Implementation of ISO Standards through Formalization of Requirements for Process Management

Alex M. Gonzalez

A Thesis
in The
Concordia Institute for Information Systems
Engineering

Presented in Partial Fulfillment of the Requirements
for the Degree of Master of Applied Science (Quality Systems Engineering) at
Concordia University
Montreal, Quebec, Canada

March 2008

Your file Votre référence
ISBN: 978-0-494-40929-9
Our file Notre référence
ISBN: 978-0-494-40929-9

Abstract

Implementation of ISO standards through Formalization of Requirements for Process Management

Alex M. González

Companies always seek ways to increase their competitiveness and performances by implementing defined quality methodologies. The present thesis aims at providing companies with a methodology that identifies specific requirements for process management using ISO standards (IST).

IST implementation can be very costly. This is due to the fact that it requires specific knowledge, resources (financial, time and others) as well as motivation on the part of organizations to pursue ISO certification. The present thesis provides a specific methodology to identify IST requirements. This methodology uses a different approach to carry out the necessary interpretation. Its advantages lie in its reduction of the apprehension time and in the enhancement of its overall understanding.

Furthermore, the present thesis proposes an effective approach for IST implementation by applying a methodology called Environment Based Design (EBD) theory and a model called Quality Implementation Practical Flowchart (QIPF).

In EBD a graphical language called Recursive Object Modeling (ROM) is developed to design the graphical representation of IST requirements, thus, providing an easy and unambiguous understanding of ISO standards' clauses. The development of QIPF involves a methodology based on on-site experience. Thus, IST requirements defined into a formal structure are taken as the starting point for developing the implementation process.

An example based on the analysis established in the present document is used to show how an IST implementation can be developed.

Acknowledgements

Once this goal has been achieved, I wish to express my acknowledgement and gratitude to my supervisor, Dr. Yong Zeng and Wei Liu for their extraordinary support, and contributions to create this thesis, and for generously sharing his experience and acquaintanceship.

I would like to thank the people who made this work a reality and their help provided over the last two years, for all their insights, comments and teachings.

Finally, I feel deeply grateful to my family and friends, who encouraged me to find my path and accomplish this dream.

Dedicated to

My Family

My parents, brother, sister and

My little nephew

Table of Contents

List of Figures

List of Tables

Chapter 1
Introduction

1.1 Motivation and Objective

Since the 1980s, IST has been implemented by all types of organizations in order to maximize resources and to reduce ineffective procedures. The International Organization for Standardization (ISO), established in 1947, has developed a set of quality standards that have been applied in almost all categories of organizations, goods, and services.

Companies have been looking for methodologies that would more effectively implement IST. The few implementation models available are: (1) The Capability Maturity Model Integration (CMMI) for process improvement that can be applied in concert with ISO 9001:2000 (Yoo et al., 2006). (2) The Dusharme Model, for which companies require management-related training courses so that the IST can be clearly understood (Dusharme, 2004). (3) The IDEF $_{9000}$ model, which attempts to implement ISO 9001 standards by identifying the links between the organization's business processes and the relevant IST involved (Gingele et al., 2003). However, failures in implementing IST have often been reported in the literature (Hiyassat, 2000).

The failure of the methodologies cited immediately above can be attributed to various factors. For example, the implementation of a strategic IST can be costly, complex, and time-consuming and, consequently, inadequate, outdated, or both (Czuchry et al., 1997; Singh et al., 2006).

One such factor encountered is related directly to difficulties surrounding the implementation of IST in general. With regards to problems in interpreting IST, the following examples are pertinent:

(a) In Singapore a survey indicated that the lack of understanding of ISO 9000 systems was one of the barriers to achieving IST certification (Yahya and Goh, 2001).

(b) A survey of companies in Greece reported that misinterpretations of ISO 9000's requirements created major roadblocks to achieving certification (Yahya and Goh, 2001).

(c) In Malaysia the Tan and Gilbert survey conducted on ISO 9000 certified companies showed that the problem most frequently mentioned was a lack of adequate understanding of the ISO 9000 standards, resulting in an increase in unnecessary paperwork (Tan and Lim Teck Sia, 2001).

(d) In Turkey, a comprehensive survey of ISO 9000 implementations in several companies was conducted by Erel and Gosh (1996). The authors found that the companies had encountered various obstacles during their certification process, of which the most frequently mentioned was (once again) a general lack of understanding of IST across all departments (Erel and Ghosh, 1997).

(e) In Sweden, several IST certified companies, when asked about their ISO system implementation, reported difficulties in interpreting the standards as one obstacle to the full achievement of IST (Carlsson and Carlsson, 1996). These difficulties are listed in Table 1.

Table 1: Difficulties experienced in implementing ISO 9000 (Carlsson and Carlsson, 1996)

Stated reasons for difficulties	Mean	SD
Time and resource-consuming	3.32	0.98
Difficulties in interpreting the standard	2.94	1.01
Cumbersome and bureaucratic documentation	2.82	0.93
Initial difficulties in making the quality system understood and accepted	2.64	1.06
Difficulties in choosing a suitable level for documentation	2.61	1.02
Difficulties in setting relevant quality goals	2.57	0.77
Difficulties in communicating the message	2.51	0.77
Difficulties in securing employee commitment	2.48	0.90
The accountants lack knowledge of our line of business	1.93	0.99
Unclear guidelines from the certifying body	1.92	0.95

Note: Mean and standard deviation in 96 ISO certified companies; scale 1 = no problem, 2 = minor problems, 3 = some problems, 4 = great problems, 5 = extremely great problems.

(f) Finally, in reference to ISO 14001 a survey of US companies evaluated the incentives and barriers that North American firms faced during implementation, and confirmed the problems reported in Table 2, where the answers were also ranked from "serious constraints" to "no constraints" (Delmas, 2000).

Table 2: Constraints to the adoption of ISO 14001 (Delmas, 2000)

Descriptive Statistics	%	%
	Mild to serious constraint (1-4)	Not a constraint (5)
Lack of top management support	77	23
Design costs of ISO 14001 EMS	75	25
Lack of regulatory flexibility	69	31
Registration costs	67	33
Lack of understanding of ISO requirements	67	33
Annual costs of maintaining an ISO 14001 EMS	67	33
Lack of time to implement a quality EMS	65	35
Uncertainty with regulatory agencies' utilization of EMS audit information	62	38
Potential legal penalties from voluntary disclosure	60	40
Lack of personnel to implement/manage EMS	58	42
Valid N (listwise)= 52.00		

As a conclusion, based on the surveys conducted in different countries, misunderstanding or misinterpretation of IST requirements was defined as the major obstacle during IST implementation.

The present thesis aims to develop an approach to support the understanding of IST by transforming their clauses into defined requirements, which can be used for organizations to achieve ISO standard certification.

1.2 Research Contribution

In order to achieve the objectives cited above, the development of IST implementation is herein considered as a design problem, and the EBD theory (Zeng, 2004a) and QIPF model are applied in order to achieve IST certification.

The main three contributions are the following:

(1) The application of EBD theory to a new field related to the identification of not-yet defined IST requirements. Organizations can use this methodology to describe activities related to the IST implementation process by fully understanding its requirements.

(2) The improvement of the existing EBD theory by using the integration of some of its components. In the present thesis a complete integration of linguistic analysis, ROM and eliciting product requirements are merged to develop a combination of those techniques to define specific IST requirements.

(3) The development of the QIPF model, based on Deming's cycle, i.e., Plan Do Check Act.

1.3 Organization of the Present Thesis

Chapter 2 reviews the literature about IST, in which different approaches to the implementation of IST are shown. In addition, the term, "process management", is defined.

Chapter 3 describes the EBD theory.

Chapter 4 shows the relationship between the EBD model and IST.

Chapter 5 applies the EBD theory and QIPF model to a selected ISO standard (ISO 22000:2005).

Chapter 6 concludes the thesis, indicates the limitations of the research, and points in the direction of future research.

Chapter 2
Literature Review

This chapter reviews the literature in the areas of process management and IST implementation. Section 2.1 introduces process management. Section 2.2 provides brief information regarding IST. Section 2.3 presents a series of approaches about how organizations implement IST. The approaches have been included in a defined classification system in which human factors, business processes, and EBD theory are part of the IST implementation' in organizations.

2.1 Approach to Process Management

2.1.1 What is a "Process"?

For organizations, success depends on their ability to understand and manage processes in order to meet customer requirements (Gotzamani, 2005). A "process" can be defined as an activity that uses resources and manages input and output interactions. Interactions are such that output activities are the inputs of the next activity (Frost, 2006).

A model of the "product development" process was developed by Kamsu-Foguem and Chapurlat (Kamsu-Foguem and Chapurlat, 2006) as shown in Figure 1. The authors defined a series of activities represented by boxes and showed the dependency relationships between the boxes by using connecting lines. Here, dependency relationships represent "constraints that must hold true in order for the process to succeed" (page 3463).

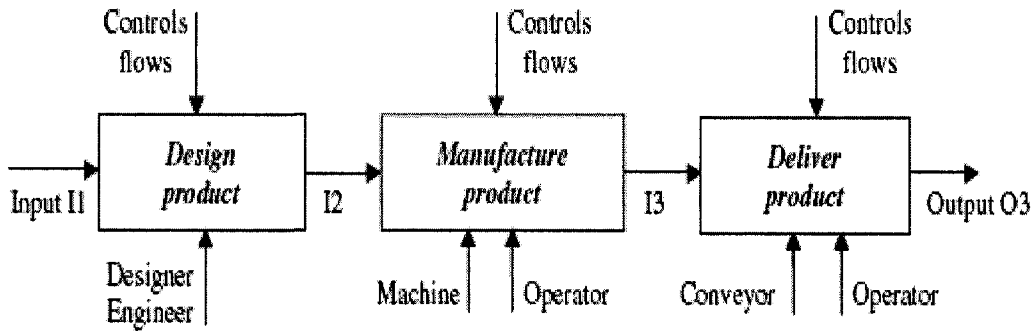


Figure 1: A model of the "product development" process (Kamsu-Foguem and Chapurlat, 2006)

2.1.2 What is "Management"?

Management refers to the complex process of decision-making, related to elements such as personnel, processes, resources, suppliers, clients, and others. Organizations should create a quality management team that proposes specific guidelines. This team, independent of other organizational activities, must define, design, develop, and effectively implement and control quality systems (Holdsworth, 2003). In addition, it should establish policies, objectives, strategy development, deployment, and priorities (Beer, 2003) that will guide the quality system process. Thus, the quality team's group efforts should lead to defined procedures, records and information.

2.1.3 What is "Process Management"?

Process management as a part of many organizations (Biazzo and Bernardi, 2003) can be defined as a compound system that is integrated with a group of interdependent processes, crossing functions, and linking organizational activities (Benner and Tushman, 2002). In process management, each single process in the company is assumed to belong to the entire organizational process (Benner and Tushman, 2003). Therefore, from the organization's point of view, individual departments generate processes that are interlinked with the processes of other departments, such that all processes are included in an overarching process management.

Applying process management, however, must yield concrete benefits. Organizations must therefore obtain tools that can improve inputs, outputs, technologies, and manufacturing techniques (Benner and Tushman, 2003). Final products that are the result of improvement processes have greater customer acceptance, enabling companies to increase their revenues and profits and decrease their costs (Benner and Tushman, 2002).

Ford Motors developed a process called Quality Operating Systems (QOS), which can be applied in manufacturing and non-manufacturing operations and which is based on eight steps that are driven by the continuous involvement of all employees, This System describes how employees interact with all of the other key players (Zairi, 1997).

2.2 ISO Standards

The International Standards for Organizations (ISO) can be defined as a worldwide network the mandate of which is to develop quality standards for businesses, governments or societies. These standards are adopted by companies through the implementation of quality procedures (ISO, 2006). The ISO has defined a list of technical sectors that include engineering technologies, materials technologies, and others as shown in Table 3. The ISO provides a unique and well-established quality system framework (Najmi and Kehoe, 2001). Among the best known are ISO 9000 and ISO 14000.

Table 3: Production by technical sector (ISO, 2007)

PRODUCTION BY TECHNICAL SECTOR

Sectors as based on the International Classification for Standards (ICS)	WORK ITEMS		INTERNATIONAL STANDARDS			
	New	Total	New	No. of pages	Total	No. of pages
Generalities, infrastructures and sciences	70	409	91	4 892	1 432	52 673
Health, safety and environment	46	173	86	4 381	667	22 271
Engineering technologies	258	911	490	25 802	4 467	189 165
Electronics, information technology and telecommunications	158	509	212	15 278	2 600	173 151
Transport and distribution of goods	109	342	136	5 494	1 791	48 782
Agriculture and food technology	69	164	65	2 071	980	21 681
Materials technologies	269	755	268	8 510	4 061	97 580
Construction	41	116	25	1 229	328	12 005
Special technologies	15	36	15	489	129	3 460
TOTAL	1 035	3 415	1 388	68 146	16 455	620 768

***New**: between 1 January and 31 December 2006 – **Total**: at 31 December 2006*

The ISO emphasizes the need to systematically identify, evaluate and improve the key business processes within an organization. ISO is best defined as a family of standards or guidelines to organizations. It manages and explains how goods or service organizations might develop quality management systems (Magd et al., 2003). IST is focused on a process approach to management (Gotzamani, 2005). However, IST recommends only the basic requirements that an organization must fulfill; they do not recommend how these standards should be applied. Thus, every organization is able to adopt a methodology that best fits its own requirements (Singels et al., 2001).

A generic quality management system, which includes all the appropriate elements of a system, such as ---inputs, transformation processes, outputs and feedback loops (Wilkinson and Dale, 2002), can be used by organizations to monitor a specific sequence of activities in which the main principle is to develop a total program of quality process management.

Figure 2 shows a model of the quality management system approach recommended by the newest standards. This model includes four key elements that correspond to the four ISO 9001:2000 standards main processes: (1) management responsibility,(2) resource management, (3) product realization, and (4) measurement, analysis, and improvement (Biazzo and Bernardi, 2003).

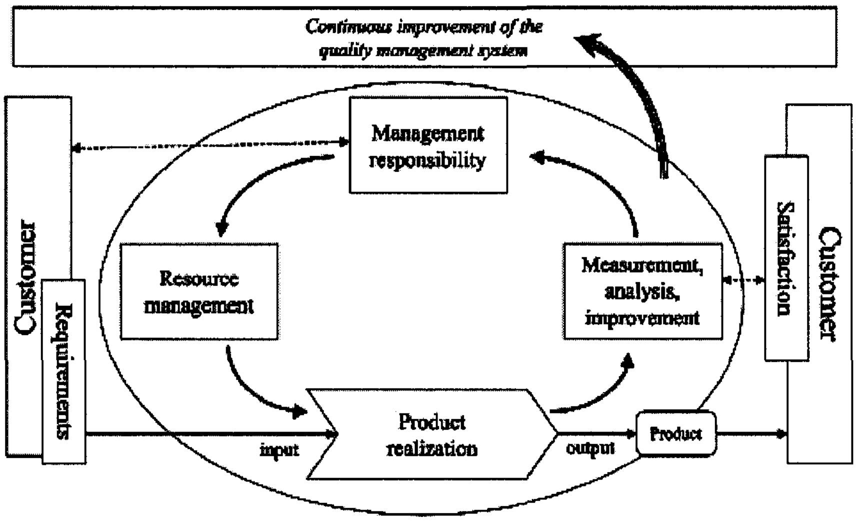


Figure 2: Model of a process-based quality management system (Biazzo and Bernardi, 2003)

The major reasons for achieving ISO certification are the following: customer or marketing demands; the need to improve process systems; the desire for global deployment; and a lack of focus within the organization (Aggelogiannopoulos et al., 2007). However, organizations benefit most when they achieve a quality certification that clearly defines what needs to be improved (Casadesus et al., 2001).

During the first stages of IST implementation, a definition of the aims and objectives of the quality program (Gingele, Childe et al. 2003) must be arrived at. Owing to the lack of understanding of IST requirements, organizations can face failures and delays, either of which can occur before, during, or even after the implementation process (Gonzalez, Adenso-Diaz et al. 2001). A company's lack of knowledge about how to interpret IST results in the loss of valuable resources (Holdsworth, 2003). However, achieving an ISO certification is not a simple task. It is not a "standardized package" that can be applied the same way for every organization (Magd et al., 2003) (Singels et al., 2001).

2.3 ISO Implementation Approaches

Using the three categories that is, ---human factors, business processes, and EBD theory, enables a company to organize its IST implementations in an optimal way. The human factors are related to how organizations, through their deployment of people, can achieve an ISO certification.

Business processes which are the most popular approach to implementing IST use defined processes that help the implementers determine which specific actions to take.

Finally, the EBD theory, which simplifies the implementation process, enables companies to achieve a quality certification through a better understanding of the IST, especially its main clauses.

These three categories into which IST implementation can fit are defined below in Figure 3.

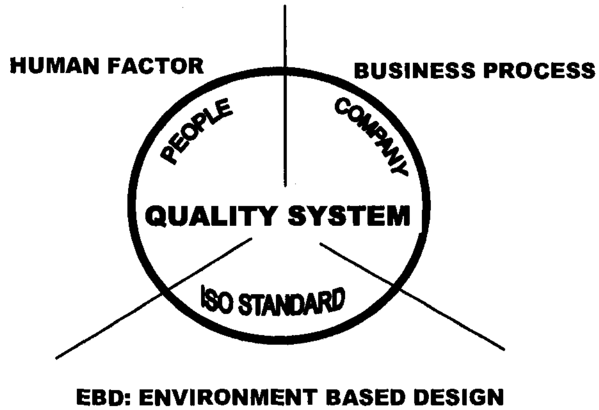


Figure 3: Quality systems implementation in organizations

2.3.1 Human Factors

The first approach is to consider the human factors that are involved in an organizational process. The implementation of IST can be developed by a Management System Team, which has the authority to define what activities must be included within each organizational process. Also, this team has the responsibility of establishing both management commitment and employee ownership. To do so, representatives from key departments and areas of the organization must be included as part of the team. This team should be small enough to facilitate its movement into organizational areas and to facilitate the transition process. Furthermore, it must be large enough to represent the scope of the company's interests (Holdsworth, 2003).

Effective implementation of IST can be achieved through pre-implementation training programs for all personnel. Training sessions can be held in the classroom, using area-specific training, reading, and computer skills.

According to Holdsworth, if a company hopes to achieve a clear understanding of IST requirements, the training of personnel is a critical factor. It must be done prior to implementation (Holdsworth, 2003).

How to implement an IST is shown in Figure 4.

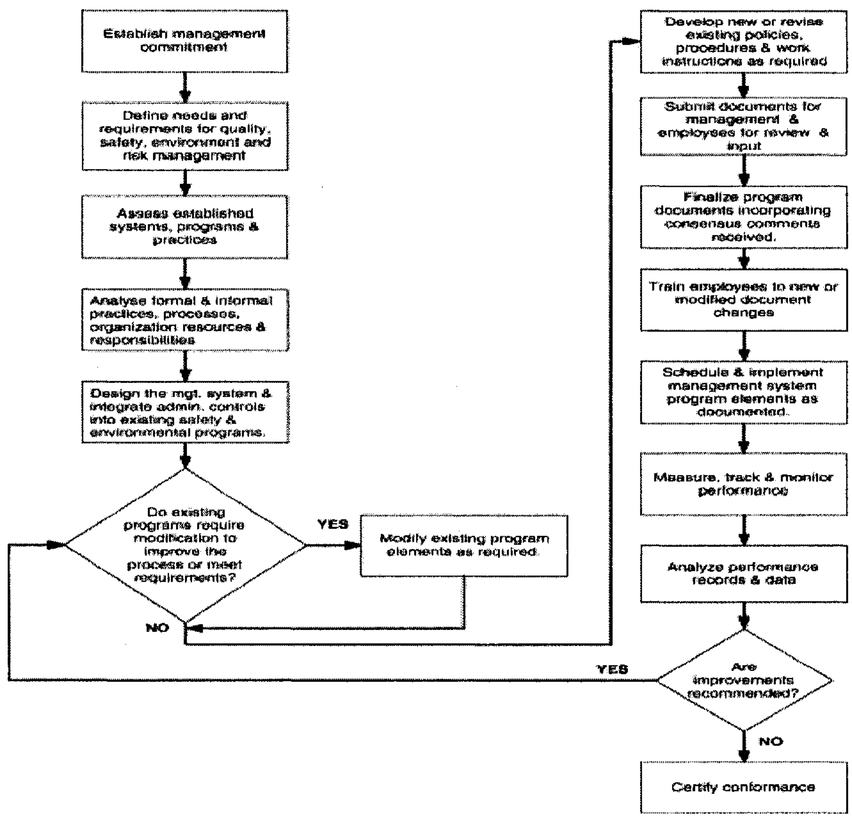


Figure 4: Management system development and implementation process (Holdsworth, 2003)

Another approach to IST implementation is to consider it as a system of codifications with which top management should be involved from the very beginning. This establishes a shared purpose among all the members of the firm. An organization can use this "codebook" as a common language. Considering IST as a "meta-language", organizations can achieve interpretation through internal communications (Benezech et al., 2001). In this case, the language that is specific to the IST should be 'mapped onto' the firm's own language conventions. After becoming more adept at interpreting each standard, organizations can readily move between the two codes: IST and organizational. At the end of the process, employees will be able to interiorize written procedures by using them in their daily work (Benezech et al., 2001).

Figure 5 demonstrates an approach to ISO standard implementation that was developed by Mo and Chan, who identified people as a relevant factor in the successful implementation of the IST. They developed a model that helps visualize the critical success factor and that provides the basis for developing an implementation strategy. Their model defines both external forces (customer expectation/satisfaction) and internal forces (benefits), both of which provide the impetus for change. Finally, the fundamental impetus is the commitment that is required from the people who are involved in the certification process (Mo and Chan, 1997).

Organizational strategies for achieving ISO certification should focus on gaining a global understanding, improving communication channels, and on establishing a continuous commitment to the IST. The workforce should be involved with ensuring broad and interactive consultation as part of the implementation process (Mo and Chan, 1997).

According to Mo and Chan, their model has been proved successful in a number of organizations with which the authors have consulted or which have otherwise participated in implementing IST (Mo and Chan, 1997).

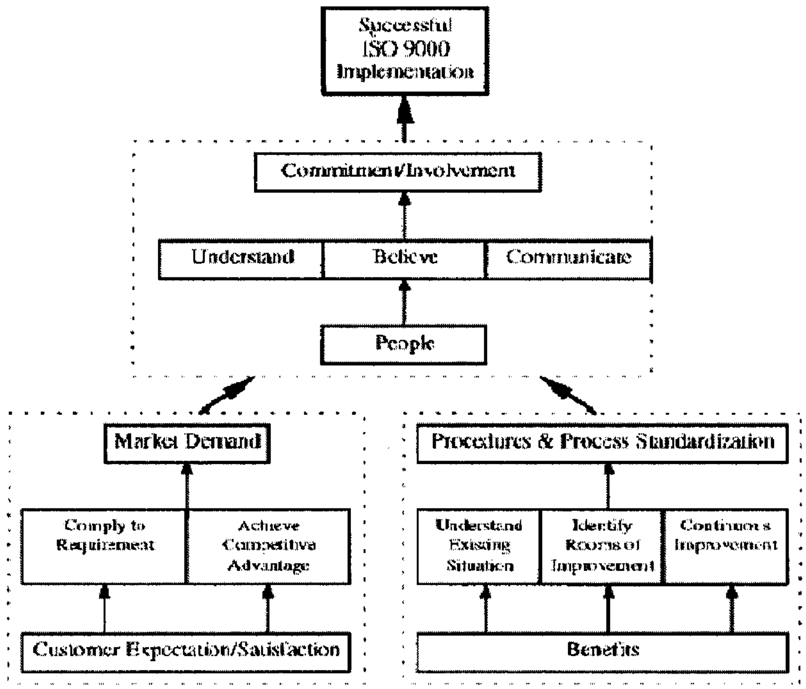


Figure 5: ISO implementation strategy (Mo and Chan, 1997)

2.3.2 Business Processes

Having considered the human factors, the next approach is related to business processes. This approach deals with methodologies that ensure efficient control over the supply chain through the integration of the specific sequence of steps carried out in each organizational unit. Langheinrich and Martin (2006) showed that by using such concepts as quality assurance and quality control within each 'link' in the supply chain, the company implements a system-wide IST (Langheinrich and Kaltschmitt, 2006).

Figure 6 defines a methodology that applies quality assurance systems that are based on the efficient control of the processes involved. Quality manuals should be published during the implementation process.

They should be made available to each party. They would illustrate how all the processes and their interactions are fully under control (Langheinrich and Kaltschmitt, 2006).

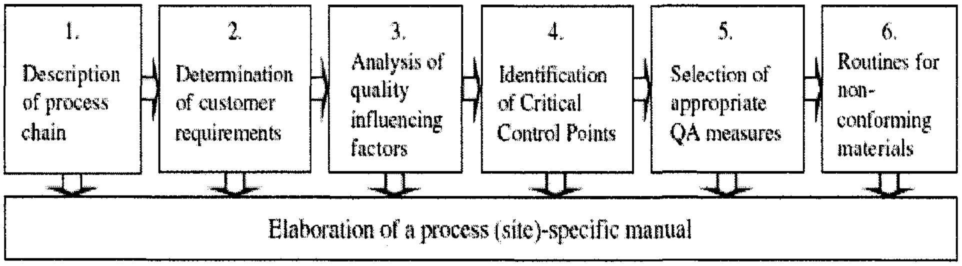


Figure 6: Methodology to apply and to implement Quality Assurance (Langheinrich and Kaltschmitt, 2006)

Defined by Czuchry, Hyder et al, Figure 7 represents in detail the first steps to IST implementation. By using this 'roadmap', an organization can define a strategic planning process for determining the tasks to be achieved (Czuchry et al., 1997).

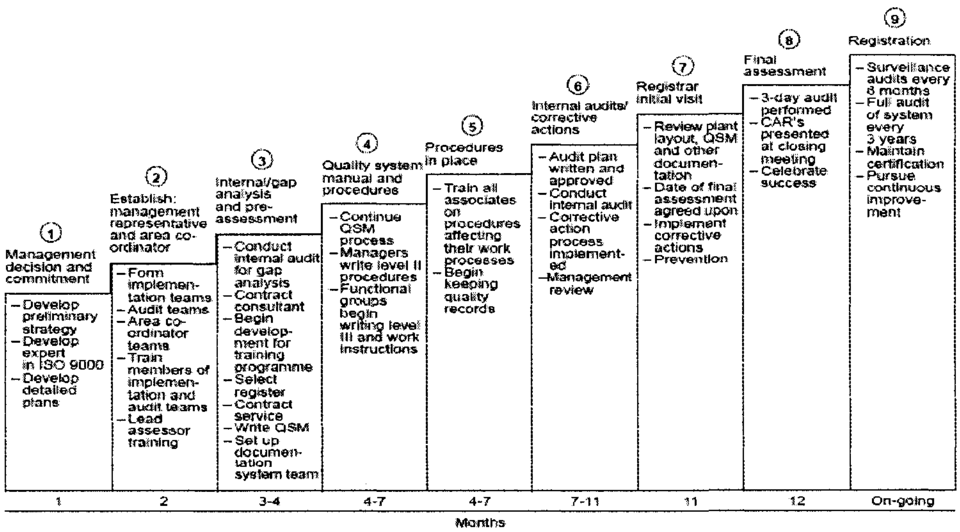


Figure 7: Roadmap to ISO 9000 registration (Czuchry et al., 1997)

Operational departments identify gaps, misalignments, or redundancies involving strategic objectives and their implementation. The process concludes with a consideration of those quality indicators that are related to organization performance and action plans, thereby helping to narrow the gaps between current and desired performance levels (Czuchry et al., 1997).

The $IDEF_{9000}$ methodology is an adaptation of the $IDEF_0$. It was developed by the US Air Force under the Integrated Computer- Aided Manufacturing program (ICAM). $IDEF_0$ works under a function-based modeling technique and can be used for design. It aims to analyze a system as a set of interrelated functions (Gingele et al., 2003).

$IDEF_{9000}$ uses a process mapping technique that combines graphics and text to gain an understanding of how process functions operate and interrelate. The modeling technique for ISO 9001 links, identifies, and graphically distinguishes those functions that are controlled by the ISO standards from those that are not (Gingele et al., 2003) as shown in Figure 8.

With the $IDEF_{9000}$ methodology, one can create a chart of all activities and flows (inputs, controls, outputs, and mechanisms) that are controlled by the ISO 9001 for all organizational processes. Thus, it can be used as part of the design of a quality management system.

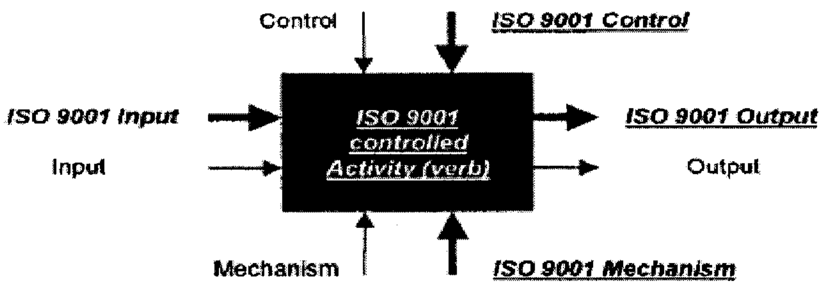


Figure 8 : Identification of an $IDEF_{9000}$ function controlled by ISO 9001 (Gingele et al., 2003)

(Gingele et al., 2003) contend that ISO 9001 identifies activities and flows that are later considered for the design of an ISO 9001 quality management system (alternately, as an exercise of redesign for a specific process). This modeling approach has been developed to design and redesign a business process and to establish and to identify its links to ISO 9001 requirements (Gingele et al., 2003).

2.3.3 EBD: Environment- Based Design

An approach to achieving an IST implementation process by using the EBD theory is defined. The advantage of this IST based methodology is to allow identifying a greater number of ISO requirements. This methodology is described in some detail in Chapter 3.

2.4 Summary

The proximity between process management and IST enables companies to meet customer satisfaction with product quality and, in turn, to achieve profits.

Organizations always require process management, regardless of the particular form that it may take (Elzinga et al., 1995). Process management is a way to implement IST. It determines the main principles of each manufacturing process, saves resources, and generates greater benefits.

In the present chapter, different approaches to IST implementation are presented. They explore different possibilities for achieving ISO quality certification. They are based on the type or size of the company, as well as on how much the company is willing to invest.

Chapter 3
Environment-Based Design: Introduction

The present chapter introduces the EBD. The EBD is a design methodology that contributes to the theoretical background of the present thesis. It is derived from the Axiomatic Theory of Design Modeling (ATDM). In Section 3.1, there is an introduction to the EBD model. In Section 3.2, a linguistic analysis is introduced. In Section 3.3, the ATDM is presented. In Section 3.3, one of the key methods for environment analysis in EBD is presented by using a ROM model. The ROM model is a graphic language that represents all of the relevant linguistic elements of technical English. Finally, Section 3.4 illustrates how to elicit additional product requirements.

3.1 Using the EBD (Environment-Based Design)

The Environment-Based Design Model (EBD) (Zeng, 2004a; Zeng, 2004b) was logically derived from the ATDM (Zeng, 2002), which was founded on the recursive logic of design (Zeng and Cheng, 1991).

EBD is both a prescriptive and a descriptive model of design. Not only does it illustrate how designers should conduct a design task but also does it describe a model of the natural design process (Chen et al., 2005).

The EBD methodology illustrated in Figure 9 includes three main stages: environment analysis, conflict identification, and concept generation. These three stages work together to generate and to refine design specifications and design solutions.

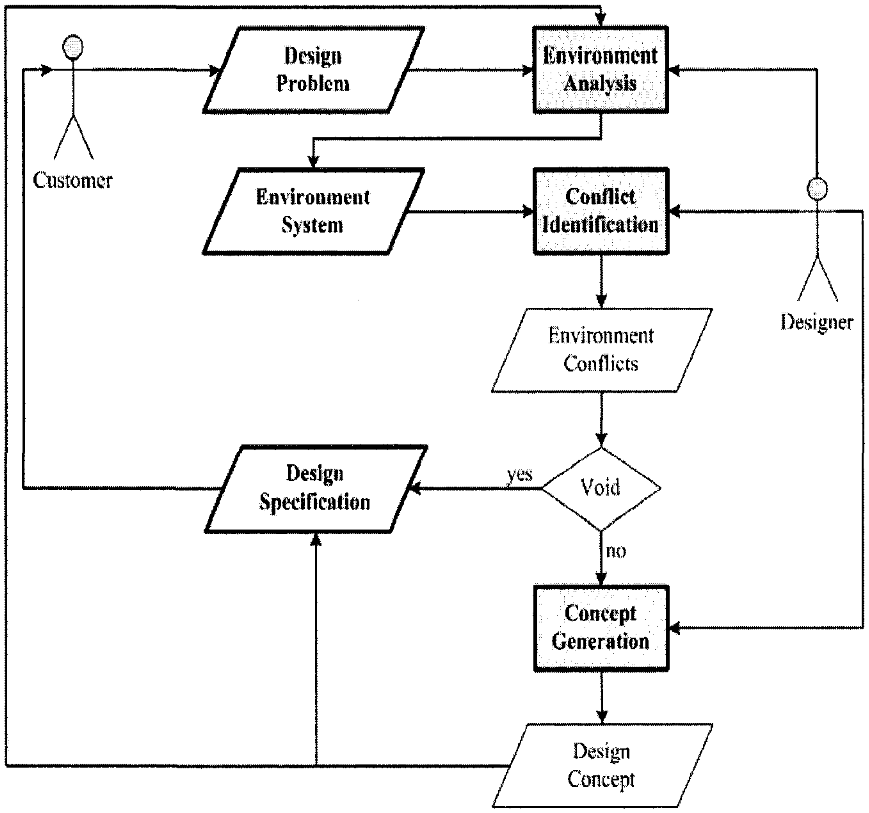


Figure 9: Environment -Based Design: process flow (Zeng, 2004b)

The results of this analysis constitute an environment system. One of the key methods for environment analysis is linguistic analysis (Chen and Zeng, 2006; Wang and Zeng, 2007).

3.2 Linguistic Analysis

The first step in the complex approach to design problems is to define product requirements, using natural language that has been converted into a formal structure.

According to Chen, Yao et al., (2005) by comparing a language with the ATDM, both "ideas in mind" and "objects in the environment" are objects in the universe. Moreover, the linguistic structure of words and sentences has been built by using the ATDM (Chen et al., 2005).

Modeling the process knowledge in a formal, probable, testable, and re-usable form (Kamsu-Foguem and Chapurlat, 2006) aids designers in designing problem interpretations.

The English language is a combination of words that are classified, grammatically, as follows: nouns, adjectives, verbs, adverbs, pronouns, prepositions, conjunctions, and interjections. A typical English sentence follows a pattern of subject plus predicate (Chen et al., 2005).

From the perspective of Chen, Yao et al., (2005) based on the predicate structure; there are five basic sentence patterns:

- Subject + intransitive verb
- Subject + linking verb + subjective complement
- Subject + transitive verb + direct object
- Subject + transitive verb + indirect object + direct object
- Subject + transitive verb + direct object + objective complement

One way to determine the formal structure of the design requirements is to submit the formal structure to three kinds of analyses: a lexical analysis, a syntactic analysis, and a structure analysis. Lexical analysis determines the particular characteristics of a word in a sentence. Syntactic analysis identifies patterns of sentences based on English grammar. Structure analysis, which is based both on the results of lexical analysis and syntactic analysis, converts each sentence into a formal structure that is defined by the ATDM (Chen et al., 2005). Chen, Yao et al have characterized structure analysis in two steps. The first step is to adapt each simple sentence into a diagram, using the representation of the linguistic structure. The second step is to integrate those representations into a formal structure and to identify and to inter-relate the various environments of the products (Chen et al., 2005).

An example is provided in Figure 10.

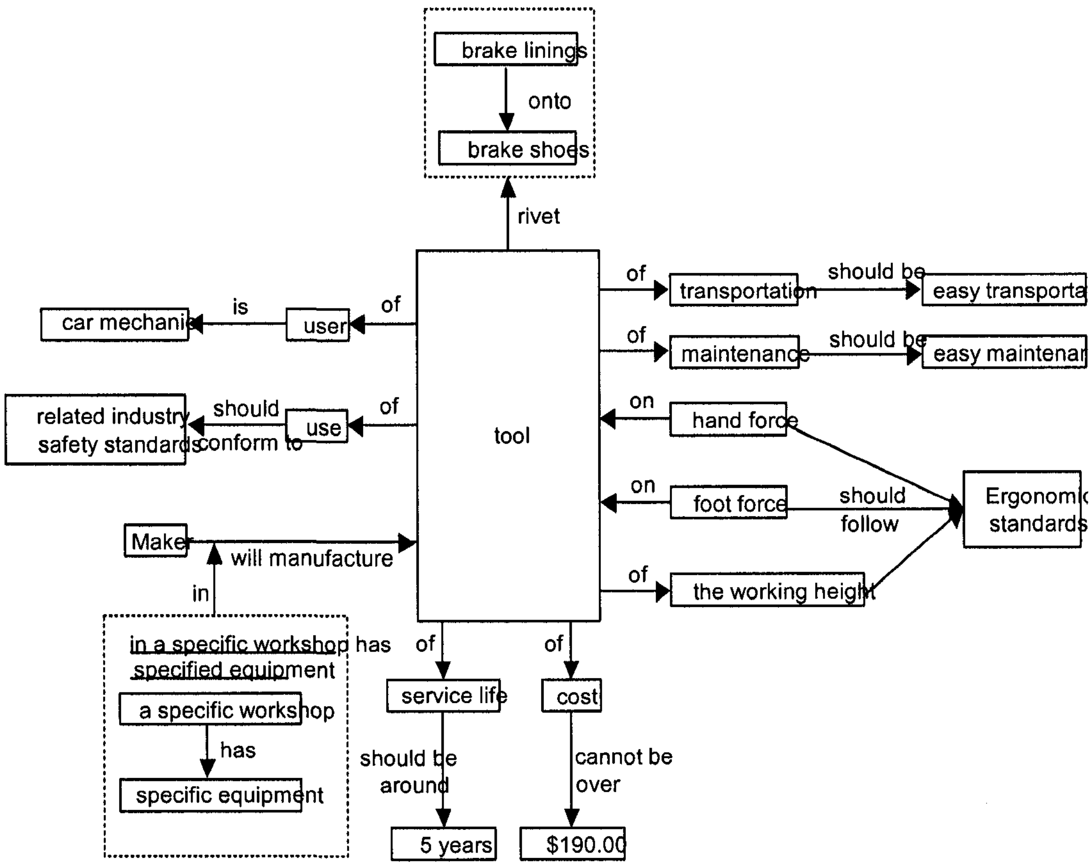


Figure 10: Formal structure of rivet setting tool design example (Chen et al., 2005)

3.3 An Axiomatic Theory of Design Modeling

The ATDM is a logical tool for representing and reasoning about object structures (Zeng, 2002). It provides a formal approach that allows the development of design theories, following logical steps that are based on mathematical concepts and axioms. The primitive concepts of universe, object, and relation are used in the ATDM.

3.3.1 Axioms of Object

Based on the concepts above, the axioms of objects are defined in the ATDM.

Axiom 1: Everything in the universe is an object

Axiom 2: There are relations between objects.

It can be seen from these two axioms that the characteristics of relations would play a critical role in the ATDM. It is essential to define a set of basic relations to capture the nature of the object representation.

Two corollaries of the ATDM are used to represent various relations in the universe:

Corollary 1: Every object in the universe includes other objects. Symbolically,

$$A \supseteq B, \forall A \, \exists B, \tag{1}$$

The symbol $\supseteq$ is the inclusion relation. Thus, B is called a sub-object of A.

Corollary 2: Every object in the universe interacts with other objects. Thus,

$$C = A \otimes B, \forall A, B \exists C, \tag{2}$$

In this case, C is called the interaction of A on B. The symbol $\otimes$ represents the interaction relation. The interaction relation is idempotent but not transitive or associative, nor commutative.

Based on the Corollaries 1 and 2, the structure operation is developed.

Definition 1: The structure operation, denoted by $\oplus$, is defined by the union of an object and the interaction of the object with itself.

$$\oplus O = O \cup (O \otimes O), \tag{3}$$

Thus, $\oplus O$ is the structure of object O.

The structure operation provides the aggregation mechanism for representing the object evolution in the design process.

Based on the structure operation given in (3), a product system can be defined as the structure of an object (Ω), including both a product (S) and its environment (E).

$$\Omega = E \cup S, \forall E, S\, [E \cap S = \Phi], \tag{4}$$

In this case Φ is the object that is included in any object.

The product system ($\oplus\Omega$) can be expanded as follows:

$$\oplus \Omega = \oplus(E \cup S) = (\oplus E) \cup (\oplus S) \cup (E \otimes S) \cup (S \otimes E), \tag{5}$$

Thus, ⊕E and ⊕S are structures of the environment and the product, respectively, whereas E⊗S and S⊗E are the interactions between the environment and the product (Zeng, 2002).

A product system can be illustrated in Figure 11. In the design process, any previously generated design concept can indeed be seen as an environment component for the succeeding design.

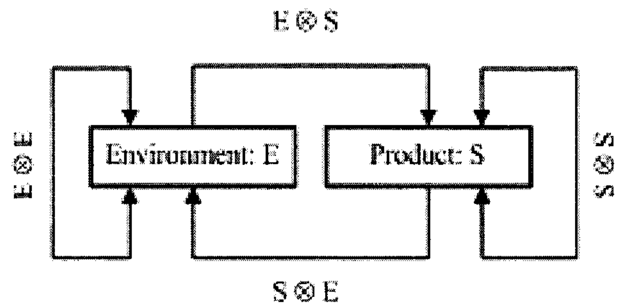


Figure 11: Product system (Zeng, 2002)

3.3.2 Two Theorems of Design

(1) Theorem of recursive logic of design. A design solution must pass an evaluation defined by the design knowledge that is recursively dependent on the design solution that is to be evaluated (Zeng and Cheng, 1991).

Based on this theorem, a design process is composed of a series of design states defined by both product descriptions and product requirements, as is shown in Figure 12 (Zeng et al., 2004).

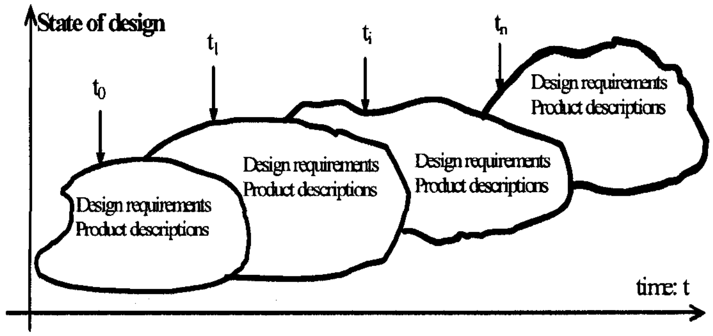


Figure 12: Evolution of the design process (Zeng, 2004b)

(2) Theorem of design driving force. The driving force behind the design process is the undesired combined conflicts that exist in an environment system.

A design process continues until no such conflicts exist. This theorem is illustrated in Figure 13.

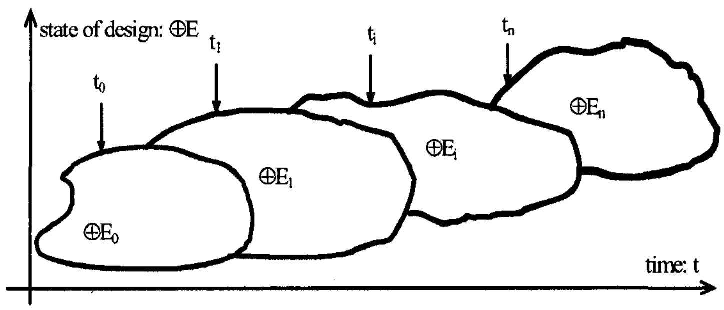


Figure 13: Environment based design: mathematical model (Zeng, 2004a)

This theorem implies that the driving force of a design process comes from the environment, including natural, human, and built environments (Zeng, 2004a). Therefore, product requirements can be defined as environment components in which the product is expected to work.

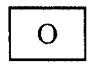
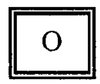
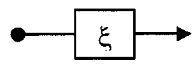
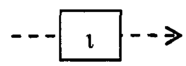
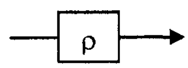
3.4 Recursive Object Model

ROM was developed by Zeng (Zeng, 2007). It is a graphic language representing all the linguistic elements of technical English, derived from the ATDM. Design problems are represented by language descriptions whereas design processes are described by designers in natural language (Zeng, 2007).

Language is a symbol system that human beings use to describe the universe (Chen et al., 2005). The symbols in a language may also fulfill certain structural functions in the language pattern, so that ideas and objects can be combined to form more complex meanings (Turner, 2006).

ROM can be used to collect, organize, interpret, and analyze the characteristics of English grammar by inferring from multiple object relationships implied in the natural language. According to Zeng, ROM is represented by two kinds of objects ('object' and 'compound object'), and three kinds of relations ('constraint', 'connection' and 'predicate') as shown in Table 4 (Zeng, 2007).

Table 4: Elements of Recursive Object Model (ROM) (Zeng, 2007)

Type		**Graphic Representation**	**Description**
Object	Object		Everything in the universe is an object
	Compound Object		It is an object that includes at least two objects in it
Relations	Constraint Relation		It is a descriptive, limiting, or particularizing relation of one object to another
	Connection Relation		It is to connect two objects that do not constrain each other
	Predicate Relation		It describes an act of an object on another or that describes the states of an object

As an example, the complex phrase "the likelihood of introducing food safety hazards to the product through the work environment" includes a noun, a gerund, and two prepositional phrases (Zeng, 2007). Their representation using ROM is shown in Figure 14.

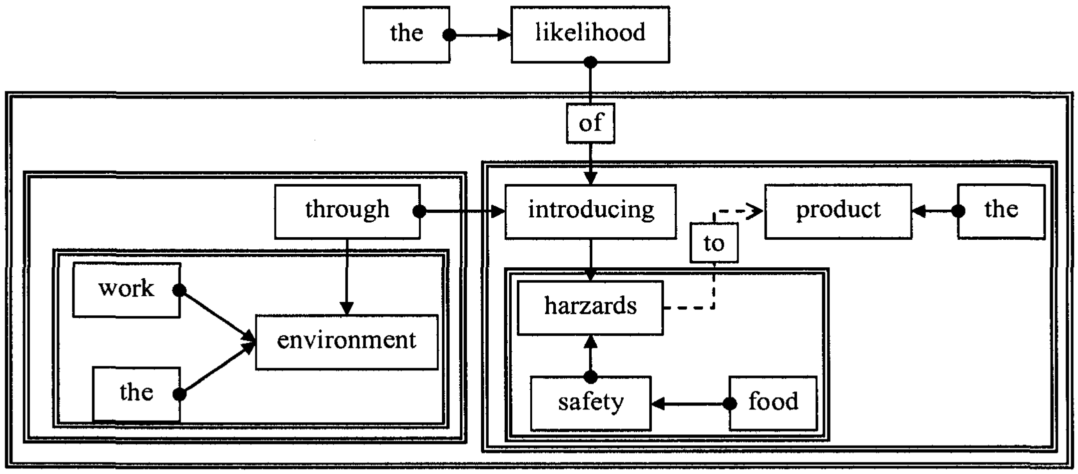


Figure 14 : The ROM structure of a complex phrase (Zeng, 2007)

3.5 Eliciting Product Requirements

Wang and Zeng have developed a methodology based on linguistic analysis through which asking questions can be a process for eliciting product requirements. Thus, "the linguistic analysis transforms a text into a graphic language called Recursive Object Model (ROM)."

To elicit product requirements, the authors propose that the identification of a customer's real intent can be achieved through a systematic, iterative question-asking approach, one that is based on a semantic analysis of a specific part of the current requirements text (Wang and Zeng, 2007).

Thus, using a linguistic tool to capture the meaning of the requirement text, as described in ROM, will help designers clearly identify those requirements.

From the ATDM, Zeng developed a theorem concerning the source of product requirements. This theorem states that all product requirements in a product are imposed by the product environment in which the product is expected to work (Wang and Zeng, 2007).

Asking questions is an effective way to understand texts. However, much depends on semantics. ROM carries the semantic information implied in a natural language-based design problem description and represents the linguistic structure of a free text through only syntactic analysis. In other words, "the ROM diagram provides the semantic foundation for the question-asking in the product requirement process" (Wang and Zeng, 2007).

The starting point for designers is to know that product requirements were made using natural language; moreover, designers should know how to ask questions in order to gather precise and complete requirements from the product.

Thus, asking questions can be an effective way to understand and to reveal a list of requirements that a product must fulfill.

A generic inquiry process for eliciting product requirements was developed by Wang and Zeng (Wang and Zeng, 2007). This process can fit into the definition of ISO standards requirements. It is shown in Figure 15.

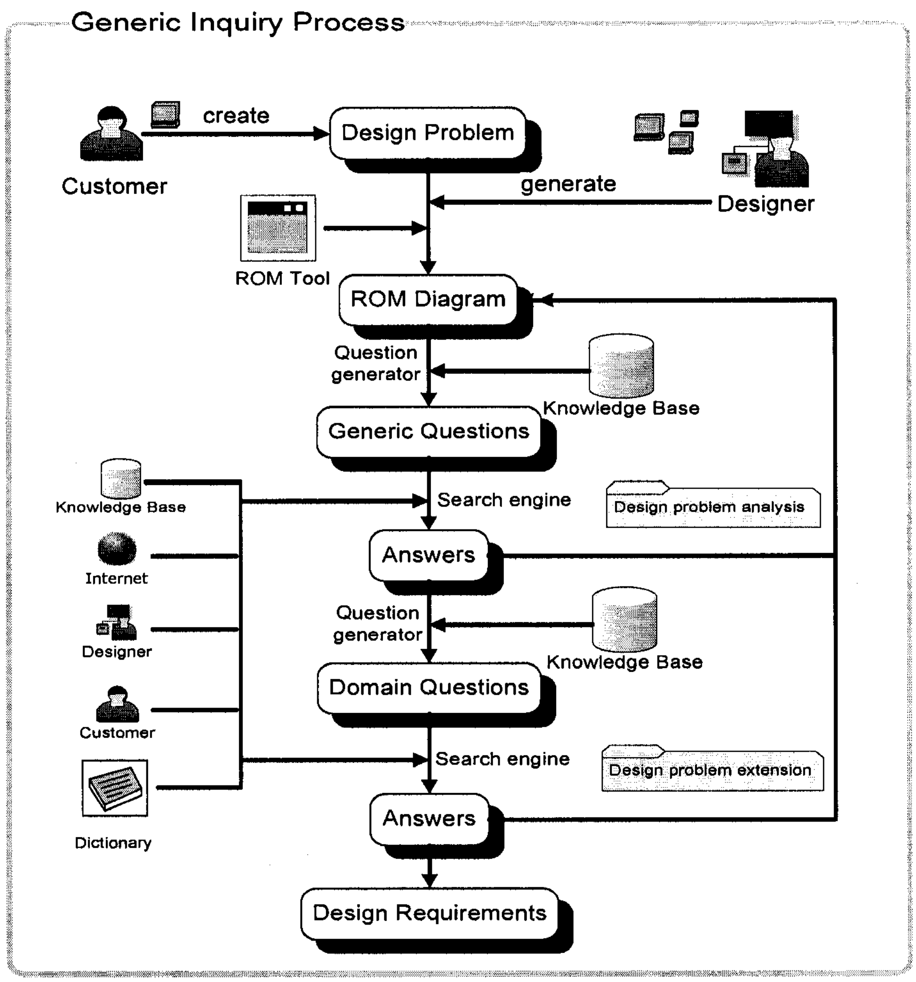


Figure 15: Generic inquiry process for requirements elicitation (Wang and Zeng, 2007)

3.6 Summary

Through the discussion of such concepts as linguistic analysis, the ATDM, ROM and the eliciting of product requirements, this chapter has introduced the theoretical background of EBD theory. EBD theory is a newly developed design methodology based on the ATDM.

The ATDM, which presents two object related axioms and two design theorems, forms the basis of this methodology. Furthermore, Eliciting Product requirements concepts, and ROM are presented as the basis for defining a graphical way to interpret design requirements, and to elicit product requirements as a method for identifying new design requirements that come from the environment of the design problem.

Chapter 4
Formulating IST by using EBD

This chapter presents an approach to the integration of EBD theory and IST that include the ROM. Section 4.1shows an approach to EBD theory. Section 4.2 shows how EBD theory transforms IST specifications into formal specifications, thereby ensuring better understanding of the specification. Section 4.3 shows how eliciting the right questions helps one better understand the IST requirements. Finally, Section 4.4 provides an example of ISO 22000:2005 which includes previous applications of EBD theory.

4.1 Approach to EBD or Environment-Based Design

In the present thesis, only the 'design problem' and the 'environment analysis' indicated in Figure 9 are used as major elements in developing an approach to implement IST. Thus, it is treated as a design problem, where each clause represents the minimal requirement that organizations must satisfy in order to achieve an IST certification.

Implementation of IST based on EBD theory focuses on design problems and environment analysis. Whereas IST implementation is taken as a design problem, IST clauses correspond to customer requirements.

Environment analysis is defined as an analysis of the surrounding activities of a specific IST clause. The objective of environment analysis is to find the key environmental components in which the clause works, as well as to identify the relationships between and among the environmental components.

Discovering these relationships is the key for carrying out environmental analysis. Thus, from the environment that is implied in the design problem described by IST clauses, organizations introduce extra environment components that are relevant to the design problem at hand.

4.2 Formulation of IST

IST requirements must be interpreted by companies. These requirements always begin with the word "shall". Since an understanding of this type of information is the clue to comprehending the standard, gaining a deep knowledge about the sentences, words, and their interrelationships can help clarify their meaning.

IST clauses can be broken down into sentences and words. Their interrelationships can be analyzed and connected graphically to generate a ROM (Chen et al., 2005). According to Zeng (Zeng, 2007), achieving effective implementation is problematic. Indeed, semantic ambiguity with respect to the IST causes the standard to be incorrectly understood. Therefore, formalizing the clauses in a standard is an important step.

Achieving and implementing programs for IST certifications is possible through a better understanding of their requirements. Organizations should have precise information related to IST requirements so as to reduce the risk of misunderstanding the standard and so as to avoid wasting financial and time resources during the implementation process.

To produce the ROM diagram in Figure 16, Zeng has used Clause 7.2.1 in ISO 22000:2005 as an example relate to quality food production (ISO, 2005). This IST clause was generated by breaking down the original clause into a few sentences. The outcome was the merger of all previous ROM diagrams into a single ROM diagram (Zeng, 2007). The standard specification is as follows:

> *The organization shall establish, implement and maintain PRP(s) to assist in controlling the likelihood of introducing food safety hazards to the product through the work environment, biological, chemical and physical contamination of the product(s), including cross contamination between products, and food safety hazard levels in the product and product processing environment (ISO22000, 2005).*

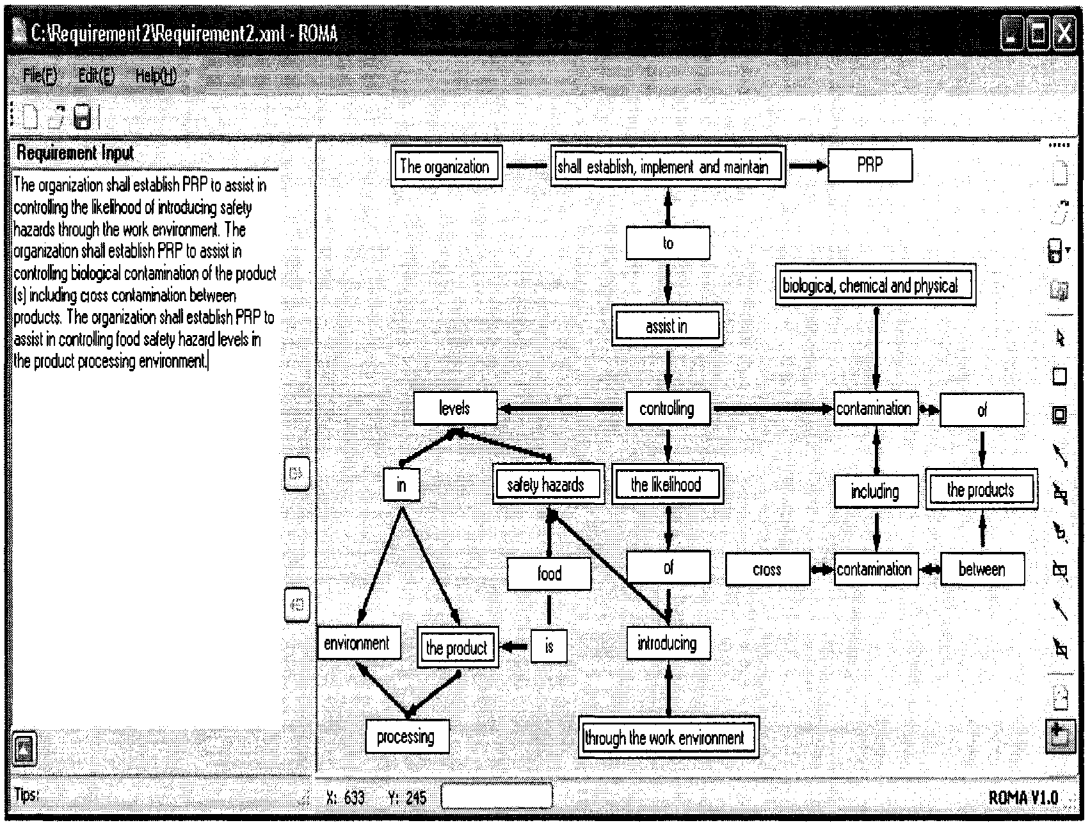


Figure 16: Part of ISO 22000:2005 represented by ROM (Zeng, 2007)

The ROM diagram above defines a specific IST clause. It was generated by Zeng as follows: "this clause is about controlling the contamination, the likelihood and the levels. There are biological, chemical, and physical contaminations, which are on the food product and may come from the interactions between the products. The food safety hazards are introduced through the working environment in which the product is processed." pg 24 (Zeng, 2007). Zeng notes that the effective understanding of the text developed by ROM diagrams is under further investigation (Zeng, 2007).

4.3 Graphical Analysis for Generic Inquiry Process

A generic inquiry process has been developed by Wang and Zeng for eliciting product requirements. These authors have described an effective way both to gather product requirements and to transform them from a natural language description into formal specifications.

Obtaining a complete list of product requirements and identifying a customer's real intention is made possible by asking questions that relate to the process as shown in Figure 17. To obtain a clear definition of product requirements, eight steps are identified that can help designers define requirements beyond those specified by the customer (Wang and Zeng, 2007):

Step 1: Create an ROM diagram.

Designers transform words used in natural language, from product requirements into an ROM diagram using an ROM analysis tool. In doing so, they are better able to see the complete picture of that standard's specification (Wang and Zeng, 2007).

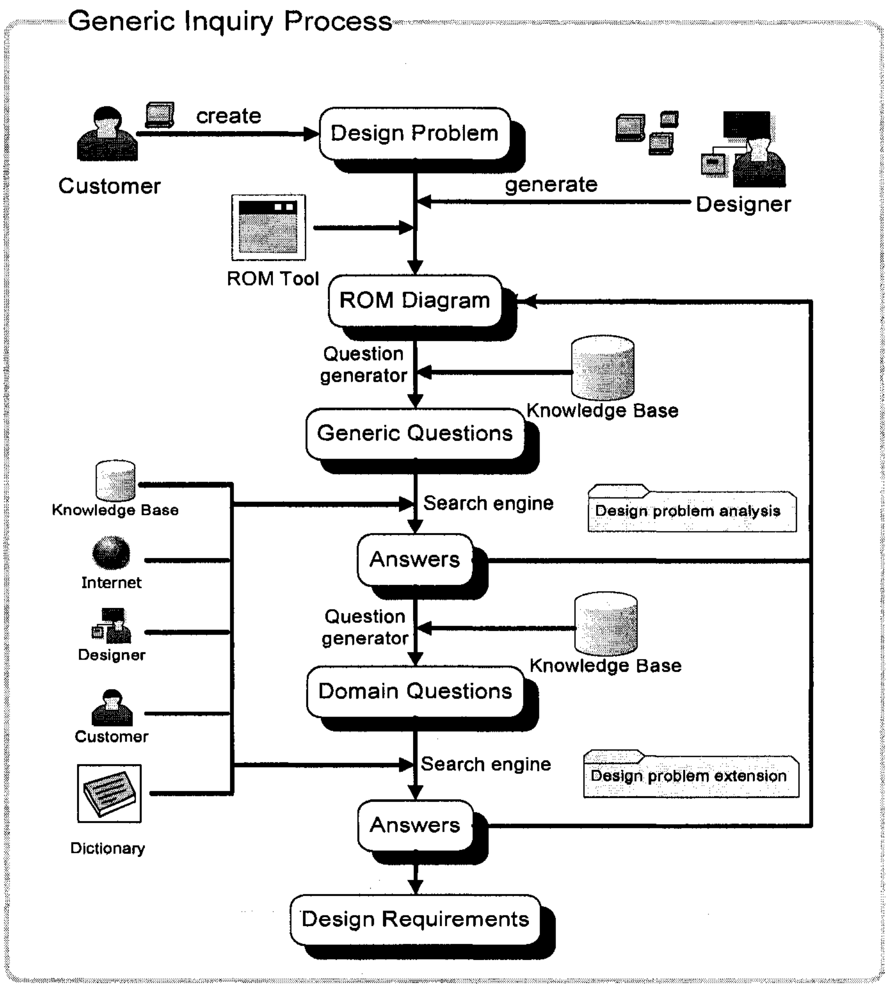


Figure 17: Generic inquiry process for requirements elicitation (Wang and Zeng, 2007)

Step 2: Generate generic questions.

After placing the specific objects into the ROM diagram, designers should identify a methodology for developing generic questions about these specific objects that have not yet been clearly defined, using predefined rules and question templates (see Figure 18; Table 5; Table 6; Table 7) (Wang and Zeng, 2007).

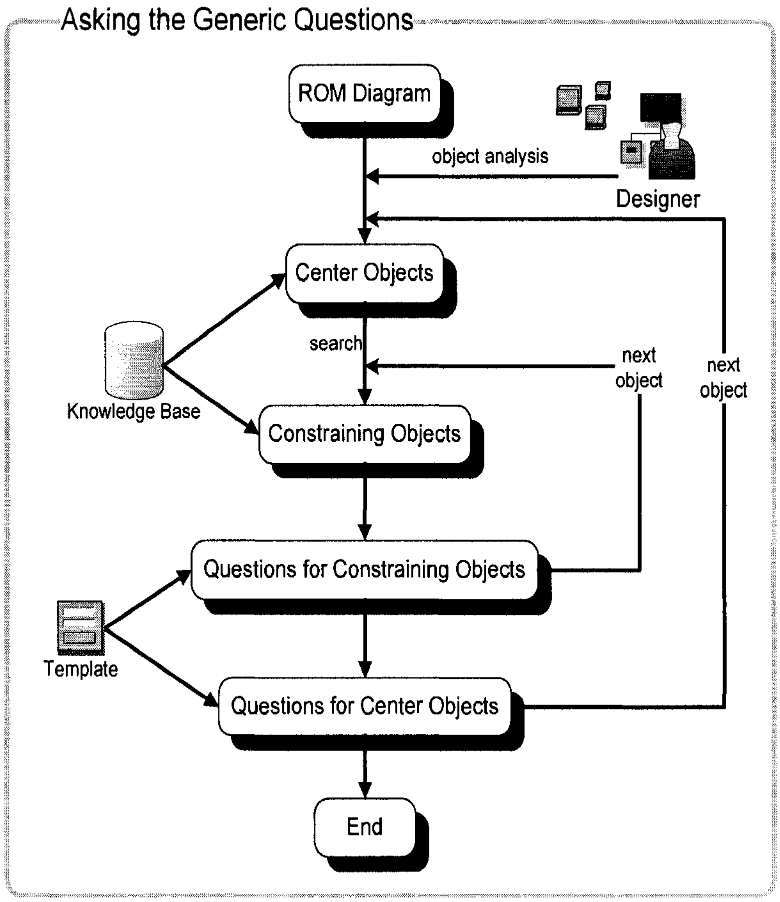


Figure 18: Asking the generic questions (Wang and Zeng, 2007)

The rules to follow in Step 2 for object analysis appear in Tables 5, 6, and 7 below:

Table 5: Rules for object analysis (Wang and Zeng, 2007)

• Rule1	Before an object can be further defined, the objects constraining them should be refined.
• Rule2	An object with the most undefined constraints should be considered first.

Table 6:Questions template for object analysis (Wang and Zeng, 2007)

T1	For a concrete, proper, or abstract noun *N*	Question: What is *N*?

T2	For a noun naming a quantity Q of an object N, such as height, width, length, capacity, and level, such as height, width, length, capacity, and level	Question: How many / much / long / big /… is the Q of N?
T3	For a verb V	Question: How to V? Or Why V?
T4	For a modifier M of a verb V	Question: Why V M?
T5	For an adjective or an adverb A	Question: What do you mean by A?
T6	For a relation R that misses related objects	Question: What (who) R (the given object)? Or (the given object) R what (whom)?

Table 7: Classification of nouns (Wang and Zeng, 2007)

• Concrete noun	A thing that one can perceive through ones physical senses such as touch, sight, taste, hearing, or smell.
• Proper noun	Represents the name of a specific person, place, or thing. It is always written with a capital letter, such as ROM, ISO.
• Abstract noun	Refers to states, events, concepts, feelings, qualities, etc., that have no physical existence, and is the opposite of a concrete noun, for example, "freedom", "happiness", and "idea".

The methodology used in Step 2 is related to the object, previously defined by using an ROM diagram, as a way to identify the customer's real intent. To do so, each defined object in the ROM diagram is analyzed and categorized, either as a center object or as a constraining object that needs to be identified or further clarified. These objects can be easily identified according to the type of relationships they have with one another.

Following the rules explained in Table 5, in which every main object is identified by the number of relations that it has, its constraints relations must be defined first (Wang and Zeng, 2007). The question should be posed according to Table 6, in which certain rules apply and as part of the ROM linguistic analysis, in which objects are distinguished as parts of speech (Wang and Zeng, 2007). At the end, designers will be able to understand what activities lay beyond the product requirements.

Step 3: Collect answers.

Designers start collecting answers for the questions generated in Step 2 (Wang and Zeng, 2007) by using different resources, such as the internet, previous knowledge, specialized dictionaries, or other available resources. Answers from Step 3 are analyzed by using ROM methodology and are identified in new ROM diagrams, which must then be added to the main ROM diagram.

Even at the end of these steps, a complete understanding of the product requirements may not yet be achieved. In this case "designers need to elicit more implicit environment information about the design " (Wang and Zeng, 2007).

Step 4: Repeat Steps 1 to 4 until no more generic questions can be asked.

Step 5: Generate domain specific questions. Using the final ROM diagram, organizations should analyze relationships between the objects and generate a set of questions that should be answered at each stage of the ISO standards requirements (Wang and Zeng, 2007).

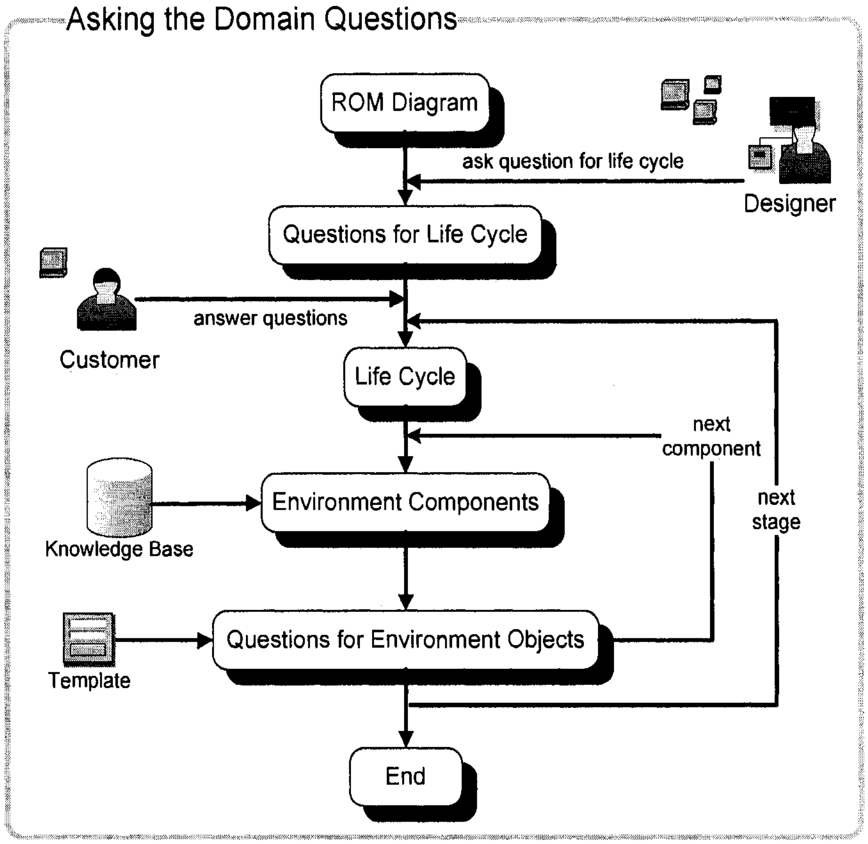


Figure 19 Ask domain-specific questions (Wang and Zeng, 2007)

By using the product life cycle and the requirements classification, a sub-process of asking domain questions is developed (see Figure 19).

The first question related to product life cycle (Wang and Zeng 2007) is asked in order to identify the related stages in which the product is involved. Later on, for each stage, questions are generated in terms of environment components at their requirement level.

At this point, predefined rules given in Table 8 help organizations define the sequence of questions, which can be determined either automatically or manually (Wang and Zeng, 2007).

Table 8: Questions generation rules for Step 5 (Wang and Zeng, 2007)

• Rule3	The first question to ask is "What is the life cycle of the product to be designed?"
• Rule4	Ask questions about the natural, built, and human environments of each stage of the life cycle of the product.
• Rule5	The sequence of questions should be determined by the levels of requirements.
• Rule6	Ask questions in response to the answers obtained from Rules 1 and 2 by applying the rules relating to Step 2.

Step 6: Collect answers to the questions generated in Step 5.

This step is similar to Step 3 (Wang and Zeng, 2007).

Step 7: Repeat Step 1 to 7 until no more domain questions remain to be asked.

In order to collect complete domain dependent product requirements, as well as to analyze the implicit domain dependent product requirements iteratively through steps 1 to 7, one must ensure that the domain dependent product requirements are accurate (Wang and Zeng, 2007).

Step 8: Output the updated ISO standard requirements description.

In Step 5, generate domain specific questions from the original model "Asking the Right Questions to Elicit Product Requirements" (Wang and Zeng, 2007). The reader will note that has been added to Wang and Zeng's original Asking the Right Questions to Elicit Product Requirements model, entitled "Seven events in product life cycle" as shown in Figure 20, one additional 'event': 'Materials' and two additional modifications:

'Sales/Marketing' and 'Warehousing/Transportation' to the events as shown in Figure 21, entitled "Eight events in the product life cycle".

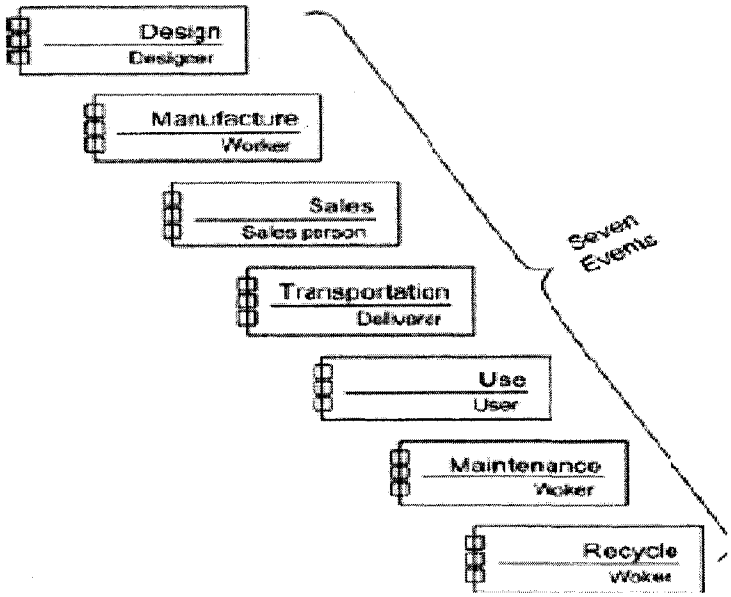


Figure 20: Seven events in product life cycle (Wang and Zeng, 2007)

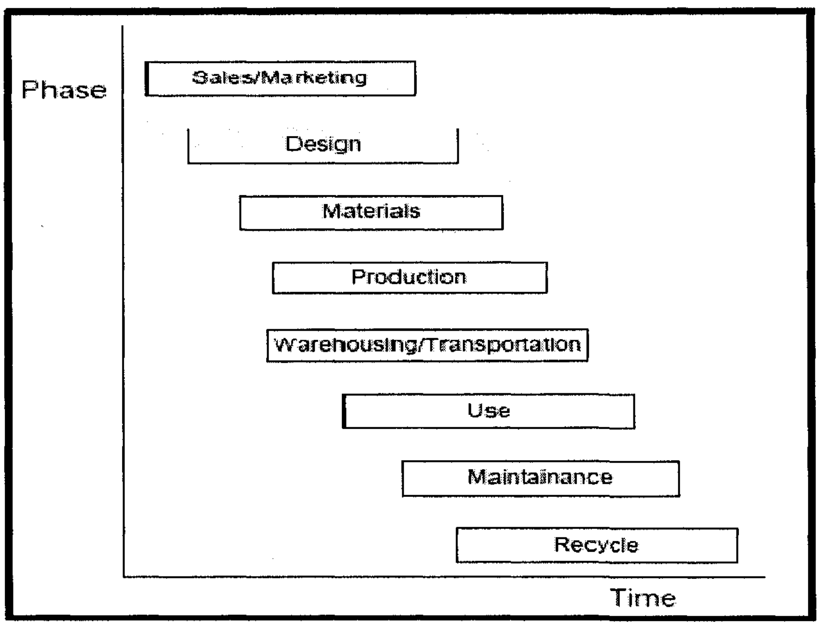


Figure 21: Eight events in product life cycle

Thus augmented, the eight events in the product life cycle, all of which rely on the support of managers and workers, include:

1. **Sales/Marketing.** This combined event refers, firstly, to the process of getting requirements from the customer and transforming these requirements into the company's requirements. Secondly, sales will support the marketing function and create interactions between the organization and its clients (Chen and Zeng, 2006).
2. **Design**. This event includes both the introduction of customer product requirements into the organization as well as the acceptance of a relevant solution, keeping in mind that the organization must collect, analyze and satisfy the product requirements from all the players in the product life cycle (Chen and Zeng, 2006).
3. **Materials.** This event is a major player in the process. Enough raw materials and others must be obtained in order to manufacture a product according to the customer's specifications.
4. **Production.** This event refers to the implementation of the design solution into an actual product (Chen and Zeng, 2006). Organizations define strict lines of execution plans to ensure that the customer's product requirements have been fulfilled.
5. **Warehousing/Transportation.** Warehousing conserves and preserves a client's product according to design requirements. Transportation carries the product to the customer to close the first cycle.
6. **Use**. This event is directly related to the customer, who will buy and use the goods and/or services to fulfill their purposes. Thus, products are designed, developed, and produced in consideration of the specific uses to which these products will typically be put (Chen and Zeng, 2006).

7. **Maintenance.** This event shows that, following delivery, the client's product needs to have maintenance support from the organization. Maintenance can be classified in four different ways: routine maintenance, corrective maintenance, preventive maintenance, and predictive maintenance (Chen and Zeng, 2006). *Routine maintenance* is defined as the regular check that should be made to a product after it is purchased by a customer. *Corrective maintenance* is related to the need to either change a product or replace product parts as a consequence of fatigue or use. *Preventive maintenance* relates to the anticipation and prevention, during production, of possible defects or problems relating to the product. Finally, *predictive maintenance* is based on the product's anticipated lifetime and usually involves periodic maintenance checks in order to prolong the life of the product.
8. **Recycle.** This event occurs either when the product reaches its retirement, or when an essential part of the product no longer functions (Chen and Zeng, 2006).

Figure 22, entitled "Eight Levels of Requirements", was developed by Chen and Zeng (2006). It helps organizations identify the various levels of their product requirements, starting, at the bottom of the triangle, with 'natural laws and rules'. The first four levels (again, starting at the bottom) provide the basic conditions that allow a product to be created and to physically exist in its environment. Thus, every product must be built according to 'natural laws and rules', must obey certain 'social laws, regulations, and other mandatory criteria', must be appropriately constrained by 'technical limitations', and must be produced within the constraints of 'cost, time, and available human resources'.

Developing a product or service solution on the basis of these four lower levels of the pyramid helps ensure an effective outcome (Chen and Zeng 2006).

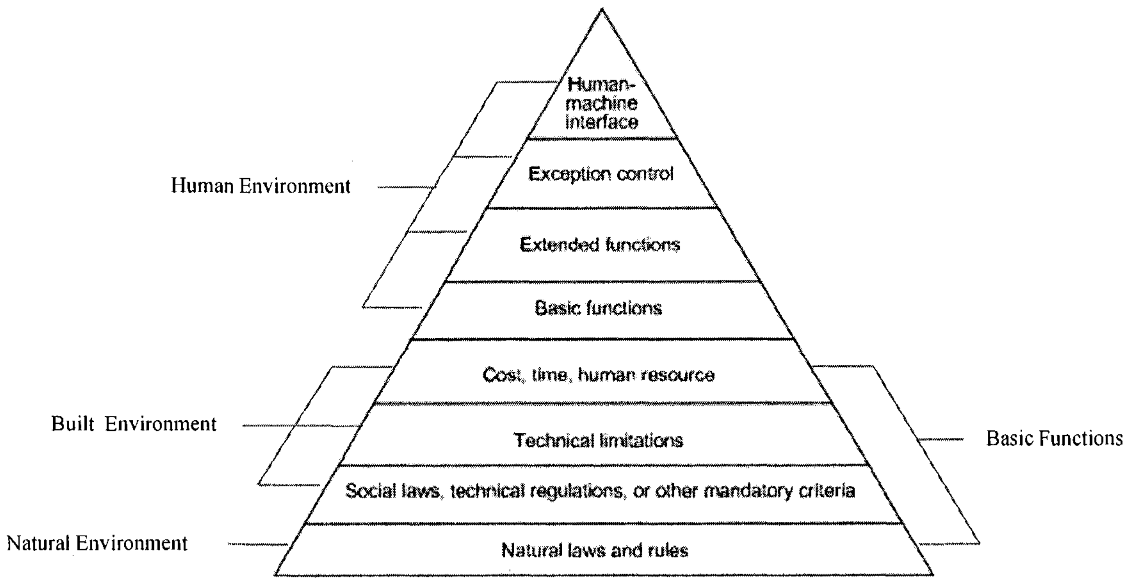


Figure 22: Eight levels of requirements (Chen and Zeng, 2006)

After considering the four lower levels, designers should then ensure that all 'basic functions' (Level 5) have been achieved, before moving on to 'extended functions', 'exception control' and 'human–machine interface' (Chen and Zeng, 2006).

Chen and Zeng (2006) have developed a brief description of each level as indicated below:

1. **Natural Laws and Rules:** All products are parts of nature from which they can never be separated.

2. Social Laws and Technical Regulations: If they are relevant, social laws, technical regulations, or other mandatory criteria should be observed first, when a design solution is being developed.

3. Technical Limitations: Consideration must be given to technical limitations due to the fact that different technical constraints exist in different contexts.

4. Cost, Time, and Human Resources: These considerations should be defined during the whole process of design. All organizations should associate their product development with acceptable cost, a reasonable time schedule, and an appropriate investment of human resources.

5. Basic Functions: These are functions that ensure that products will fulfill their specific purposes.

6. Extended Functions: Some extended functions are added to products so as to help them meet diverse demands made by different users. They enable users to apply the product to uses that extend beyond their basic functions.

7. Exception Control: This level of requirements is important when the reliability of a product is vital for its use.

8. Human–Machine Interface: These requirements introduce high usability products to users. As defined by 'The International Engineering Consortium', human–machine interface (Langheinrich and Kaltschmitt) is where people and technology meet.

Product environment can also be segmented into natural, built, and human environments, in which the eight levels of product requirements given above are related. The first four levels of product requirements come from the human environment. The lowest level comes from the natural environment. The other levels are the result of the built environment (Chen and Zeng, 2006) as shown in Figure 22.

In Figure 17, entitled "Generic inquiry process for requirements elicitation", Step 5 refers to "domain questions". These domain questions should be formulated according to the order that appears in Figure 21, entitled "Eight events in product life cycle," beginning with the Sales/Marketing event and ending with the Recycle event. Each of these 8 event activities must be described in terms of the type of environment in which they are located, whether natural, built, or human. As soon as the domain questions are asked, the whole product life cycle and its environment must be integrated. This integration allows organizations to reduce the risk of missing important information related to the requirements.

Figure 23 shows how the effectiveness of the original question-generation method can be reinforced by the proposed improvements to the implementation of IST as follow:

- The integration, in one diagram, of the product life cycle and the levels of requirements.
- A definition of a new event, Materials, and two additional modifications: 'Sales/Marketing' and 'Warehousing/Transportation', for the benefit of manufacturing organizations.

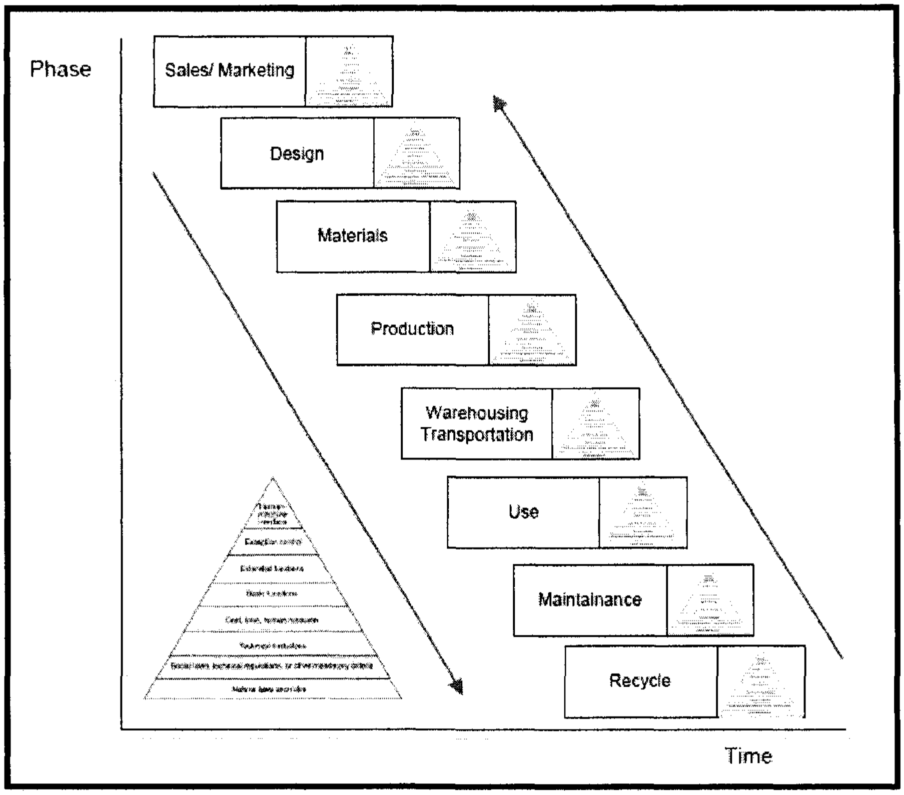


Figure 23: Event of product life cycle and levels of requirements

4.4 Example Using IST with ROM Methodology

The methodologies of ROM, when combined with asking the right questions, help support the proposed generic process. They are used in the presentation of a practical example of the IST requirement. The application of ROM discloses more semantic information behind the text.

In this case, one is likely to follow the generic formalization process provided below, using the standard ISO 22000:2005, a food safety industry IST example.

7.2 Prerequisite programmes (PRPs)

7.2.1 The organization shall establish, implement and maintain PRP(s) to assist in controlling

a) The likelihood of introducing food safety hazard to the product through the work environment,
b) Biological, chemical and physical contamination of the product(s), including cross contamination between products, and
c) Food safety hazard levels in the product and product processing environment.

Step 1: Create an ROM diagram based on a description of the design problem. The ROM diagram appears in Figure 24.

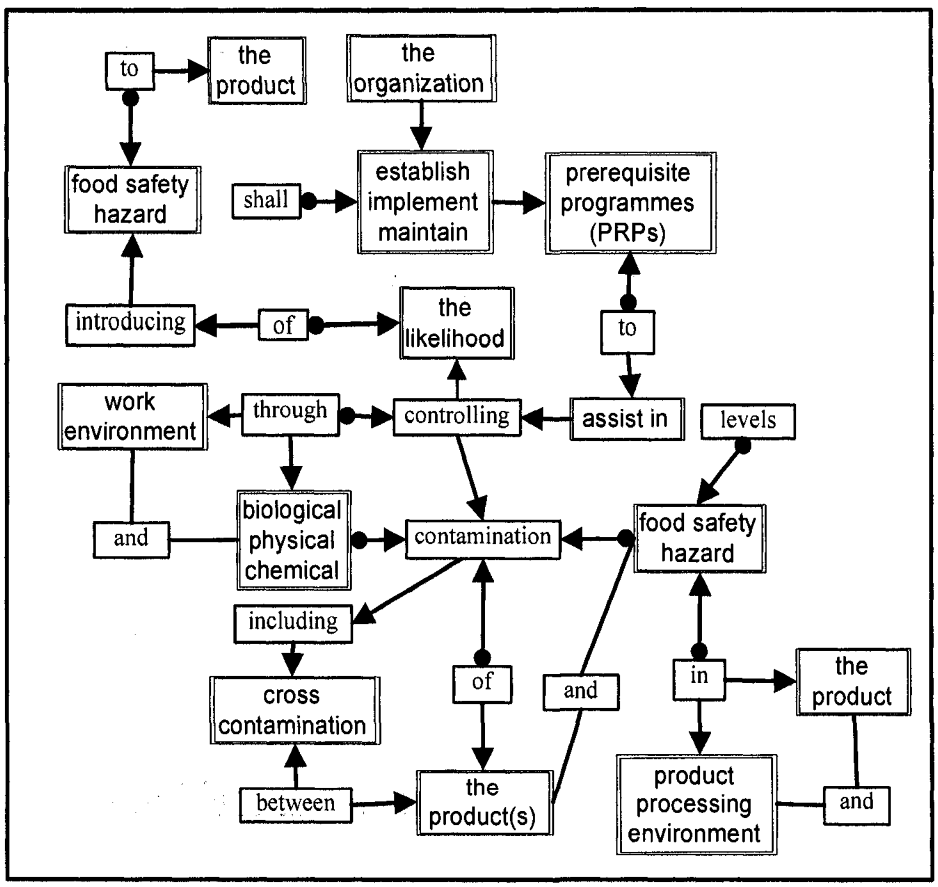


Figure 24: ROM diagram for Step 1

Step 2: Generate Questions based on the ROM diagram.

In this step, organizations generate some primary questions based on a set of predefined rules as described in Table 5. Aspects such as food safety hazard, work environment, cross contamination, and product processing environment should be clarified first, based on Rules 1 and 2.

The list of questions for Step 2 is listed in Table 9

Table 9: Questions for Step 2

• Q1	What are Prerequisite Programmes?
• Q2	What is the Food Safety Hazard?
• Q3	What is work environment?
• Q4	What is cross contamination?
• Q5	What is product processing environment?
• Q6	What type of organization should use the standard?

Step 3: Collect answers for the generated questions.

Based in Table 9, organizations then look into all available information resources; such as dictionaries, the internet, journal literature, etc.

The answers to the questions in Table 9 can be found in Table 10.

Step 4: Repeat steps 1 to 4 to analyze the collected answers in Step 3 until no more questions remain to be asked.

Each answer should go through Steps 1 to 4. The following details show the ROM analysis, answer by answer.

Table 10: Answers for Step 3

• A1	Prerequisite programs are basic conditions and necessary activities to maintain a hygienic environment throughout the food chain suitable for the production (ISO 22000:2005).
• A2	Food Safety Hazard. Condition of food, with the potential to cause an adverse health effect (ISO 22000:2005).
• A3	Work environment. Consists of the employer's premises and other locations where employees are engaged in work-related activities/, or are present as a condition of their employment (http://www.ctdol.state.ct.us/osha/appd95.htm).
• A4	Cross Contamination. The transfer of micro-organisms from one place to another or from one food to another (http://www.foodforum.org.uk/cgi-local/glossary.pl?let=c).
• A5	Processing environment refers to contamination or proliferation of food safety hazard during the product manufacture (ISO 22000:2005).
• A6	Organizations are defined as feed producers and primary producers through food manufacturers, transport and storage operators and subcontractors to retail and food services outlets such as producers of equipment, packaging material, cleaning agents, additives and ingredients (ISO 22000:2005).

A1: Prerequisite programs are basic conditions and activities necessary for the maintenance of a hygienic environment throughout the food chain suitable for the production. The ROM diagram for A1 is shown in Figure 25.

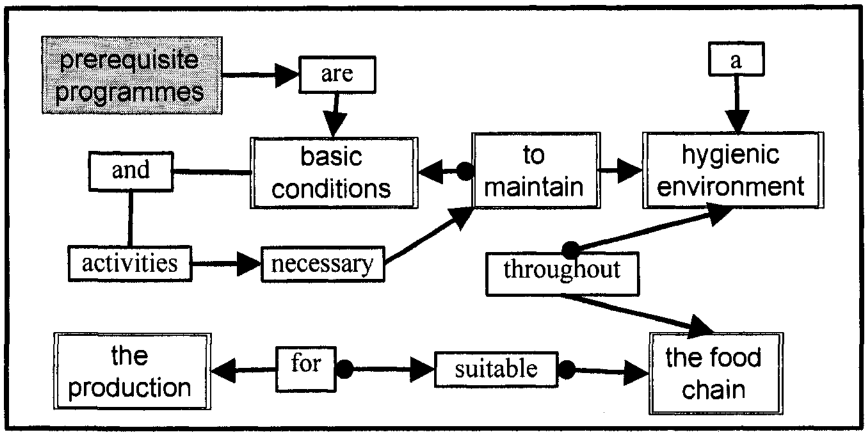


Figure 25: ROM diagram for A1

A2: Food Safety Hazard is the condition of food, where potential causes of an adverse health effect are examined. The ROM diagram for A2 is shown in Figure 26.

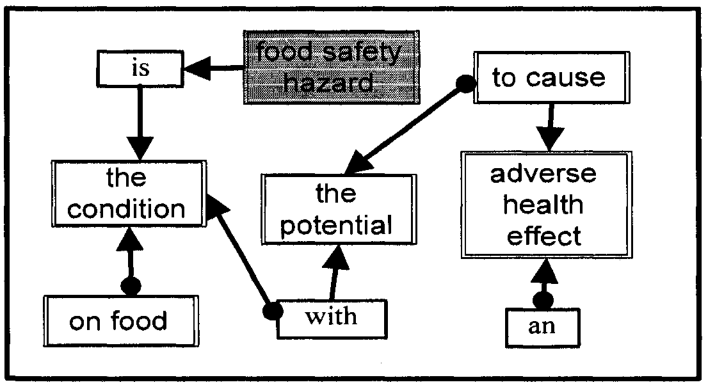


Figure 26: ROM diagram for A2

A3: Work environment. Consists of the employer's premises and other locations where employees are engaged in work-related activities or are present as a condition of their employment. The ROM diagram for A3 is shown in Figure 27.

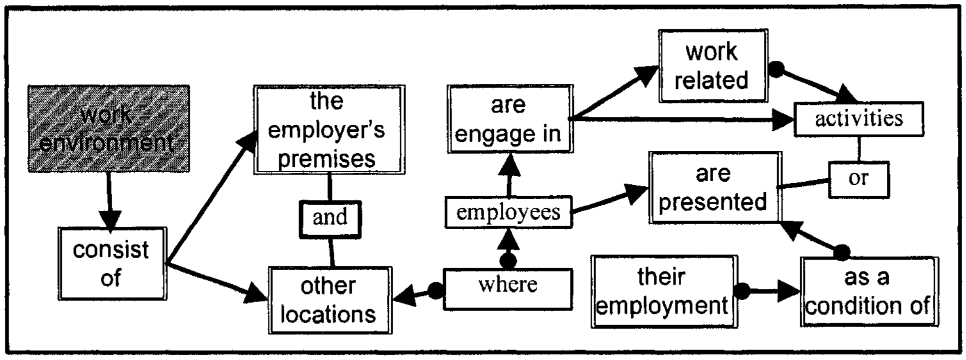


Figure 27: ROM diagram for A3

A4: Cross Contamination is the transfer of micro-organisms from one place to another or from one food to another. The ROM diagram for A4 is shown in Figure 28.

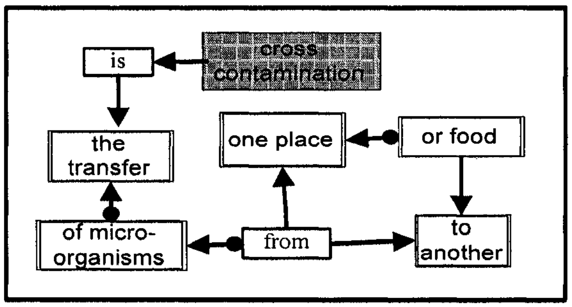


Figure 28: ROM diagram for A4

A5: Processing environment refers to contamination or proliferation of food safety hazard during the product manufacture. The ROM diagram for A5 is shown in Figure 29.

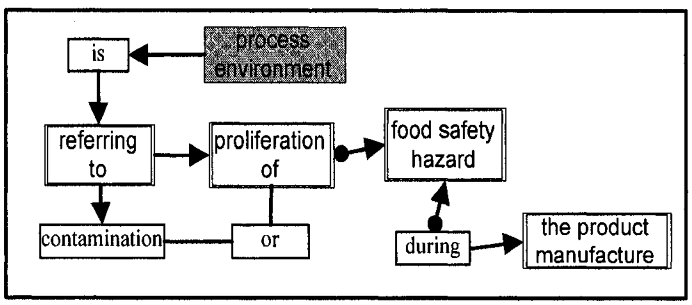


Figure 29: ROM diagram for A5

A6: Organizations are defined as feed producers and primary producers through food manufacturers, transport and storage operators and subcontractors to retail and food services outlets such as producers of equipment, packaging material, cleaning agents, additives and ingredients. The ROM diagram for A6 is shown in Figure 30.

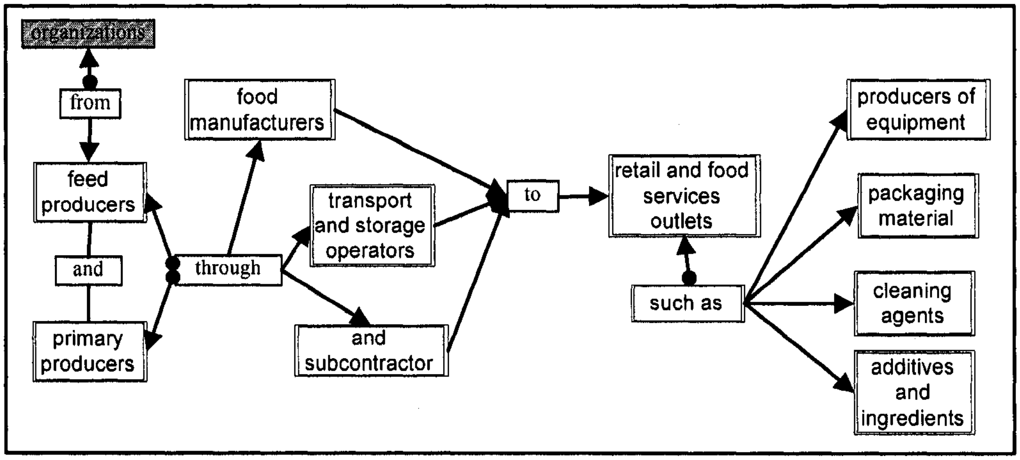


Figure 30: ROM diagram for A6

In this example, Step 1 to Step 4 did not call for additional questions to ask. The explicit design problem description is extended further at the end of the step.

The new ROM diagram is shown in Figure 31, which is merged with the ROM diagrams of Figure 25; 26: 27; 28; 29, and 30 into the original ROM diagram of Figure 24.

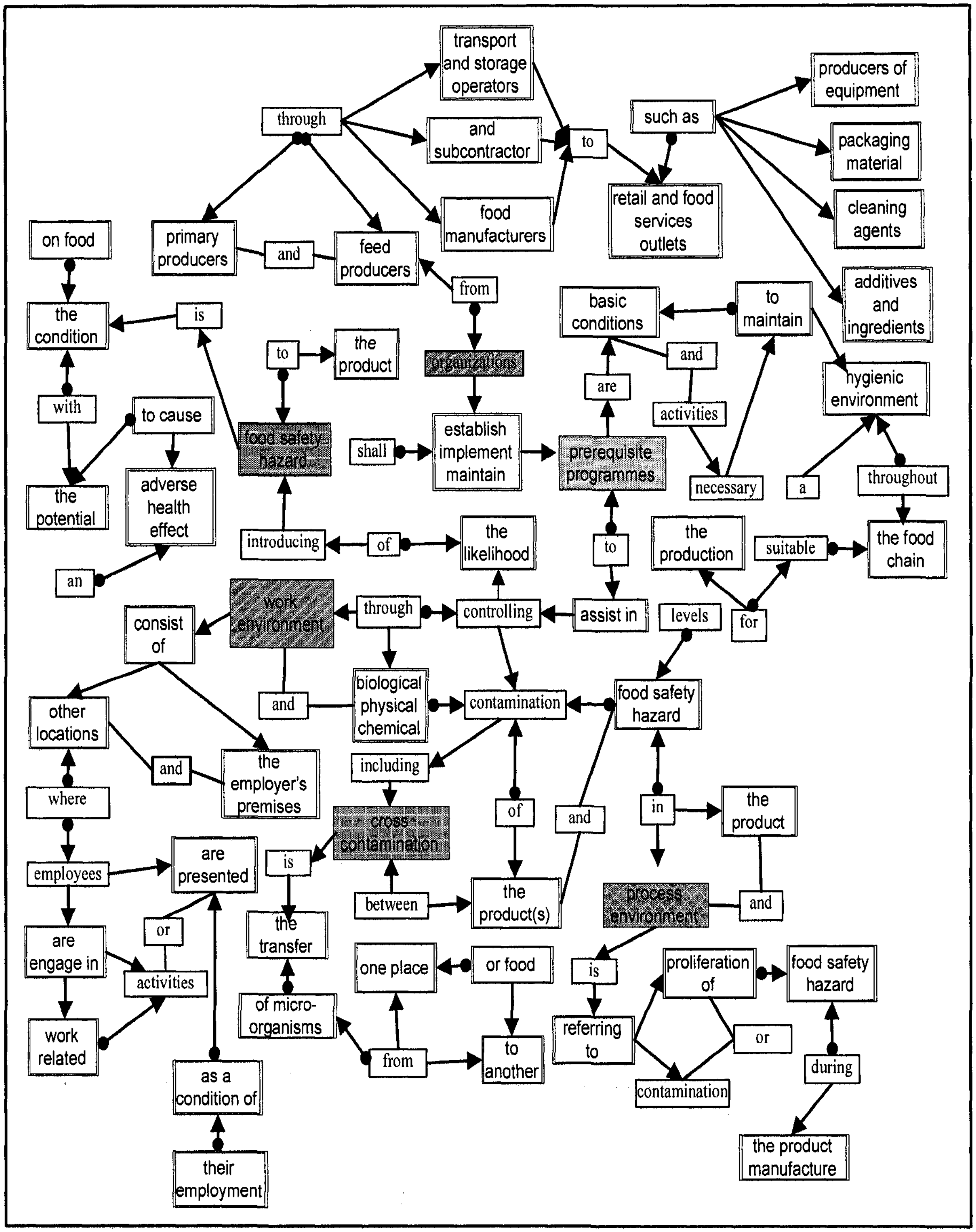


Figure 31: Merged ROM diagrams for Step 4

Step 5: Generate domain specific questions.

In this step, after obtaining answers to the primary questions, questions regarding a specific domain must be asked to continue the process for the elicitation of requirements.

These must follow the predetermined rules that appear in Table 8.

The question, "Q3: what is the life cycle of the tool" is asked first in order to determine the life cycle in which the tool is involved.

The answer to Q3 appears in "A3: The life cycle includes design, production, warehousing/transportation, use and maintenance".

Based on the classification of requirements in terms of the product life cycle of the tool, the questions asked in Step 5 are shown in Table 11.

Table 11: Questions for Step 5

• Q7	What others prerequisite programs should be considered?
• Q8	How will human beings be involved into these prerequisites programs?
• Q9	How to measure prerequisites programs?
• Q10	How to avoid cross contamination during production time?
• Q11	Who is in charge of the implementation process?

Step 6: Collect answers for the questions generated in Step 5.

The corresponding answers are listed in Table 12.

Table 12: Questions for Step 6

• A7	The standards are the codex alimentary; Hazard Analysis and Critical Control Points (HACCP); Good Manufacturing Practices (GMP); ISO 9001:2000.
• A8	To provide for the integration of human beings, they must be included in each step along the implementation process, to ensure their involvement.
• A9	Through periodical quality internal and external audits, organizations are able to support the prerequisite programs.
• A10	To do so, employees must follow defined procedures and work instructions.
• A11	The quality program coordinator should be the Quality Manager.

Step 7: Repeat Step 1 to 7 until no more domain questions can be asked.

The ROM diagram should be analyzed according to each answer through steps 1 to 7 and merged into a unique ROM diagram.

In this case, the final ROM diagram is shown in Figure 31, which is specifically related to the ISO standard implementation issue.

Step 8: Output the updated design problem description.

Based on the ISO standard partial ROM diagram generated in the generic formalization process, it is possible to determine the basic concept and activities by using natural language.

This must be done in order to properly implement the standards into organizations. Descriptions are listed below.

Organizations such as, feed producers, primary producers, food manufactures, retail food services, transport and storage operations, and others belonging to the food chain, should establish, implement and maintain conditions and activities to preserve a hygienic environment using food chain for production.

Preservation of a hygienic environment will help to control conditions on food so that to avoid, through the employer's premise, adverse health effect in the product.

Contamination such as biological, chemical or physical of the products must be avoided, as well as transfer of micro-organisms from one place to another or from one food to another.

Food Safety Hazard levels control the contamination or proliferation of food safety hazard during the product manufacture.

4.5 Summary

Using the Environment-Based Design (EBD) theory, we showed that IST can be implemented with considerable less effort.

This chapter analyzes how companies will be able to more clearly characterize specifications that appear in an IST. To provide a successful IST implementation, organizations can count on the EBD tool to identify which activities must be done first. EBD can give companies the opportunity to define, by using the iterative question-asking approach, accurate action plans to implement as well as to propose precise and complete requirements by eliciting the right questions.

Chapter 5
Implementation of ISO Standards

The International Organization for Standardization (ISO) regulates almost all the norms that companies providing goods and services must follow. This chapter presents information that helps clarify the implementation of IST. Section 5.1 introduces the IST implementation. Section 5.2 offers an approach on how to perform IST implementation by using the EBD theory. Section 5.3 presents a hypothetical case study, in which the implementation of IST is developed, by using requirements classification and formal structure. Section 5.4 defines a new methodology for achieving IST implementation after first identifying the main requirements. Finally, in Section 5.5, a comparison is made between the existing and the proposed methodology.

5.1 Understanding IST Implementation

ISO standards are internationally recognized. They acknowledge and demonstrate a basic level of quality achieved by companies throughout the formalization and documentation of their quality management system (Koc, 2007). However, an IST certificate does not ensure that organizations can always avoid poor quality service or defect-free products. It simply ensures that a basic quality system is in place, and that the organization has the capability of providing its customers with quality products and services (Poksinska et al., 2002).

Quality Specialists, having various levels of knowledge or experience, have been working in companies, seeking the best methodology to use in implementing IST.

However, the lack of a well- defined implementation process has caused many organizations to sustain significant losses of resources.

According to Charles J. Corbett, achieving an ISO certification through ISO standards implementation is by no means "a piece of cake" (Corbett, 2006). Moreover, it is necessary to keep in mind that IST certification is not a standard package that can be implemented the same way in every organization (Singels et al., 2001).

ISO standards are defined as specific rules or guidelines that companies must follow. For that reason, business organizations begin their first approach to quality with the IST itself. Thus, organizations themselves will often formalize IST requirements. However, the standards clauses are often ambiguous and thus hard to understand. This makes it more difficult for companies to meet these standards.

Therefore, given the confusing meanings and complex sentences that appear in many of the IST, both interpreting and implementing them are major challenges. Thus, interpreting IST remains a major roadblock, even during the very first steps of the intended implementation.

Information that is structured and presented at an appropriate level of abstraction (Kamsu-Foguem and Chapurlat, 2006) can help clarify one's understanding of specific IST. Consequently, good conceptual modeling that includes a clear and accurate description of the domain can reduce the risks associated with IST implementation as well as prevent costly reworking that may occur later in the development process (Evermann et al., 2005).

5.2 ISO Standard Implementation by Using EBD

IST can be characterized as a code that, to become useful within the organization and to provide relevant knowledge, must be properly 'translated'. As a codebook, an IST provides all firms with a common language; its proper implementation implies an effective grasp of the underlying code. Completion of the codification depends on the interpretation of the standards within the organization (Benezech et al., 2001). Thus, at the early stages of the development of the implementation process, the lack of understanding of IST requirements may result in an unnecessary reworking of the definition of requirements. This, in turn, causes potential delays in process, runaway costs, and process malfunctions.

In fact, it is often difficult to predict the type of requirements that may arise as a result of the IST implementation process. This means that a flexible structure should be used to manage quality requirements. The most often referred source of quality requirements is the product environment itself (Chen and Zeng, 2006). In the context of IST implementation, it is paramount to classify the players involved in the product life cycle.

EBD theory can be used as a logical tool for understanding IST requirements. The application of EBD theory should occur before any other implementation process begins, for it provides a formal approach that allows the development of design theories following logical steps that are based on mathematical concepts and axioms.

All components in a requirement identification problem can be defined through the product environment. Therefore, the product environment provides a foundation for the classification and management of the IST requirements (Chen and Zeng, 2006).

Using the requirements elicitation method, we propose to carry out an integration of the events product life cycle and levels of requirements (see Figure 32), also, to add a model called 'the Deming cycle' (Gryna et al., 2007). This differs from Zeng's approach insofar as this methodology has included new elements for its development in aspects of quality management. The levels of requirements that are included in the 'Deming cycle' include Plan, Do, Check, and Act (Gryna et al., 2007). Later this merging is assigned to each event in the product life cycle classification (see Figure 32).

By appealing to the Deming cycle methodology, it is possible to understand the specific characteristics that lie behind each level of the requirements. The procedure in the Deming methodology is defined as follows:

1. The Plan step: This represents the tasks that workers should define at first as a way to achieve a state of self control (Gryna et al., 2007).

2. The Do step: This represents the action of doing the activities previously planned. In this phase, employees develop best practices methods, evaluate their effectiveness, and document the standardized process (Gryna et al., 2007).

3. The Check step: This is the evaluation step. A comparison is made between the planned activities, the organized activities, and the implemented activities. This comparison reflects whether the activities were made according to the initial plan.

4. The Act step: This refers to the activities that were planned, executed, and checked. Those that did not fulfill specific requirements in the course of the process must be reviewed, analyzed, and set into new actions. The IST implementation process is completed when the analyses of all of the elements are integrated.

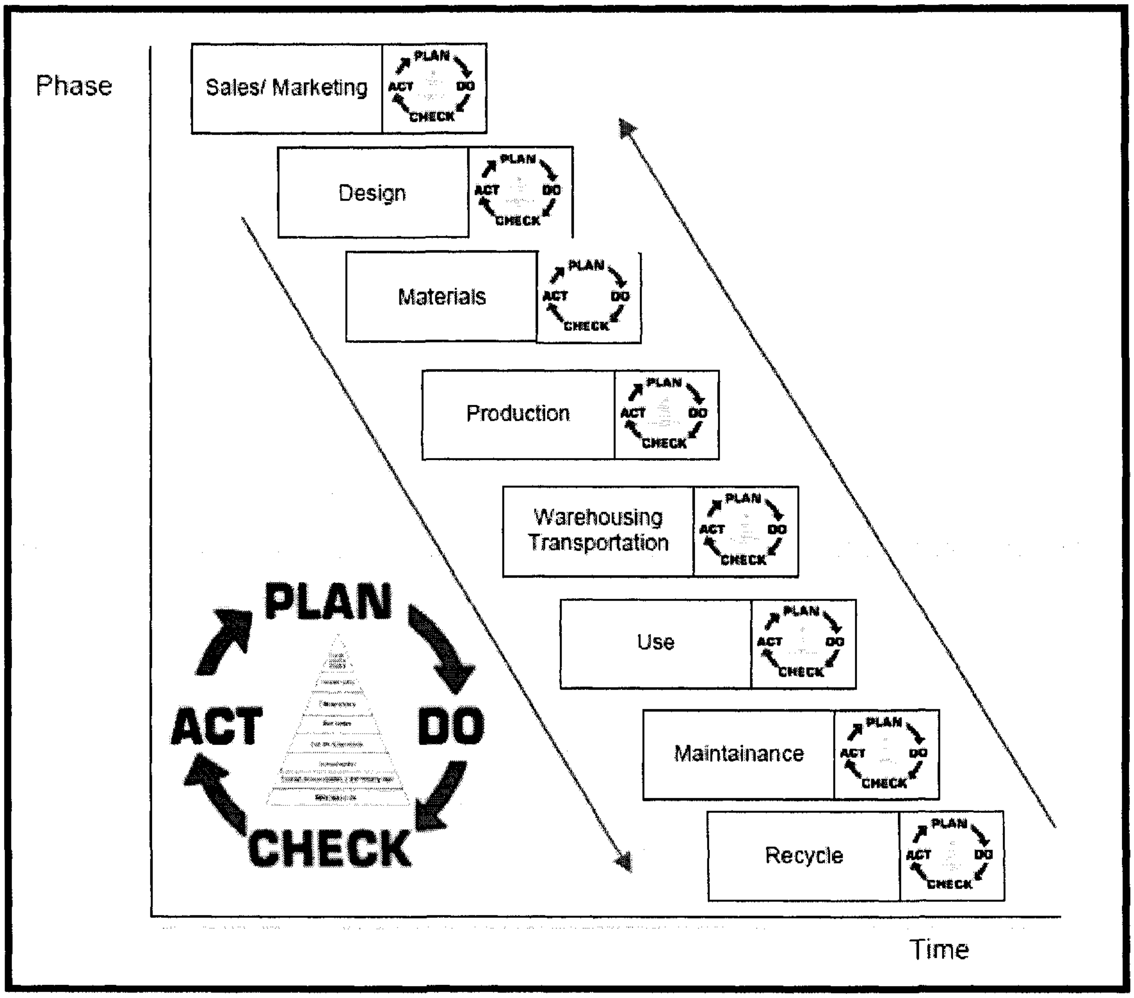


Figure 32: Implementation of ISO standards using EBD

5.3 Case Study

A specific clause of the ISO 22000:2005 provides an example that illustrates the concepts presented in the present study. The task that is related to this clause is to implement prerequisite programs in the supply food chain.

The problem is described as follows:

> *Organizations such as, feed producers, primary producers, food manufactures, retail food services, transport and storage operations, and others belonging to the food chain, should establish, implement and maintain conditions and activities to preserve a hygienic environment using food chain for production.*
>
> *Preservation of a hygienic environment will help to control conditions on food so that to avoid, through the employer's premise, adverse health effect in the product.*
> *Contamination such as biological, chemical or physical of the products must be avoided, as well as transfer of micro-organisms from one place to another or from one food to another.*
>
> *Food Safety Hazard levels control the contamination or proliferation of food safety hazard during the product manufacture.*

5.3.1 Requirements Classification

The EBD model will now be applied to the above ISO 22000:2005 clause. This clause contains several sentences which I have classified as follows:

1. *Organizations [include] ... feed producers, primary producers, food manufactures, retail food services, transport and storage operations, and others belonging to the food chain.*

This sentence belongs to the **Use event** (see Figure 21). It describes the basic function of the organization (see Figure 22, Level 5, "**Basic function**").

2. *Organizations should establish, implement and maintain conditions and activities to preserve a hygienic environment using food chain for production.*

This sentence belongs to the **Production event** (see Figure 21). It describes which main activities are necessary when fulfilling production goals (see Figure 22, Level 1, **"Natural laws and rules"**).

3. *Preservation of a hygienic environment will help to control conditions on food so that to avoid, through the employer's premise, adverse health effect in the product.*

This sentence belongs to the **Production event** (see Figure 21). Specific activities must be carried out before, during, and after a production run is defined. Workers' rules must be defined in order to reduce risks (see Figure 22, Level 2, "**Social laws, technical regulations or other mandatory criteria**").

4. *Contamination such as biological, chemical or physical of the products must be avoided.*

This sentence belongs to the **Design event** (see Figure 21). The definition of clear and precise procedures reduces the risk of any type of contamination (see Figure 22, Level 1, "**Natural laws and rules**").

5. *Transfer of micro-organisms from one place to another or from one food to another [must be avoided]*

This sentence belongs to **Production event** (see Figure 21). Here there is concern owing to the fact that a possible contamination could arise at any time, at any place, and by anyone (see Figure 22, Level 1, "**Natural laws and rules**").

6. *Food Safety Hazard levels control the contamination or proliferation of food safety hazard during the product manufacture.*

This sentence belongs to **Production event** (see Figure 21). Developing work instruction as part of quality training must be settled in workstations in order to reduce the possibility of contamination risk (see Figure 22, Level 1, "**Natural laws and rules**").

5.3.2 Formal Structure

Table 13 reveals the specific events that are involved in the process of implementing all aspects of the clause. This table helps us understand what activities can next be done in the implementation process. Table 14 explains what management activities must be carried out. Organizations can use this table to prioritize theirs activities.

In summary, each part of the clause is located below in relation to the particular event to which it belongs:

Table 13: Location of the sentences that comprise the sample clause according to the particular event to which they belong

The Use event

- Organizations such as, feed producers, primary producers, food manufactures, retail food services, transport and storage operations, and others belong to the food chain.

The Production event

- Organizations should establish, implement, and maintain conditions and activities to preserve a hygienic environment using food chain production.
- Preservation of a hygienic environment helps control the conditions of food so as to avoid, on the employer's premises, adverse health effects in the product.
- The transfer of micro-organisms from one place to another or from one food to another must be avoided.
- Food Safety Hazard levels in the product help to quantify the contamination or proliferation of food safety hazards during the product manufacture.

The Design event

- Contaminations such as biological, chemical or physical of products must be avoided.

Table 14: Management activities that must be carried out

Basic functions (Figure 22, Level 5)

- Organizations such as, feed producers, primary producers, food manufactures, retail food services, transport and storage operations, and others belong to the food chain.

Natural laws and rules (Figure 22, Level 1)

- Organizations should establish, implement and maintain conditions and activities to preserve a hygienic environment using food chain production.
- Contamination of the products such as biological, chemical or physical must be avoided.
- The transfer of micro-organisms from one place to another or from one food to another must be avoided.
- Food Safety Hazard levels in the product and the contamination or proliferation of food safety hazards during the product manufacture must be avoided.

Social laws, technical regulations or other mandatory criteria (Figure 22, Level 2)

- Preservation of a hygienic environment helps to control the condition of food so as to avoid, on the employer's premises, adverse health effects in the product.

5.4 How to Do ISO Standard Implementation

Achieving an IST certification is not an easy task and, for that reason, organizations typically need to make several important changes in order to acquire this certification. Singles, Ruel et al. have characterized the external and internal benefits that result from acquiring ISO certification. External benefits can include competitive advantages, an increase in sales and market share (including the possibility of entering new markets), maintaining customer relationships along with finding new customers and increasing customer satisfaction, increasing company reliability, and the enhancing company reputation (Singels et al., 2001).

Some of the internal benefits of achieving IST certification include reductions in operating costs, the elimination of excessive wastes, the development of employees' skills, along with an increase in their motivation, clearer definitions of procedures, and the fulfillment of requirements for producing quality products and services.

Organizations should create clear and precise administrative procedures and working instructions that are suitable to an implementation of IST. According to Singels, Ruel et al., procedures developed inside organizations should focus on "increasing productivity, improvement in efficiency, reduction in cost and waste, better management control, clearly defined organizational task structure responsibilities, improved co-ordination structure, support in decision making and increase in personal motivation" (Singels et al., 2001). To understand how organizations can best implement an IST, a Quality Implementation Practical Flow chart (QIPF) was developed. It reveals what to do at each step of this process (see Figure 33). This new model integrates the major concepts that have been presented in the preceding pages.

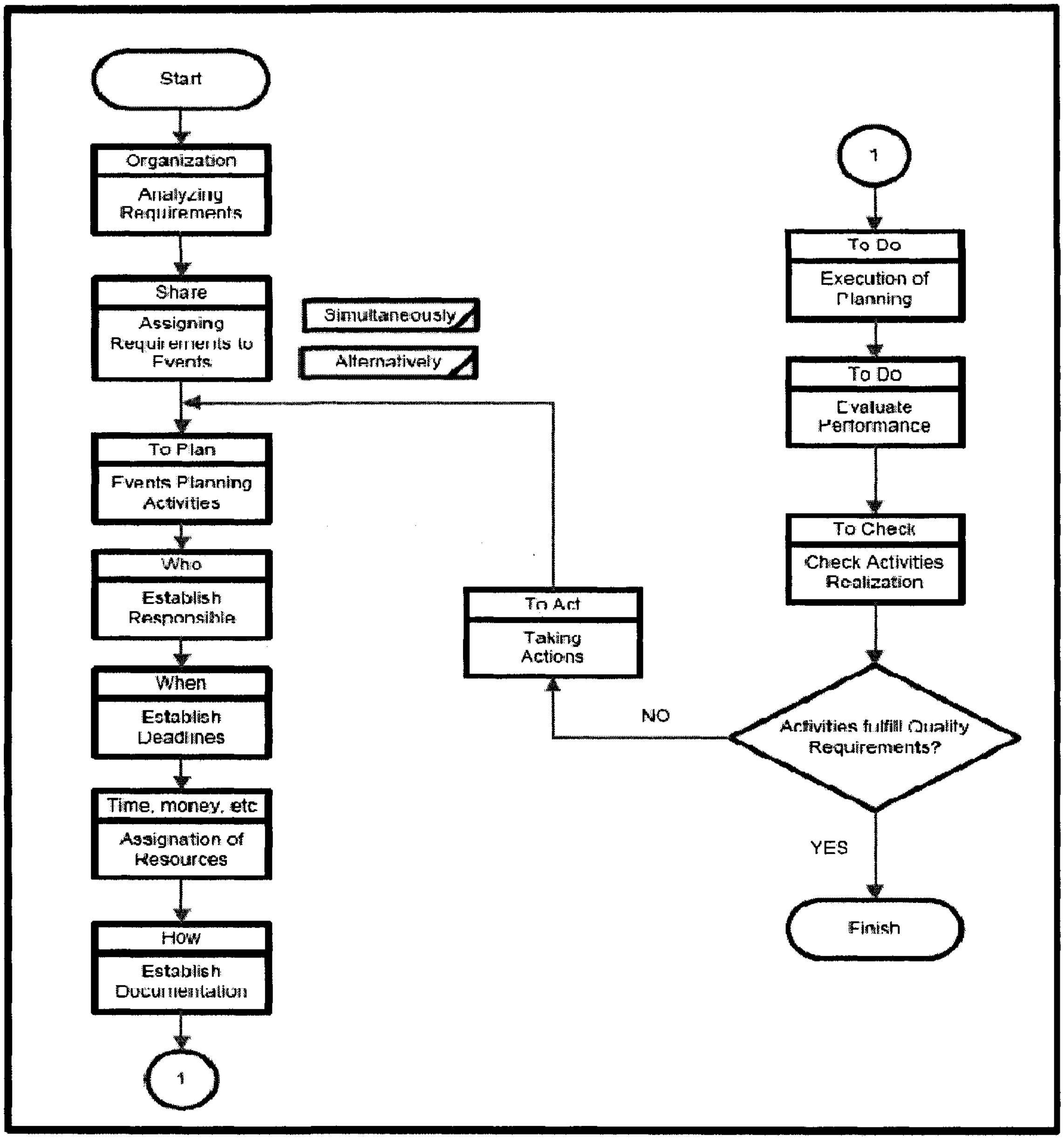


Figure 33: Quality Implementation Practical Flowchart (QIPF)

This flowchart uses the Deming cycle as the basis of a new methodology for implementing IST in goods and services organizations.

The model contains the following steps:

Step 1 Analyzing Requirements

Referring to Table 13, a detailed analysis of the activities described must be carried out. This analysis should be conducted by someone who has a firm knowledge of and experience in the organization.

Step 2 Assigning requirements to each event

After the requirements specified in the sentences of each clause are analyzed, they will be assigned to one or another event. Requirements can be assigned to different events, either simultaneously or alternatively, owing to their interrelationships.

Step 3 Events planning activities

This step is the key point at which the activities of each event take place. Here, each event shares its activities with the other events. As a result, a complete list of activities is achieved. Based on the Deming cycle, Step 3 defines Deming's first step, "Plan".

Step 4 Establish Responsibility

At this point it is necessary to establish the individuals who will be responsible for carrying out specific tasks. This step should be done by Quality Managers, who are able to determine who will be able to fulfill the tasks most effectively.

Step 5 Establish Deadlines

This step should be handled only by the Quality Manager or by others holding key management positions. According to specific constraints deadlines, they should establish the time line for each activity to be carried out in the organization.

Step 6 Assignations of Resources

This step occupies a central role. Organizations should be able to assign resources depending on the number of people assigned to the various tasks. One should also consider adding resources and activities as needed during the implementation process.

Step 7 Establish documentation

All activities that could be included within the implementation process should be defined, analyzed, and documented with respect to specific procedures, instructions, and records. This would put in place a completely new set of "to do" activities. Each worker would then be able to access specific information regarding his/her duties activities.

Step 8 Execution of Planning

Once the planning process is set, the execution phase can commence. Organizations should start working on the implementation process by applying Deming's second principle: "Do".

Step 9 Evaluate Performance

Performance indicators can be composed, and, in specific cases, sub-indicators (Singels et al., 2001) might be developed. Indicators and sub-indicators should be checked, analyzed, and evaluated on a regular basis.

The main activities that can be evaluated in organizations include the following: the production process, company results, customer satisfaction, personnel motivation, and investment of means (Singels et al., 2001). These five indicators are elaborated in the following section. However, once ISO certification has been achieved, other indicators may emerge that can also measure organizational performance (Singels et al., 2001).

1. The production process indicator refers to improvement over time, an increase in technical flexibility, an improvement in the co-ordination of activities, an improvement in product specifications, an increase in internal and external delivery performance, and an improvement in efficiency.
2. Company results relate to cost savings, sales increase, increase in market share, and an increase in the net margin profit.
3. Customer satisfaction is measured according to improvements in the company's interactions with its buyers or customers, as well as in a reduction in the number of complaints.
4. Personal motivation relates to an improvement in personnel qualifications, an increase in their involvement and motivation, and a general increase in multi-skilling among the employees.

5. Investment in means refers to an increase in the activities that an organization should carry out in order to gain and hold ISO certification.

Step 10 Check Activities Realization

One of the most important activities during the implementation process is to check whether the planned activities correspond to the activities achieved. Organizations should review whether and to what extent the designated activities, those assigned responsibility to carry them out, the proposed deadlines, and the allocated resources have all been fulfilled. This step should be scheduled on a regular basis. The Step 10 belongs to the third part of Deming's cycle: "Check", which is one of the key factors in the quality process.

Step 11 Taking Action

The final step in Deming's cycle is "Act". Organizations should define and plan action as needed. To establish a complete setup for implementing ISO standards a feedback loop pertaining to each of the processes above should be implemented.

A mathematical model is presented to obtain a better understanding of the Quality Implementation Practical Flowchart (QIPF). This model shows that the system initially works until baseline quality and its revision go equal to zero.

In this case, resources are not considered since they are considered a variable in the formulation.

The mathematical model of this process is as follows:

Baseline

$$Q_s + R_{(m,t)}, \quad (6)$$

Performance

$$Q_a + R_a \quad (7)$$

New Baseline

$$(Q_s - Q_a) + (R - R_a) \quad (8)$$

This new baseline work until

$$(Q_s - Q_a) = 0 \quad (9)$$

where

Q_S = Quality implementation program (QIPF)

Q_a = Revision of the (QIPF)

R = Resources planned at the baseline

R_a = Resources used by the QIPF

m= money

t= time

The tools required to manage specific functions, such as managing quality, managing cost, or managing time, should have specific features. However, according to Turner, three major premises should be taken into account: first, define the objectives; second, define the means of obtaining the objectives; and third, define the means of monitoring progress (Turner, 2006). To manage a specific function, Turner defines the following steps:

- Planning what has to be done
- Organizing, by deciding who is responsible for what
- Implementing, by getting people to take on responsibility
- Controlling progress as the work is done

5.5 Comparison with Existing Methodologies

Our findings regarding the methodologies used by certain companies to implement IST have been compared against the use of EBD theory. Following are the results of this comparison:

Approaches to the implementation of IST on the basis of human factors alone are liable to fail, owing to the fact that people have to be undergoing training all the time. Moreover, whenever a change of position takes place, such training may have been of little avail. Even though the human factor is the most important part in the ISO implementation tactic, its requirement of continual training tends to cause fatigue. Nonetheless, specific training must still be given to employees as a way of maintaining their knowledge and performance throughout the ISO implementation process, as well as a way of maintaining their certification. Thus quality training is useful in producing high levels of process quality management efforts (Ahire and Dreyfus, 2000), which will influence the impact of the IST implementation on the individual and collective beliefs (Benezech et al., 2001).

A business process approach is the most common way for organizations to achieve ISO certification. After an IST program has been implemented, a lack of appreciation of its importance across departments and an unwillingness to change the existing system might appear (Erel and Ghosh, 1997). One could well argue that many managers consider the achievement of IST certification as an end in itself, rather than a means to an end (Terziovski et al., 1997; Mahadevappa and Kotreshwar, 2004).

In addition, the continual removal and changing of process makes it difficult to preserve the integrity of a function at all times. Business processes are affected by having multiple updates during and after the IST implementation. Thus, difficulties to establish operative and supportive process and documentation in organizations and management could occur due to the fact that processes are been updated every time.

The contribution of the present thesis has been to define with precision the requirements that underlie the clauses of each IST, as well as to demonstrate that it is possible to achieve a clearer identification of requirements by specifying the activities that surround each clause. Applying this framework to any set of IST can be achieved in future research.

5.6 Summary

Precise identification of IST requirements makes it possible to define, more accurately, the activities that the organization must carry out. This can help organizations reduce misunderstandings during the quality requirements analysis, as well as give them the opportunity to be more effective in defining the activities and in thereby reducing the implementation time.

Implementation of IST requires modifications that are made primarily by workers. Having defined which types of IST should be applied, it is mandatory to identify and define the specific models and methodologies that are available (Holdsworth, 2003).

Based on EBD theory, a complete identification of those requirements can be carried out, thereby reducing actions and delays before, during and after the IST implementation. By using the Quality Implementation Practical Flowchart (QIPF), any organization is able to implement IST. This model contains components that have been successful in implementing ISO 9001:2000.

Chapter 6
Conclusions and Future Work

6.1 Conclusions

The objective of the present thesis is to improve an understanding of ISO standard requirements before their implementation in various organizations. Using description, linguistic analysis, and the ROM as a formal graphic tool, it is now possible to represent, graphically, and in an optimal manner, ISO standards requirements. The Environment Based Design (EBD) theory in conjunction with the Quality Implementation Practical Flowchart (QIPF) is used to define a new alternative to ISO standard implementation.

ISO standards are based on documented quality requirements, which focus on the company and on customer expectations and needs. The present thesis shows how to perform ISO standards implementation through the use of two models: EBD and QIPF, showing, first, that EBD theory is a tool for processing many of the requirements established in ISO standards requirements and, second, that QIPF can be used as a model for implementing ISO standards.

The present methodology seeks the reduction of misunderstanding or misinterpretation of ISO standards and defines how companies can best maximize valuable resources, such as time and money. Thus, two factors make a special contribution: first, gaining a better understanding of ISO standards is a major achievement; second, analyzing the different environments of each ISO standard clause yields important knowledge that is essential when starting the implementation process.

6.2 Future Work

Our future work will focus on finding an organization that is willing to engage in a practical exercise in which the EBD and QIPF models are applied. Results of such an application will be reported and compared with the results obtained using other methodologies.

Publications

Gonzalez, Alex, Zeng, Y. "Effective Implementation of ISO 22000 through formalization by using Recursive Object Modeling language". Paper presented at the 17^{th} International Conference on Flexible Automation and Intelligent Manufacturing, Philadelphia 2007.

Gonzalez, Alex, Zeng, Y. "Implementation of ISO standards through formalization into requirements for Process Management". Montreal, Canada 2008.

References

Aggelogiannopoulos, D., E. H. Drosinos and P. Athanasopoulos (2007). "Implementation of a quality management system (QMS) according to the ISO 9000 family in a Greek small-sized winery: A case study." Food Control 18(9): 1077-1085.

Ahire, S. L. and P. Dreyfus (2000). "The impact of design management and process management on quality: an empirical investigation." Journal of Operations Management 18: 549-575.

Beer, M. (2003). "Why Total Quality Management Programs Do Not Persist: The Role of Management Quality and Implications for Leading a TQM Transformation." Decision Sciences 34: 623-642.

Benezech, D., G. Lambert, B. Lanoux, C. Lerch and J. Loos-Baroin (2001). "Completion of knowledge codification: an illustration through the ISO 9000 standards implementation process." Research Policy 30(9): 1395-1407.

Benner, M. and M. L. Tushman (2003). "Exploitation, Exploration and Process Management: The Productivity Dilemma Revisted." Academy of Management Review 28: 238-256.

Benner, M. J. and M. Tushman (2002). "Process Management, Technological Innovation, and Organizational Adaptation."

Biazzo, S. and G. Bernardi (2003). "Process management practices and quality systems standards: Risks and opportunities of the new ISO 9001 certification." Business Process Management Journal 9: 149-169.

Carlsson, M. and D. Carlsson (1996). "Experiences of implementing ISO 9000 in Swedish industry." International Journal of Quality & Reliability Management 13: 36-47.

Casadesus, M., G. Gimenez and I. Heras (2001). "Benefits of ISO 9000 implementation in Spanish industry." European Business Review 13: 327-336.

Chen, Z., S. Yao and Y. Zeng (2005). "Formalization of Product Requirements: From Natural Language Descriptions to Formal Specifications." International Journal of Manufacturing research 2(3): 362-387.

Chen, Z. Y. and Y. Zeng (2006). "Classification of Product Requirements Based on Product Environment." Concurrent Engineering 14(3): 219-230.

Corbett, C. J. (2006). "Global Diffusion of ISO 9000 Certification Through Supply Chains " Manufacturing & Service Operations Management 8(4): 330-350.

Czuchry, A. J., C. Hyder, M. Yasin and D. Mixon (1997). "A systematic approach to improving quality: a framework and a field study." International Journal of Quality & Reliability Management 14: 876-898.

Delmas, M. A. (2000). Barriers and incentives to the adoption of ISO 14001 by firms in the United States. Duke Environmental Law & Policy Forum. XI: 1.

Dusharme, D. (2004). ISO 9001 Survey. Quality Digest: 24-30.

Elzinga, D. J., T. Horak, L. Chung-Yee and C. A. B. C. Bruner (1995). "Business process management: survey and methodology." Engineering Management, IEEE Transactions on 42(2): 119-128.

Erel, E. and J. B. Ghosh (1997). "ISO 9000 implementation in Turkish industry." International Journal of Operations & Production Management 17: 1233-1246.

Evermann, J., J. Evermann and Y. Wand (2005). "Toward formalizing domain modeling semantics in language syntax
Toward formalizing domain modeling semantics in language syntax." Software Engineering, IEEE Transactions on 31(1): 21-37.

Frost, R. (2006). How to implement a food safety management system. ISO Management systems. 1: 24-25.

Gingele, J., S. J. Childe and M. E. Miles (2003). "Incorporating links to ISO 9001 into manufacturing process models using IDEF9000." International Journal of Production Research 41: 3091-3118.

Gotzamani, K. D. (2005). "The implications of the new ISO 9000:2000 standards for certified organizations: A review of anticipated benefits and implementation pitfalls." International Journal of Productivity and Performance Management 54: 645-657.

Gryna, F. M., R. C. H. Chua and J. A. Defeo (2007). Juran's Quality Planning & Analysis for Enterprose Quality.

Hiyassat, M. A. S. (2000). "Applying the ISO standards to a construction company: a case study." International Journal of Project Management 18(4): 275-280.

Holdsworth, R. (2003). "Practical applications approach to design, development and implementation of an integrated management system." Journal of Hazardous Materials 104: 193-205.

ISO22000 (2005). ISO 22000 Food safety management systems- Requirements for any organization in the food chain, International Organization for Standarization.

ISO (2005). Food safety management systems Requirements for any organization in the food chain-ISO 22000:2005

ISO. (2007). "ISO in figures for the year 2006." 2007-01.

ISO, S. C. (2006). ISO in brief International Standards for a sustainable world.

Kamsu-Foguem, B. and V. Chapurlat (2006). "Requirements modelling and formal analysis using graph operations." International Journal of Production Research 44(17): 3451-3470.

Koc, T. (2007). "The impact of ISO 9000 quality management systems on manufacturing." Journal of Materials Processing Technology 186(1-3): 207-213.

Langheinrich, C. and M. Kaltschmitt (2006). "Implementation and application of Quality Assurance systems." Biomass and Bioenergy 30(11): 915-922.

Magd, H., N. Kadasah and A. Curry (2003). "ISO 9000 implementation: a study of manufacturing companies in Saudi Arabia." Managerial Auditing Journal 18: 313-322.

Mahadevappa, B. and G. Kotreshwar (2004). "Quality Management Practices in Indian ISO 9000 Certified Companies: an Empirical Evaluation." Total Quality Management & Business Excellence 15(3): 295 - 305.

Mo, J. P. T. and A. M. S. Chan (1997). "Strategy for the successful implementation of ISO 9000 in small and medium manufacturers." The TQM Magazine 9: 135-145.

Najmi, M. and D. F. Kehoe (2001). "The role of performance measurement systems in promoting quality development beyond ISO 9000." International Journal of Operations & Production Management 21: 159-172.

Poksinska, B., J. J. Dahlgaard and M. Antoni (2002). "The state of ISO 9000 certification: a study of Swedish organizations." The TQM Magazine 14(5): 297-306.

Singels, J., G. Ruel and H. Van de Water (2001). "ISO 9000 series - Certification and performance." International Journal of Quality and Reliability Management 18: 62-75.

Singh, P. J., M. Feng and A. Smith (2006). "ISO 9000 series of standards: comparison of manufacturing and service organisations." International Journal of Quality & Reliability Management 23: 122-142.

Tan, L. P. and G. Lim Teck Sia (2001). "ISO 9000: The answer for total quality management implementation? The Malaysian case." Total Quality Management 12: 223-229.

Terziovski, M., D. Samson and D. Dow (1997). "The business value of quality management systems certification Evidence from Australia and New Zealand." Journal of Operations Management 15: 1-18.

Turner, J. R. (2006). "Towards a theory of project management: The nature of the functions of project management." International Journal of Project Management 24(4): 277-279.

Wang, M. and Y. Zeng (2007). "Asking the right questions to elicit product requirements." (Proceedings of the 17th International Conference on Flexible Automation and Intelligent manufacturing, Philadelphia, USA.): 250-257.

Wilkinson, G. and B. G. Dale (2002). "An examination of the ISO 9001:2000 standard and its influence on the integration of management systems." Production Planning and Control 13: 284-297.

Yahya, S. and W. K. Goh (2001). "The implementation of an ISO 9000 quality system." International Journal of Quality & Reliability Management 18: 941-966.

Yoo, C., J. Yoon, B. Lee, C. Lee, J. Lee, S. Hyun and C. Wu (2006). "A unified model for the implementation of both ISO 9001:2000 and CMMI by ISO-certified organizations." Journal of Systems and Software 79(7): 954-961.

Zairi, M. (1997). "Business process management: a boundaryless approach to modern competitiveness." Business Process Management Journal 3: 64-80.

Zeng, Y. (2002). "Axiomatic theory of design modeling." Transaction of SDPS: Journal of Integrated Design and Process Science 6(3): 1-28.

Zeng, Y. (2004a). Environment-based design: process model. Montreal, Concordia Institute for Information Systems Engineering, Concordia University: 40.

Zeng, Y. (2004b). "Environment-based formulation of design problem." Transaction of SDPS: Journal of Integrated Design and Process Science 8(4): 45-63.

Zeng, Y. (2007). "Recursive Object Model (ROM) - Modeling of Linguistic Information in Engineering Design."

Zeng, Y. and G. D. Cheng (1991). "On the logic of design." Design Studies 12(3): 137-141.

Zeng, Y., B. Q. Yan, B. Chen and S. J. Yao (2004). A Theoretical and Experimental Study on Design Creativity. The Inaugural CDEN Design Conference, Montreal, Canada.