TECHNICAL RESEARCH REPORT

Development of Variant Design in ISO 9000 Certification

by M. Woo and G.M. Zhang

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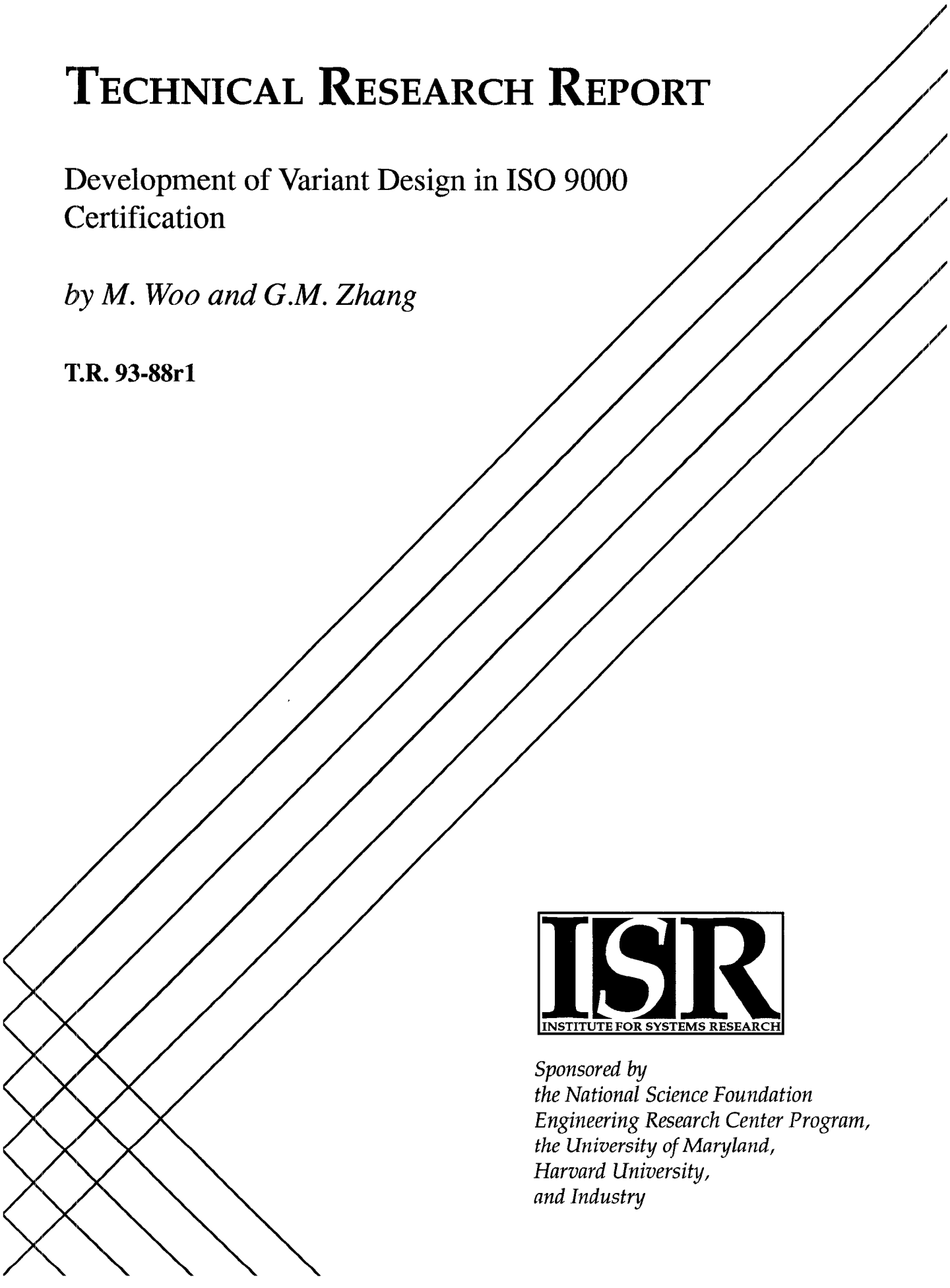

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Development of Variant Designs in ISO 9000 Certification

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ABSTRACT

This paper presents the research results from developing a computer database system using a variant design approach to assist in the preparation of quality manuals. The basic principle is "the most common one of design assignments modifies or uses an existing design to make a 'new' component." Such an information flow mainly relies on a database, which stores all the information about ISO 9000 certification requested by a desired company. Integration of system architecture and communication protocol allows to accommodate different types of business (electronics, mechanical, etc.). The developed information system o illustrates the process of generating quality manuals through an intelligent user-interface and to demonstrate a new and unique business strategy to enhance quality improvement and management.

INTRODUCTION

Spurred by the global competitive environment, many efforts have been devoted to developing effective quality systems. Most of them, however, do not last long due to poor documentation of the quality procedures. Lack of systematic planning by management, the time-consuming nature of creating and updating documents, and improper implementation of quality standards are all detrimental to the establishment of the quality system. A quality manual, serving as the core of the quality system, is a collection of documented procedures to assure that quality standards in design, manufacturing, and service are fully implemented in a company.

Quality is considered to be vital in improving productivity and is a key to economic survival in a competitive environment. ISO 9000 is a standard of quality management. By establishing a set of generally accepted accounting principles for documenting quality procedures, it is rapidly becoming an internationally recognized system, comprehensive to buyers and sellers. Our experience with ISO certification for small and medium size companies indicates that implementation of ISO 9000 helps promote quality improvement and management significantly [13, 14, 17].

A variant design approach is used in this research to assist the implementation of a quality system. The basic principle is "the most common one of design assignments modifies or uses an existing design to make a 'new' component". It's framework required (1) a quality guideline, (2) a methodology, and (3) tools. The quality manual development framework, developed through the Systems Engineering approach, includes (1) the ISO 9000 standards, which provides the goals; (2) the Systems Engineering methodology, which provides methods for reaching the goals; (3) information technology (IT), which is a tool to control the documentation process; (4) training, which is a tool used

to integrate IT into the company environment; and (5) the company, which provides the creativity and resources.

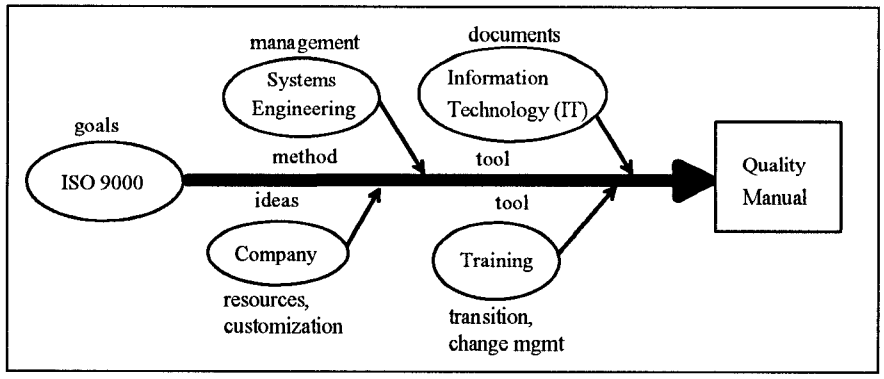

FIGURE 1: Framework Development

The developed framework is capable of implementing all twenty elements required by ISO 9000. Key factors under consideration include customer satisfaction, market share, and company image, as well as internally improving work efficiency and reducing rework and scrap costs. The framework also defines the information flow mechanism to perform data collection, storage, analysis, and reporting of information in order to meet quality objectives.

ISO 9000 INTERNATIONAL QUALITY STANDARD

Throughout the standard, several themes are repeated. First, document what you plan to do, and do what you say that you will do. Second, prevent problems rather than finding and fixing them. The ISO 9000 is made up of five standards -- ISO 9000, 9001, 9002, and 9003. The ISO 9000 is a general standard that defines fundamental quality concepts, provides guidance in selecting and tailoring one of the three quality models (9001, 9002, 9003), and provides guidance on using ISO 9004. ISO 9001 requires quality procedures to be created for product design, manufacturing, maintenance and support. The ISO 9002 model requires quality procedures in product manufacturing and support. The last standard, ISO 9003, defines the area of testing and inspection. This relationship between the standards is illustrated below in figure 2.

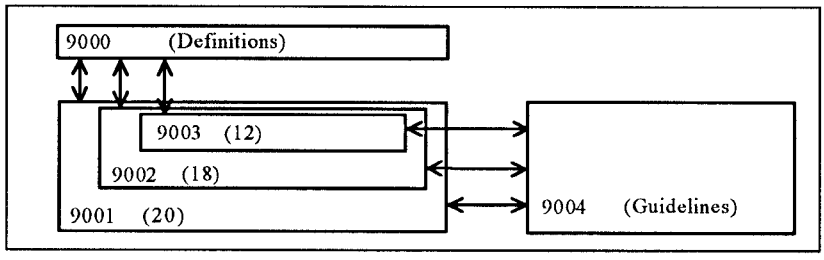

FIGURE 2: Relationship Between ISO 9000 Standards

The ISO 9000 is process-oriented and document-intensive with continuous improvements through evaluation of audit results and records. It is important to remember that the standard certifies a process, not a product. Also, the ISO 9000 does not define specific methods for satisfying their defined guidelines. It provides a very generic and basic set of goals and lets each company determine how it will implement them. These goals can usually be achieved in twelve (12) to eighteen (18) months depending

on the quality model chosen. To become certified under one of the three models, a company must meet the requirements of 12 or more of the 20 elements in Table 1. A quality system that is based on the ISO 9000 is a baseline solution that can be upgraded later as the company grows to cover Total Quality Management (TQM) in more detail.

The quality system developed using the ISO 9000 provides a competitive advantage for a company by improving the internal quality system, fulfilling customer requirements, providing a marketing tool, and reducing costs by reducing the number of audits. The European Economic Community's (EEC), as part of the unification effort, and many Asian countries will start requiring that all suppliers be certified.

TABLE 1: Elements of ISO 9000 Quality Models

	9001	9002	9003
1.1 Management Responsibility	x	x	x
1.2 Quality System	x	x	x
1.3 Contract Review 💣*	x	x	
1.4 Design Control	x		
1.5 Document Control 💣*	x	x	x
1.6 Purchasing	x	x	
1.7 Purchaser-Supplied Product	x	x	
1.8 Product Identification and Traceability	x	x	x
1.9 Process Control	x	x	
1.10 Inspection and testing	x	x	x
1.11 Test equipment calibration and maintenance 💣*	x	x	x
1.12 Inspection and test status	x	x	x
1.13 Control of nonconforming product	x	x	x
1.14 Corrective action	x	x	
1.15 Handling, storage, packaging and delivery	x	x	x
1.16 Quality records 💣*	x	x	x
1.17 Internal quality audits	x	x	
1.18 Training 💣*	x	x	x
1.19 Servicing	x		
1.20 Statistical Techniques	x	x	x

symbols: 💣* = often poorly handled [8]

INFORMATION TECHNOLOGY

Before procedures are designed or refined in each section of the quality manual, information technology (IT) should be considered. Information technology is the integration of computer, communication, and software. It often can provide unique solutions that would otherwise not be considered using traditional tools. For example, if a bank wanted to increase customer satisfaction by providing 24-hour banking services, the solution would be to either hire many more people, or automate banking functions using computers, communication, and software. Business process that is designed or with using information technology in mind should understand the strengths of IT's capabilities in terms of (1) communication and coordination, (2) data access, (3) analysis power, (4) structure, (5) automation, (6) multitasking, and (7) competitive advantage.

Organizations can and have used information technology to transcend time and space barriers to improve communication and coordination and support the globalization trend of market competition. Through IT processes become independent of geography for those companies that are either spread out all over the world, or have global partners in business [6, 9].

Information technology's informational capability allows management to control access of data, and at the same time, distribute data to more people and locations. Since power is defined by the level of access to information in the database, IT can provide more empowerment to lower levels while also relinguishing some of the control at the management level by providing more monitoring information.

Traditionally, the analytical power of IT has played a major role in business processes. IT provides more powerful complex analytical methods for processes such as statistical data analysis, modeling, process control, or tracking. The goal ultimately is to convert data to information, and analyze the information to gain superior knowledge. IT supports the business process of knowledge management by allowing the capture and dissemination of knowledge and expertise to improve the process. Detailed tracking of task status, inputs, and outputs is also facilitated by its analytical capabilities.

In process management, functions and tasks are examined carefully and weak processes are redesigned. With IT in mind, the unstructured processes can be transformed into routine transactions based on new design ideas that are unique to information technology. Another IT capability that has been used a great deal in the past is the automation of business processes. When carefully planned, information technology can be applied to perform certain tasks more quickly or with less errors through process automation. The result is often the replacement or reduction in routine human labor. The multitasking capability of information technology introduces the possibility of changing the sequence of tasks in business processes to increase effectiveness. The software development process is one that has gained much benefit from the multitasking features of IT.

In the past, information technology was used to gain a competitive advantage. However, as it becomes more powerful and less expensive, IT is becoming a necessity to compete rather than a competitive advantage due to the globalization of the market. By connecting distributors and suppliers with a computer-to-computer ordering system, or creating electronic links between customers and retailers, order-entry costs, number of shipments, total procurement cycles, inventory costs, and manpower requirements could be reduced. The result was that suppliers improved customer service, provided lower prices, remained responsiveness to local tastes with product mix, and provided faster reordering. In terms of the quality manual development, IT can provide competitive advantage if it is used to take shared data such as market demands, convert it to information, and analyze information to get superior knowledge.

To access the many advantages information technology towards the development of a quality manual, several factors must exist. First, IT capabilities must be fully understood and cannot be interpreted as more than a tool. Alone, IT cannot change or improve a process. The process must be examined to determine if IT can be effective. Also, management must be completely willing to change because IT often demands management and workers to leave the comfort of traditional work habits and adopt new processes with different power distribution and new control mechanisms.

THE FRAMEWORK

The developed framework resulted from the definition of the ISO 9000 as the framework's quality guideline, the tailoring of the Systems Engineering method into a quality effort chain, the expansion of this chain to cover the 20 elements of the ISO 9000, and the integration of information technology, company efforts, and training into this expanded chain. In this life cycle form, the ISO 9000 standard itself can be implemented more easily into a company's unique business process. The resulting quality manual development framework, which is illustrated in figure 3 below, is made up of the documented procedures grouped under the components of (1) management, (2) information systems, (3) internal audit, (4) corrective action, (5) training, (6) customer interface, (7) product design, (8) procurement, (9) manufacturing and process control, (10) inspection, testing, and calibration, (11) handling, storage, packaging, delivery, and (12) service. For each component, there are procedure and data that should be created and collected.

The quality manual is the result of documenting the quality system. The quality manual should be clear, concise, and easy to read. It should describe only those procedures that a company will use in

its quality system. Of course, the quality manual is not a collection of statements etched in stone forever. It also must follow the spirit of continuous improvement. The quality manual must be used, and revised whenever the results of audits indicate any problems with any documented procedure.

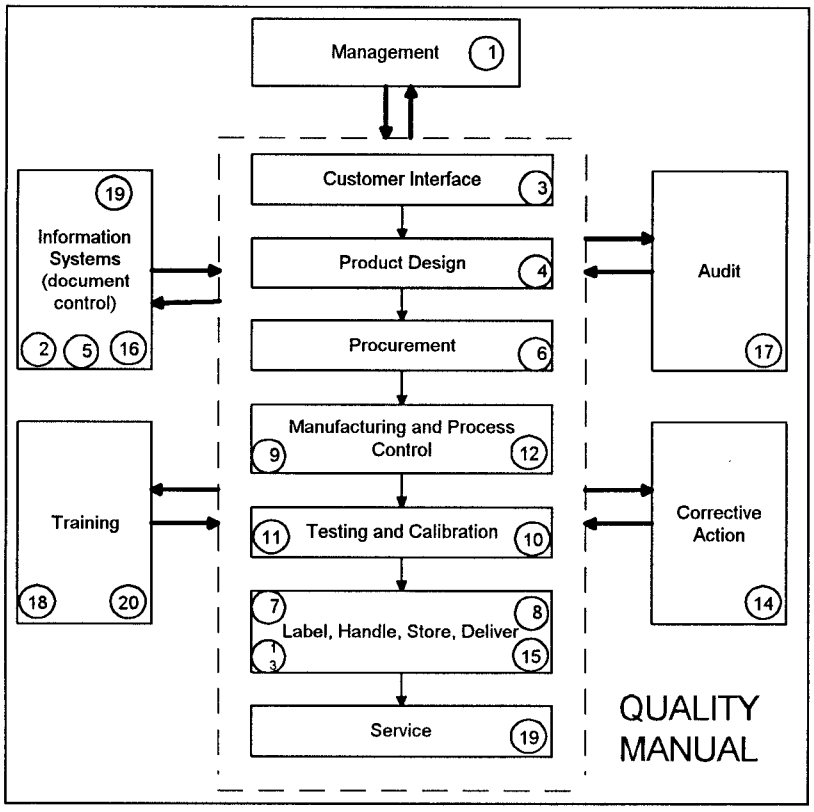

FIGURE 3: Quality Manual Development Framework

The Management Element

A quality system's success starts at the top with management involvement. This is common element in TQM, Deming, ISO 9000, and all other quality standards [7, 10, 16, 18]. Therefore, the quality manual must start with a description of the management function in the quality system. The management function involves (1) setting a vision, (2) organizing company structure for the quality system, (3) providing necessary resources, (3) making decisions, and (4) communicating these decisions.

The quality manual must state the objective of the quality system, which is management's vision, in the form of a quality policy statement. The goals of the quality system should be linked to other company goals, such as increasing customer satisfaction, or reducing operating costs, to avoid conflicts. By linking quality to existing company goals, the quality policy becomes more tangible, employees better understand why they should create, modify, document, and implement the quality procedures.

Once decisions have been made, management is responsible for communicating this continuously to the company. The communication function is one of information technology's inherent features. Networks, e-mail software, video conferencing, group decision support systems, and groupware are technologies that enable management to quickly distribute information across long distances through many time zones.

Groupware, which is a network application that allows a group of people in one room to discuss ideas anonymously by using a computer to type in their thoughts to a question, has been used more as an effective communication tool. VisionQuest, a groupware applications, has been implemented in the

AT&T and IBM teaching theaters at the University of Maryland at College Park. In the corporate environment, research by Dr. Maryam Alavi has shown that groupware can help companies reduce the time to generate ideas, generate more and better quality ideas in each meeting, more easily prioritize ideas, and make participants feel more comfortable in offering ideas [1, 2, 12].

The management data that should be collected in the "management" database includes quality policy, personnel roles, level of authority, review date, suggestion ID, reviewer name (mgmt), response, and course of action. This database should also be linked to the "audit" database.

Internal audits, or verifications, are critical processes to continuously improve every component of the documented quality system. It involves following the flow of the data, such as customer inquiries, product status, and billing, to determine if the documented quality procedures are being executed, how well they are executed, and whether or not existing or potential problems exist.

Audits in this framework can be facilitated here also by the combination of teamwork and IT. The total time to audit a quality system can be shortened by designing automated processes to simplify the comparison of requirements in computerized checklist format to computerized quality results. Procedures needed in this component include determining quantity and skills of required personnel, documenting the reasons for audit, verification steps, summarizing audit findings in a report that management will review. Reference should be made to the management section for review procedures.

The data that should be collected from this component include audit date, document ID number, auditor name, quality manual section or process that was violated or is causing problems, description of the problem found, recommended solution, solution project leader, date to finish implementing changes, and report id. This data should be placed in the "audit" database, and linked to the management database.

The roles of the quality information system (QIS) include being a facilitator, a tool provider, a support function in the areas of document management, version control, database management, and process analyst. A quality information system does not necessarily include computers. However, competitive advantage can be gained by applying information technology to the quality information system. There are several advantages to a computerized document control system. They include:

1. Immediate Access -- on-line documents are quickly retrieved if the system has a user-friendly retrieval system and if users are properly trained.
2. Authenticity -- document changes are controlled by managing the read/write attributes of final documents, as well as any other passwords or network security.
3. Completeness -- on-line access allows all involved to easily retrieve, check, edit, and sign-off on the document before it is approved and released.
4. Integration -- on-line document editing and review that requires other information can be integrated with other computer information sources such as spreadsheets and databases.
5. Better control and coordination -- review process

The Information System Element

The procedures in the quality information system are based on this definition of the quality information system. First, the company documentation process needs to be modeled to determine where application of IT is potentially useful. Next, type of data to be collected should be determined. Also, personnel skill level and quantity requirements should be determined. Then determine a standard format for data storage, retrieval, and sharing. Create a numbering system for document id, and a master list for version control. Procedures are needed for retrieving document, filling out document, and getting approval. Identify the personnel with authority to approve document for storage into quality information system. Finally, create procedures for data analysis.

The information and analysis should actually be considered the backbone of a company to create a smooth flow of data, documentation, and records between each group inside a company [5, 11]. An example would be the requirements documents. Good leadership would insist on a well-defined requirements document as the first step in systems development. All subsequent work and design would

have to be accomplished to meet this document. A verification document after each design phase would be a good way to ensure that the requirements are being met.

The data that should be collected in this component is related to document control. It includes title, document #, data, version, author, inspection data, test data, qualification data, validation data, audit data, material review, calibration data, quality cost, mechanical drawings, circuit schematics, and process flow charts. This data can then be analyzed to assess the quality of the subcontractor, assess the effectiveness of corrective action, analyze quality trends, and verify that the final product meets defined customer requirements.

The Training Element

The training procedures are based on the early phases of the Systems Engineering process [3, 4, 15]. Training starts with a work description document. Based on this document, a functional analysis is then performed to breakdown the work. The resulting functions are then further decomposed in a task analysis. Next, procedures for human resource analysis need to be defined to match the task to either man or machine. Procedures should be created to determine the what subjects will be taught, and who will teach it. Effective training is based on its timeliness, active participation by top managers, interactive style of teaching, good communication skills, and documents of the training material.

Data resulting from the training procedures that should be collected for the "training" database include name, skill level, training received, date, source of training, project, requirement document number, and project WBS document number.

The Corrective Action and Audit Elements

The corrective action component of the quality manual should describe a formal methodology for evaluating and fixing those products that fail inspection and testing. There are five key procedures that should be followed. First, understand the problem. Second, analyze the product functions to identify the problem source. Next, determine the course of action to fix the problem. Then, determine the skill level and quantity needed to carry out the correction. Finally, collect data about the product id, defect, cause, solution, and personnel involved and record in the computerized "fix" database. This database of the corrective actions should then be linked to the "customer", "test", and "parts" databases.

The Design, Manufacturing, and Testing Elements

The goal of the customer interface component is to obtain feedback from customers and be responsive to their requirements to increase overall customer satisfaction. Procedures needed here start with determining what the customer wants, and filling out the customer requirements document. Then procedures should define how to create a checklist documenting customer requirements. Verification procedures should check that the product to be developed and delivered does satisfy the checklist. These procedures should cover the handling of customer negotiations to reach an agreement if all items on the checklist are not met. These negotiations and conclusions should be documented, approved, and stored. Reference to the quality information system section is needed to handle the documents properly.

The customer interface data that should be collected and stored in the "customer" database include customer name, address, phone, fax, inquiry, performance and costs requirements, schedule and delivery requirements, contract review checklist and report document number. It should be linked to the "fix" database of the corrective action to assess internal and external supplier quality.

The procedures in the design component should be designed with the goal of covering all aspects of a product's life cycle. This requires that the design start with a clearly written requirements document, which can come from the customer interface section. Then, plan the design and development effort. Assign roles and supply resources for project. Identify all design inputs and interface between

various inputs. Document all design outputs, including drawings, instructions, and schematics. Verification procedures are needed to assure that the design output meets customer requirements. Also, it is important to establish procedures for reviewing and approving design changes resulting from new or modified design inputs.

The data that will result from these procedures include product id, designer name, design document type, and design document number. This collection should be stored in the "design" database for analysis later.

Information technology should be applied in the design and modification of procurement procedures. By using IT in the form of electronic links between groups in the product development chain, a value-added partnership or quick response system is created for procurement. Procedures based on such systems can improve both internal inventory management and responsiveness, as well as a supplier's compliance and responsiveness. As a result, the procurement function gains all the same advantages of a quick response system.

Procedures should cover clear definition of parts to be purchased. Checkpoints along the parts procurement path should be created. This may include parts request forms, signatures of approval, or verification of subcontractor supplying parts based on past compliance. There should be procedures to handle disputes. Also, verification procedures should be in place to assess purchaser-supplied products against requirements documents.

The procurement-related data to be collected includes part number, product id, supplier, supplier address, supplier phone, supplier fax, quantity, and price. This group of data should be stored in the "parts" database. To analyze the data for more information, the "parts" database is linked with "fix" database.

Manufacturing teams and information technology can have a significant impact in this section. Communication and coordination is very important in manufacturing and process control. Designing processes that apply computer analysis and automation can provide insightful knowledge about the manufacturing process and existing level of variation. Data collection for process control and tracking of a part's inspection status are both easily enabled by the application of IT here. Once the data is collected, automatic statistical analysis of the defect data can be performed to determine the source of variations.

Manufacturing and process control procedures include creating procedures for up-front planning, referencing detailed assembly and test instructions, and process measurements. Workmanship standards should be defined clearly. Again, verification procedures are needed here to check the inspection and test status of parts before their use.

The data resulting from these manufacturing and process control procedures should be stored in the "manf" database. The data includes product serial number, assembly personnel involved, skills requirements, and certification of personnel. This database should be linked to the "test" and "parts" database to obtain more information.

The inspection, and testing procedures should cover the incoming, in-process, and final stages of production. These procedures can rely on checklist and review documents of both parts and suppliers. Proper measurement steps should be covered in the procedures. Final inspection procedures should be high-level and reference by document number can be made to more detailed test instructions. The appropriate equipment should be determined in product conformance procedures. Procedures should exist for determine the accuracy and limitations of each equipment on the list. Also, establish procedures for periodically calibrating all equipment on the list to traceable national standards. Document the results of these calibrations. There should be procedures that outline how to maintain an environment recommended for optimal operation of each piece of equipment. Also, define procedures for the storage and handling of each piece of equipment to ensure the accuracy and function.

The data related to the inspection, testing, and calibration procedures include type of inspection, equipment requirements, certificate of equipment calibration, and calibration date. This data should be stored in the "test" database.

Labeling, handling, storage, and delivery procedures are critical for tracking quality throughout the product development. Create label procedures for parts traceability. A part should be labeled with its inspection status. These procedures should handle (1) new incoming parts, (2) partially assembled

products, (3) purchaser-supplied products, (4) final outgoing products, and (5) defective parts. The procedures should clearly define the pertinent data that should be recorded. Identification of parts should be linked to applicable drawings, specifications, and other documents throughout the product's life cycle. Procedures should consider the nature of the product when creating handling, storage, packaging, and delivery procedures. Verification procedures should be created to assess the effectiveness of the above handling, storage, packaging, and delivery procedures.

Labeling, handling, storage, and delivery data includes part id, inspection status, serial number, inspection date, status, inspector, and parts release authority. This data should be a part of the part's label as well as the "handle" database. For further analysis, this database should be linked to the "parts" database.

Service procedures are critical to achieve high levels of customer satisfaction. To establish these procedures, first determine service to provide. Then, determine skill type and quantity needed to provide service using human resource analysis. Document the service procedures, such as call routing to proper service personnel. Determine the type of equipment needed to provide the service. Also, procedures should provide backup technical support, spare parts, and training where necessary. Verification procedures are needed here to get feedback to analyze effectiveness of corrective actions.

The service data to be collected includes product, customer, service, customer feedback, date, service personnel name, equipment, skill required, number of complaints, product operation data, and description of complain. This database is very useful in determining cause of problems, solving problems, and improving designs.

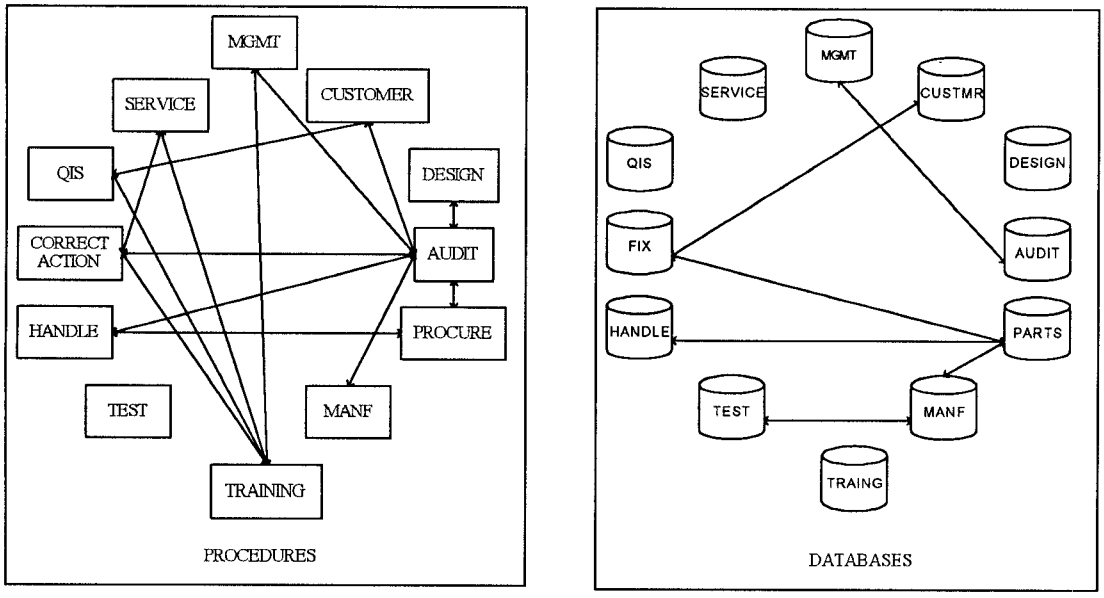

FIGURE 4: Procedure and Database Links

The integration of quality guidelines, the life cycle, information technology, and training in the framework is done by sections referencing other procedures and linking databases. Component procedures that require determining quantity and skills of required personnel should reference the human resource analysis procedures defined in the training section. Any procedure related to data analysis should be referred to the training section for statistics. In many sections, verification procedures are required. These sections should make reference to the internal audit/verification component of the framework. All the references and links of the variant design based on the ISO 9000 guidelines is summarized in figure 4. From the two diagrams, the audit, corrective action, and training are the most accesses components. Therefore, emphasis should be placed on procedures for these three elements.

CONCLUSIONS

As demonstrated in this paper, the proposed framework has its unique features. First, the quality manual will be developed in a systematic manner. The quality manual will be developed to fit the quality guidelines directly into the business process. This results in a better understanding of the quality procedures role in the business. A very important lesson to be learned about implementing standards and methodologies, whether it is the ISO 9000 standards, TQM, or the Systems Engineering principles, is that the method should be tailored to fit into the company's culture gradually. Reaching high quality standards takes time to implement and requires complete commitment. This commitment must come from top management.

Also, by using information technology as a development tool, the framework assures that the documentation developed within acceptable time, and distribution of reports and quality records is more convenient. The application of information technology (IT) also causes the company to rethink and possibly redesign procedures to incorporate new solutions. Information technology is the key to succeed in this endeavor. An information-based quality system offers the following advantages:

1. Facilitate communication
2. Facilitate data sharing
3. Improve coordination process
4. Faster response
5. Flexible to globalization of organization structure

The framework developed in this research effort is capable of not only creating the quality manual, but providing a path for the quality system to be upgraded as needed by the company. This upgrade path is available because the ISO 9000 standard is used in the framework as the baseline quality guideline, and the life cycle of the quality system is accounted for. Upgrading to meet the criteria of a more comprehensive quality guideline, such as TQM or the Balderidge Award, means adding to the current system rather than throwing it out and starting all over.

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