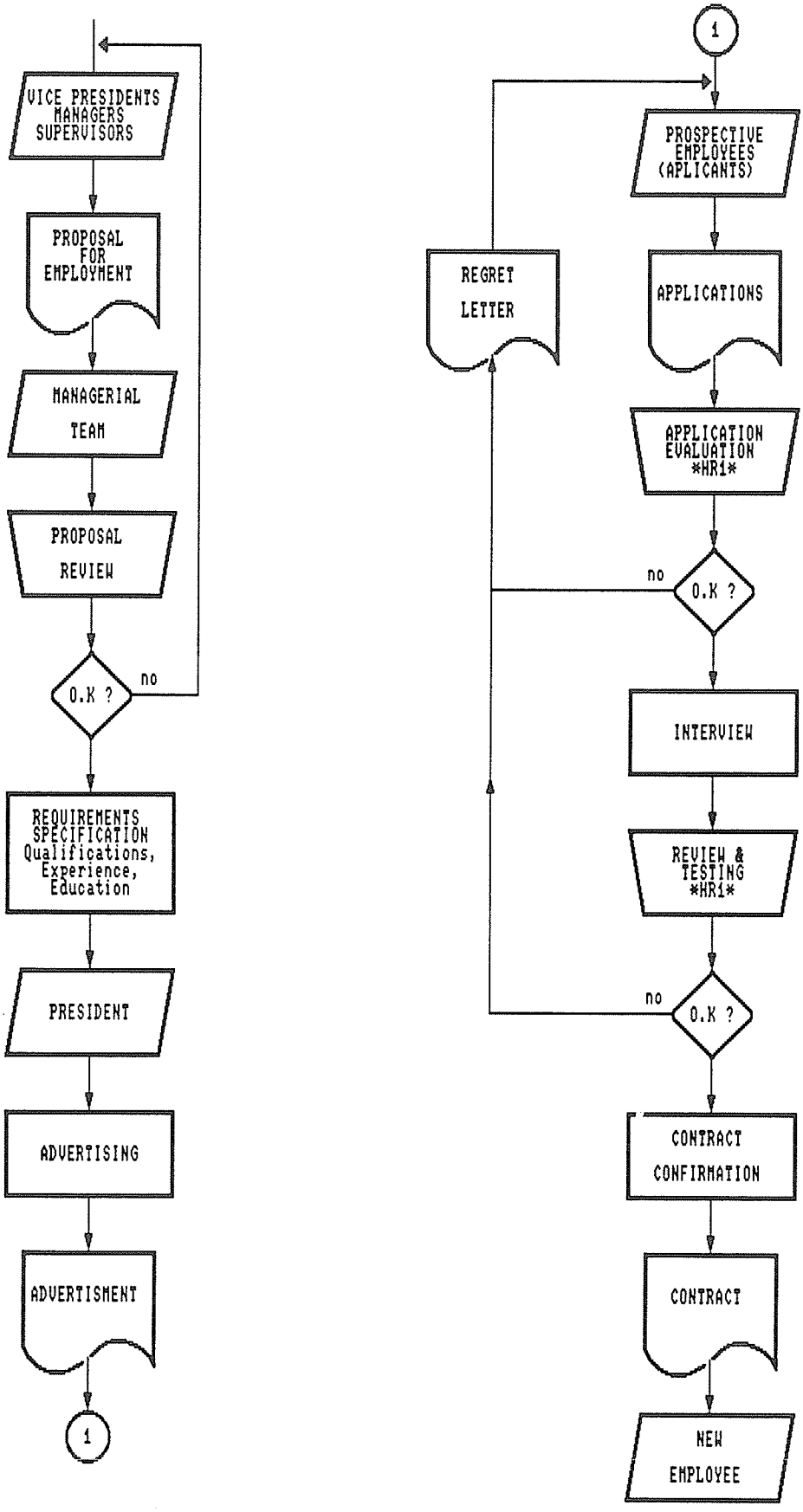


Training


VICE PRESIDENTS
MANAGERS
SUPERVISORS
DEFINING
TRAINING NEEDS
T1
ISO 9004
18.1
EVALUATION OF
TRAINING NEEDS
T2
ISO 9004
18.1.1
O.K ?
no
ASSIGN THE
TRAINOR
T3
TRAINER
ASSIGNMENT
REVIEW *T4*
O.K ?
no
TRAINING PROCESS
SPECIFICATION
T5
TRAINING
PLAN
2
TRAINING
1
1
2
TRAINING
PROCESS REVIEW
T6
O.K ?
no
TRAINEE
PROBATION
PERIOD
REVIEW
T7
no
O.K ?
PRESIDENT
MANAGERIAL
DECISION
TRAINOR
TRAINEE
TRAINING
RECORDS
ISO 9004
17.2
STORAGE

Human Resources



APPENDIX VI

Production Process Work Instructions

1. Knitting Operation (IOK-1)
2. Washing & Drying Operation (IWD-1)
3. Pressing & Ironing Operation (IOP-2)
4. Cutting Operation (IOC-1)
5. Sewing Operation (IOS-1)
6. Final Visual Inspection (IIF-1)
7. Final Light Inspection (IIF-2)
8. Sorting Operation (IOS-2)
9. Pressing & Blowing Operation (IOB-1)
10. Packing Operation (IOP-1)

Company Name: PROSPERITY KNITWEAR LIMITED	Title: KNITTING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 10, 1995
		Page 1 of 5
		Instruction Number: IOK-1

1. Purpose

The purpose of this instruction is to provide detailed knitting operation guidelines to the operator. This instruction shall be used by all operators performing the knitting operation, regardless of the machines they operate on.

2. Responsibility

The responsibilities of the knitting operator include:
(a) Maintaining high quality and productivity of knitted garments by following the practices stipulated in this instruction. Following the instruction and the guidelines provided by the Knitting Department Head and/or Knitting Supervisor or the foreman on duty is mandatory.
(b) Daily machine maintenance activities.

Knitting Department Head is the manager responsible for programming, daily production and machine maintenance, whilst the Production Manager has overall responsibility for the quality of work performed in the knitting department.

3. Definitions

N/A : Non-Applicable

4. Equipment

The equipment required in this operation is the following:

(1) Knitting Machine
(2) A cart for bundle handling and transport
(3) Ropes for bundle embracing and tying
(4) Clippers and scissors for identifying defect location and removing defected piece
(5) Maintenance equipment, including:
    (a) Cleaning liquid sprayer
    (b) Cleaning brush
    (c) Oil can with nozzle
    (d) Air compressor.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

The equipment is provided at the workplace. Otherwise, it is supplied by the Department Head.

5. Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Yarn Cones	1.	Production Preparation
2.	Yarn Disbursement Voucher		
3.	Knitting + Defect Parts Ticket		
4.	Production Record	2.	Knitting Department Head
5.	Knitting Machine Program		
6.	Production Order		

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Body & Sleeve Bundles	1.	Washing & Drying Operator
2.	Knitting Ticket		
3.	Production Order	2.	Knitting Supervisor
4.	Production Record		
5.	Yarn Disbursement Voucher		
6.	Knitting Machine Program	3.	Knitting Department Head

5.3 Work Instructions

5.3.1 Specific Instructions

The following steps are to be followed while performing the knitting operation:

(1) At the beginning of each shift :

(a) Blow and clean the machine with a liquid sprayer and a brush.

(b) Oil carriage running rail, yarn carrier, needle bed, and all holes marked by red colour signs.

(2) Before placing new yarn cones on the machine, especially when changing style and colours, always inspect the following:

(a) *Dirt on the yarn support.* If you spot that it is not clean, clean it with rag and liquid sprayer

(b) *Lot number.* It must correspond to the number on the yarn disbursement voucher.

(c) *End of yarn on cone.* The end of the yarn cone placed on the machine should be properly tied up with the beginning of the new yarn cone.

(d) *Machine display.* The programme installed must correspond to the production order style, size, and colour specification. If it does not correspond, immediately call the technician and/or the supervisor before starting production.

(e) *Documents supplied to you.* If there is any doubt about the contest of the documents, contact the department head or the supervisor immediately.

(3) Set-up the machine by placing the yarn cones on appropriate supports. Follow the instructions from display.

(4) Start the machine by pushing the yellow rod down.

(5) **Knitting Inspection**

Inspect the garments knitted down visually according to the specific instruction(s) given by the supervisor. If you spot a defect, do the following:

(1) Stop the machine immediately, or after the whole defected piece is knitted

(2) Cut off the defected piece from the rest of knitted bundle by scissors.

(3) Evaluate if the defect is repairable or not according to the training instructions given by the supervisor. If you can not perform the evaluation, contact the Production Manager or the Department Head immediately. If they are not available, place the defected piece in the box designated with **"Awaiting for Resolution"** sign and continue the production.

(4) If the defected piece is estimated as **repairable,** proceed as follows:

(a) Fill out pink (for body), or blue (for sleeves) defective parts ticket

(b) Attach it to the rope
(c) Embrace and tie the piece with the rope
(d) Attach a clipper to the piece on a defect location
(e) Place the piece in the box designated as **"For Repair".**

(5) If the part is estimated as **non-repairable,** proceed as follows:
(a) Fill out the defective parts ticket and stipulate a **"Non-Repairable"** sign on the ticket. It is mandatory to stipulate the machine number on the ticket.
(b) Attach the ticket to rope
(c) Embrace the piece with the rope
(d) Place the part in a cell designated for non-repairable parts.

(6) After the whole bundle is knitted, stop the machine.

(7) Attach the Knitting Ticket to a rope. If one or more pieces belonging to the bundle were damaged, place a red sticker designated for non-completed bundles.

(8) Embrace the bundle with the rope.

(9) Transport the bundles to a designated area with a cart.

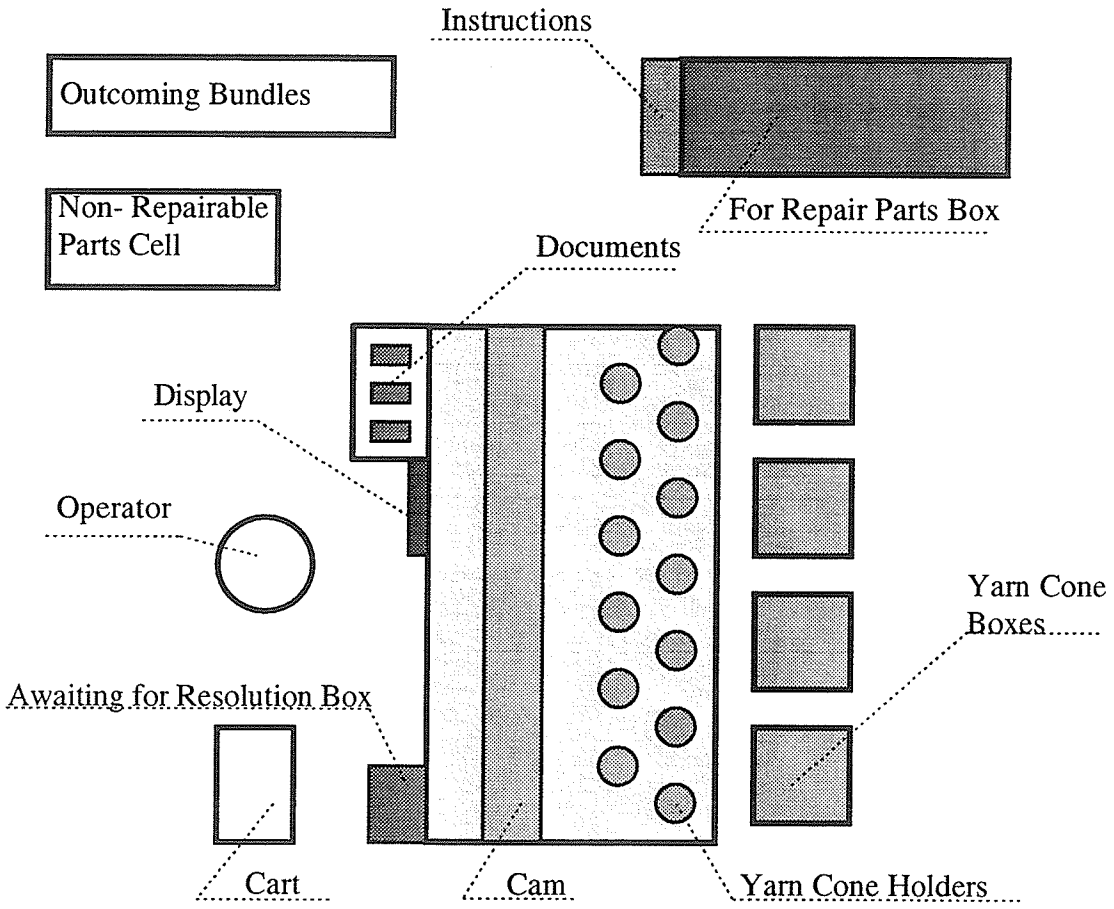
(10) Fill out the production record daily. Return the documents to internal customers as described in 5.2 Output Elements.

5.3.2 General Instructions

Apart from the daily maintenance described in 5.3.1, knitting operator shall, in coordinance with the technician, perform the maintenance operations according to the Knitting Machine Maintenance Manual, stored in the Production Preparation office. These operations include needles and cam cleaning, and broken brushes and needles replacement as needed. He will also participate in a yearly general remount of the machine.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.4 Work Place Layout



6. Reference Documents

(1) PPC-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) PWI-1 Procedure for Writing Instructions
(4) P-11 Inspection and Testing Procedure
(5) R-18 Knitting Machine Maintenance Manual
(6) R-1 Knitting Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: WASHING & DRYING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 10, 1995
		Page 1 of 4
		Instruction Number: IWD-1

1.0 Purpose

The purpose of this work instruction is to provide detailed washing, drying, and separation instructions and guidelines to the operator performing the operation.

2.0 Responsibility

Responsibilities of the Washing & Drying Operator include the following:

(a) Maintaining product quality by following workmanship practices stipulated in this instruction and following other specific instructions and/or guidelines from the Production Manager.

(b) Machine maintenance activities - keeping the machines in a good work order.

Production Manager is the manager in-charge for this operation. He has overall responsibility for the quality of work performed in this operation.

3.0 Definitions

N/A : Non-Applicable

4.0 Equipment

Equipment required for this operation includes:

(1) Washing Machines. Currently there are four in the facility.
(2) Drying Machines. Currently there are seven in the facility.
(3) Washing Detergent
(4) Scissors
(5) Time cards for washers.

Equipment is provided at the workplace.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Work Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Body & Sleeve Bundles	1.	Knitting Operator
2.	Knitting Ticket		
3.	Production Record	2.	Production Manager

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Body & Sleeve Pieces Bundled	1.	Pressing & Ironing Operator
2.	Knitting Ticket		
3.	Filled Production Record	2.	Production Manager

5.3 Instructions

5.3.1 Specific Instructions

The following steps shall be followed while performing the operation:

(1) Before starting the machines, inspect :

(a) If maintenance activities described in 5.3.2 have been performed. If not, follow the steps from 5.3.2.

(b) If time cards and soap (detergent) are available and in place. If not, contact the Production Manager or the supervisor in-charge.

(c) If tickets from incoming bundles correspond to the production record. If not, contact the Production Manager or the supervisor in-charge.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(2) Untie the bundles for washing & drying. For performing the operation, comply to the following rules:

RULES FOR WASHING & DRYING

Incoming garments belong to one of the following three groups. Wash and dry them accordingly, and/or as advised by the production manager.

(A) 100 % COTTON

(1) If garments are of solid color(s), wash in **warm** water, dry at medium temperature for 40 (forty) minutes.

(2) If garments have stripped color(s), wash in **cold** water, dry as (A1).

(B) 70 % ACRYLIC, 30 % WOOL

(1) Most of garments should not be washed. Act according to Production Manager's instructions. Dry in low temperature for 5 minutes.
WARNING : **Do not overheat.**

(C) 100 % WOOL

(1) For washing, use 100% wool washing program **card**

(2) If garments are of solid color(s), wash in **warm** water, dry at **medium** temperatures for 30 (thirty) minutes.

(3) If garments have stripped color(s), wash in **cold** water, dry as in (C2).

THE END OF RULES

(3) Place the bundles in washer/dryer. Keep the corresponding ticket on the door knob of the machine to avoid mixing them up.

(4) After finishing washing/drying, place the bundle on a table and separate pieces with scissors by cutting the threads that keep the pieces together.

(5) Put the pieces back in the bundle with a corresponding ticket.

(6) If a problem occurs at any time, contact the production manager or the supervisor in charge immediately.

(7) Make sure that all washing and drying machines are empty at the end of shift. Continue the operation as necessary.

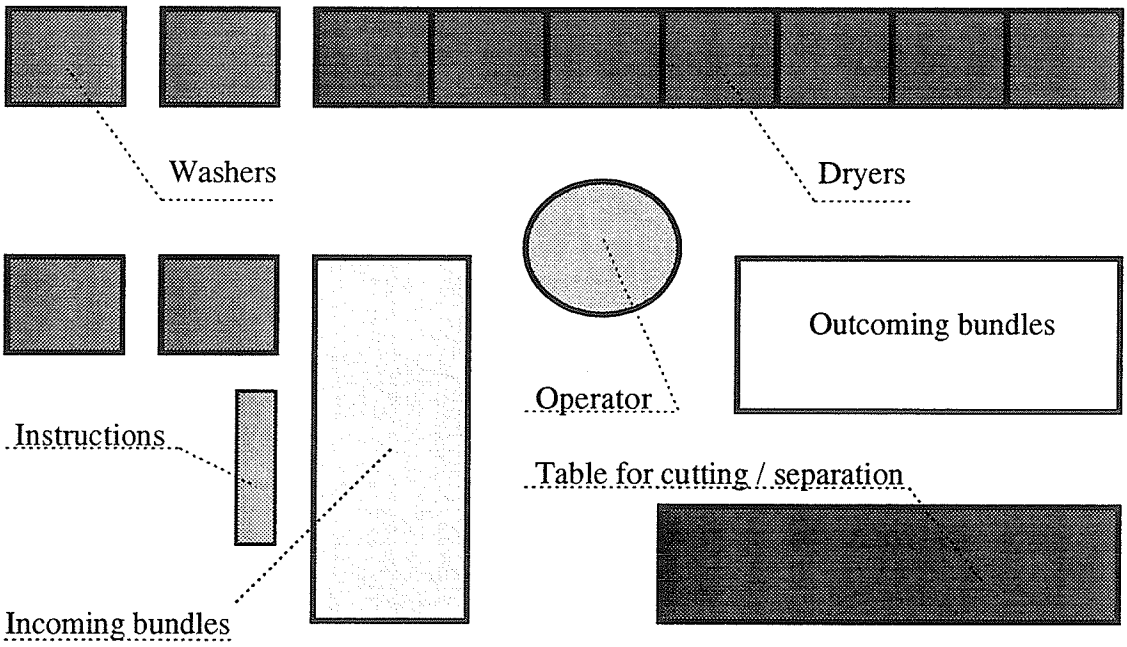
	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(8) Fill up the production record.

5.3.2 General Instructions

Maintenance activities to be performed by the operator include:
(a) Dryer lint compartment cleaning three times a week (Mondays, Wednesdays and Fridays before the first shift).
(b) Cleaning the burning portion on the top of the dryer once a month (on the first working day).

5.4 Work Place Layout



6.0 Reference Documents

(1) PPC-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) PWI-1 Procedure for Writing Instructions
(3) R-18 Washing & Drying Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PRESSING & IRONING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 10, 1995
		Page 1 of 3
		Instruction Number: IOP-2

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator for performing pressing/ironing operation.

2.0 Responsibility

The responsibilities of a pressing/ironing operator include:

(a) performing the operation according to the workmanship practices stipulated in this instruction and/or the guidelines given by the production manager. The operator is obliged to maintain high quality of both his/her work and the products he/she is performing the work on.

(b) maintaining the equipment required for the operation in good work order.

Production Manager has overall responsibility for the quality of work performed during this operation.

3.0 Definitions

- *Nonconformity* : the nonfulfilment of specified requirements (ISO 8402).

4.0 Equipment

Equipment required for this operation includes:

(1) 35-inch roller
(2) A brush for cleaning/removing dirt
(3) Ropes
(4) A pair of scissors

The equipment is provided at the workplace. Otherwise, it is supplied by the Production Manager or the Production Preparation Technician.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Work Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Body & Sleeve Bundles	1.	Washing & Drying Operator
2.	Knitting Ticket		
3.	Size Table (Lengths)	2.	Production Manager
3.	Production Record		

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Body & Sleeve Pieces Bundled	1.	Cutting Operator
2.	Knitting Ticket		
3.	Filled Production Record	2.	Production Manager

5.3 Instructions

5.3.1 Specific Instructions

The steps to follow during pressing/ironing operations:

(1) Untie the incoming bundle.

(2) Place the piece against the table with size patterns.

(3) Iron the piece. Press it against the size patterns table.

(4) Inspect the piece size according to the size tables provided. The tolerance field is 0.5 inch. If at least one size does not conform to the requirements given, report to the Production Manager or supervisor on duty immediately. If the size exceeds the tolerance limits for more that 1 inch, cut the piece open with scissors according to the instructions given by the Production Manager during training period.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

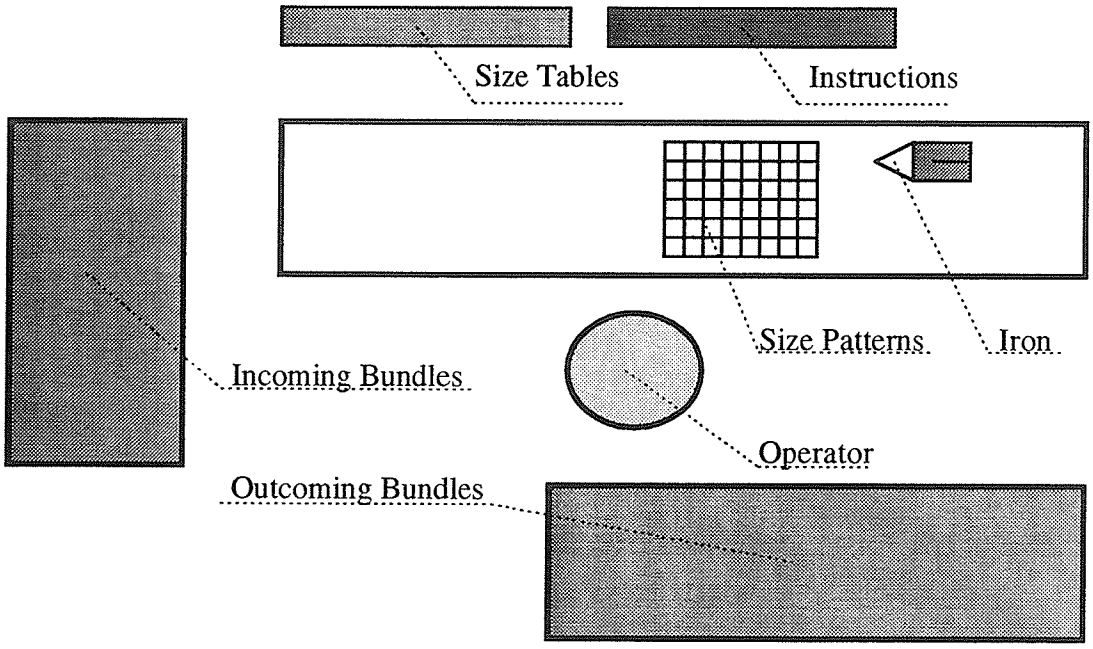
(5) After the bundle has been completed, tie it up with the rope and place it in outcoming bundles box.

5.3.2 General Instructions

(1) Maintain the iron in a good work order by following the maintenance rules provided by the Production Manager.

(2) Fill up the record of your activities daily.

5.4 Work Place Layout



6. Reference Documents

(1) P-9 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) PWI-1 Procedure for Writing Instructions
(4) P-10 Inspection and Testing Procedure
(4) R-20 Pressing/Ironing Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: CUTTING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 12, 1995
		Page 1 of 4
		Instruction Number: IOC-1

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator for performing the cutting operation and maintaining the uniformity of the quality of work he/she performs.

2.0 Responsibility

The responsibilities of a cutting operator include:

(a) performing the operation according to the workmanship practices stipulated in this instruction and/or the guidelines given by the production manager. The operator is obliged to maintain high quality of both his/her work and the products he/she is performing the work on.

(b) maintaining the equipment required for the operation in good work order.

Production Manager has overall responsibility for the quality of work performed during this operation.

3.0 Definitions

- *Nonconformity* : the nonfulfilment of specified requirements (ISO 8402).

4.0 Equipment

Equipment required for this operation includes:

(1) Electric-Powered Cutting Device
(2) A brush for cleaning/removing dirt
(3) A pair of scissors
(4) Chalk

The equipment is provided at the workplace. Otherwise, it is supplied by the Production Manager or the Production Preparation Technician.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Work Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Body & Sleeve Bundles	1.	Pressing/Ironing Operator
2.	Knitting Ticket		
3.	Cartoon Pattern Markers	2.	Production Manager
3.	Production Record		

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Body & Sleeve in a Bundle Placed Together	1.	Sewing Supervisor
2.	Knitting Ticket for Body		
3.	Filled Production Record	2.	Production Manager

5.3 Instructions

5.3.1 Specific Instructions

The cutting operation consists of the following steps:

(1) Track the body and sleeve bundles that correspond to the same style number, colour, size, knitting ticket and bundle number.

(2) Place the corresponding bundles on a table, side by side.

(3) Separate the front and back parts of body by cutting the threads holding them together with scissors.

(4) Remove the threads from the garment. Place the threads in a disposal box.

(5) Pile the front and back parts of a body up - front on top of back.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(6) Adjust front and back edges so that the garments cover one another

(7) Take an appropriate garment pattern marker from the hanger. Pattern markers are identified with the style number.

(8) Place the pattern marker on the top of garment.

(9) Mark the edges to be cut with yellow chalk.

(10) Cut the garment with scissors. If the pile is too thick, or the instructions from the Production Manager or Supervisor on duty indicate so, perform the operation with an electric cutter. Figure 1 illustrates the operation.

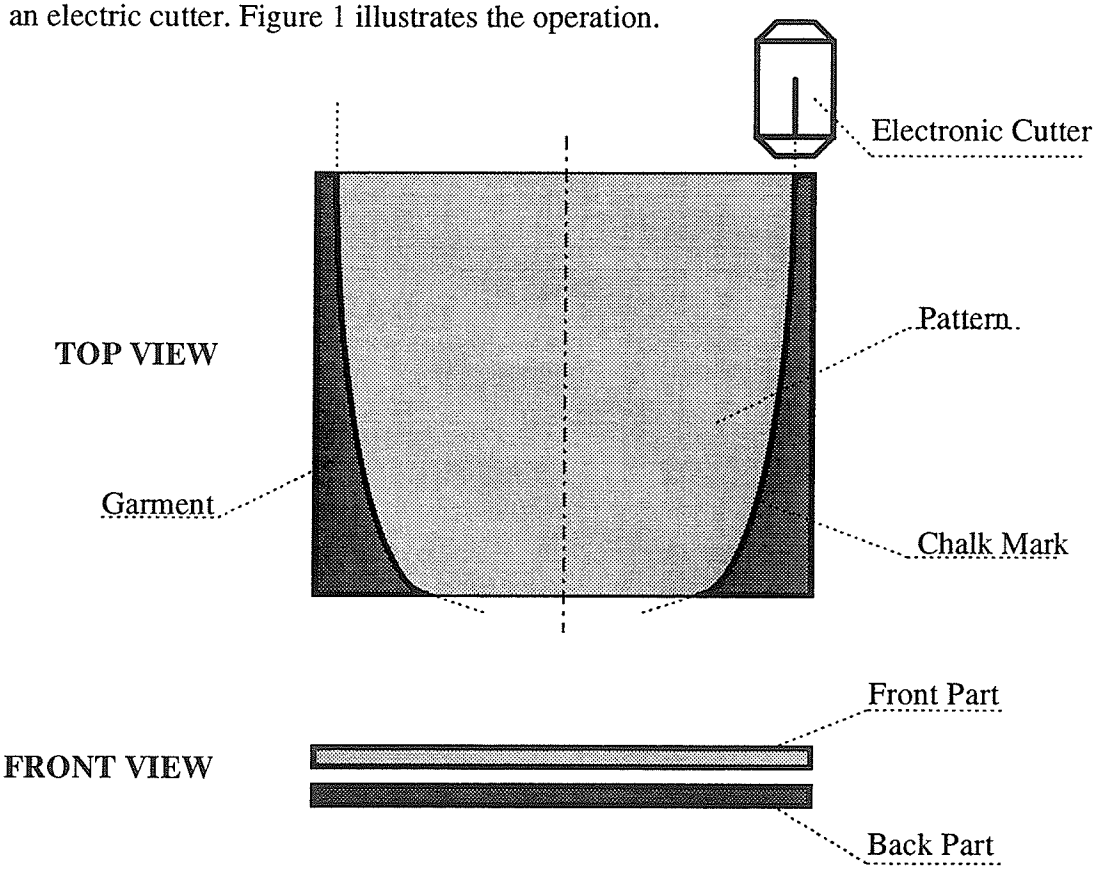
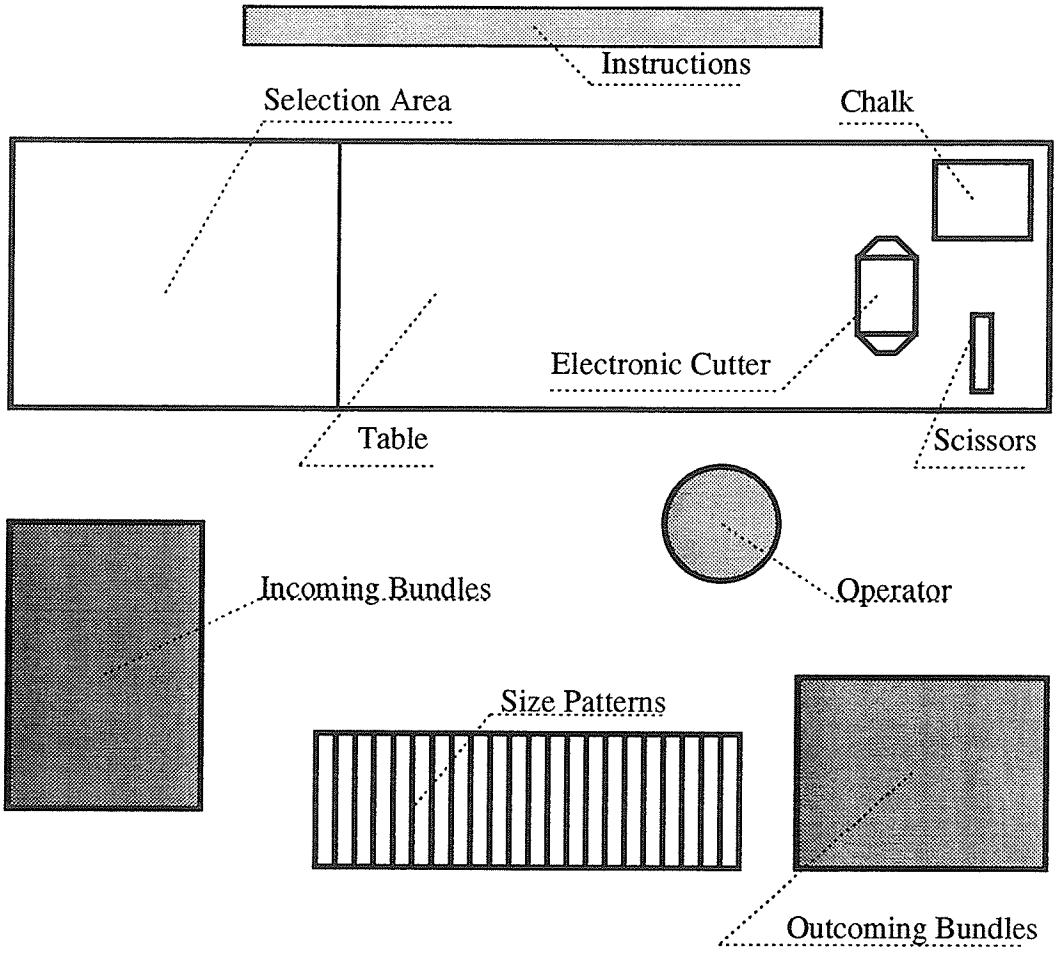


Figure 1 : Cutting Operation

(11) After performing the operation on the whole bundle, tie the bundle consisting of both bodies and sleeves with the rope.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.4 Work Place Layout



6. Reference Documents

(1) PPC-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) PWI-1 Procedure for Writing Instructions
(4) R-21 Cutting Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: SEWING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 12, 1995
		Page 1 of 3
		Instruction Number: IOS-1

1. 0 Purpose

The purpose of this work instruction is to provide the necessary generalities and guidelines to an operator for performing sewing operations and maintaining the uniformity of the quality of work she/he performs.

Following the guidelines stipulated in this instruction is mandatory for all operators performing sewing operations, regardless of the machine they operate on. It applies to operators performing the work on linking, serging, hamming, seam cover, buttons and single needle machines and the operator performing labeling operation.

2.0 Responsibility

The responsibilities of a sewing operator include:

(a) performing the operation according to the workmanship practices stipulated in this instruction and the guidelines given by the sewing supervisor and/or production manager. The operator is obliged to maintain high quality of both her/his work and the products she/he is performing the work on.

(b) maintaining the equipment required for the operation in good work order.

Sewing supervisor bares responsibility for training and supervising sewing operators, whilst the production manager has overall responsibility for the quality of work performed during this operation.

3.0 Definitions

- *Nonconformity* : the nonfulfilment of specified requirements (ISO 8402).

4.0 Equipment

Equipment necessary for sewing operations consists of :

(1) Sewing machine

(2) A pair of scissors

(3) A table and a chair.

There are six different types of sewing machines in the facility: linking, hamming, seam cover, serging, single needle and buttons machine.

The equipment is provided at the workplace. Otherwise, it is supplied by the sewing supervisor.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Body & Sleeve in a Bundle Placed Together	1.	Sewing Supervisor
2.	Knitting Ticket		
3.	Thread & Shoulder Tape		
4.	Accessories		
5.	Production Record	1.	Production Manager

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Completed Garments in Bundles	1.	Sewing Supervisor
2.	Filled Production Record	2.	Sewing Supervisor

5.3 Work Instructions

5.3.1 Specific Instructions

Specific instructions for performing sewing operation(s) shall be given by the sewing supervisor. The supervisor allocates specific tasks and material to all operators. Training instructions shall be provided by the supervisor during the training period and/or as needed.
It is mandatory to follow both training and specific tasks instructions.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.3.2 General Instructions

The following general rules are mandatory:

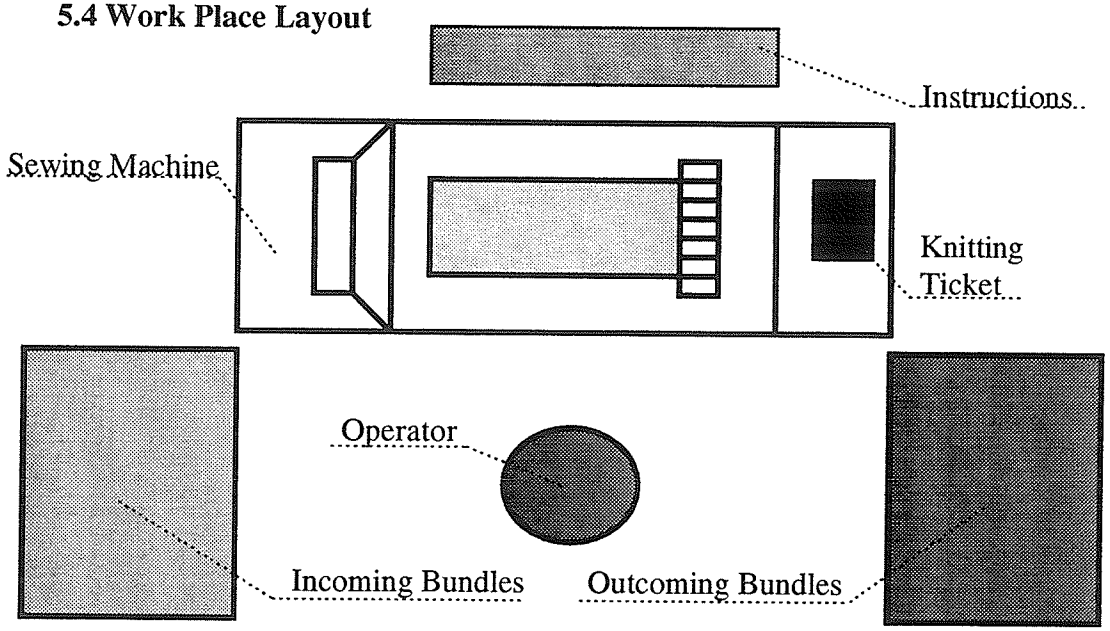
(1) In order to avoid mixing-up, garments should be sewed bundle by bundle. Prior to the operation, untie the bundle and place the knitting ticket on the table. After the operation on one bundle has been completed, tie the bundle and stipulate the knitting ticket back to the bundle.

(2) Accessories shall be provided by the sewing supervisor. After the operation has been completed, return unused accessories to the supervisor or as instructed.

(3) If a nonconforming product has been anticipated, contact the supervisor immediately.

(4) Operator is obliged to clean her/his machine daily.

5.4 Work Place Layout



6.0 Reference Documents

(1) PPC-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) PWI-1 Procedure for Writing Instructions
(4) R-21 Sewing Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: FINAL VISUAL INSPECTION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 14, 1995
		Page 1 of 4
		Instruction Number: IIF-1

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator performing FINAL VISUAL inspection. Inspecting the products according to the instructions stipulated herein is mandatory.

2.0 Responsibility

The responsibilities of an employee performing final inspection, thereto called INSPECTOR, include:

(a) performing the operation according to the practices stipulated herein, and/or the guidelines given by the production manager and/or sewing supervisor. Inspector is obliged to maintain high quality of both his/her work and the products he/she is performing the work on.

(b) maintaining the equipment required for inspection in good work order.

Production Manager has overall responsibility for final inspection and quality control methods implemented in the facility.

3.0 Definitions

- *Nonconformity* : the nonfulfilment of specified requirements (ISO 8402).

4.0 Equipment

Equipment required for visual inspection includes:

(1) A table
(2) A pair of scissors
(3) Inspection labels.
(4) Clippers

The equipment is provided at the workplace. Otherwise, it is provided by the sewing supervisor.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Completed Garments in Bundles - Individually Labeled	1.	Sewing Supervisor
2.	Visual Inspection Record - Weekly		Production Manager

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Garments Visually Inspected in "Conforming" or "Nonconforming" Boxes	1.	Light Inspection Operator
2.	Filled Visual Inspection Record - Daily	2.	Production Manager

5.3 Work Instructions

5.3.1 Specific Instructions

Follow the next seven steps during inspection:

(1) Inspect the garments individually - one by one. Place the garment on a table, revert it upside down. Inspect the inner part of a garment for defects described herein.

(2) Inspect the garment from outside. Check for defects illustrated herein.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

A LIST OF DEFECTS TO LOOK FOR DURING VISUAL INSPECTION

(1) *Yarn breakage.* Holes.
(2) *Nonconforming colour(s).* Garment colour combination does not correspond to a colour combination swatch.
(3) *Nonconforming yarn tension.* Stitches too loose.
(4) *Nonconforming pattern.*
(5) *Yarn missing.*
(6) *Inadequate material process* from washing/drying.
(7) *Nonconforming style.*
(8) *Reversed patterns.*
(9) *Dirt.*
(10) *Noncorforming thread colour.*
(11) *Nonconforming sewing/linking.* Seam(s) not straight.
(12) *Thread ends not clean*

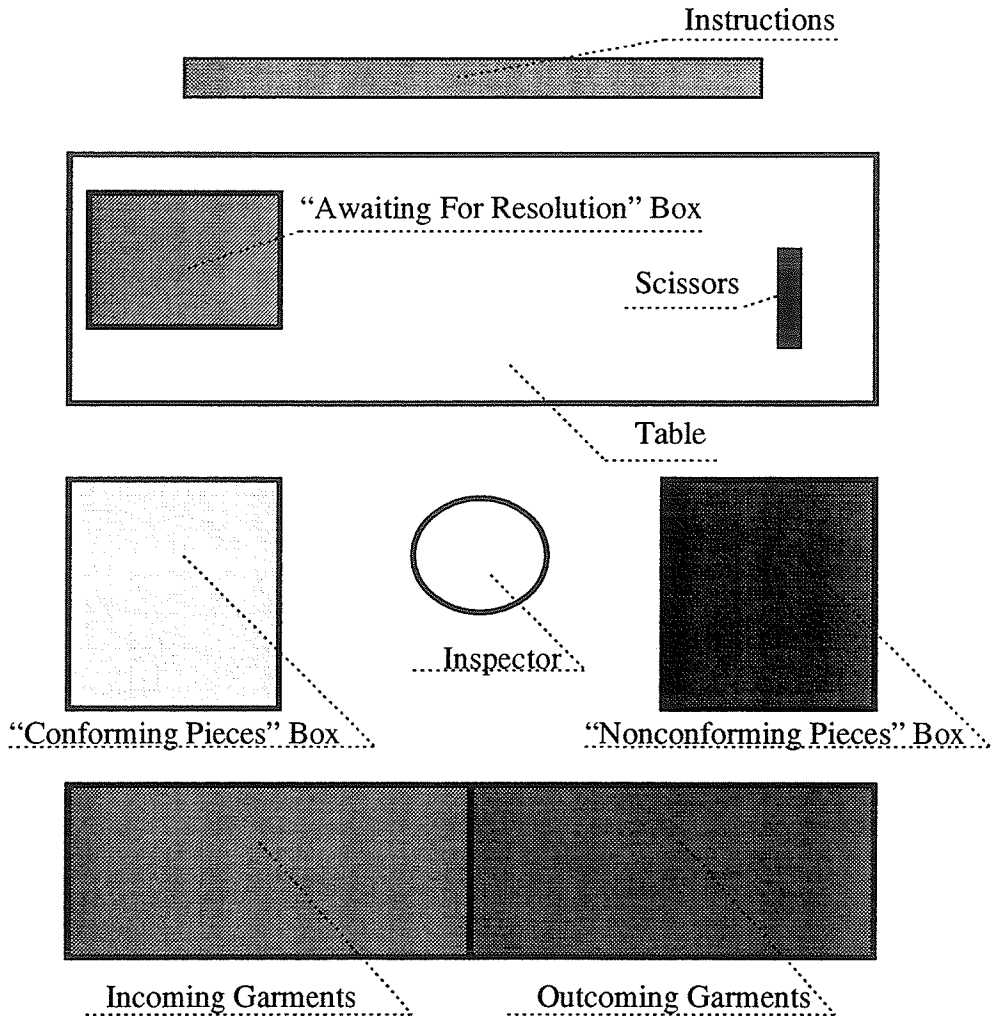
If there is a feature you consider not to meet specified requirements, and is not at this list, contact the sewing supervisor or production manager immediately. If they are not available immediately, place the garment in a box designated as "Awaiting for Resolution".
(3) Stick the inspection label on the inner side of garment.
(4) If a garment is found to be nonconforming (defective), put a clipper on a defect location, and place it in a box designated as: "Nonconforming Pieces".
(5) If a garment is found to be conforming, place it in a box designated as: "Conforming Pieces".

5.3.2 General Instructions

You will get a "Visual Inspection Record" from the Production Manager weekly. Fill up this record daily according to the instructions given from the manager.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.4 Workplace Layout



6.0 Reference Documents

(1) PCP-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) P-10 Inspection & Testing Procedure
(4) PWI-1 Procedure for Writing Instructions
(5) R-30 Visual Inspection Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: FINAL LIGHT INSPECTION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 14, 1995
		Page 1 of 4
		Instruction Number: IIF-2

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator performing final LIGHT INSPECTION. Inspecting the products according to the instructions stipulated herein is mandatory.

2.0 Responsibility

The responsibilities of an employee performing final inspection, thereto called INSPECTOR, include:

(a) performing the operation according to the practices stipulated herein, and/or the guidelines given by the production manager and/or sewing supervisor. Inspector is obliged to maintain high quality of both his/her work and the products he/she is performing the work on.

(b) maintaining the equipment required for inspection in good work order.

Production Manager has overall responsibility for final inspection and quality control methods implemented in the facility.

3.0 Definitions

- *Nonconformity* : the nonfulfilment of specified requirements (ISO 8402).

4.0 Equipment

Equipment required for light inspection includes:

(1) Cylinder check light for garment's body inspection
(2) Cone check light for garment's sleeves inspection
(3) Clippers

The equipment is provided at the workplace. Otherwise, it is provided by the sewing supervisor.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Garments Visually Inspected in "Conforming" or "Nonconforming" Boxes	1.	Light Inspection Operator
2.	Visual Inspection Record - Weekly		Production Manager

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Conforming Garments (Piece by Piece) in Boxes -other than samples-	1.	Sorting Operator
2.	Repairable Nonconforming Garments	2.	Repairs Operator
3.	Non-Repairable Garments	3.	Production Manager
4.	Filled Visual Inspection Record - Daily		
5.	Sample Garments	4.	Pressing/Blowing Operator

5.3 Work Instructions

5.3.1 Specific Instructions

Follow the next steps while performing the inspection

(1) Inspect the garments individually - one by one. Pull the garment over the light inspection cylinder. Inspect the body for defects described herein.

(2) If a garment is found to be nonconforming (defective), put a clipper on a defect location, and place it in a box designated as: "Nonconforming Pieces".

A LIST OF DEFECTS TO LOOK FOR DURING LIGHT INSPECTION

(1) *Yarn breakage.* Holes.
(2) *Nonconforming colour(s).* Garment colour combination does not correspond to a colour combination swatch.
(3) *Nonconforming yarn tension.* Stitches too loose.
(4) *Nonconforming pattern.*
(5) *Yarn missing.*
(6) *Inadequate material process* from washing/drying.
(7) *Nonconforming style.*
(8) *Reversed patterns.*
(9) *Dirt.*
(10) *Noncorforming thread colour.*
(11) *Nonconforming sewing/linking.* Seam(s) not straight.

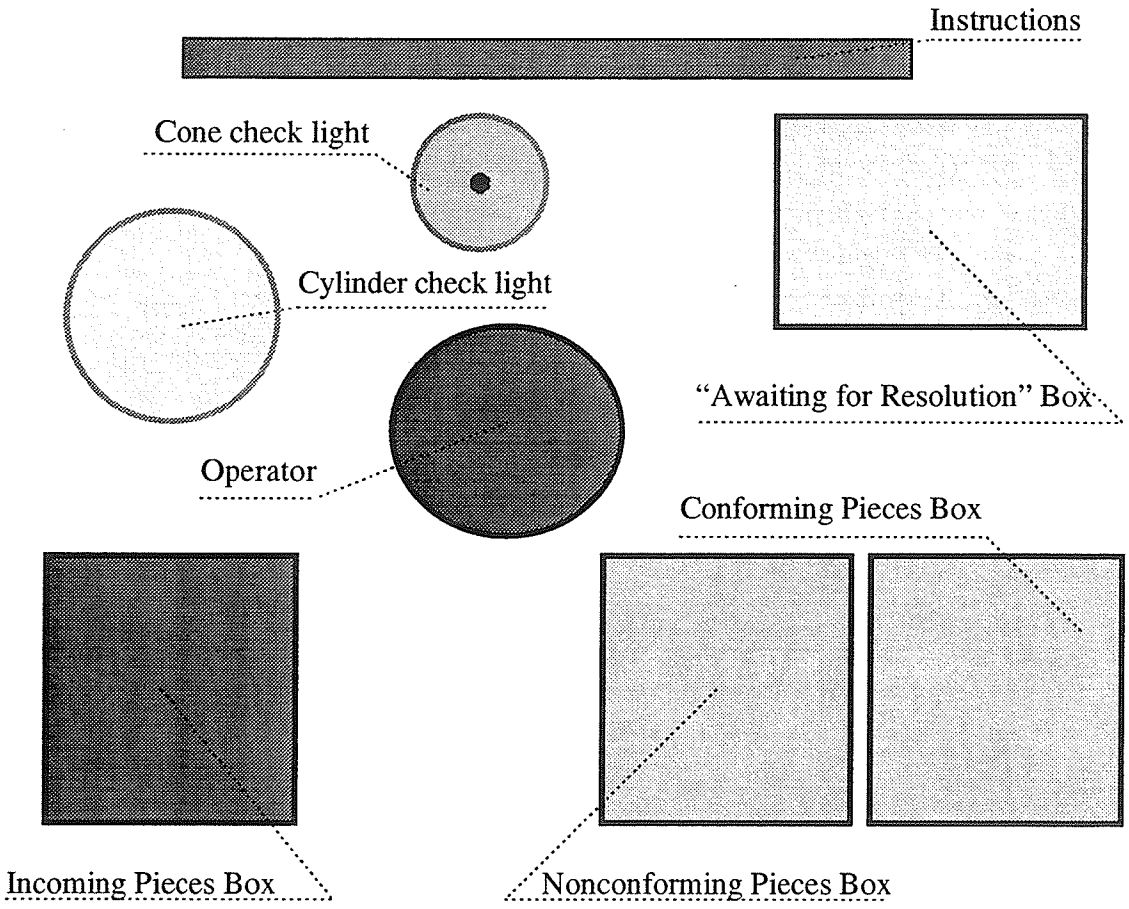
If there is a feature you consider not to meet specified requirements, and is not at this list, contact the sewing supervisor or production manager immediately. If they are not available immediately, place the garment in a box designated as "Awaiting for Resolution".
(3) Repeat steps (1) and (2) for sleeves. Use cone light check.
(4) If a garment is found to be conforming, place it in a box designated as: "Conforming Pieces". Stick a label "LIGHT CHECKED" to the box.

5.3.2 General Instructions

You will get a "Light Inspection Record" from the Production Manager weekly. Fill up this record daily according to the instructions given from the manager

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.4 Workplace Layout



6.0 Reference Documents

(1) PCP-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) P-10 Inspection & Testing Procedure
(4) PWI-1 Procedure for Writing Instructions
(5) R-31 Light Inspection Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: SORTING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 12, 1995
		Page 1 of 3
		Instruction Number: IOS-2

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator for performing final sorting operation.

2.0 Responsibility

The responsibilities of a sorting operator include:

(a) performing the operation according to the workmanship practices stipulated in this instruction and/or the guidelines given by the production manager. The operator is obliged to maintain high quality of both his/her work and the products he/she is performing the work on.

(b) maintaining the equipment required for the operation in good work order.

Production Manager has overall responsibility for the quality of work performed during this operation.

3.0 Definitions

- *Nonconformity* : the nonfulfilment of specified requirements (ISO 8402).

4.0 Equipment

Equipment required for this operation includes:

(1) A table
(2) Size labels

The equipment is provided at the workplace.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Conforming Garments (Piece by Piece) in Boxes	1.	Final Light Inspection Operator
2.	Yellow Sorting Ticket	2.	Production Preparation
3.	Color Swatches	3.	General Office
4.	Sorting Production Record	4.	Production Manager

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Sorted Garments in Bundles	1.	Pressing/Blowing Operator
2.	Yellow Sorting Ticket		
2.	Filled Production Record	2.	Production Manager

5.3 Work Instructions

5.3.1 Specific Instructions

Sorting operation consists of the following steps:
(1) Take a number of garments from the incoming box.
(2) Inspect garment's individual label for style number, order number and size
(3) Inspect garment's colour combination according to colour swatches
(4) Compare the top and bottom label. If they do not correspond, place the garment to a box marked with "Awaiting for Resolution" sign. Call the sewing supervisor immediately.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(5) If a problem is anticipated, contact the sewing supervisor or the production manager immediately for resolving the problem.

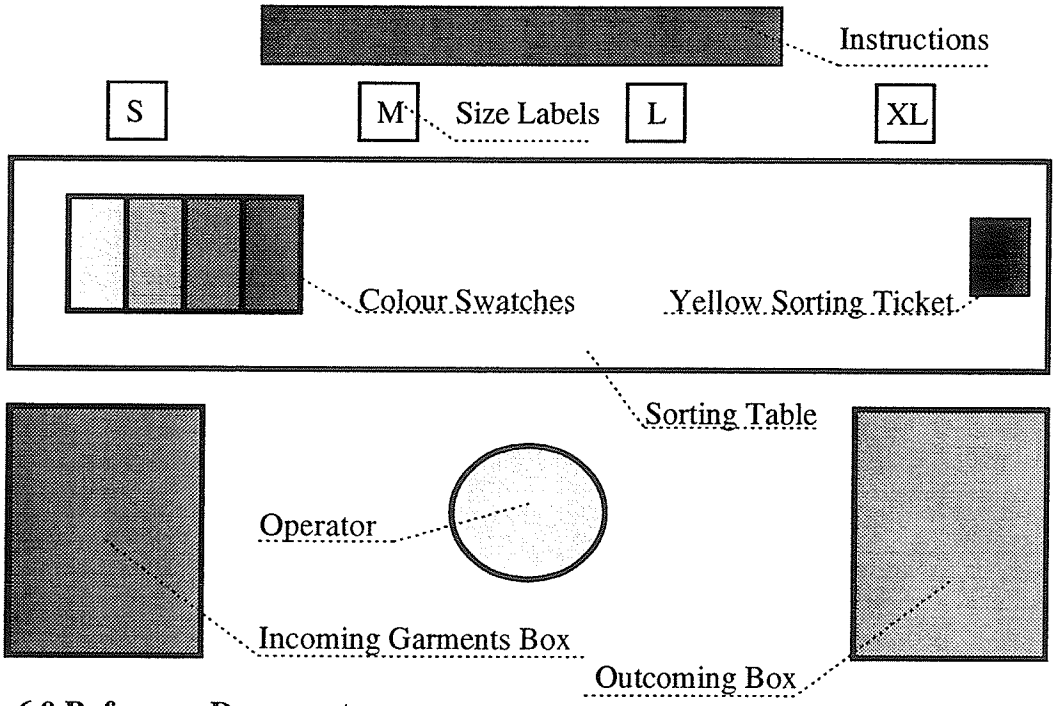
(6) Sort the sweaters according to size, style number, and colour combination

(7) Place the garments in a bundle with a corresponding yellow sorting ticket.

5.3.2 General Instructions

N/A : Non-Applicable

5.4 Work Place Layout



6.0 Reference Documents

(1) PPC-1 Production Process Control Procedure
(2) PWI-1 Procedure for Writing Instructions
(3) P-10 Inspection and Testing Procedure
(3) R-24 Sorting Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PRESSING & BLOWING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 19, 1995
		Page 1 of 3
		Instruction Number: IOB-1

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator performing the pressing/blowing operation and maintaining the uniformity of the quality of work he/she performs.

2.0 Responsibility

The responsibilities of a pressing/blowing operator include:

(a) performing the operation according to the workmanship practices stipulated herein, and/or the guidelines given by the production manager. Pressing/blowing operator is obliged to maintain high quality of both his/her work and the products he/she performs the work on.

(b) maintaining the equipment required for the operation in good work order.

Production Manager has overall responsibility for the quality of work performed in this operation.

3.0 Definitions

N/A : Non-Applicable

4.0 Equipment

Equipment required for pressing/blowing operation includes:

(1) Garment blower
(2) A table
(3) Iron
(4) 35-inch roller

The equipment is provided at the workplace. Otherwise, it is provided by the Production Manager.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Sorted Garments in Bundles	1.	Sorting Operator
2.	Yellow Sorting Ticket		
3.	Size Tables	2.	Production Manager

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Garments in Bundles	1.	Packing Operator
2.	Signed Yellow Sorting Ticket		
3.	P/B Production Record	2.	Production Manager

5.3 Work Instructions

5.3.1 Specific Instructions

Follow the next eleven (11) steps while performing the operation:

(1) Prepare a garment for blowing by inverting it inside-out

(2) Place the garment on a blower

(3) Turn on the blower

(4) After the garment has been inflated, take it from the blower and spread it on a table

(5) Iron the garment

(6) Inspect the garment size by measuring the characteristics shown on a Size Table. If at least one characteristic does not exist between the tolerance limits, contact the production manager for resolution. While waiting, place the nonconforming garment in a box designated with "Awaiting for Resolution" label.

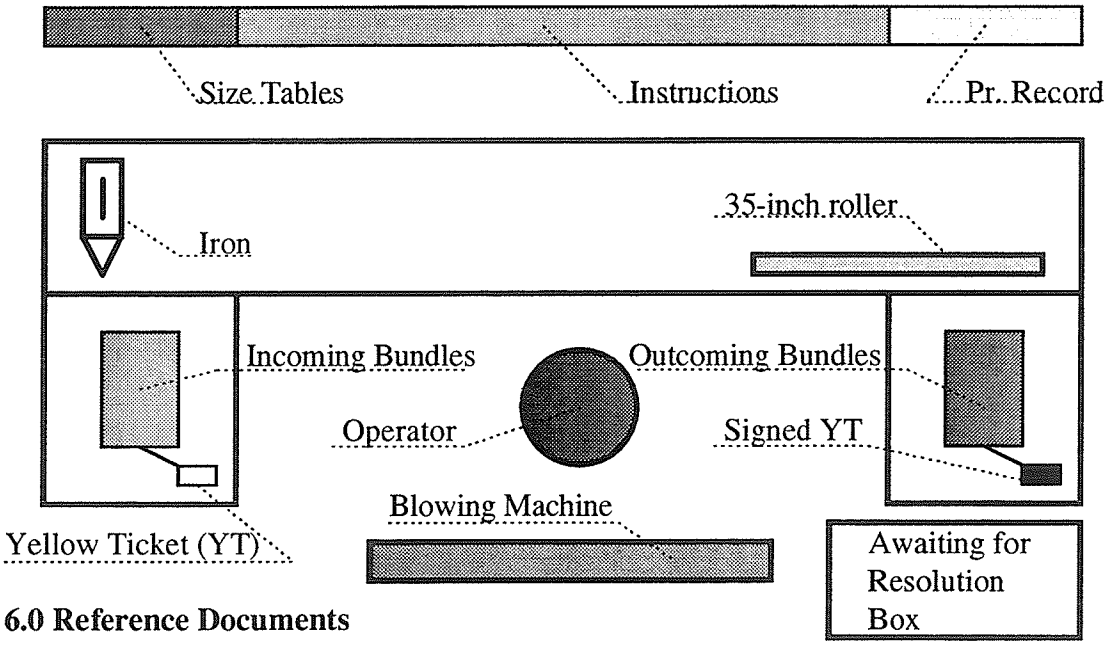
	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(7) Fold only the conforming garments.
(8) Place the garment on the table left from the blowing machine
(9) Embrace the bundle with a rope
(10) Sign the Yellow Sorting Ticket
(11) Assign the ticket to the bundle

5.3.2 General Instructions

(1) Fill up the P/B production record after completing each bundle.
(2) Pass the record to the production manager or staple it to the board beside this instruction after each shift.

5.4 Workplace Layout



6.0 Reference Documents

(1) PCP-1 Production Process Control Procedure
(2) P-4 Design Control - Sample Preparation Procedure
(3) P-10 Inspection & Testing Procedure
(4) PWI-1 Procedure for Writing Instructions
(4) R-15 Pressing/Blowing (P/B) Production Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PACKING OPERATION INSTRUCTION	Status & Issue Number : A1
		Date of Issue: July 17, 1995
		Page 1 of 3
		Instruction Number: IOP-1

1. 0 Purpose

The purpose of this work instruction is to provide the necessary details to an operator performing the packing operation and maintaining the uniformity of the quality of work he/she performs.

2.0 Responsibility

The responsibilities of a packing operator include:

(a) performing the operation according to the workmanship practices stipulated herein, and/or the guidelines given by the production manager. Packing operator is obliged to maintain high quality of both his/her work and the products he/she is performing the work on.

(b) maintaining the equipment required for the operation in good work order.

Production Manager has overall responsibility for the quality of work performed in this operation.

3.0 Definitions

N/A : Non-Applicable

4.0 Equipment

Equipment required for packing operation includes:

(1) Labeling machine
(2) A table
(3) Cleaning brush
(4) Tape

The equipment is provided at the workplace. Otherwise, it is provided by the Production Manager.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0 Instructions

5.1 Input Elements

Input Elements		Internal Suppliers	
No.	Name	No.	Name
1.	Garments in Bundles	1.	Pressing/Blowing Operator
2.	Signed Yellow Sorting Ticket		
3.	Plastic Bags for Individual Garments - Sweaters	2.	General Office
4.	Labels		
5.	Packing Records - R33 + R34		

5.2 Output Elements

Output Elements		Internal Customers	
No.	Name	No.	Name
1.	Boxes for Shipping	1.	Shipping & Receiving Operator
2.	Packing Record - R33		
3.	Packing Record - R34	2.	Production Manager

5.3 Work Instructions

5.3.1 Specific Instructions

Follow the next seven (7) steps while performing the operation:

(1) Take a garment from an incoming bundle and fold it according to the instructions provided during training.

(2) Clean the dust with a brush.

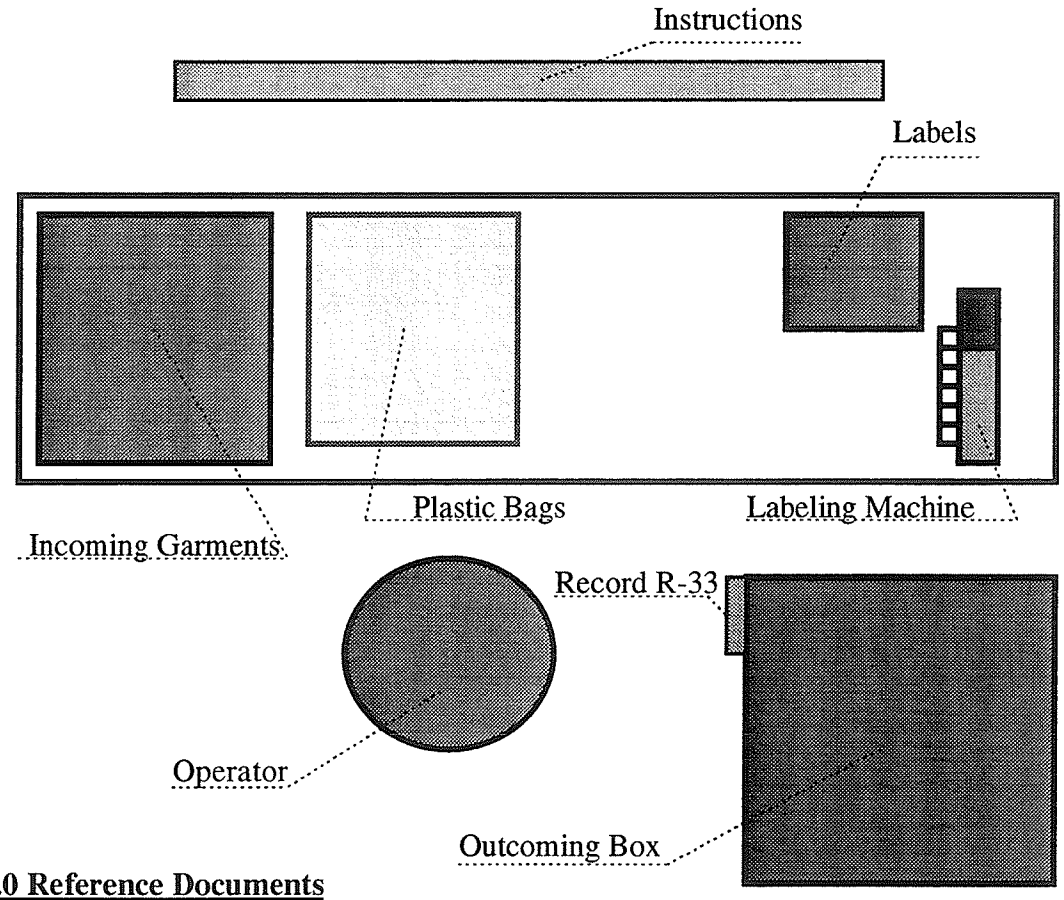
(3) Place the garment in a plastic bag using hand tape and/or price ticket. Close the beg.

(4) Print the label with a labeling machine.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

(5) Place the garment in a designated box.
(6) After completion of the operation, fill in packing records R-33 and R-34.
(7) Attach R-33 record to the box. R-34 record is to be handed out to the Production Manager daily.

5.4 Workplace Layout



6.0 Reference Documents

(1) PCP-1 Production Process Control Procedure
(2) PWI-1 Procedure for Writing Instructions
(3) R-33 Packing Record
(4) R-34 Packing Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

APPENDIX VII

Production Process Control Procedure

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PRODUCTION PROCESS CONTROL PROCEDURE	Status & Issue Number : A1
		Date of Issue: Aug. 31, 1995
		Page 1 of 10
CONTROLLED COPY DO NOT DUPLICATE		Procedure Code : PCP-1
	Compliance with ISO 9001: 4.9 Process Control	

1.0 Purpose

The purpose of this procedure is to document and control the production processes. The procedure defines the manner of production processes carried out in the company, the use of suitable production and servicing equipment, suitable maintenance of equipment to ensure controlled conditions, monitoring and control of process parameters and product characteristics, the approval of processes and equipment, workmanship criteria and compliance with reference standards, quality manual, documented procedures, instructions and records.

2.0 Scope

This procedure applies to:

(a) production preparation activities from the issuance of a production order through the issuance of the suitable documentation and material for production

(b) the manufacturing activities from the issuance of the suitable documentation and material to packaging

(c) the repair and/or disposal of nonconforming product

3.0 Application

The Originator of this procedure and all personnel participating in production preparation and manufacturing activities are governed by this procedure. It includes production manager, production supervisors and department heads, operators and inspectors.

Specific responsibilities for production process control are outlined in the sections 5.3 Responsibility Matrix of this procedure and the Procedure for Writing Procedures.

Any deviations and/or changes are subject to approval of the Originator and the President.

4.0 Definitions and Terms

Originator: The person formally assigned for the preparation and writing of a procedure.

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Procedure: A formal and mandatory directive and guideline for work performance that provides all the necessary information and performance criteria. The procedure is a second level document in company's documentation tier.

Operator: The person performing value-adding work in a production process

Inspector: The person performing activities such as measuring, examining , testing, gauging one or more characteristics of a product and comparing these with specified requirements to determine nonconformity.

Nonconformity: The nonfulfillment of specified requirements.

5.0 Procedure for Production Process

5.0.1 Documentation

This section of the procedure outlines documentation defining the manner of production.

ISO 9000 representative, in coordination with the production manager, develops the written manufacturing procedures and work instructions.

The following is a list of documentation, other than this procedure, used for production process control and the person responsible for the document (see PDC-1 Document Control Procedure)

DOCUMENTATION	PERSON RESPONSIBLE
Production order with drawings	Production manager
Functional specifications	
Work Instructions	
Quality Control Records	
Production Records	
Maintenance Manuals	Knitting Department Head
Knitting machine programme	
Material Disbursement Vouchers	Production Preparation Technician
Travel tickets	

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

5.0.2 Production equipment and working environment

The production process machinery carries Manitoba Labour Department certificates of compliance with safety requirements. The President keeps records of compliance. The records are stored in the President's office for a period of ten (1o) years.

The following table indicates the areas in which environment controls are in place and type of control.

TYPE OF CONTROL	AREA OF CONTROL
Temperature	Complete facility
Humidity	Knitting
Protective masks	Sewing & knitting

5.0.3 Compliance with reference documents

Production process is in compliance with the documents defined in the section 6.0 Reference Documents of this procedure.

5.0.4 Process and product characteristics control

The process and product characteristics are controlled by following means.

◆ Inspection Activities

(a) **First piece - sample inspection** (PDC-2 Design Control Procedure)

(b) **In-process inspection** is performed at the following stages of the process:

(1) Knitting Inspection (IOK-1 Knitting Operation Instruction)

(2) Size Inspection (IOP-1 Pressing/Ironing Operation Instruction)

(3) Labeling Inspection (IOS-1 Sewing Operation Instruction)

(c) **Final Inspection** includes:

(1) Visual Inspection (IIF-1 Final Visual Inspection Instruction)

(2) Light Inspection (IIF-2 Final Light Inspection Instruction)

(3) Size Inspection (IOB-1 Pressing/Blowing Operation Instruction)

(4) Labeling Inspection (IOP-2 Packing Operation Instruction)

◆ Process Revision Control

Production manager is authorized to initiate a change to a process by completing the Process Change Request Record. The change may be temporary or permanent. It's status is indicated on the Record. President approves the record.

The time frame and responsibility to resolve the problem is assigned at the meeting of the managerial team for production initiated by the President.

The President approves problem resolution. Process Change Record illustrates the resolution, and is stored in the Production Manager's Office.

Records of the activities described herein are kept according to the PDC-2 Procedure for Document Control.

◆ Production Hold

Operator is authorized to initiate a hold to the process because of the problem impossible to resolve by completing the Production Stop Record, and immediately contacting the Production Manager or the Supervisor on duty. Production Manager approves production hold.

Production Manager is responsible for problem resolution. The Production Process Corrective Action Record indicates the resolution. Production Manager is responsible for resuming production and measuring the progress of the corrective action.

5.0.5 Approval of processes and equipment

The following machines require internal verification prior to being used in the production process: knitting, cutting, sewing, washing, drying and pressing. Production manager ensures that the machines are verified . Records of verification are stored in the production manager's office for a period of one (1) year.

5.0.6 Workmanship criteria

The following defines workmanship criteria used in the process:

(a) Representative garment samples and colour swatches as criteria for knitting, washing/drying, cutting, sewing and sorting operation and final inspection

(b) Size tables for pressing operations

(c) Drawings stipulated in the production order for all operations

(d) Criteria stipulated in IIF-1 and IIF-2 instructions for final inspection

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

These samples are available to operators and inspectors at any time.
Consistent interpretation is provided by training (PTR-1 Training Procedure).
Production manager is responsible for maintaining examples of workmanship

6.0.7 Maintenance of equipment

Responsibility for equipment maintenance and repair is defined in section 6.4 Responsibility Matrix of this procedure.

Maintenance records are kept by the Production manager..

Equipment maintenance is referenced in production operations work instructions, machine maintenance manuals and PME-1 Equipment Maintenance Procedure.

A list of the equipment upon which process capability depends, specified step by step preventive maintenance activities and their schedule, actions required in the event of equipment malfunction and specified maintenance activities records are referenced in PME-1 Equipment Maintenance Procedure.

6.1 Input Elements

INPUT ELEMENTS			SUPPLIERS		
No.	Name	Code	No.	Name	Function
1.	Production Order	N/A	1.	President	N/A

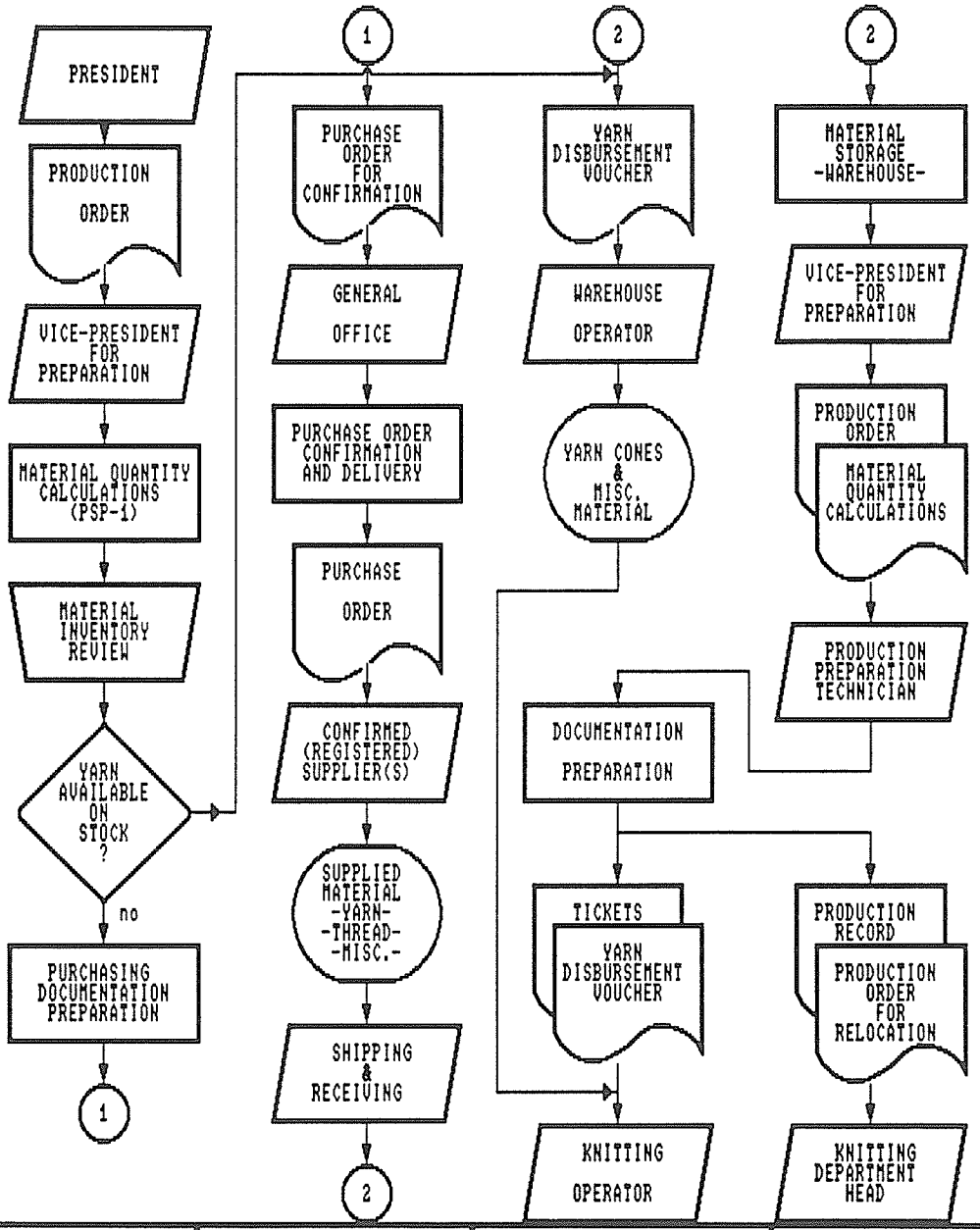
6.2 Output Elements

OUTPUT ELEMENTS			CUSTOMERS		
No.	Name	Code	No.	Name	Function
1.	Final Product Packed in a Box	N/A	1.	Supervisor	Shipping & Receiving
2.	Production Records by Operations	N/A	2.	Production Manager	Production

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

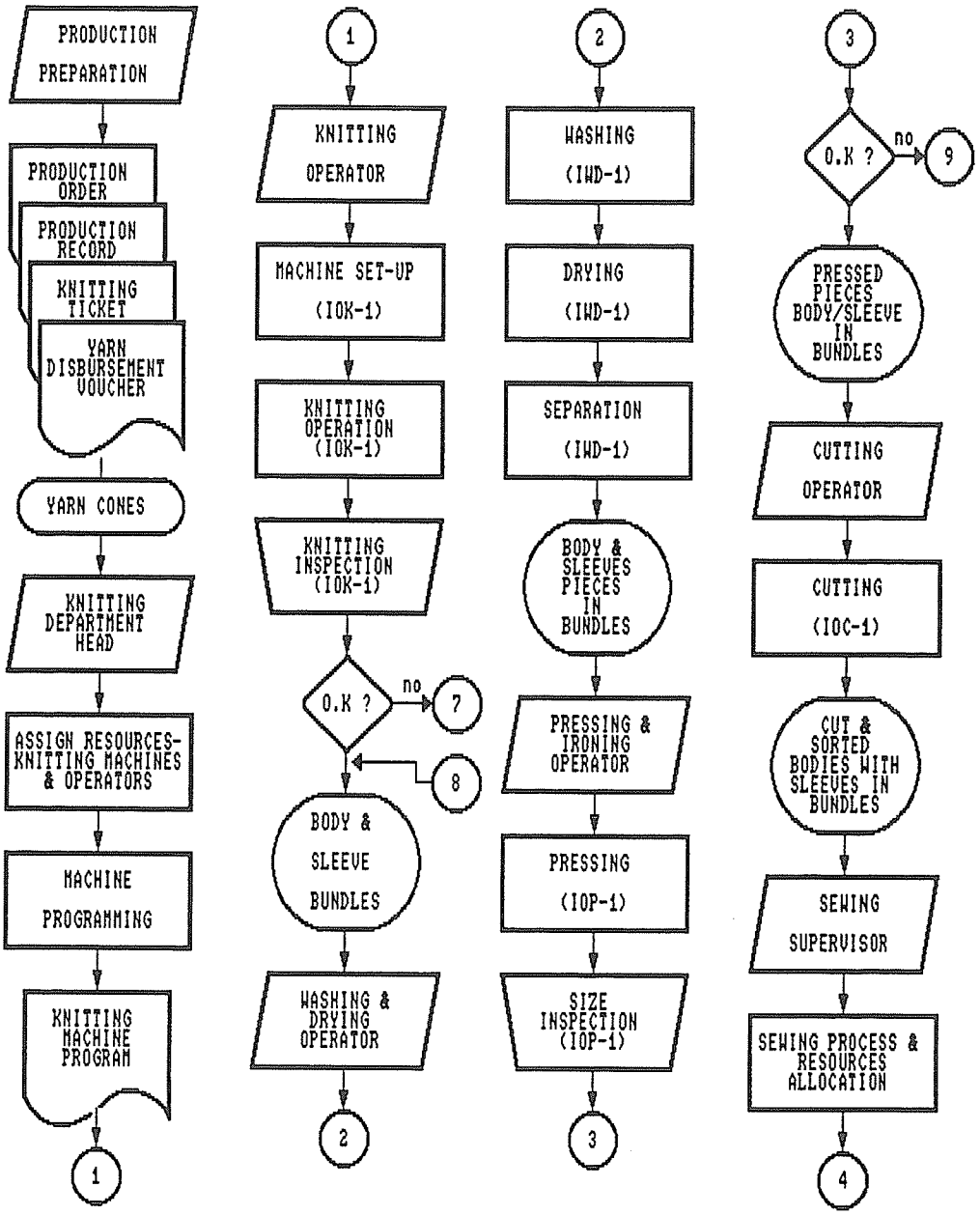
6.3 Production Process Flow Chart

A. PREPARATION



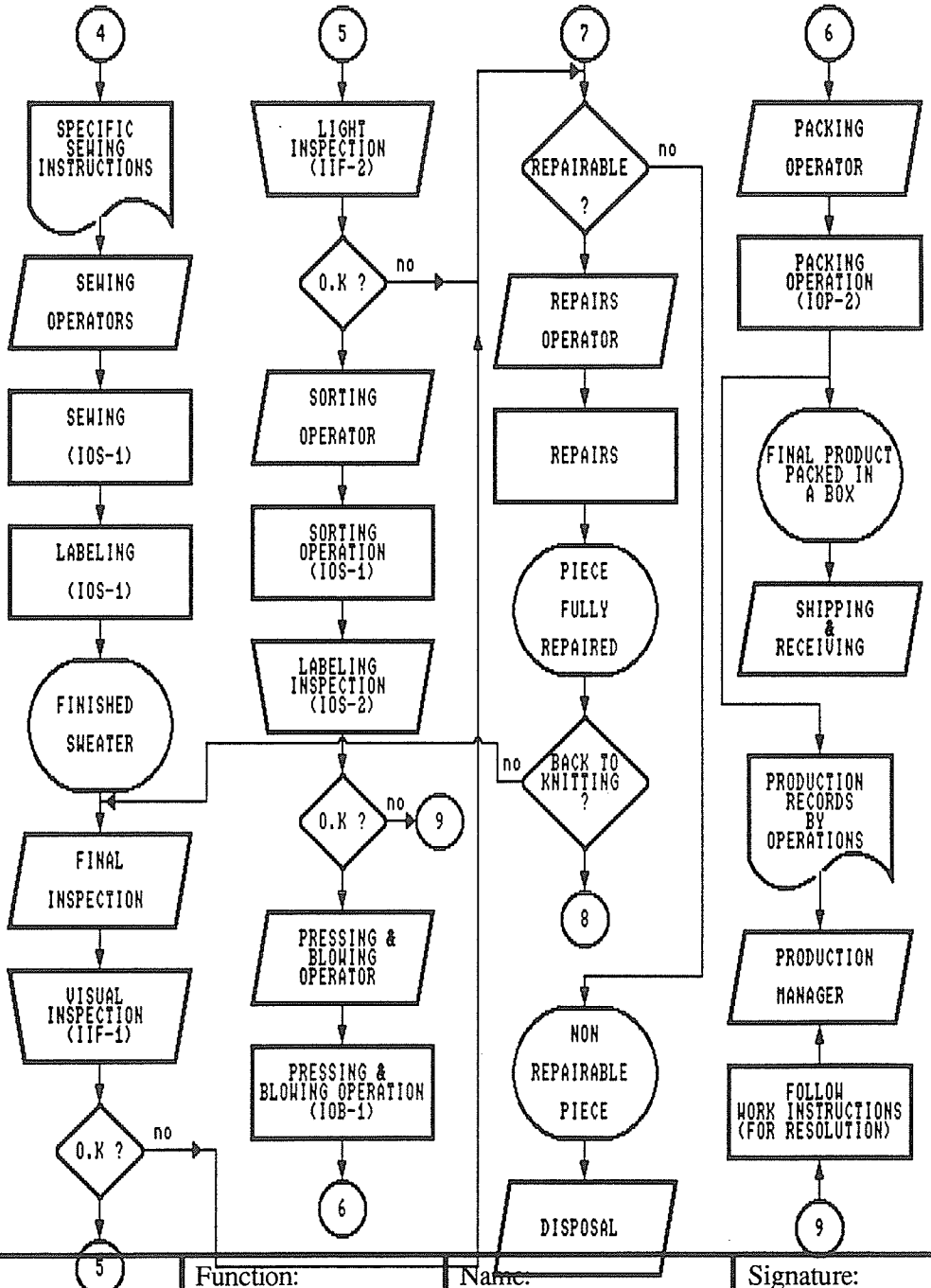
	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

B. PRODUCTION



	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

Company Name: PROSPERITY KNITWEAR LIMITED	Title: PRODUCTION PROCESS CONTROL PROCEDURE	Status & Issue Number : A1
		Date of Issue: Aug. 31, 1995
		Page 8 of 10
CONTROLLED COPY DO NOT DUPLICATE		Procedure Code : PCP-1
	Compliance with ISO 9001: 4.9 Process Control	



	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

6.4 Responsibility Matrix

FUNCTIONS RESPONSIBLE						
activities	President	Production Manager	Production Preparation Technician	Vice-President Preparation	Knitting Department Head	Sewing Supervisor
production documents preparation			in-charge			
purchasing documents preparation			participate	in-charge		
raw material preparation			in-charge	participate		
machine program					in-charge	
knitting machine maintenan. & repair					in-charge	
equipment maintenan. & repair (exc. knitt)		in-charge				
on-the-job training sewing						in-charge
on-the-job training (exc. sew.)		in-charge				
corrective actions & problem solving		in-charge			participate	participate
actions approval	in-charge					

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	

7.0 Reference Documents

(1) Company's Quality Manual (Not Yet Prepared - NYP)
(2) PDC-1 Design Control Procedure (NYP)
(3) PDC-2 Document Control Procedure (NYP)
(4) PIT-1 Inspection & Testing Procedure (NYP)
(5) PNP-1 Procedure for Control of Nonconforming Product (NYP)
(6) PCA-1 Procedure for Preventive & Corrective Actions (NYP)
(7) PTR-1 Training Procedure (NYP)
(8) PME-1 Equipment Maitenance Procedure (NYP)
(9) IOK-1 Knitting Operation Instruction
(10) IOP-1 Pressing/Ironing Operation Instruction
(11) IOB-1 Pressing/Blowing Operation Instruction
(11) IOS-1 Sewing Operation Instruction
(12) IOS-2 Sorting Operation Instruction
(13) IIF-1 Visual Inspection Instruction
(14) IIF-2 Light Inspection Instruction
(15) RFI-1 Final Inspection Record

	Function:	Name:	Signature:
Prepared by:	Originator	Stanislav Karapetrovic	
Revised by:	Production Manager	Sam Lee	
Approved by:	President	Henry Tang	