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Model for the Design and Implementation of Reliable and Cost Effective ISO 9000 Quality Control Systems

Elvira S. Perez

A Thesis

in

the Department

of

Mechanical Engineering

Presented in Partial Fulfillment of the Requirements

for the degree of Master of Applied Science at

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ABSTRACT

A Model for the Design and Implementation of Reliable and Cost Effective ISO 9000 Quality Control Systems

Elvira Perez

A specific tool that depicts the roadmap to an effective quality control system as per ISO 9000 is required, one that is effective in terms of cost, time and results. The present approach has given a complete and safe answer to this issue. It is complete because it relies on both experience and on data and safe because the results are consistent, cost effective and known in advance. And, as with all global market driven ISO 9000 systems, it is tailored and specifically designed for the particular setting that a manufacturer has: i.e. technology, personnel experience, available raw material.

A systematic approach for the design and implementation of quality control systems has been developed: a model in which a large number of variables that interact stochastically in a quality control system are studied using the principles behind the technique known as Design of Experiments. The model consists of four phases. In the first phase, an ISO 9000 quality control system is designed using current practices: experience and common sense. The second phase is a screening phase, where each inspection point is reclassified as relevant or non-relevant by measuring its influence on the final quality of the prod-

uct. Those points classified as relevant are analyzed in detail in a third phase, the scrutinizing phase, in which combinations of factors and levels are determined by using principles from Design of Experiments (DOE) such as orthogonal arrays and from Taguchi signal-to-noise ratio. Factors, such as frequency of calibration, training of personnel and instruments and levels such as every month/every two months, in-house training/formal training and vernier/micrometer are determined based on experience and research of the manufacturing process and available inspection techniques. A series of experiments are carried out to obtain the best combination of factors and levels that confirm that the product is exceeding customers' expectations at a minimal cost. The different effects of each of these combinations on the final quality is measured. With the final phase, data analysis and a confirmatory run, inspection and quality control efforts are then directed to those areas where they are truly required. Added value to final quality is verified in-house as opposed to reactively from customer rejections or from market reactions.

The use of Design of Experiment ensures that the selected combination of factors and levels reduces the variability of the results of the implemented ISO 9000 quality control system, hence there is confidence that defective pieces are detected prior to shipment to the customer. A case study of the model has been successfully carried out in a friction welding company, reducing quality times by 59 %, quality costs by 41% and improving final quality by 16%.

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I highly thank my thesis supervisor Dr. G. Abdou-Mechanical Engineering Department, Concordia University for all his guidance and specially for accepting the research subject. I also thank my sponsor, the Venezuelan Government through the Fundación Gran Mariscal de Ayacucho, Caracas and LASPAU, University of Harvard, Cambridge, MA. Special thanks to my colleague and husband, Marco Castelli for his original and resourceful support.

DEDICATION

TO ALL MANUFACTURING COMPANIES FOR WHICH I HAVE BEEN A QUALITY CONTROL CONSULTANT OR AN AUDITOR:

THEY TRIGGERED MY CONCERN FOR THIS RESEARCH.

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ACRONYMS

AQL	Acceptance Quality Level
ASME	American Society of Mechanical Engineers
ASNT	American Society of Non Dstreuctive Testing
ASTM	American Society of Testing and Materials
BEP	Break Even Point
CMS	Cellular Manufacturing Systems
DOE	Design of Experiments
EC	European Community
ISO	International Standards Organization
JIT	Just-In-Time
NDT	Non Destructive Testing
QA	Quality Assurance
QC	Quality Control
SPC	Statistical Process Control
TQM	Total Quality Management

1. INTRODUCTION

With the realization of the European Community, a set of quality standards to promote global quality standardization were developed and issued by the International Standards Organization under the name ISO 9000.

While ISO 9000 is well known and has been widely used throughout Europe since 1986, it has been only at the turn of the decade of the 90's that it has become an issue for the Americas. Adopted by more than 90 countries as a quality management (QM) system, the ISO 9000 series are guidelines and definitions for implementing a QM system tailored to a particular organization. It is considered a management as well as a trade tool. Its intention is to provide consistency hence reliability. It is important to stress that ISO 9000 DOES NOT refer to a specific product or service but to the SYSTEM that produces it. These standards have been designed to provide a uniform framework to manufacturers which, in turn, gives buyers confidence.

Some of the common questions in implementing an ISO 9000 system and, in general, any quality control system, are: How much inspection? What to inspect? What not to inspect? What to calibrate? How often? What level of training is needed? Is the procedure that is being used the optimal?, etc. Another main issue is whether it is adding true value to the product. Most importantly, is it improving the quality of the product so that market share is increased?

Or is it raising costs and, therefore, the selling price?

All the above is occurring when important shifts in the field of quality are happening. No longer is the objective of the quality team to "eliminate the lots that are unsatisfactory in quality". It is to ratify the quality built in through design and manufacture. This is due to the fact that quality has become preventive rather than corrective, proactive rather than reactive. Even the term inspection is now being changed to terms that depart from the idea that Quality Control is in conflict with Production, i.e. verification, auditing. Verification is to be used as "the testing for suitability of an object for its intended purpose".

Other aspect is the definition of quality. It is no longer defined as "within specifications" or fitness-for-use. It is customer driven. It is the consumer who establishes the quality of the delivered product. The producer must arrange his manufacturing procedures and provide a verification routine that ensures the quality demanded. Variability, then, becomes an issue; "a specified proportion of the delivered lots are of unsatisfactory quality" is no longer acceptable. Confidence on expected results has to be designed into the quality control system.

The need for a scientific and systematic approach exists. It is the objective of the thesis to provide a model for planning and designing quality control systems as per ISO 9000. This quality management tool, based on the principles of Design of Experiments (DOE) , has given an educated answer to "How to Design Reliable and Cost Effective ISO 9000 Systems?"

The International Standards Organization welcomes studies that represent a contribution to the quality of the standard and its implementation. A copy of the thesis may be sent to this institution.

1.1. Problem Definition

When confronted with the need of complying with ISO 9000, manufacturers find that the issued guidelines are extremely generic. For example, the Inspection clause reads (See Appendix 1):

"The supplier shall

a) inspect, test and identify product as required by the quality plan or documented procedures;

b) establish product conformance to specified requirements by use of process monitoring and control methods;

c) identify nonconforming product."

The common and, of course, challenging question is, How much of each? For example, regarding inspection: How much incoming inspection? How much in-process inspection? At what points? Regarding calibration: How often do I calibrate? What instruments to use? What instruments have to be calibrated? Regarding personnel: What training is necessary? What is sufficient? Regarding procedures: Is the method adequate?

All this happens in the middle of a market driven environment that is compelling manufacturers to comply with ISO 9000. Even with an already existing ISO 9000 quality control system, the quality of the final product is not necessarily improved or assured. Quality systems that are certified as ISO 9000 can be so "fragile" that any minor perturbation prevents them from detecting non-compliances. As a result, defective pieces are shipped to the consumer. An effort that has represented time and money is not rewarded by an increased market share. In fact, in some cases, the existing system has made manufacturing more costly which is unacceptable in a global market environment.

Therefore, a major improvement related to the design, implementation and results of an ISO 9000 system is to be considered. Using quality terminology, "we are dealing with the quality of the quality system". The cost effectiveness and improved market share has to be the aim.

The goal has been to provide manufacturers with a cost effective, scientific and systematic tool to design and implement new quality control systems as per ISO 9000 or improve existing ones.

This extremely important issue, which has not yet been tackled and dealt with in a systematic and scientific manner, constitutes the theme of this thesis. That is, the soundness of a ISO 9000 quality control system. The above mentioned tool has given a safe answer to questions such as "What quality aspects to control cost effectively ? At what level? When? Is the system reliable ?" .

1.2.Literature Review

Many articles and papers have been written in the last six years regarding ISO 9000. Well over 100 documents are available in technical journals. Most of them are purely informative, given the confusion that the standards have generated when they were first edited in 1986. Numerous are the success stories and case studies. For the purpose of this thesis, an extensive review of these articles was carried out. The documents were classified as Development, Implementation and Information. See Tables 1.1 through 1.3.

As far as going beyond ISO 9000 many efforts have been made. In general, quality professionals agree that ISO 9000 is to be implemented within the context of a Total Quality Management (TQM) environment. In fact, the next revision -1997- represents a major change in the standard to include TQM.

1.2.1 Documented Developments

The ISO 9000 family of standards is vast in its applicability. Existing developments have been triggered with its issue and adoption by the European Community. To date, most of the efforts have gone into understanding and implementing as quickly as possible the standards, given the international market requirements, leaving unattended the improvements based on scientific techniques. Those suppliers and institutions that have a serious commitment to quality improvement are using the ISO 9000 quality wave to optimize systems and

Classification	Content	Bibliography No.
DEVELOP-MENT	Forum on ISO 9000	46
	IEE Colloquium on ISO 900	114
	ISO 9000 + JIT + TQM	66
	ISO 9000 + SPC + TQM	132
	ISO 9000 + Q/Plans + Reliability	102
	ISO 9000 + Dependability	117
	ISO 9000 + Reliability	119
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	Information systems	110
	Software for QC documentation	5
	Software for QC documentation	21
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Table 1.1. Articles and Papers related to ISO 9000: Development

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	Defense and Food Drug USA	49
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	Electronics	106
	Communications Technology	122
	Transportation	22
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IMPLEMEN-TATION	Computer Manufacturing	58
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Classification	Contents	Bibliography No.
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	Registration	26
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Table 1.3. Articles on ISO 9000 : Information

procedures. Some have been rewarded by time and cost reduction within their processes.

As far as developments are concerned, documented efforts use ISO 9000 either as an operational aspect of a quality philosophy such as Total Quality Management or as an addition to a new aspect of quality such as reliability or dependability. Of course, many quality professionals have made comments criticizing the content of the standards.

A. Wilson (8) views ISO 9000 as a marketing tool to combine with Just-In-Time and Zero-Defect Capability. The drive to attain ISO 9000 compliance comes from a JIT purchasing strategy in which only a few reliable suppliers are chosen . In this context, an ISO 9000 quality system breeds the "reliability" required in a JIT environment. ISO 9000 is used as part of a JIT production and marketing strategy. It does not add to the standard.

B. Hallingen (3) combines ISO 9000 with Total Quality Management (TQM) to achieve better employee relations, higher productivity, greater customer satisfaction, increased market share and improved profitability. ISO 9000 is considered to be "a good beginning" because it provides employee involvement, establishes the necessary employee understanding of the quality system and maintains quality improvement gains. On the other hand, TQM reduces costs and increases efficiency.

J. Oakland (5) goes a step further and includes Statistical Process Control

(SPC) to the ISO 9000 + TQM formula, reducing process variability to increase process capability and market share. ISO 9000 is here considered as a necessary value-added service for global competition.These last two cases view ISO 9000 as necessary part of a TQM program due to the fact that these standards are accepted worldwide as a market requirement.

W. Gerling (2) from Siemens-Germany departs from the idea of only assuring quality and moves towards assuring reliability. For integrated circuits, he considers design tools, basic product elements, materials and manufacturing processes as the "system" and qualifies it with respect to the consistency and efficiency of all implemented reliability assurance measures. This approach is based on the manufacturer's "system" knowledge and responsibility. Its main concept is not the qualification of the Quality Assurance system -as in ISO 9000-but the qualification of the manufacturing technology. This approach is compatible with ISO 9000 because it places emphasis on the system qualification rather than the product qualification. In this sense, design rules, materials selection and processing conditions are "system parameters", which have to be established, evaluated and optimized, including their interdependencies during the development phase. This qualification checks the system for consistency and conformity to the quality and reliability requirements. Once the system is established and qualified, its reproducibility is verified by statistical process control (SPC). The qualification is carried out in "blocks" such as technology, pilot product, failure

rate, product reliability, package reliability.

This interesting approach moves the qualification of a system further upstream to the development phase and without the necessity for a first product. It has been developed for integrated circuits but certainly can be applied in other areas by changing the reliability test factors for technology qualification. An illustration of the various activities of quality and reliability assurance proposed by W. Gerling (2) may be seen in Fig. 1.1.The system is considered to be ISO 9000 compatible, due to the fact that it considers the consistency of the measures and provisions of design, test and manufacturing. Many of the new concepts presented in this paper can be of value to improve the next ISO 9000 revision, even though it was not the intention of the writer to improve this standard.

J. Klock (4) from AT&T uses ISO 9000 + Reliability + Quality Improvement to obtain conforming material, continuously improved quality and reduced variability. This supplier management program was designed to closely monitor quality and reliability of over 3500 suppliers. This is a very interesting and complete application of ISO 9000.

The supplier management program begins by identifying potential suppliers and products that meet customers' needs. In a first phase, acceptance inspection is used for new suppliers, especially those that have an inspection-based quality system or those for which there exists historical data . During the acceptance inspection phase, a quality representative visits the supplier's facility to

inspect the product at the source, lot by lot. Frequent interaction enables the company to establish a rapport with suppliers, clarify customers' requirements and learn how well the suppliers can meet those requirements. The results are stored in a lap-top computer, uploaded to a main frame and then analyzed by quality engineers. In AT&T they realize that it is one thing to measure the quality to see whether or not it meets certain standards, and quite another thing to make use of those measurements to predict and control the quality in the future. The collected data is used for prediction and control.

Although lot-by-lot acceptance inspection gives customers a sense of security, it proves to be expensive and redundant. It does not add value to the value of the product and its effectiveness varies with the sampling scheme used.

Profile of pilot product →concept → reliability target →reliability risks→ reliability qualification →process & product development→ materials → reliability development →qualification plan →process documentation → release of materials→ routine start → quality assurance→ reliability monitor→ qualification tests →process control →qualification of product → →reliability met.

Fig. 1.1 Reliability Assurance Systems

Since it is reactive rather than proactive, it has done little to encourage suppliers to improve their designs and processes, reduce variability and prevent non-conformances, which is the trend of quality nowadays. Therefore, suppliers are moved towards the next phase.

Phase II starts after the supplier has had ten consecutive conforming lots under MIL-STD-105D. This is called the periodic inspection phase. The decision to reduce inspection is based on the analysis of the inspection data and an audit of the supplier's product control. To qualify for this phase, the supplier's quality system is audited using the guidelines of the ISO 9003 "Quality Systems-Model for Quality Assurance in Final Inspection and Testing". The ISO 9003 criteria are supplemented with additional requirements such as control of changes, data management, quality improvement, specification agreements and others. Initially, the visits are done monthly, until the inspector verifies that procedures are done as specified. If nonconformances are found, corrective actions are required. A full ISO 9003 audit is repeated annually. The suppliers are disqualified if they fail an ISO 9003 re-audit, if they receive significant customer complaints or if the products fail to meet customer requirements. Additional to the ISO 9003 audit, a risk analysis is done on the product. Low technology items remain in this phase indefinitely and lot-to-lot inspections might be changed to quarterly visits. For high-risk products the next objective is to progress to the third phase.

The third phase is considered a long term partnership between the customer and the supplier. This program emphasizes prevention, improvement and process controls with the goal of approving the quality system for the supplier's entire facility. To qualify, candidates are audited using the ISO 9004 guideline (Quality Management and Quality Systems Elements). Additional requirements cover quality improvement, component reliability, quality plans, process controls and monitoring. SPC is required for all suppliers and is evaluated based on the IPC-PC-90 SPC audit requirements. Once on this status, visits are carried out annually to review their improvements.

This is an excellent setup that uses ISO 9000 as the core for an external quality system assessment. Additional requirements are based on improvements recommended by quality engineers to the standards. It does not provide a design tool but it certainly provides an analytical tool to manage the external assessment of quality from the purchaser's point of view.

K. Strandberg (6), from Ericsson Telecom AB Sweden, has complemented the ISO 9000 with dependability related standards through the international standard IEC 300 on Dependability Management, developed by the International Electrotechnical Commission (IEC). This development is to provide a modern, strategic contribution for a unified approach. Dependability is a new concept that is not the sole responsibility of either the supplier or the customer. It is the responsibility of both. The main focus is to allow the ISO 9000 "quality wave"

to include reliability and maintainability as essentials for the prevention of unwanted costs and damages.

Although interesting, this is yet another international organization issuing technical documents to develop and maintain a coherent set of standards in the field of dependability. It does not improve the ISO 9000 set of standards.

1.2.2. Limitations on the Literature Review

As seen in the previous chapter, up to the moment all the documented information on ISO 9000 is related to implementation. In some cases it has been complemented with quality philosophies such as TQM or JIT or by adding concepts such as reliability which is related to the design of the product and the manufacturing process, or dependability which relates to the use and maintainability of the product.

The reliability of the implemented system, the "quality of the quality system", has not yet been addressed and dealt with. Only general considerations are given regarding the setting up of a system to verify quality.

In an ISO 9000 context, the broad purpose of inspection, called verification, is to assure quality by critical examination at critical points of the whole process: raw materials, rough and finished parts. In a real life application the distribution of these inspection activities throughout any process is to be ordered such that the net cost of production is consistent with the cost of verifying qual-

ity. How much inspection, when and where to inspect, etc. remains to be answered.

In recent years a simple new scientific technique, based on statistical analysis, has been developed for the design of robust manufacturing processes, hence reducing variability and improving quality. This technique, known as Design of Experiments (DOE), has been used for research and development of products and manufacturing processes. The principles behind this technique were used as the foundation on which the present thesis is developed. This systematic approach has been used to design a model to provide the best combination of parameters of the quality control system. The resulting QA system complies with ISO 9000, is reliable as well as cost effective and adds value to the manufactured piece by improving the final quality obtained. This comes close to J. Klock's approach to ISO 9000 except that, in AT&T it is used for second party appraisals. The tool developed is to be used as an in-house aid for implementing cost effective ISO 9000 systems. It is targeted to quality engineers and consultants.

The principles of the DOE techniques were applied to the quality control system as far as quality plan points are concerned. This does not imply that the required production controls are to be superseded. Quality control is here seen as the function that checks quality, not the function that produces it. It verifies that quality has been designed and built in. Given that DOE has provided fast

DOCUMENTED DEVELOPMENTS ON ISO 9000							
Name	ISO 9000	JIT	TQM	SPC	Reliability	Dependability	DOE
A. Wilson	■	■					
B. Hallingen	■		■				
J. Oakland	■		■	■			
W. Gerling	■				■		
J. Klock	■		■		■		
K. Strandberg	■					■	
E. Perez (proposed)	■						■

TABLE 1.4. PROPOSED CONTRIBUTION

and efficient knowledge of the complex relationships between factors and quality as well as quick identification of the key control factors in a process, an interesting breakthrough for quality control plans has been designed.

Two important aspects must be kept in mind. First, we are dealing with quality systems, NOT manufacturing processes NOR products. Second, this tool is to be used as part of a Total Quality Management (TQM) scheme, where improvements are being made to the manufacturing process as well as to the design of the pieces.

Many efforts have been made to improve designs and processes. The present effort is targeted to improve the design and implementation of the quality control system as per ISO 9000.

1.3. Objectives and Procedure

1.3.1. Objectives

A quality control system can comply with ISO 9000 but is neither cost nor time effective. Inspection points might be adding no true value to the quality of the piece, only making it more expensive. On the other hand, vital inspections might be overlooked hence producing a percentage defectives that are shipped to the client. Therefore, the main goal is to provide manufacturers with a systematic and scientific tool for the design, implementation and optimization

of reliable and cost effective ISO 9000 quality systems. The objectives are

1) To design and implement sound ISO 9000 systems using a systematic approach.

2) To obtain optimal level of inspection parameters and levels of an ISO 9000 quality system.

3) To reduce the cost of designing and implementing an ISO 9000 quality control system, hence, reducing the cost of the product.

4) To reduce the cost of operating and optimizing an ISO 9000 quality control system, hence, reducing the cost of the product.

5) To implement the proposed approach, as a case study, in a friction welding company located in Pto. Ordaz, Venezuela.

1.3.2. Procedure

Phase 1 : Theoretical Phase

1.1) Conduct in-depth analysis of the ISO 9000 family of standards applicable to external auditing (Chapter 2).

1.2) Conduct in-depth analysis of DOE techniques, principles and applicability to an ISO 9000 QC scheme (Chapter 2).

1.3) Design a systematic approach for the design and implementation of a cost effective ISO 9000 QC system (Chapter 3).

Phase 2 : Practical Phase (Chapter 4)

2.1) Implement the above procedure in a manufacturing company with an ISO 9000 QC system.

2.2) Obtain and analyze results.

2. BACKGROUND

ISO 9000 is a short term used to identify a family of documents that provide definitions and requirements for the implementation and documentation of a quality management system capable of being tailored to any particular organization. The series is intended to be relevant to all types of businesses for the demonstration of the existence of a quality assurance system. It does nos standardize quality systems, only quality system requirements.

It provides a uniform approach to quality systems that today is accepted worldwide. Initially designed as a set of general quality systems requirements, it has disciplined quality practice.

2.1.1 Origins

With the increased focus on quality issues, various national and international standards organizations had prepared standards and guidelines in the quality field to be used between purchasers and suppliers. Although there were similarities among the many standards, they were not sufficiently consistent for widespread use in international trade. Terms such as quality management, quality control, quality system, quality assurance and quality policy acquired different meanings from country to country and even within an industry.

To bring standardization to an international level in 1987 the International Standards Organization (ISO) published standards recognized throughout the world as the ISO 9000 series. It had been by resolution of May 1985 that the European Commission Council endorsed this project to this specialized institution, consisting of 91 member nations and headquartered in Geneva-Switzerland.

This publication of the ISO 9000 series has brought harmonization on an international scale and has supported the growing impact of quality as a factor in business in the '90s. Globalization has come a reality in the few years since these standards were published. The rapid implementation of the European Community (EC) single-market arrangement has become a major driving force. ISO 9000, in effect, is becoming a market requirement.

Currently, over 90 countries have adopted the ISO 9000 standards as national technical documents. The registration and certification process differs from one country to another. In the Europe, each country has its certification body. In North America, certified registrars carry out the ISO 9000 audit. In other countries, second party certification appraisals are used. This constitutes an international barrier given the fact that a certification valid in one country may not be valid in another. At the moment there is the intention amongst representatives from several countries of the European block and the American Society for Quality Control to recognize each other and initiate the process of harmonizing the certification process on a global scale.

2.1.2. The ISO 9000 Approach to Quality

The ISO 9000 quality approach is founded on two main concepts. First, a quality system based on the idea that if the production and management systems are right, the result is also right; and second, for third party assessments: ISO 9000 promotes assessment through certified third party audits rather than second party, that is, those carried out by individual purchasers.

The ISO 9000 standards call for a proactive management of the quality system. This places emphasis on the system itself, moving the focus away from the reactive product-driven approach to quality systems which has been often used. Thus, the ISO 9000 auditors do not audit the final product; they audit the quality system. This quality management as opposed to product quality is the key strategic element in ISO 9000. In the context of ISO 9000 and Total Quality Management, quality means to exceed the expectations of the client at a minimal cost.

The series, intended to be advisory in nature, embodies comprehensive quality management concepts and guidance, together with several models for external quality assurance requirements. Using an integrated systems architecture, the standards are packaged under an easy memorized numbering system.

2.1.3. Structure of the ISO 9000 Standards

These quality related standards are presented in a family of documents outlined in Fig. 2.1. Numerous comments have been made by quality engineers regarding the ISO 9000 series of 1986 (1). Some consider them too generic; others affirm that important definitions are not included, such as "Quality plan" and "Quality Manual" and many recognize that it has no provisions for quality improvement. All these comments are to be included in the 1992-93 revision, which is expected to be published in late 1993 (7).

2.1.3.1. External Assessment ISO 9000 Standards (See Appendix 1)

ISO 9001, 9002 and 9003 are specifically related to models for external quality assurance requirements. Fig 2.2 and 2.3 depict their hierarchy. ISO 9000 standards have rapidly become not only a growing interest but a strategy for business and industry. It is important to stress that the series does not provide a certification for quality of the product; it provides a certification of a quality system at the moment of the appraisal.

ISO 8402	Quality vocabulary
ISO 9000	Quality management and quality assurance standards-guidelines for selection and use.
ISO 9000-2	Generic guidelines for the application of ISO 9001, 9002 & 9003.
ISO 9000-3	Guidelines for the application of ISO 9001 to the development, supply and maintenance of software.
ISO 9001	Quality systems-Model for quality assurance in design, development, production, installation and services.
ISO 9002	Quality systems-Model for quality assurance in final production and installation.
ISO 9003	Quality systems for quality assurance in final inspection.
ISO 9004	Quality management and quality systems elements-guidelines
ISO 9004-2	Guidelines for services.
ISO 9004-3	Guidelines for processed materials.
ISO 9004-4	Guidelines for quality improvement.
ISO 9004-5	Guidelines for quality plans.
ISO 9004-6	Guidelines for project management.
ISO 9004-7	Guidelines for configuration management.
ISO 10011-1	Guidelines for auditing quality systems: Auditing
ISO 10011-2	Guidelines for auditing quality systems: Auditors
ISO 10011-3	Guidelines for auditing quality systems: Audit Programmes
ISO 10012-1	Quality assurance requirements for measuring equipment

Fig. 2.1 ISO 9000 family of standards

1. Statistical Methods	✓	✓	✓
2. Personnel & Training	✓	✓	✓
3. Documentation & Records	✓	✓	✓
4. Handling and Post-production	✓	✓	✓
5. Non-conformities	✓	✓	✓
6. Measuring & Test Equipment	✓	✓	✓
7. Product Verification	✓	✓	✓
8. Verification Status	✓	✓	✓
9. Material Control and Trace	✓	✓	✓
10. Quality System	✓	✓	✓
11. Management Responsibility	✓	✓	✓
12. Quality Records	✓	✓	✓
13. Purchaser Suppliers		✓	✓
14. Corrective Action		✓	✓
15. Production		✓	✓
16. Purchasing		✓	✓
17. Contract Review		✓	✓
18. Auditing		✓	✓
19. Design/ R&D			✓
20. Servicing			✓
ISO Standard	9003	9002	9001

Fig 2.2 Generic comparison of ISO 9001 through 9003

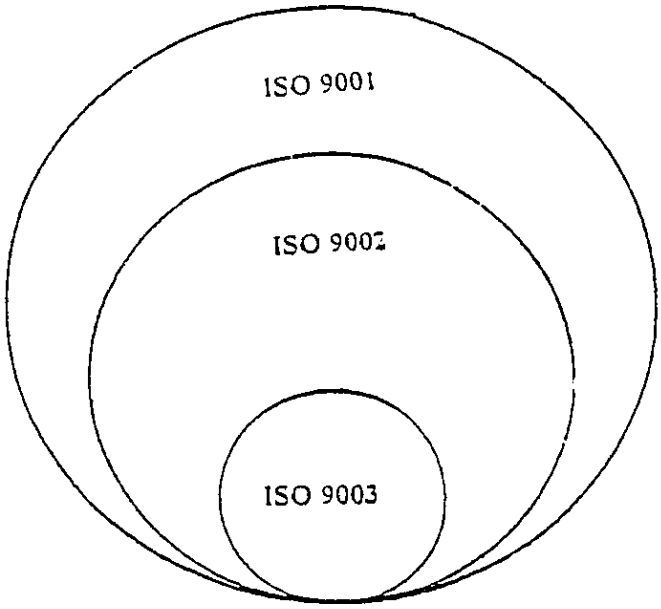


Fig 2.3 Hierarchy of ISO 9001, 9002 and 9003

2.2. Introduction to Design of Experiments

This technique is a systematic and efficient way of meeting the challenges of designing high quality products at low cost. It uses a mathematical tool called orthogonal arrays to study a large number of decision variables with a small number of experiments. Thus, the most economical product and manufacturing process design can be accomplished from both the manufacturing and customer's point of view at the smallest affordable development cost.

The fundamental principle behind DOE is to define process parameters that can be changed easily and inexpensively. In other words, the aim is to im-

prove quality by minimizing the effect of the causes of variation in a process. Step one in optimization is no longer investing in new technology. Rather it is learning how to manage an existing production system properly, which then creates a foundation for the application of advanced technology.

The method, extensively used in product design, achieves product performance that is insensitive to raw material variations allowing the use of low grade material and components in most cases. It also makes designs robust against manufacturing variations, reducing labor and material costs due to rework and scrap. It achieves minimal sensitivity to the variations in the operating environment of the piece.

The technique has been applied to a variety of problems and industries. It has drawn many ideas from statistical experimental design for obtaining dependable information about variables involved in making engineering decisions. It explicitly addresses how to reduce variability of a product as a function of the changes in the working environment as well as how to ensure that decisions found to be optimum during the experimental phase are optimum also in the manufacturing stage.

2.2.1. Brief overview of Taguchi's Methods

Dr. Taguchi (1) has added significant concepts to enhance DOE. Quality has been established dependant on the quality characteristic involved. A quality

characteristic is whatever we measure to judge performance (quality). There are five types of quality characteristics: smaller-the-better (minimizing a response- e.g. shrinkage and wear), nominal-the-best (achieving target values), larger-the-better (maximizing a response- e.g. tensile strength), attribute (classifying or counting data-e.g. appearance), and dynamic (response varying depending on temperature).

To achieve quality with the task of producing a product at optimum levels and with minimal variations on its quality characteristic, Taguchi classifies two types of factors: control factors (controllable) and noise factors (uncontrollable) . Control factors are factors that can easily be controlled such as choice of material, cycle time or heat temperature. Noise factors, on the other hand, are those nuisance variables that are difficult, impossible or expensive to control, e.g. the ambient temperature and humidity. Noise factors are usually responsible for causing a product's quality characteristic to deviate from its target value. Our goal, nevertheless is NOT to control noise factors just to identify them. Instead, it is preferred to select values for the control factors so that the product or process is least sensitive to changes due to the noise factors, hence, eliminating or reducing the impact of the causes.

When tentative nominal values of an existing system are tested over specified ranges during what is called parameter design, the best combination of levels is determined. Parameter design is the key stage of Dr. Taguchi's methodolo-

gy. This is where improving quality the most without increasing costs is possible: to find the nominal values for the controllable factors so that maximum product performance is achieved with minimal sensitivity to noise.

Taguchi's quality engineering method reduces variation, which always results in improved quality. The processes are optimized in a way that makes them insensitive to factors beyond the manufacturer's control. This technique has been used extensively for product designs and their manufacturing systems. Now it shall be applied to a quality control system, that is, to the operational techniques and activities carried out to prevent defective pieces from being shipped to the customer.

2.3. Framework

The present model is aimed at the following:

Application domain

The model is applicable to ISO 9001 and 9002 external assessment standards.

Quality Function and Organization within the Company

The model is applicable to companies that have or intend to have a quality control system where the quality function is independent of production and includes:

- Incoming inspection
- In-process inspection
- Final inspection
- Calibration
- Training
- Procedures

Chronic vs. Sporadic Quality Problems

It is intended for regular inspection activities that deal with chronic problems, not sporadic ones. This is, situations that are often not classified as problems; they are apparently inherent to the process or the working environment. Generally, they are difficult to solve without better understanding of the process and represent a tremendous opportunity for reducing costs. Sporadic problems are to be dealt with by Control Charts.

Company genre

It is applicable to manufacturing companies, that is, those where raw materials are transformed through a manufacturing process in order to obtain a finished product.

Product Range

It is focused on stable processes, cellular manufacturing systems (CMS) and group technology. It is not intended for flexible manufacturing. If this procedure was to be applied to a flexible manufacturing process, a designed experiment would be required for each product. Nevertheless, it is not discarded as a tool for nonconveyorized manufacturing.

Optimal Design of Quality Control Systems

This approach is intended to be used in the design of new quality control systems or in the optimization of already existing ones.

Operational Aspects of the QC system

The model is aimed at the operational aspects of a Quality Control System, those that are performed on a day-to-day basis such as process control, inspection and testing, inspection, measuring and test equipment, training and statistical techniques.

Areas such as Quality Policy, Organization, Management Review and others that are related to the suprastructure of the QC system or are recognized as healthy for the continuous improvement of the system are considered to be compulsory. See Fig. 2.4 and Appendix 1.

2.4. Sampling

Sampling is to be widely used as one of the QC techniques in this model. Definitions and brief of its applications follows.

2.4.1. Sampling Techniques for the Model

Sampling plans are chosen to benefit the factory and the customer. Any technique used has to be well understood by all personnel. Also, the cost of the operation has to be considerably less than the overall benefit. Therefore, a sampling plan has to be easy to use and cost effective. The purpose of any sampling method is to provide information on the severity of a defective lot. Evidence of poor quality is aided by the use of a sampling plan. The result is the elimination of individual lots of unsatisfactory quality in a scientific and cost effective manner.

ISO 9001 Clause No. and Title	Control	Noise
4.1 Management Responsibility		X
4.2 Quality System		X
4.3 Contract Review		X
4.4 Design Control		X
4.5 Document Control		X
4.6 Purchasing		X
4.7 Purchaser Supplied Product		X
4.8 Product Identification & Traceability		X
4.9 Process Control	X	
4.10 Inspection and Testing	X	
4.11 Inspection, Measuring and Test Equipment	X	
4.12 Inspection and Test Status		
4.13 Control of Nonconforming Product		
4.14 Nonconformity Review and Disposition		
4.14 Corrective Action		
4.15 Handling, Storage, Packaging and Delivery		
4.16 Quality Records		
4.17 Internal Quality Audits		
4.18 Training	X	
4.19 Servicing		
4.20 Statistical Techniques	X	

Fig. 2.4. Classification of ISO 9001 clauses

Single, Double and Multiple Sampling

There are several features of 100% inspection that are undesirable. It is costly; it may lead to false assurance about the completeness of the inspection job, it involves sorting; it does not assure that the nonconforming material or defective material is detected or that some satisfactory material is rejected. In many cases, it may be impractical. The type of product and the way the product is presented for sampling, whether on a conveyor, in boxes piled on top of each other, etc.are important factors to bear in mind when choosing the sampling plan.The advantages of sampling over 100 percent inspection have been long recognized. There may be:

- Single sampling, that is, basing acceptance or rejection of a lot upon the units in one sample drawn from that lot.
- Double sampling, that is, selecting one sample of units from a bad lot and, under certain conditions, selecting a second sample before accepting or rejecting the lot
- Multiple sampling, that is, basing the acceptance or rejection of a lot upon the results of several samples of units drawn from that lot.

Comparison of Sampling Methods

Single sampling may be the only practical type of sampling plan under conveyorized production conditions when it is physically impossible to select only one sample. With lots of material whose percentage of nonconformance is

close to the AQL, single sampling may offer more economical inspection than double sampling. It is easy to use and understand.

Double sampling permits a smaller first sample than is called for by the sample size of the corresponding single-sampling plan. When the percentage of nonconformance is either low or high in material submitted for inspection, it is frequently possible to accept or reject lots based upon the results of the first sample. In these instances, double sampling permits lower costs.The idea of giving the material a "second chance" before rejecting it has a popular appeal to manufacturers and, in particular, to production personnel. On the other hand, customers are wary about this method and generally specify in their technical data the use of single sampling.

Double sampling is often easier to administer than multiple sampling plans. The need for selecting successive samples in the proper fashion may require greater administrative control and more highly skilled inspection operators. In theory, multiple sampling may permit lower total inspection than double sampling for a given degree of protection because of the smaller sample sizes required. In practice, however, the greater complexity of multiple sampling may, in some cases, return the overall cost advantage to double sampling . This is particularly true when the percentage of nonconformance in submitted lots is low in these cases. By definition, it should be discarded in a quality control environment where variability is controlled.

When administrative costs are to be kept low, multiple sampling may permit lower inspection costs for a given degree of protection than either single or double sampling. Aided by computer based sampling, it may result in improved efficiency in administering these sampling plans.

2.4.2. Proposed Sampling Plans for the Model

Attributes vs. Variables

The main goal of the model is the final quality of the product. Therefore, the qualification will be by attributes: the piece is either OK or NOT OK.

Standard MIL-STD-105D

This standard is an effort to provide a set of standardized plans. It is simple and easy to use. It offers many standardized plans applicable to a variety of situations. To use this standard, three aspects are to be defined: AQL, Type of sampling, Lot Size.

Type of Sampling Plan

Simple Sampling, given the fact that variability is being controlled.

Lot Size

A lot is defined as: "A definite quantity of a product or material accumulated under conditions that are considered uniform for sampling purposes". For the purpose of this model, a lot is formed by an homogeneous group of products, made of homogeneous raw material and in homogeneous manufacturing process conditions.

Acceptance Quality Level (AQL)

AQL is defined as : "The maximum percentage of units that do not meet requirements in a lot, which for the purpose of acceptance sampling can be considered as a process average". An AQL of 0.65% is recommended for sampling plans that are to be used as part of the present model. Exceptions to this are those instances in which the possibility of property damage or personal injury where 100% inspection is mandatory or when the customer requires a more stringent AQL.

2.5. Blocking

Blocking is a concept related to DOE and consists of choosing experimental units in groups. This technique allows experiments to be carried out in the presence of instability of the process without affecting the final results. With blocking, fewer runs are needed and time and money is saved.

For the present model, a block has no more than three inspection points . Blocks generally consist of four or eight runs. The criteria to choose the blocks are as follows:

1) A group of no more than three raw materials that constitutes a semi-finished part of the process, for raw material classified as "Requires Incoming Inspection".

2) A group of no more than three inspection points of semifinished products that constituteS a finished product.

3) A group of no more than three consecutive inspection points of the In Process Inspection.

In practice, blocking with two or three inspection points is to be used when the effect of the interactions between those inspection points is to be studied. And randomization of the order of the runs eliminates bias due to any trends or patterns within blocks.

3. PROPOSED MODEL

A general overview of the proposed model is depicted in Figure 3.1. A detailed description of the phases follows:

PHASE I: ANALYSIS OF THE PROCESS PLAN

The process plan must be known and understood by the group of specialists who designs and develops or improves a quality control system. The procedure for Phase I is presented graphically in Fig. 3.2.

Step 1: Analyze the production process, from beginning to end. Create the flow diagram, if it does not already exist, or update the existing one. The flow diagram must include all steps of the manufacturing process. Material purchasing, storage and handling are to be included as operational aspects of manufacturing. No longer are they to be considered a non-technical feature of the process plan. Include designing if it is done in-house (applicable to ISO 9001).

Step 2: Once the flow chart is complete, add QC and inspection points as per ISO 9000. There should be QC checkpoints at:

1) each stage where the material is transformed. Examples of transformations are forming, machining, joining ; welding, heat treating; mixing and adding or any activity that changes the form or the content of the material.

Phase	Objective	Results
Phase I	Analysis of the Process Plan	=> Flowchart with QC points
Phase II	Screen QC points	=> Significant inspection points
Phase III	Scrutinizing	=> Levels of factors
Phase IV	Data Analysis & Confirmation Run	=> Best levels of factors

FIG. 3.1 PROPOSED APPROACH

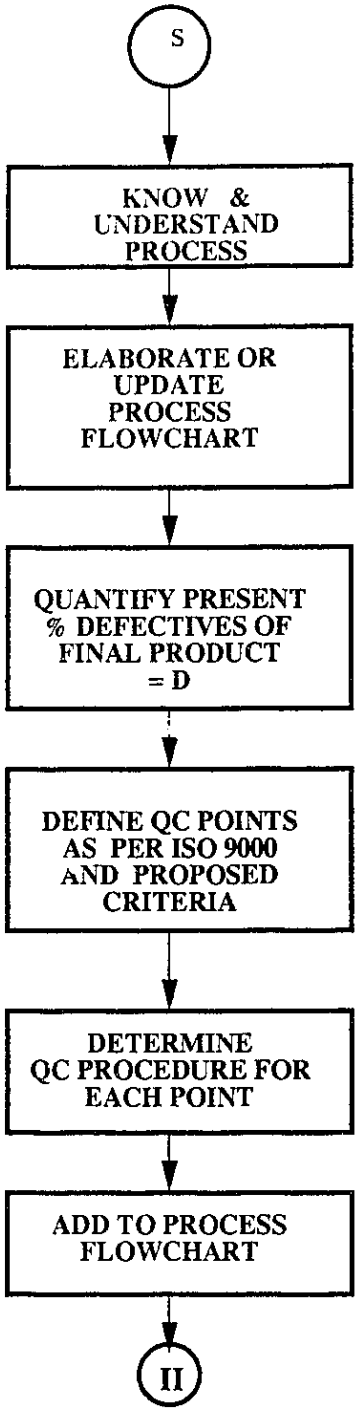


FIG. 3.2 PROPOSED APPROACH: PHASE I

2) whenever the material has been received from the client (second party), from a supplier or a contractor (third party) or from another department within the works.

Step 3: Quantify the percentage defectives obtained with current manufacturing process and quality controls.

PHASE II: SCREENING

All inspection points determined in Phase I are screened in order to obtain the significant few. See Fig. 3.3 . The objective is to determine whether each individual point is adding value to the final quality of the product. If not, it is reclassified as a periodical audit point. The performance measure is the percentage defective produced by the process and detected by the quality control system. In this context, materials that are repaired or reworked are quantified as defectives. This measure is done by a QC engineer or other that has such sufficient QA/QC background as to determine the quality of the lot with veracity. It excludes all inspectors that take part in Phases I or II. This ensures a transparent and trustworthy measure.

Two measures are obtained for each inspection point: one when the inspection was actually carried out and one when it was not. The final quality obtained indicates which inspection points are adding to the value of the product

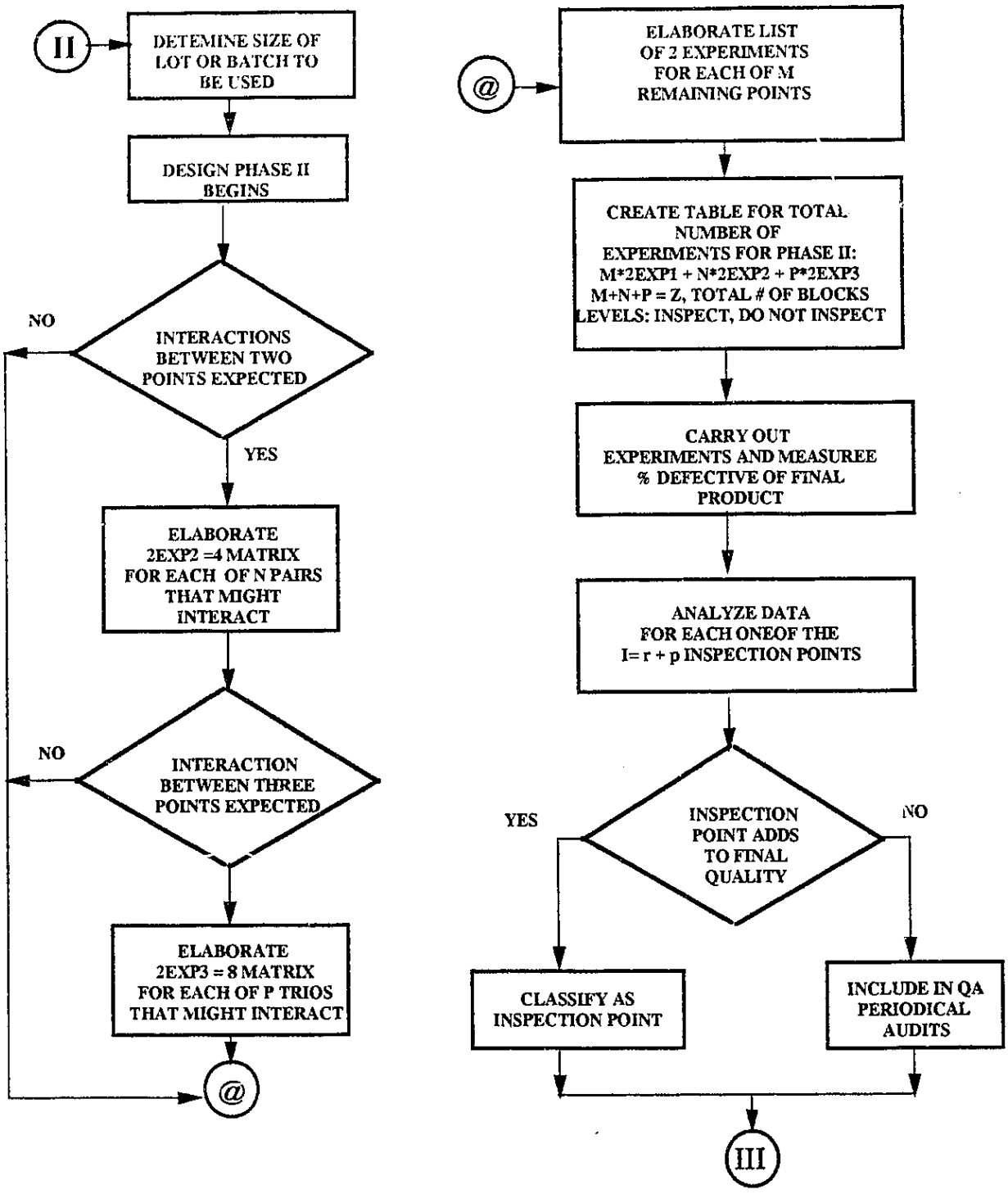


FIG. 3.3 PROPOSED APPROACH: PHASE II

and which are not. Those "insignificant" points are then included as part of the periodical QA (Quality Assurance) audits to maintain healthy controls active, instead of checking them on a day-to-day basis which would be an unnecessary time and money burden.

When interactions between inspection points are expected, a block of experiments of 2^2 or 2^3 is carried out. The word interact is used to indicate situations where the presence or absence of one inspection point directly affects the results of another. Any two or three points that are expected to interact are to be set up in this matrix. More than three is troublesome and unnecessary.

By the end of Phase II the decision Inspect or Do not inspect-Audit is obtained (See Fig. 3.4).

The sequence for Phase II is as follows:

1) List inspection points for raw material. Number them from 1 to r.

2) List in-process inspection points. Number them from 1 to p.

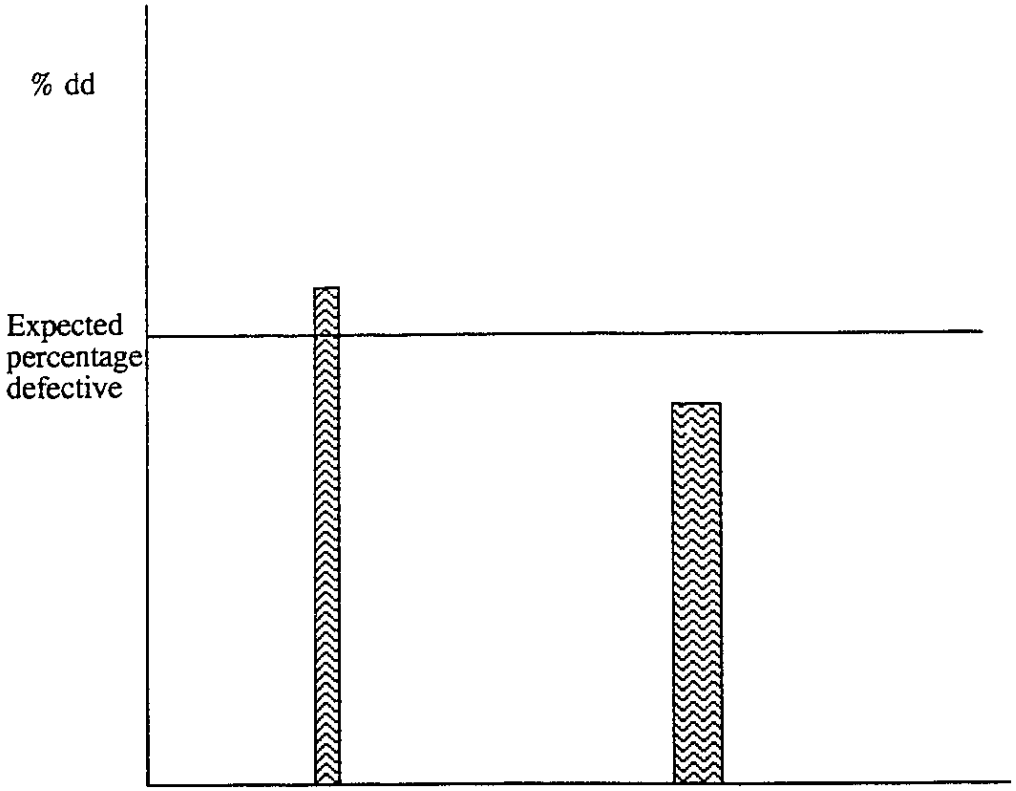
3) Total number of inspection points: $I = r + p$.

4) Block the I inspection points in M groups of one, N groups of two and P groups of three, according to expected interactions. The total number of blocks is $Z = M + N + P$.

5) Create tables to collect data.

6) Schedule experiments and measurements.

7) Carry out experiments and measure final quality of each run.



% dd: measured percentage defective
% de: expected percentage defective

Note: In this approach defectives include all pieces reworked, repaired or scrapped during manufacturing process .

FIG. 3.4 EXPECTED RESULTS/ PHASE II

PHASE III: SCRUTINIZING

Inspection points determined as relevant in Phase II are further analyzed in Phase III. (See Fig. 3.5) These are the points that are adding value to the final quality of the product in this particular manufacturing setup and working environment.

Each relevant inspection point is analyzed to determine factors and levels. A guide of factors and levels for different inspection points is given in Table 3.1. Contractual matters, legal and other issues that affect the product are to be included as factors and levels, i.e. health and safety regulations. For each inspection point, groups of up to three influential factors are chosen. Blocking in this fashion avoids extensive working matrixes that complicate and needlessly extend the implementation of the model.

When the set of factors and levels are determined, outlines of the inspection procedures are written for each run. The results of the model in this phase provide combinations of factors and levels that have the greatest effect the final quality of the product (See Figs. 3.6 and 3.7). The sequence for Phase III is as follows:

1) For each one of I inspection points that are classified as relevant, as per results of Phase II, designated I', analyze the different factors and levels.

2) For each point I', choose up to three factors f_n, $n \leq 3$. Define two lev-

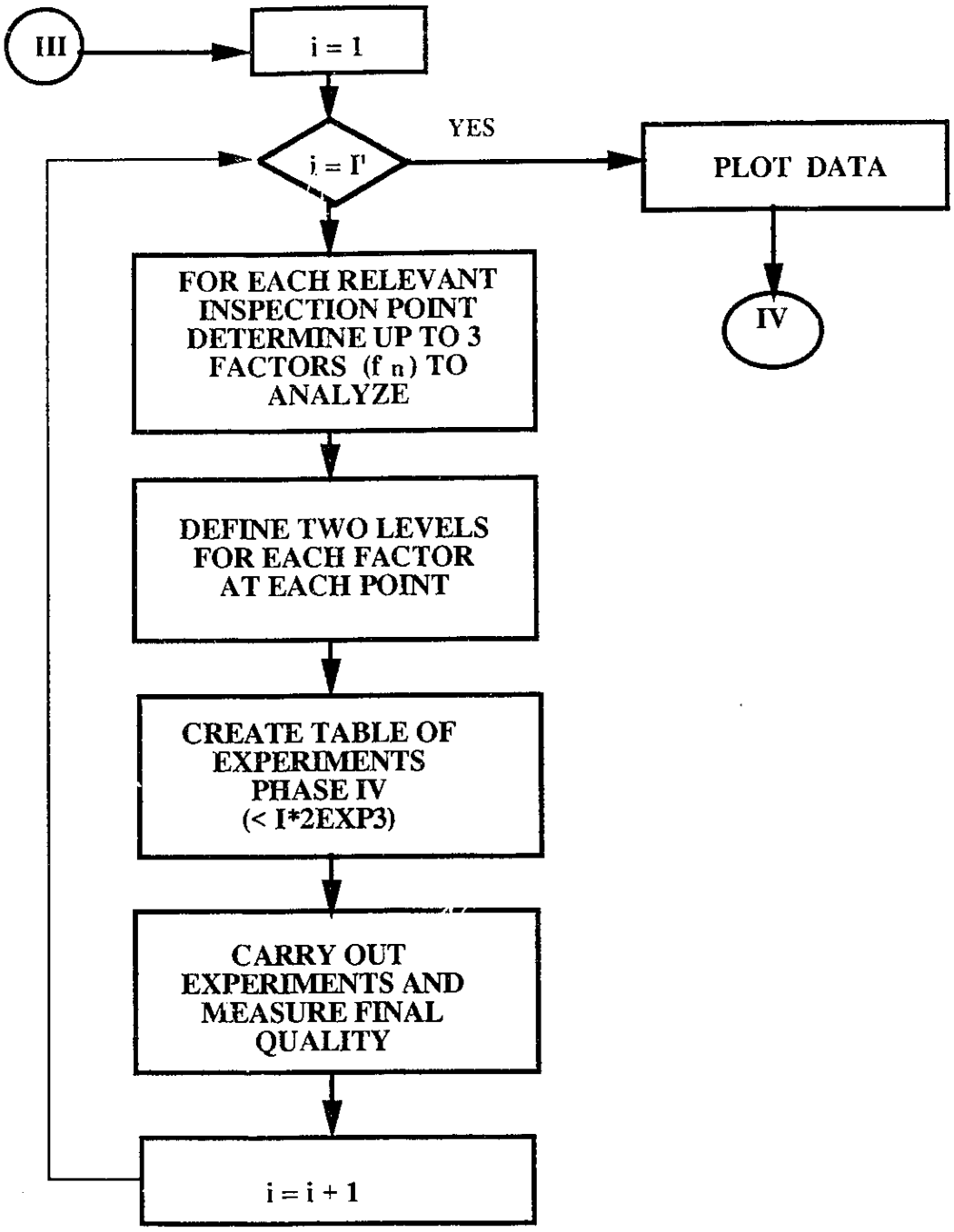


FIG. 3.5 PROPOSED APPROACH: PHASE III

els of inspection. As a guide use Tables 3.1.for each factor.

3) Create a table for each inspection point with f_n rows (number of factors) and 2 columns.

4) Schedule runs.

5) Carry out experiments. Bear in mind that final quality is to be determined by a senior member of the quality team. Induce defectives in the lot, if the process allows it, to be used as a comparative measure.

6) Obtain results and graph.

Table 3.1. Guide to Factors and Levels

General

▸ Inspection upon receipt, Suppliers and Contractors:

No inspection

Quality Certificate Required

Quality certificate required, must be approved by QC personnel

Inspection upon receipt, all lots

Inspection upon receipt, every predetermined number of lots

Pre-despatch inspection of all lots

In-process verification

Design verification

Design approval

Second party audit of technology, reliability

Third party audit of technology, reliability

- Instruments:

Certificates required upon receipt

Check calibration upon receipt

Check calibration periodically

Check calibration through qualified metrology laboratories

Specific

- Cast Moulds

Permeability

Mould Hardness

Percentage Humidity

Percentage Resins

Resistance to Compression

- Chemical Composition

Wet Method

Leco

Quantometer

For steels: Carbon Equivalent: C + Mn/6 + ...

- Concrete

  Resistance to Shear

  Percentage Mesh Size

- Dimensional: Length, width

  Vernier

  Micrometer

  Go-No Go

  Computer aided (cameras)

- Dimensional: Thickness

  Vernier

  Micrometer

  Ultrasonics

  Go-No Go

  Vision System

- Dimensional: Threads

  Go-No Go

  Shadowgraph

- Heat Treatment

  Register: Temperature vs. Time

Surface hardness

Metallography

- Mechanical Properties

Tension Tests

Hardness:

Brinell, portable

Brinell, fixed

Rockwell, portable

Rockwell, fixed

Vickers

Charpy impact

Hydraulic test

Pneumatic test

- Paint Adherence

By ASTM recommended practices

By procedures developed in-house

- Paint Thickness

Magnetic Instruments

Mechanical Instruments

- Surface Finish

Visual

Visual aided with mechanical instruments

Visual aided with cameras

- Welding: Internal defects, Destructive testing

Tension tests

Bend Tests

Microhardness: Vickers

Metallography

- Welding: Internal defects, Non Destructive Testing

Penetrant Liquids

Magnetic Particles

Radiography

Ultrasonics

Acoustic Emission

- Welding Procedures

Qualified as per ASME

Qualified as per ASTM

Qualified as per other International or National Standard

- Welders

Qualified as per ASME

Qualified as per ASTM

Qualified as per other International or National Standard

Not Qualified

- Training, welding

Basic inspection techniques

Advanced inspection techniques

- Training, Non Destructive Testing

In-house training

Level I ASNT-TC-II

Level II ASNT-TC-II

Level III ASNT-TC-II

- Visual

Eye vision

Eye aided with augmenting lenses

Eye aided with chemicals: i.e. macroetching

Eye aided with color charts

Computer aided

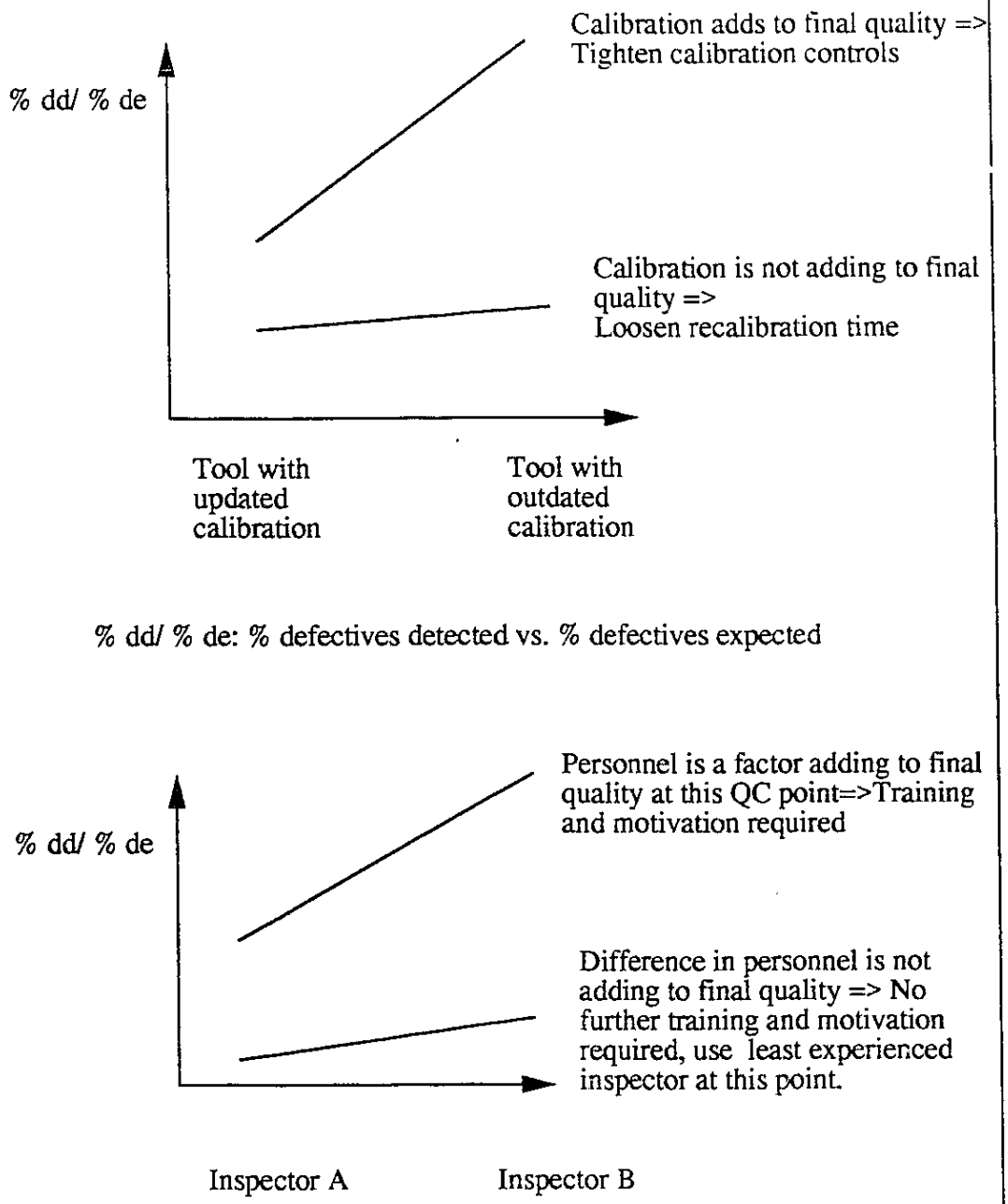


Fig. 3.6. Expected results in Phase III: Optimal factors and levels for a quality control system

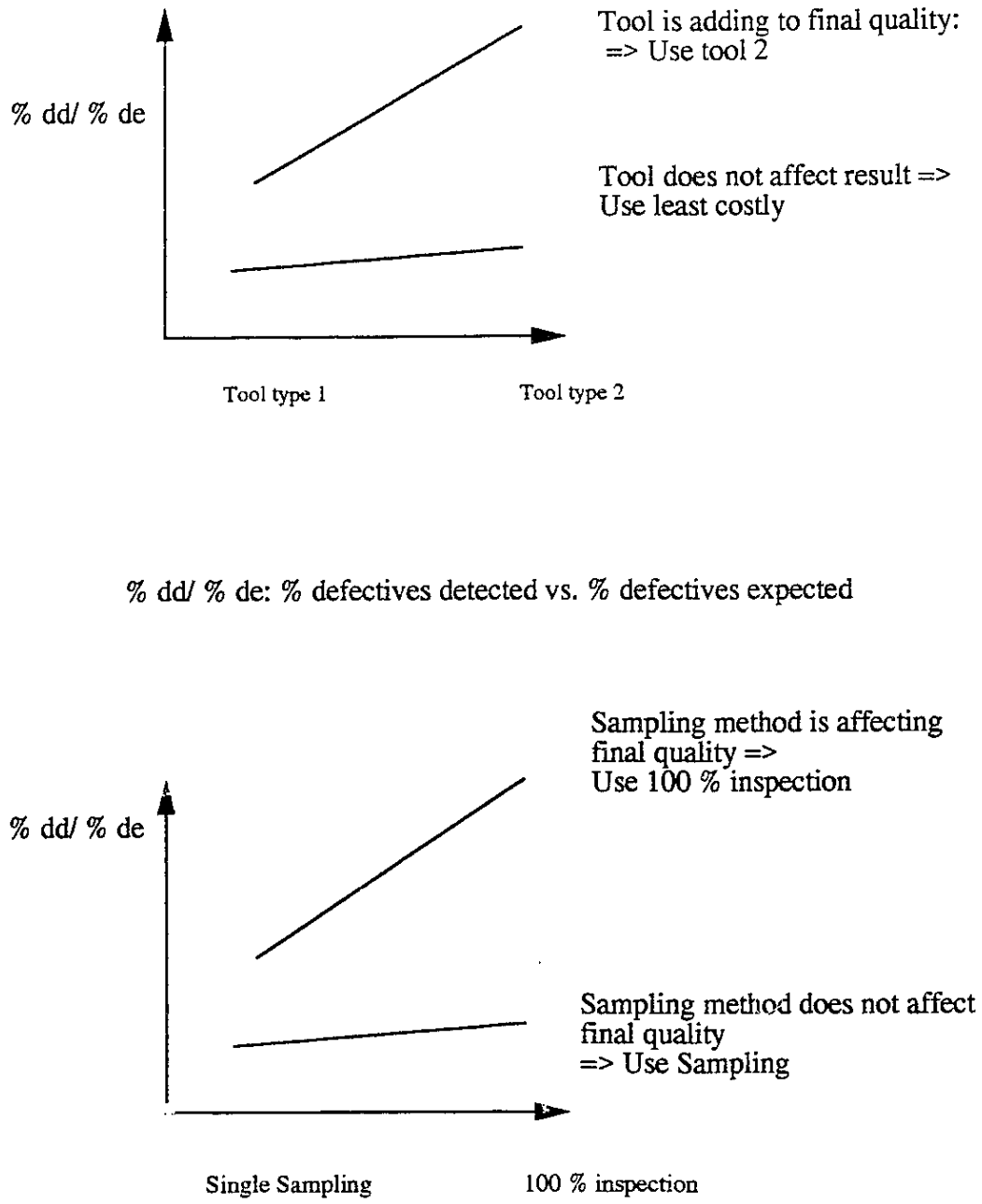


Fig. 3.7. Expected results in Phase III: Optimal factors and levels for a quality control system

The following example clarifies the above procedures:

Inspection point "Y" has been classified as relevant from Phase II. The quality team that is carrying out the model implementation analyzes the inspection point and determines that the possible factors and levels are (See Table 3.2.):

Factor	*Level*
Instrument	*Use instrument type Go-No Go*
	Use instrument XYZ
Sampling	*Use a single sampling, AQL 1%*
	Use 100% inspection
Inspector	*Inspector A with more expertise on dimensional*
	Inspector B, basic training.

For this inspection point "Y", eight runs are planned (2^3=8), as follows:

Run No.	***Description***
1	*Instrument 1,Single Sampling Inspector A*
2	*Instrument 1,Single Sampling,Inspector B*
3	*Instrument 1,100% inspection,Inspector A*
4	*Instrument 1,100% inspection,Inspector B*
5	*Instrument 2,Single Sampling, Inspector A*
6	*Instrument 2,Single Sampling,Inspector B*
7	*Instrument 2,100% inspection, Inspector A*
8	*Instrument 2,100% inspection, Inspector B*

Table 3.2 Runs for the example

Final quality of the eight lots is measured and the combination/s that result in the least percentage defectives are highlighted for the data analysis.

PHASE IV: DATA ANALYSIS AND CONFIRMATORY RUN

Data Analysis

Variation in the response is one of the principles on which this model is based. Since the experimental phase design is orthogonal, the effect of each factor is seen separately. Once the effects are graphed, the identification of the best combination of factors is straightforward. A confirmatory run of the optimal setup is recommended. See Figs. 3.8 and 3.9.

Final quality is the measured through percentage defective. The higher-the-better gives the best combination of factors and levels for a quality control system that, at a minimal cost, most effectively verifies quality designed and built in and detects defectives prior to shipment.

Guideline to Data Analysis

Determining the best setup can become complicated when different levels or combinations produce the same results. The following expert system rules assist themodel user in the final decision. These guidelines provide information by combining lowest cost, simplicity of operations, reproducibility of results, industrial safety and least reliance on expertise and motivation. They are specific to this model and are applicable when no other compulsory requirement exists.

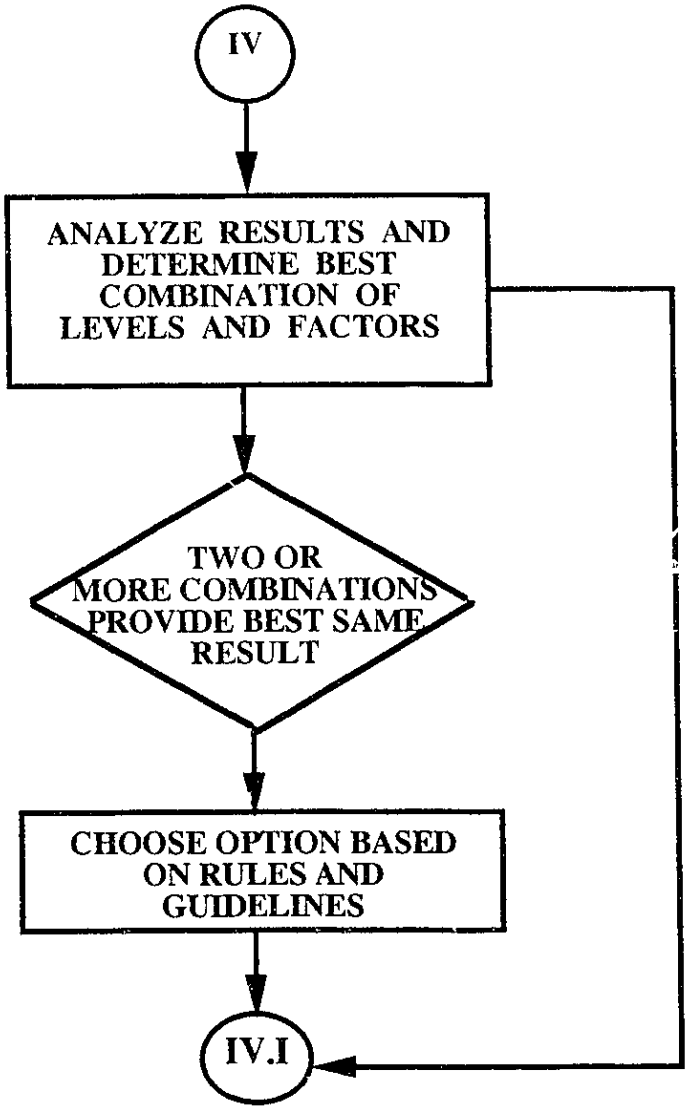


Fig 3.8 DATA ANALYSIS

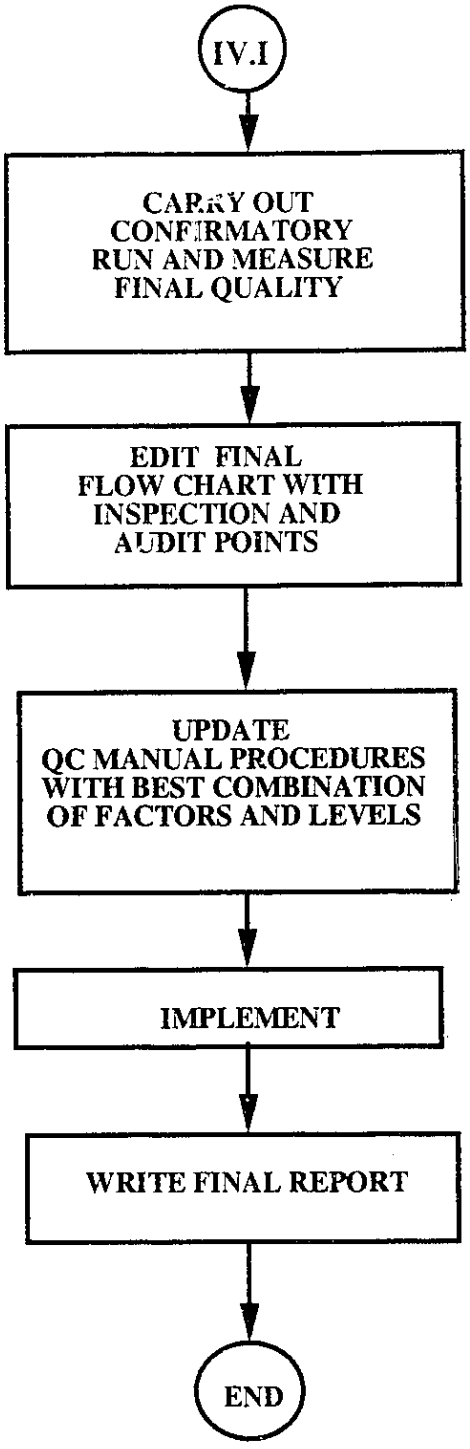


FIG. 3.9. CONFIRMATORY RUN

Expert System Sample Rules

Set 1: General

Rule 1:

IF

Results when using Instrument A = Results when using instrument B

THEN

use less expensive.

Rule 2:

IF

results when using different nondestructive techniques are the same

THEN

choose the least costly.

Rule 3:

IF

results when using nondestructive and destructive techniques are the same

THEN

choose the least costly.

Rule 4:

IF

calibration does not add to the performance of the instrument

THEN

Check calibration upon receipt.

Rule 5:

IF

Two or more combinations give the same results

THEN

choose least costly.

Rule 6:

IF

Two or more combinations give the same results and are equal in cost

THEN

choose the simplest in operation, i.e. the one least reliant on personnel training, experience and motivation.

Set 2: Measuring device

Rule 7:

IF

Results when measuring with the Go-No Go = when measuring with the Vernier or Micrometer

THEN

use Go-No Go.

Set 3: Welded pieces

Rule 8:

IF

Results when welding with procedure qualified by standard A = when qualified by standard B

THEN

choose least costly.

Rule 9:

IF

Results when controlling mechanical properties by bend tests= when verifying with tension tests= when verifying with Vickers=when verifying Metallography

THEN

use bend test to verify mechanical properties.

Rule 10:

IF

Results when verifying mechanical properties with tension test= when verifying with Vickers=when verifying with metallography

THEN

use tension tests to verify mechanical properties.

Rule 11:

IF

Results when using Penetrant Liquid= when using Ultrasonic= when using Magnetic Particles= when using Radiography

THEN

discard radiography (industrial safety) and choose the least expensive.

Rule 12:

IF

In-house training produces the same results as other qualifications

THEN

use in-house training.

Rule 13:

IF

qualified Level II produces same results as Level III

THEN

choose Level II.

Set 4: Inspection Points

Rule 14:

IF

Wet method OR Leco produce same results AND quantometer is available

THEN

choose quantometer.

Rule 15:

IF

Mechanical tests provide the same results

THEN

choose a method in the following order of preference:

Portable

Fixed

Rockwell

Brinell

Vickers

Tension Test

Charpy Impact

Hydraulic

Pneumatic.

Rule 16:

IF

Tests for cast molds produce the same results

THEN

Choose one in the following order of preference:

Hardness

Percentage Humidity

Resistance to compression

Rule 17:

IF

Heat treatment control produces the same results

THEN

choose one in the following order of preference:

Surface hardness

Register

Metallography.

3.2. Time

Model implementations are estimated to range from two weeks to three months, depending on the size of the company, the existing quality control system and the process plan.

A small company with up to 50 workers would have the following schedule:

Phase I:	1 week
Phase II & III:	2 weeks
Phase IV:	1 week
Total:	4 weeks

A medium size company of up to 100 workers:

Phase I:	2 week
Phase II & III:	3 weeks
Phase IV:	3 weeks
Total:	8 weeks

The above estimates apply when there is medium level management involvement and commitment. A full time coordinator is advisable as is the participation, as required, from production and quality control personnel.

CHAPTER 4. MODEL IMPLEMENTATION

4.1. Introduction

A practical implementation of this QC tool for reliable and cost effective quality control systems that comply with ISO 9000 was carried out. The company that permitted this exercise is a friction welding company, medium size capital, located in Puerto Ordaz, Venezuela. As a result, the best combination of levels of inspection and quality control that comply with the international standard and provide a product that exceeds the customer's expectations at a low cost were obtained.

4.1.1. Presentation of the Company

This case study was carried out in the actual manufacturing works of a company that provides the service of repairing pieces by friction welding. The company is located in the vicinities of the steel and aluminum ores in Venezuela, South America. Their main client is the aluminum industry in which alumina is transformed into aluminum semi-manufactured goods. They provide friction welding of dissimilar metals such as steel to aluminum and aluminum to copper, offering this alternative technique opposed to manual welding.

The friction welding machine, manufactured and imported from Norway, has been modified to carry out this new application. It was originally designed to service the oil industry: joining oil well piping. This technology, although ex-

istent in other industries and countries, is new for this geographical zone. Therefore, high quality welds are a priority as a marketing tool.

4.1.2. Organization

The company is a privately owned company with a hierarchical functional scheme. The organization chart is shown in Fig. 4.1. Their main product is friction welding repair of the tips to the yoke that forms the anodic part of the electrical cell in which the aluminum is obtained with a current of 7000-9000 Amp. This has traditionally been done by SMAW (Submerged Metal Arc Welding) using manual processes and electrodes. The company operates with a technical staff that carries out the actual work and a support staff, at the corporative offices, that assists production activities. The manufacturing process is shown in Fig. 4.2. Process Diagram.

4.2. Implementation of the Proposed Model

The model was implemented in the company on the production that was available at the moment of the study, that is, joining new stub ends to a yoke. This piece is used as an anode bar in the high amperage furnaces that transform the alumina into aluminum. No structured quality control system existed, other than activities carried out by the machine operators. Following the steps of the model, previously detailed in Chapter 3, inspection and quality control points

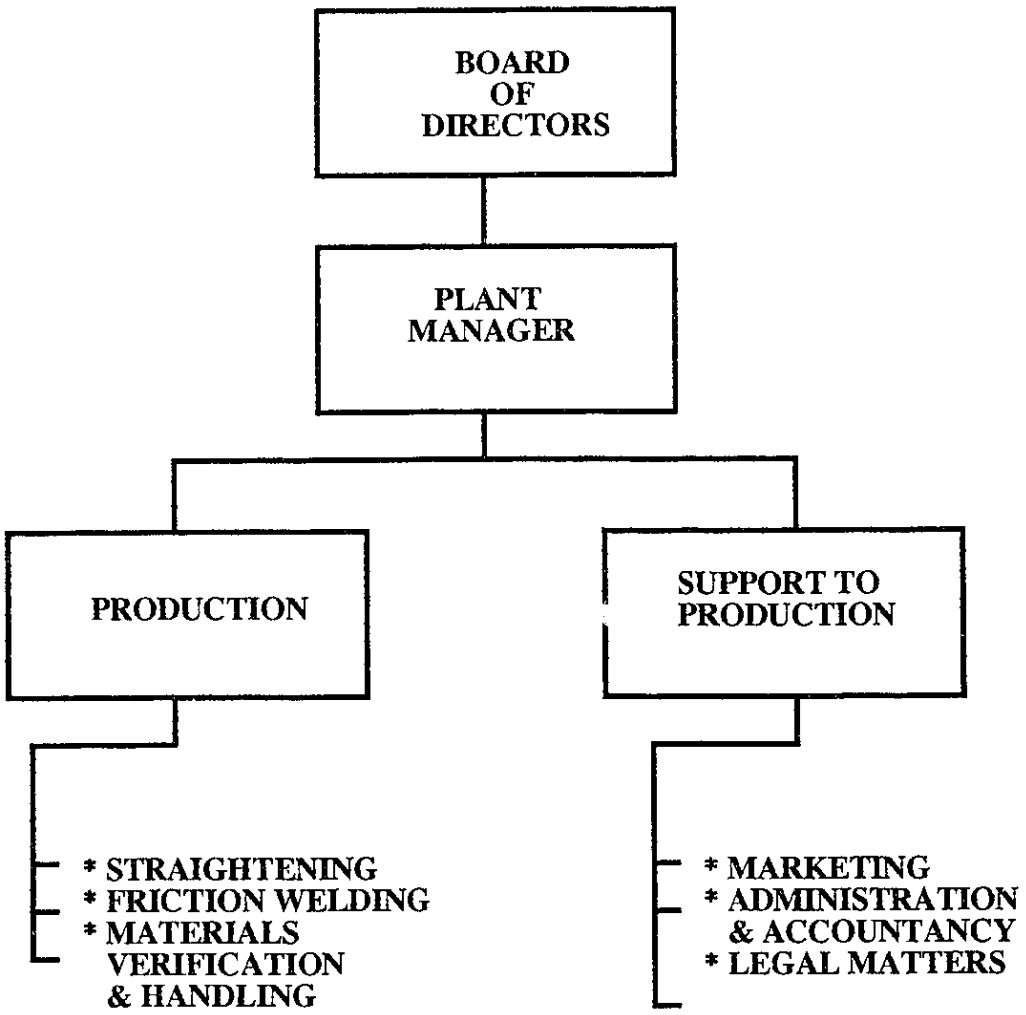


FIG. 4.1. ORGANIZATIONAL CHART

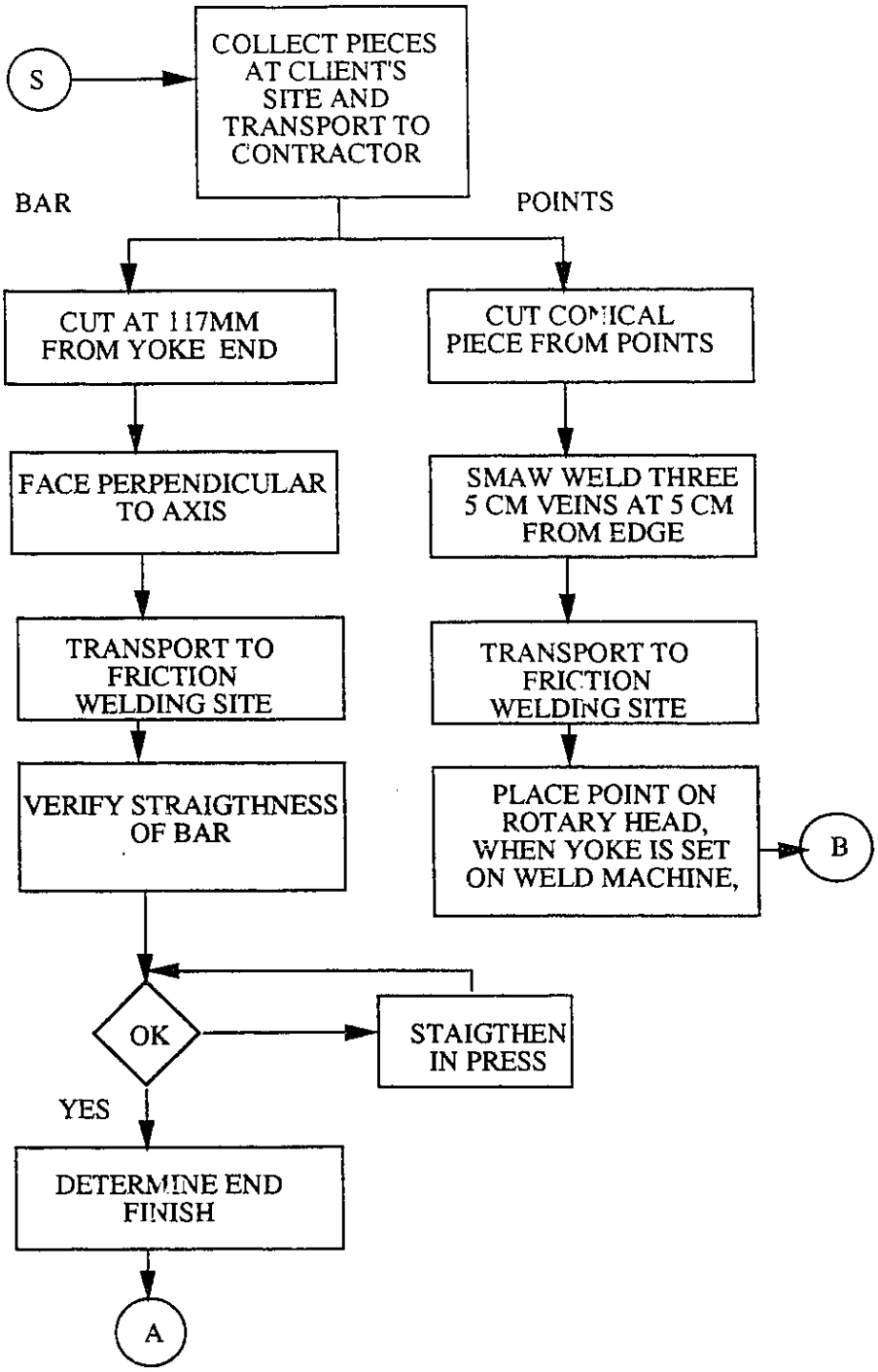
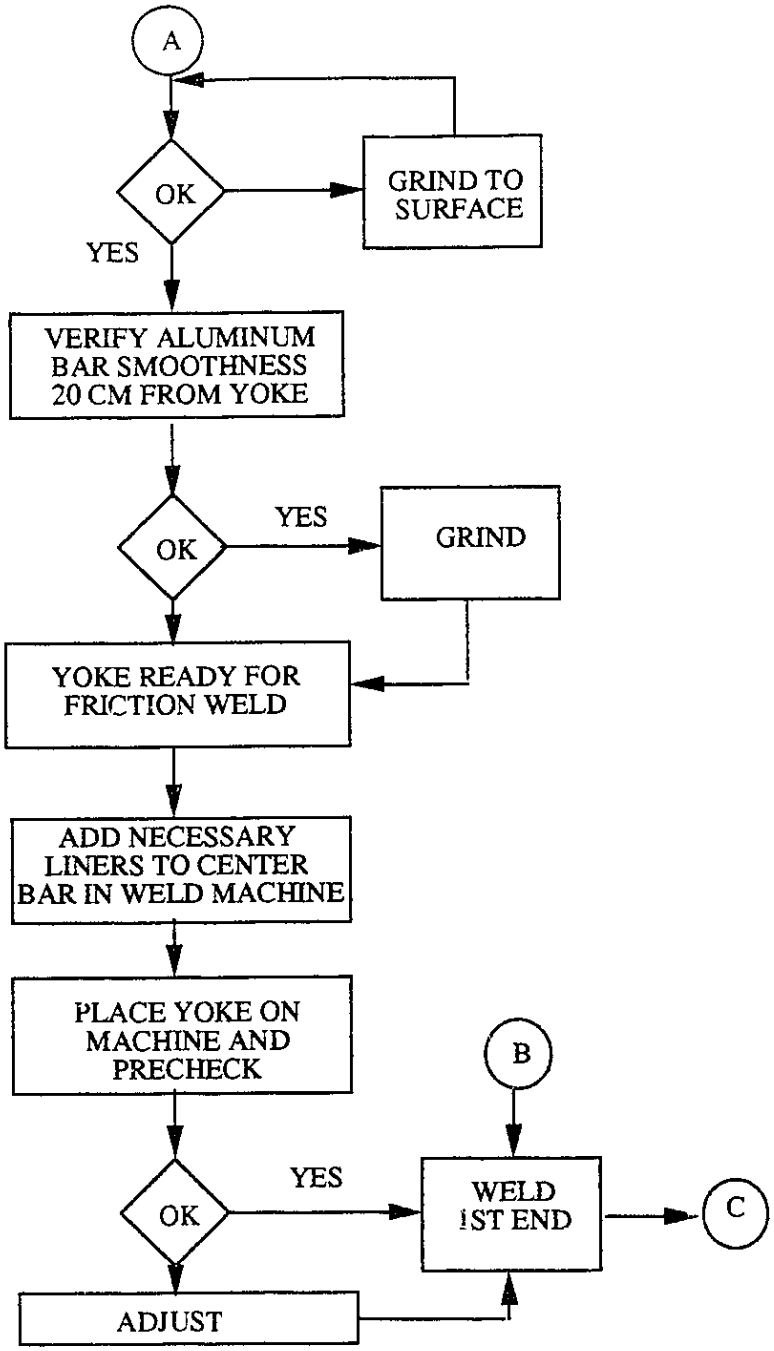
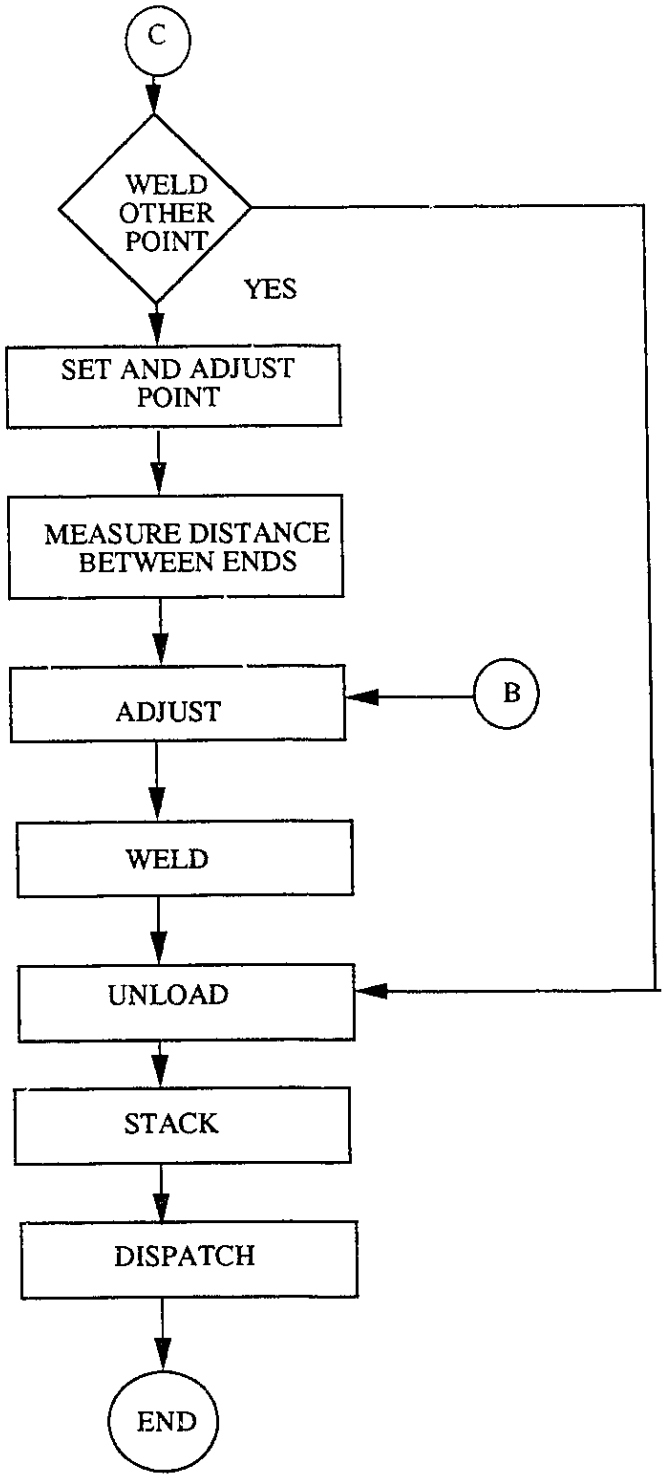


FIG. 4.2 PROCESS DIAGRAM



CONT. FIG. 4.2 PROCESS DIAGRAM



CONT. FIG. 4.2 PROCESS DIAGRAM

were added to this flow chart that complies with an ISO 9000 quality controlsystem. Four measuring tools were designed to be used as Go-No Go's. An inspection point was added with every transformation of the material, whether mechanical, chemical or dimensional.

4.2.1. Inference for Worst Possible Case

Each inspection point was analyzed for the implications of the "worst possible case". This exercise proved to be a valuable source of information for the further design of the experiment, therefore, it is to be included as an analysis tool of this model. The inferences are as follows:

Inference for Worst Possible Case

	Required Inspection Training			Manufacturing Process results are		Defective piece is		Occurrence Probabilty		
(*)	N	M	H	RM	CN	RP	RJ	R	M	H
1.1		x			x		x	x		
1.2		x			x	x		x		
2.1		x			x	x		x		
2.2		x			x		x	x		
2.3	x				x		x	x		
3.1	x			x		x				x
4.1	x			x		x			x	
5.1	x			x		x			x	
6.1			x		x		x	x		
7.1	x				x	x		x		

(*) Inspection Points	Key:	
1.1 Inspection point 1, Cut	N:	Normal
1.2 Inspection point 1, Facing	M:	Medium
2.1 Inspection point 2, Cut	H:	High
2.2 Inspection point 2, Facing	RM:	Random
2.3 Inspection point 2, Weld	CN:	Consistent
3.1 Inspection point 3, Straighten	RP:	Repairable
4.1 Inspection point 4, Grind	RJ:	Rejected
5.1 Inspection point 5, Grind	R:	Random
6.1 Inspection point 6, Friction weld	M:	Medium
7.1 Inspection point 7, Pile and despatch	H:	High

4.2.2 Procedure

Phase I

The company had no formal quality control system or manuals. Therefore, the first step was to elaborate the process diagram, Fig. 4.2. A quality control system as per ISO 9000 was proposed and identified on this same process diagram. See Fig. 4.3: Process Diagram /Inspection as per ISO 9000. As it is shown, the inspection points are located after each material transformation. As previously stated, the model is intended for periodical or routine QC practices:day-to-day quality control points. Kick-off tests such as chemical composition of the yoke and tips and on-the-job performance are not included in the process diagram, even though they are considered to be quality control points. They are

carried out at the prior to production, as a client requirement, not on a day-to-day basis. Inspection procedures to be used in Phase II have been also defined:

▸ GENERAL PROCEDURE

A) Prior to Production:

1) On site trial: Voltage measures.

2) Chemical composition of parts to be welded: Yoke, forged tip and metal deposit of previous weld.

B) During production: (Refer to Fig. 4.3)

I1: Dimensional inspection of yoke: Distance of end more than 117mm from yoke; face perpendicular to axis.

I2: Dimensional inspection of end: Surface finish of face to weld;Length: 190mm. Quality of welded veins.

I3: Dimensional: Verify straightness of bar.

I4: Visual: Verify finish.

I5: Visual: Verify surface finish in a length of 20 cm, at 5 cm from yoke end.

I6: Visual: Weld finish. Dimensional: total length of finished piece and separation between yokes points.

I7: Pre-dispatch inspection: Verify handling, storage and documentation.

SPECIFIC PROCEDURES

Inspection Procedure for Point 1: Dimensional inspection of yoke

Object:

To ensure that:

1) Final dimensions of welded piece is as per client's specifications.

2) Faces are perpendicular so as to permit the contact and weld by friction.

Description:

Check that the distance from yoke end to the U is 117mm or more.

Check that the yoke face is perpendicular to axis.

Inspector's Training: Basic .

Inspection Tools: A Go-No Go designed for the job and regular dimensional tools.

Calibration of inspection tools: In-house

Sampling: 100 % inspection

Inspection Procedure for point 2: Inspection of tip

Object:

To ensure that:

1) Length of tip is as specified by client.

2) Finish of face is as required for welding by friction.

3) Veins have been welded to permit the use of the welding machine chuck.

Description:

Length of tip: 190mm or less

Quality of finish: Machine grind

Veins: Three longitudinal veins placed at 120 grades/transversal cut: A length of 5mm, 5mm from the finished end.

Inspector's Training: Basic.

Inspection Tools: Visual inspection and regular dimensional tools.

Calibration of inspection tools: Dimensional tools calibrated by certified laboratories.

Sampling: 100% inspection

Inspection Procedure for Point 3: Inspection of bar

Object:

To ensure that the bar is straight to be able to place and grasp with welding machine clamps.

Description:

Verify the straightness of the overall length of the bar.

Inspector's Training: Basic

Inspection Tool: A Go-No Go designed for the job

Calibration of Inspection Tool: In-house calibration

Sampling:100% inspection

Inspection Procedures for Points 4 and 5: Pre-weld inspection

(Given the nature and resemblance of these two points, they are treated jointly)

Object:

To ensure that surface finish allows the use of the welding machine clamps.

Description:

Verify that there are no protuberances neither on the tip nor on the yoke in a length between 5 and 25 cm from end of machined faces.

Inspector's Training: Basic

Inspection Tool: Go-No Go Tool

Calibration of inspection tool:In-house

Sampling: 100% inspection

Inspection Procedure for Point 6: Inspection of welds

Object:

To ensure that a sound and cosmetic weld has been obtained

Description:

Verify that burrs have been removed.

Verify that dimensions of finished piece are as per client's specifications.

Inspector's Training: Basic

Inspection Tools: A Go-No Go and regular dimensional tools.

Calibration of inspection tools:In-nouse calibration for Go-No Go and calibration by certified laboratories for dimensional tools

Sampling: 100% inspection

NDT: Ultrasonics using a Krautkramer equipment, 60 grades piezoelectric sensor, type A Scan, Level II qualified as per ASNT-TC-II.

Inspection Procedure for Point 7: Pre-despatch inspection

Object:

To ensure that material moving and handling has been as per client's requirements. Check that required documentation is sent to client as per specified.

Description:

Carry out visual inspection of material storage and handling onto transport truck. Verify that shipping documents are sent.

Inspector's Training: Basic.

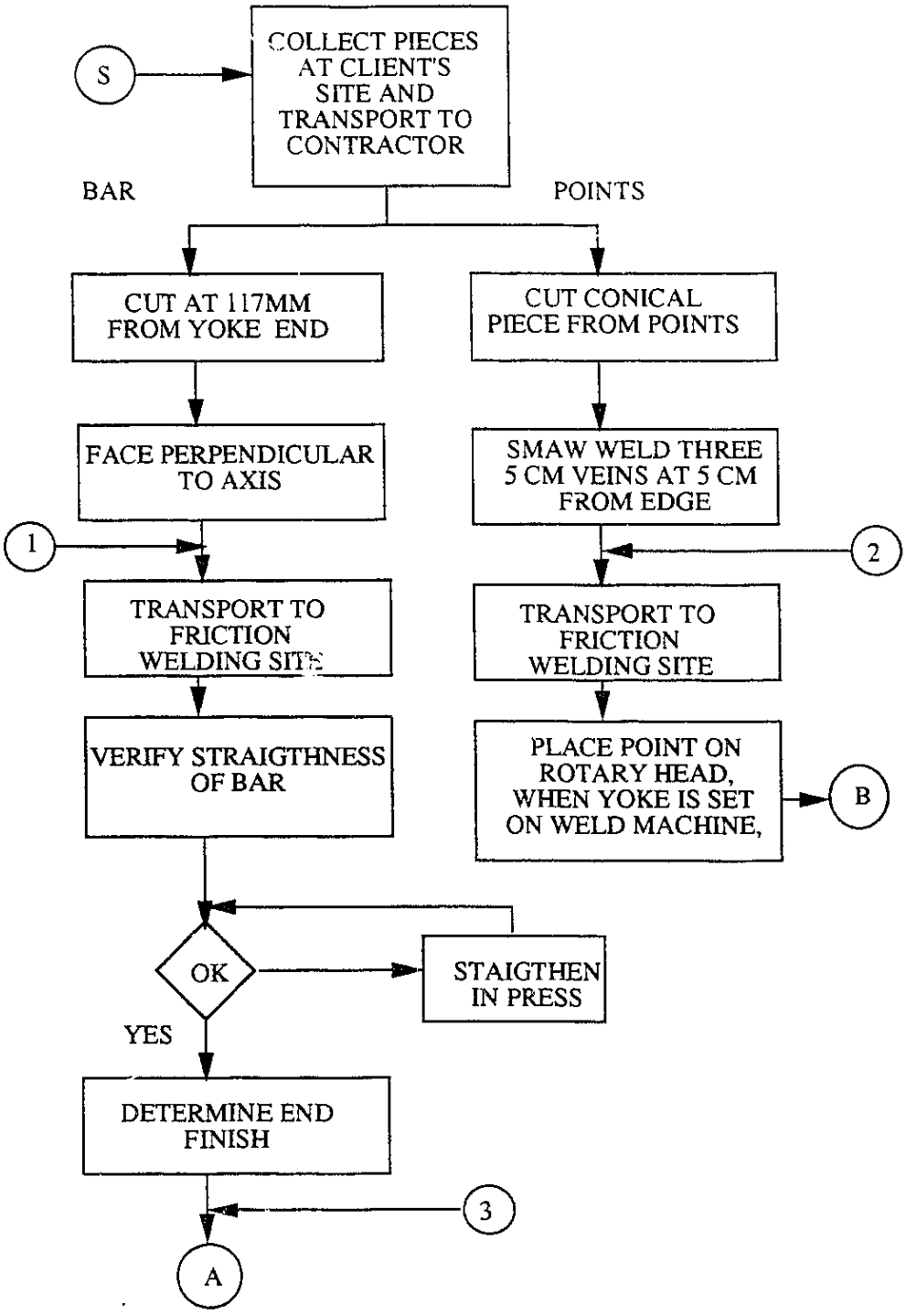
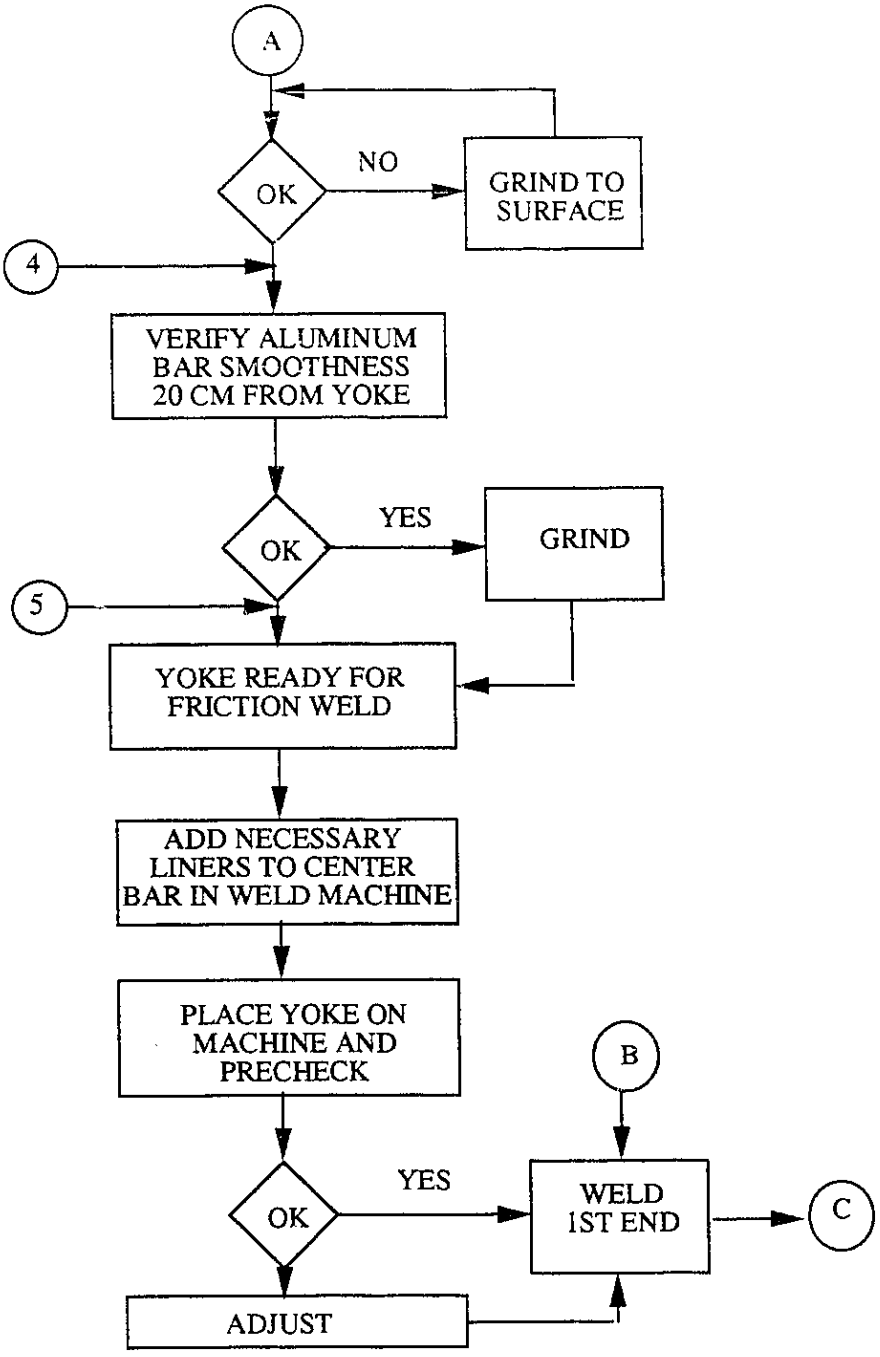
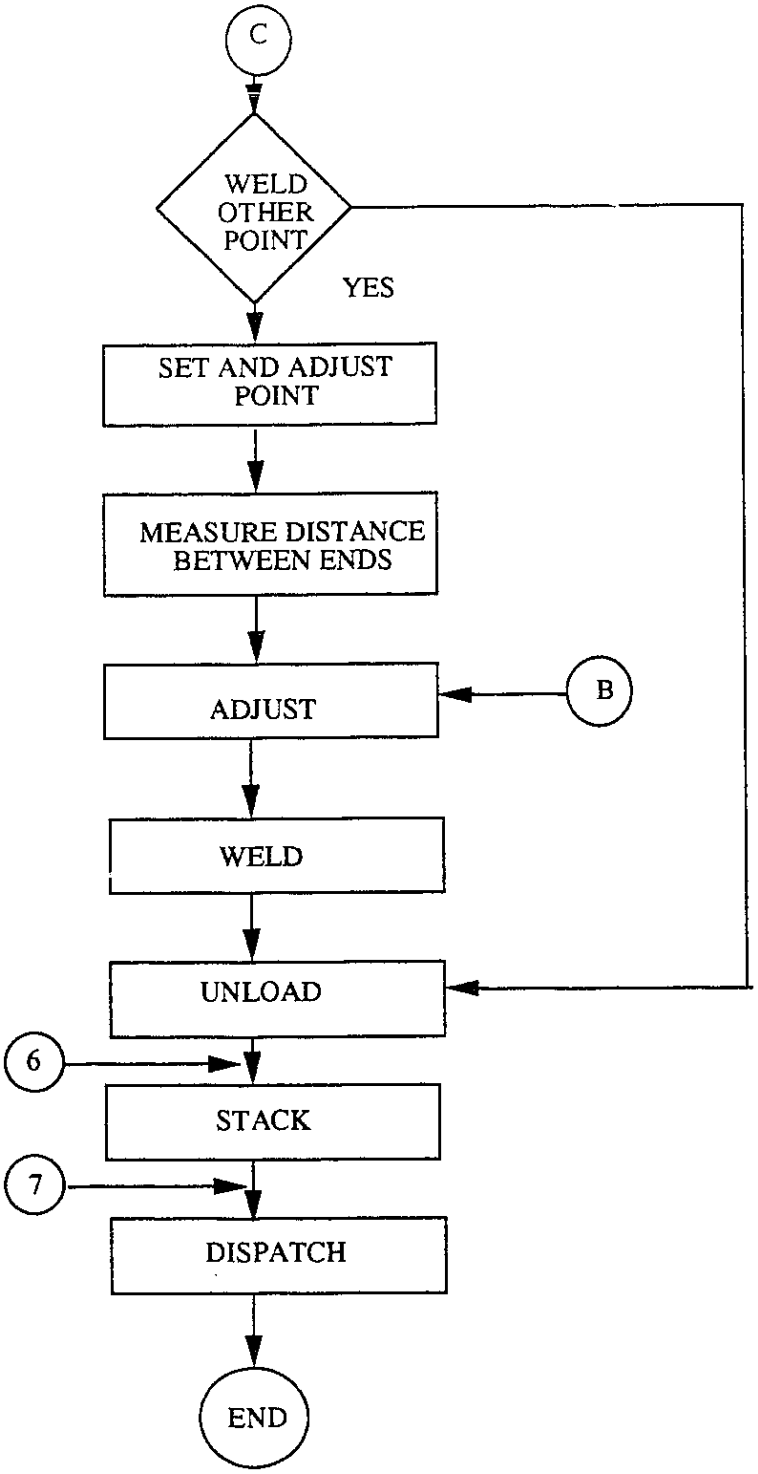


FIG. 4.3 PROCESS DIAGRAM WITH INSPECTION AS PER ISO 9000



CONT. FIG . 4.3 PROCESS DIAGRAM WITH INSPECTION AS PER ISO 9000



CONT. FIG . 4.3 PROCESS DIAGRAM WITH INSPECTION AS PER ISO 9000

Phase II

The second phase carried out was the screening phase. The runs for the experiments are detailed in Table 4.1. The object of this phase was to determine those points that are of importance to the final quality of the product and those that are not. Each one of the fourteen runs was carried out using a lot of five finished pieces. For run 11, Ultrasonics was used opposed to visual inspection.

Run No.	Description	Levels
1	Inspection Point 1: Yoke	Inspection
2	Inspection Point 1: Yoke	No inspection
3	Inspection Point 2: Tip	Inspection
4	Inspection Point 2: Tip	No inspection
5	Inspection Point 3: Bar	Inspection
6	Inspection Point 3: Bar	No inspection
7	Inspection Point 4: Pre-weld, Yoke	Inspection
8	Inspection Point 4: Pre-weld, Yoke	No inspection
9	Inspection Point 5: Pre-weld, tip	Inspection
10	Inspection Point 5: Pre-weld, tip	No inspection
11	Inspection Point 6: Weld	Inspection
12	Inspection Point 6: Weld	No inspection
13	Inspection Point 7: Pre-despatch	Inspection
14	Inspection Point 7: Pre-despatch	No inspection

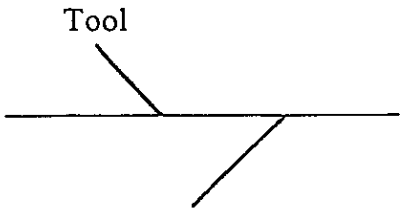
Table 4.1 Screening Stage

Phase III

The third phase consisted of defining factors and levels for each inspection point classified as relevant as a result of Phase II. Levels and factors were determined by using Ishikawa diagrams. For each relevant inspection point, a table was elaborated indicating the number of required runs with the different combinations of levels and factors. As in Phase II, measurements were done based on lots of five. Ishikawa diagrams and tables of runs for inspection points 3, 4, 5 and 6 follow.

Inspection Point 3:

Ishikawa diagram:

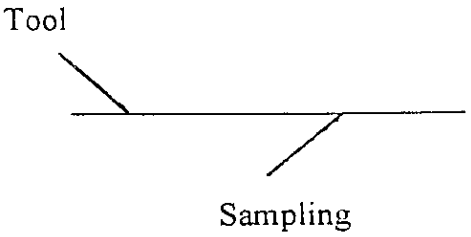


The table of runs required for inspection point 3 is a 2^2 matrix as follows:

Run No.	Description
3.1	Single sampling, Tool: Custom made bar
3.2	Single sampling, Tool: Custom made bar with visual aids
3.3	100% inspection, Tool: Custom made bar
3.4	100% inspection, Tool: Custom made barwith visual aids

Inspection Points 4 and 5:

Ishikawa diagram:

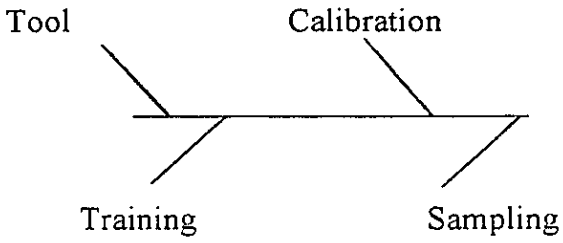


The table of runs required for inspection points 4 and 5 is a 2^2 matrix as follows:

Run No.	Description
4.1, 5.1	Single sampling,Visual inspection
4.2, 5.2	Single sampling, Custom made Go-No Go Tool
4.3, 5.3	100% inspection,Visual inspection
4.4, 5.4	100% inspection, Custom made Go-No Go Tool

Inspection Point 6:

Ishikawa diagram:



The table of runs required for inspection point 6 is a 2^3 matrix as follows:

Run No.	Description
6.1	100% inspection, Go-No Go, Calibrated
6.2	100% inspection, Go-No Go, Not calibrated
6.3	100% inspection,Vernier and rulers, Calibrated
6.4	100% inspection, Vernier and rulers, Not calibrated
6.5	Single sampling, Go-No Go, Calibrated
6.6	Single sampling, Go-No Go, Not calibrated
6.7	Single sampling, Vernier and rulers, Calibrated
6.8	Single sampling, Vernier and rulers, Not calibrated

4.3 Results

4.3.1. Results from the Screening Phase

From Table 4.2 the following is obtained:

1) Carrying out inspection at point 1 gives 0% defectives.Wheteher inspection is carried out, there is no difference in the measurements therefore, it is concluded that inspection point 1 does not add to final quality of product. The use of inspection personnel and equipment here is an unnecessary waste.

At this manufacturing stage, the machine-tool used is a oxyfuel torch cutter used with a copier; facing is done on a lathe. The manufacturing process is automatic and technology is widely known. It is carried out by a contractor. From the expert system rules it is concluded=>

Carry out inspection upon receipt of manufactured lots using simple sampling techniques with an AQL of 1%, using rulers and verniers. Write report and file.

Appraise the manufacturer's quality control system, applicable to this product: training of personnel, calibration and maintenance of machines and instrumentation. Follow up recommendations.

2) Carrying out inspection at point 2 gives 0% defectives. Not carrying out gives 0% as well, therefore it is concluded that inspection point 2 does not add to the final quality of product. The use of inspection personnel and equipment here is an unnecessary waste, as well as for inspection point 1.

The process which is used is manual welding with E-6010 electrodes. Welding technology is widely known. It is carried out by a contractor.From the knowledge base::

Carry out inspection upon receipt, with simple sampling, AQL 1%, visual inspection. Write report and file.

Appraise the manufacturer's quality control system, applicable to this product: training of personnel, calibration and maintenance of machines and in-

strumentation. Check welding machines, procedures and personnel qualification. Write report and file. Follow up recommendations.

3) Inspection points 3, 4, 5 and 6 are evidently of great importance. Not carrying them out produce rejects of up to 90%. A detailed analysis of these points were carried out in Phase III.

4) Carrying out inspection at point 7 gives 0% defectives. Not carrying out gives 0% as well , therefore it is concluded that inspection point 7 does not add to final quality of product. The use of inspection personnel and equipment here is an unnecessary waste as in points 1 and 2.

For this repetitive and simple activity and from the expert system:

Supervise training. Audit activities of operators once a month.

4.3.2. Results from the Scrutinizing Phase

From Table 4.3 and Fig. 4.4 the following is concluded:

1) Inspection points 3, 4 and 5: the manufacturing process is manual, without any automatic aids. The required operative tolerances on this point are so stringent that they cannot be determined by simple visual inspection. Any rejected piece can be reworked, but this affects considerably productivity, creating a "bottle neck". From the results of the experiment and the expert system, this is the required action:

Carry out 100 % inspection, using specially designed go-no go classifier

At Inspection Station No.	Percentage Defectives when Inspection was carried out on point	Percentage Defectives when Inspection was not carried out
1	0	0
2	0	0
3	43	90
4	33	58
5	12	57
6	23	0
7	0	0

Note: Percentage defectives =

$$(\Sigma\ rw + \Sigma\ rp + \Sigma\ df) / P \times 100$$

where:

rw: number of reworked pieces

rp: number of repaired pieces

df: number of defective pieces at final stage

P: Total number of manufactured pieces.

Table 4.2. Results from Screening Phase

Inspection Point No. 3	Level 1	Level 2
Method	–	+
Sampling Plan	–	+

Inspection Point No. 4	Level 1	Level 2
Method	–	+
Sampling Plan	–	+

Inspection Point No. 5	Level 1	Level 2
Method	+	–
Sampling Plan	–	+

Table 4.3. Results from the Scrutinizing Phase

Levels	Method	Sampling Plan
1	Visual inspection	Single Sampling
2	Go-No Go Tool	100% inspection

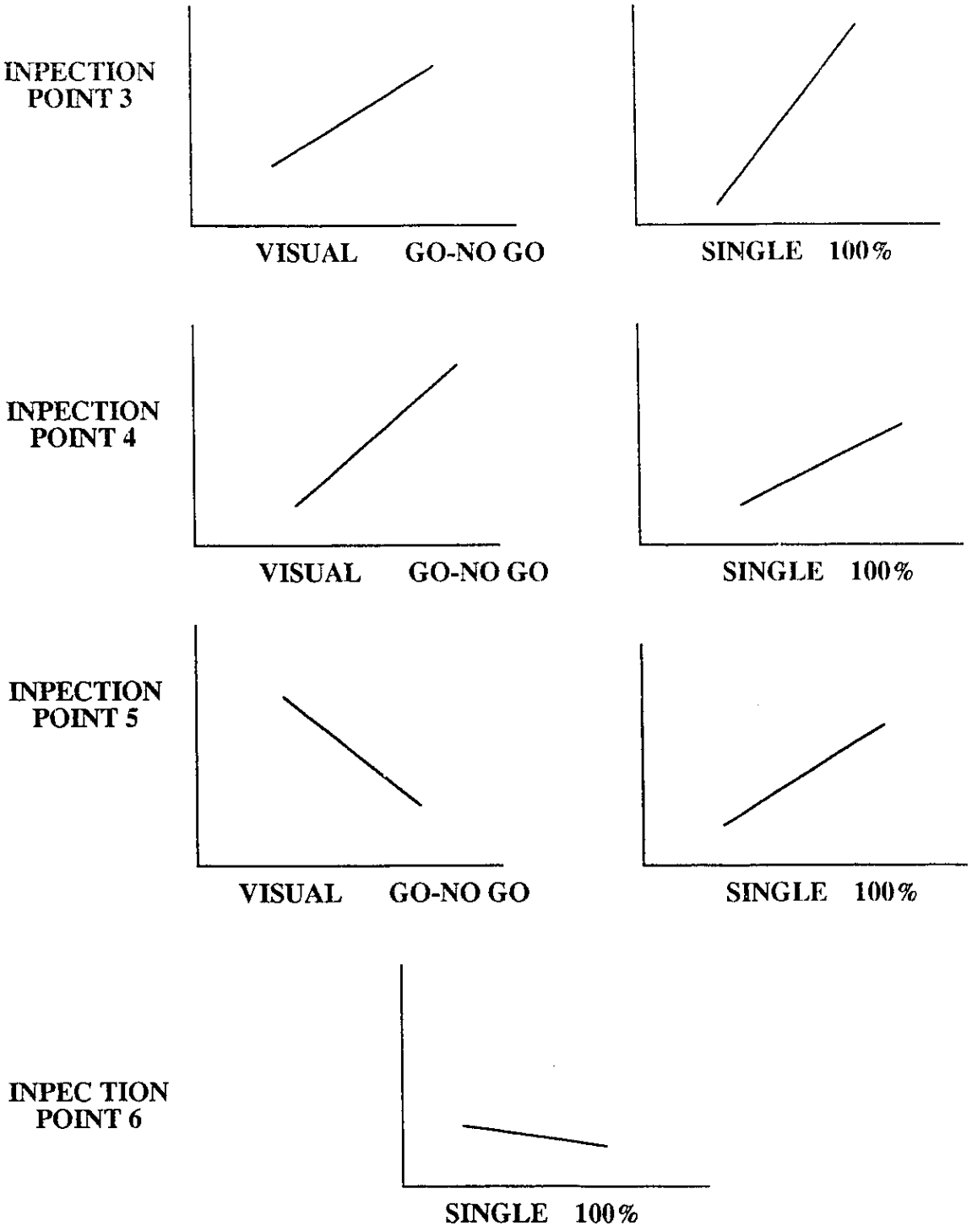


FIG. 4.4 RESULTS FOR INSPECTION POINTS 3,4,5 AND 6

tool.

2) Inspection point 6: Process is automatic, but technology is new and personnel is still on learning curve. Results of the model show that 100 % inspection and sampling give same results. The defectives occur when process is not controlled and stable. Therefore, from the expert system rules:

Carry out inspection of first five pieces starting each working shift or when operators are changed. Continue inspection, if necessary, until process is stable and producing acceptable results. Check aligning of pieces and quality of welding deburring.

4.3.3 Time, Costs and Final Quality

Time

Based on a lot of 100 finished pieces, the difference in times required to carry out inspections as per ISO 9000 prior to the model and after the model are involved:

Inspection Point	**Before Model**	**After Model**
No.	min	min
1	29	14
2	29	14

Inspection Point	Before Model	After Model
3	112	47
4	38	23
5	33	18
6	212	37
7	105	77
Total	558	230

The time required to operate an ISO 9000 compliant quality control system has been reduced by 59%.

Costs

The estimated costs of operating the ISO 9000 compliant QC system before and after the model are as follows:

Before the Model:

Wage of the QC engineer x time	\$ 0.038/min x 205 min	\$ 0.779
Wage of inspectors x time	\$ 0.019/min x 123 min	\$ 0.233
	Total wages	\$ 1.012
Calibration costs		\$ 0.225

Audit costs		$ 0.100
	Total cost	$ 1.337

After the model was implemented		
Wage of the QC engineer x time	$ 0.038/min x 160	$ 0.608
Wage of inspectors x time	$ 1,90/min x 70	$ 0.133
	Total wages	$ 0.741
Calibration costs		$ 0.023
Audit costs		$ 0.025
	Total Cost	$ 0.789

The cost of operating an ISO 9000 compliant quality control system has been reduced by 41%.

Final Quality

Before the model, the mean of rejected pieces that would have been shipped to the client were 1 out of a lot of 6. After the model, number of pieces shipped to were 0. Quality has been improved by 16 %.

CHAPTER 5. ANALYSIS OF RESULTS

From the extensive literature review carried out for the present research, implementation of ISO 9000 has not been quantified by measuring quality improvement of final quality or quality cost reductions, due to the fact that it has been a market driven requirement: a compulsory requirement to obtain market share. Focus has been on how to implement it as far as obtaining a certification is concerned. It has opened a new door for consultants around the world, burdening the manufacturer with sometimes unnecessary efforts and costs. Although successful in obtaining the qualification, ISO 9000 systems have not assured final quality at least cost. The proposed model has considered these two main factors and the QC systems are reliable and consistent in terms of final results. As the case study confirmed, the proposed model has fulfilled the objective of providing manufacturers with a systematic approach for sound and cost effective ISO 9000 quality systems.

From the Screening Phase (Refer to Table 4.2) it is seen that when carrying out inspection on inspection point 1, final quality of the product is the same as when it is not carried out: No defectives were found for either case. The same occurs for inspection points 2 and 7. There has been no value added to the product when executing these inspection points. In other words, designed and built-in quality has been obtained without the need of close inspection. As

pointed out in Sec. 4.3, manufacturing processes and technology have produced reliable results. Only general quality auditing is required, as a recommended healthy QC practice.

Regarding ISO 9000, the system is compliant because the product is *"inspected, tested and identified as required by the quality plan"* and *" product conformance is established to specified requirements by the use of process monitoring and control methods"* (Refer to Appendix. 1, Clause 4.9.2. In-process inspection). Reclassifying inspection points 1, 2 and 7 as non-relevant and redefining them as audit points has contributed with the 41% reduction in quality costs and 59% reduction in QC times.

Also from the Screening Phase, it is made clear that inspection points 3, 4, 5 and 6 are critical, some more than others, in order to obtain a quality product. From Table 4.2 it can be seen that when carrying out inspection at point 3, 43 % of defectives (that include rework and repair) are detected, whereas when no inspection has been carried out a 90% defectives have been obtained. Evidently, point 3 is critical and not only quality controls but quality engineering efforts are to be allocated here. As exposed in 4.3, the type of raw material received, a used yoke that the client has sent to have repaired, is a non-controllable factor. The controllable factor becomes the inspection that has to be done and how. The same applies to inspection points 4 and 5. These three points are candidates for the following phase, the scrutinizing phase.

An interesting result is available with inspection point 6. When inspection is carried out a 23% of defectives is obtained. When not carried out, 0% defectives are reported, the reason being that at point 6, a more accurate method, a nondestructive technique -ultrasonics-, was used, instead of visual inspection that is regularly carried out at the final inspection point and by the client. An interesting aspect of the model is highlighted: when comparing results between two sets of experiments the analysis of results cannot be solely based on the numbers, but aided with the general set of rules exposed in section 4.3.2.

Following on to the results of the scrutinizing phase (Refer to Table 4.3) the feasible and available opportunities of inspection have been put together in a series of experiments. For inspection point 3, the best results are obtained when using 100% inspection and the Go-No Go tool specially designed for this purpose. For inspection point 4, best results have been obtained when using 100% inspection/Go-No Go combination, aided with the general set of rules. A similar discussion applies to inspection points 5. The best combination proved to be 100% inspection/Go-No Go. On the other hand, inspection point 6 has showed that a Go-No Go is not necessary and that visual inspection is more important and effective than other methods. Inspection point 6 is also interesting in the sense that it exposes the situation of having several combinations of methods that are very similar in results: they only vary in 1%. Again, the general set of rules aid in the required action which, in this particular case is inspection of

first five pieces or until process is stable. Even though it was not part of the objectives of the research, the model also provides information regarding the inspection point in which quality engineering efforts should be allocated. For the case study, inspection point 3 is the one to look at for improvements in not only quality but productivity.

All results from the Case Study Phase III have contributed to the reduction of quality costs by 41% and quality inspection times by 59% and the improvement in final quality of 16%. The results of the scrutinizing phase also comply with ISO 9000. All required and documented inspections are carried out and reported. Aspects such as measurements, calibration, documentation, test methods handling and storage have been considered in the design of the system, and the final combination of factors and levels are as per the standard (Refer to Appendix 1, Clause 4.10).

The quality system designed and implemented for a friction welding company using the developed model complies with ISO 9000, is cost effective and adds value to the final quality of the product. The implementation of the model in a real case study has shown the applicability of the model. It has shown to be simple to use, provided that the user has a basic knowledge of the manufacturing process and carries out a reasonable research in order to find inspection methods, instruments and other available in his working environment and market. Times involved in the implementation of the model were less than those

required for current practices for an ISO 9000 implementation on a company similar top of a similar size, the main reason being that final implementation of the system is based on a combination of best factors and levels that produces consistent and reliable detection of defective pieces prior to shipment. It is important to stress: results are obtained AND verified before the final implementation of the ISO 9000 QC system, instead of negative results seen in time such as rejected products or, repetitive and useless inspection procedures that require time and money and that do not add value, in terms of quality, to the product. The case study has shown that by using DOE's principles and techniques, the process of obtaining the best combination of factors and levels is catalyzed. And, most important of all, the objective of the research has been fulfilled: sound quality control systems designed by using the developed model comply fully with ISO 9000 and are ISO 9000 certifiable.

CHAPTER 6. CONCLUSIONS AND RECOMMENDATIONS

The research focus has been on the development of a model which provides the best combination of levels and factors of inspection points for ISO 9000 compliant quality control systems. The resulting QC system verifies that pieces produced by the manufacturing setup and inspected by the QC system exceed the customer's quality expectations at a minimal cost. The variability of the results of the system has been reduced by using a systematic, scientifically based model. Added value is assured for the final quality of the product. These quality systems are sound and reliable. The best possible final quality is consistently obtained and confirmed and, most importantly, cost effective. The "significant few" quality controls have been made relevant with a small number of experiments by using Design of Experiments principles and techniques. A case study was carried out in a friction welding company. As a result, quality costs were reduced by 41 %, inspection times by 59% and final quality improved by 16%.

As far as the developed model is concerned, future studies are advisable in order to expand the framework to

- Companies that provide services.
- Companies that comply with ISO 9003: distribution.
- Nonconveyorized manufacturing.

Also, the present approach implies that not only ISO 9000 but any set of general requirements can be systemized using the model. Future research should aim at expanding the application of the model to other international, national and association standards related to not only to quality control systems but others such as environmental regulations.

The International Standards Organization in Geneva, Switzerland, welcomes contributions to the reliable and cost effective implementation of ISO 9000 worldwide. A copy of the thesis may be sent to this institution.

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Appendix 1: Extracts of ISO 9001 & 9002

INTERNATIONAL STANDARD

ISC
900

First edit
1987-03-

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Quality systems — Model for quality assurance in design/development, production, installation and servicing

Systèmes qualité — Modèle pour l'assurance de la qualité en conception/développement, production, installation et soutien après la vente

Reference
ISO 900

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality assurance.*

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management shall define and document its policy and objectives for, and commitment to, quality. The supplier shall ensure that this policy is understood, implemented and maintained at all levels in the organization.

4.1.2 Organization

4.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined; particularly for personnel who need the organizational freedom and authority to

a) initiate action to prevent the occurrence of product nonconformity;

b) identify and record any product quality problems;

c) initiate, recommend or provide solutions through designated channels;

d) verify the implementation of solutions;

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Verification resources and personnel

The supplier shall identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities (see 4.18).

Verification activities shall include inspection, test and monitoring of the design, production, installation and servicing processes and/or product; design reviews and audits of the quality system, processes and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.

4.1.2.3 Management representative

The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of this International Standard are implemented and maintained.

4.1.3 Management review

The quality system adopted to satisfy the requirements of this International Standard shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained (see 4.16).

NOTE — Management reviews normally include assessment of the results of internal quality audits, but are carried out by, or on behalf of, the supplier's management, viz management personnel having direct responsibility for the system. (See 4.17.)

4.2 Quality system

The supplier shall establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements. This shall include

a) the preparation of documented quality system procedures and instructions in accordance with the requirements of this International Standard;

b) the effective implementation of the documented quality system procedures and instructions.

NOTE — In meeting specified requirements, timely consideration needs to be given to the following activities :

a) the preparation of quality plans and a quality manual in accordance with the specified requirements;

b) the identification and acquisition of any controls, processes, inspection equipment, fixtures, total production resources and skills that may be needed to achieve the required quality;

c) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

d) the identification of any measurement requirement involving capability that exceeds the known state of the art in sufficient time for the needed capability to be developed;

e) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

f) the compatibility of the design, the production process, installation, inspection and test procedures and the applicable documentation;

g) the identification and preparation of quality records (see 4.16).

4.3 Contract review

The supplier shall establish and maintain procedures for contract review and for the coordination of these activities.

Each contract shall be reviewed by the supplier to ensure that

a) the requirements are adequately defined and documented;

b) any requirements differing from those in the tender are resolved;

c) the supplier has the capability to meet contractual requirements.

Records of such contract reviews shall be maintained (see 4.16).

NOTE — The contract review activities, interfaces and communication within the supplier's organization should be coordinated with the purchaser's organization, as appropriate.

prevented from inadvertent use or installation. Control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product and for notification to the functions concerned.

4.13.1 Nonconformity review and disposition

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures. It may be

a) reworked to meet the specified requirements, or

b) accepted with or without repair by concession, or

c) re-graded for alternative applications, or

d) rejected or scrapped.

Where required by the contract, the proposed use or repair of product (see 4.13.1b)) which does not conform to specified requirements shall be reported for concession to the purchaser or his representative. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

Repaired and reworked product shall be re-inspected in accordance with documented procedures.

4.14 Corrective action

The supplier shall establish, document and maintain procedures for

a) investigating the cause of nonconforming product and the corrective action needed to prevent recurrence;

b) analysing all processes, work operations, concessions, quality records, service reports and customer complaints to detect and eliminate potential causes of nonconforming product;

c) initiating preventative actions to deal with problems to a level corresponding to the risks encountered;

d) applying controls to ensure that corrective actions are taken and that they are effective;

e) implementing and recording changes in procedures resulting from corrective action.

4.15 Handling, storage, packaging and delivery

4.15.1 General

The supplier shall establish, document and maintain procedures for handling, storage, packaging and delivery of product.

4.15.2 Handling

The supplier shall provide methods and means of handling that prevent damage or deterioration.

4.15.3 Storage

The supplier shall provide secure storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt and the despatch to and from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

4.15.4 Packaging

The supplier shall control packing, preservation and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements and shall identify, preserve and segregate all product from the time of receipt until the supplier's responsibility ceases.

4.15.5 Delivery

The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

4.16 Quality records

The supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records.

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent sub-contractor quality records shall be an element of these data.

All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually quality records shall be made available for evaluation by the purchaser or his representative for an agreed period.

4.17 Internal quality audits

The supplier shall carry out a comprehensive system of planned and documented internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

Audits shall be scheduled on the basis of the status and importance of the activity.

The audits and follow-up actions shall be carried out in accordance with documented procedures.

requirements. The supplier shall establish and maintain records of acceptable sub-contractors (see 4.16).

The selection of sub-contractors, and the type and extent of control exercised by the supplier, shall be dependent upon the type of product and, where appropriate, on records of sub-contractors' previously demonstrated capability and performance.

The supplier shall ensure that quality system controls are effective.

4.6.3 Purchasing data

Purchasing documents shall contain data clearly describing the product ordered, including, where applicable,

a) the type, class, style, grade or other precise identification;

b) the title or other positive identification, and applicable issue of specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel;

c) the title, number and issue of the quality system International Standard to be applied to the product.

The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release.

4.6.4 Verification of purchased product

Where specified in the contract, the purchaser or his representative shall be afforded the right to verify at source or upon receipt that purchased product conforms to specified requirements. Verification by the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

When the purchaser or his representative elects to carry out verification at the sub-contractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the sub-contractor.

4.7 Purchaser supplied product

The supplier shall establish and maintain procedures for verification, storage and maintenance of purchaser supplied product provided for incorporation into the supplies. Any such product that is lost, damaged or is otherwise unsuitable for use shall be recorded and reported to the purchaser (see 4.16).

NOTE – Verification by the supplier does not absolve the purchaser of the responsibility to provide acceptable product.

4.8 Product identification and traceability

Where appropriate, the supplier shall establish and maintain procedures for identifying the product from applicable drawings, specifications or other documents, during all stages of production, delivery and installation.

Where, and to the extent that, traceability is a specified requirement, individual product or batches shall have a unique identification. This identification shall be recorded (see 4.16).

4.9 Process control

4.9.1 General

The supplier shall identify and plan the production and, where applicable, installation processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following :

a) documented work instructions defining the manner of production and installation, where the absence of such instructions would adversely affect quality, use of suitable production and installation equipment, suitable working environment, compliance with reference standards/codes and quality plans;

b) monitoring and control of suitable process and product characteristics during production and installation;

c) the approval of processes and equipment, as appropriate;

d) criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples.

4.9.2 Special processes

These are processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met. These processes shall be qualified and shall also comply with the requirements of 4.9.1.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

4.10 Inspection and testing

4.10.1 Receiving inspection and testing

4.10.1.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.1.2) until it has been inspected or otherwise verified as conforming to specified requirements. Verification shall be in accordance with the quality plan or documented procedures.

4.10.1.2 Where incoming product is released for urgent production purposes, it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformance to specified requirements.

NOTE – In determining the amount and nature of receiving inspection, consideration should be given to the control exercised at source and documented evidence of quality conformance provided.

INTERNATIONAL STANDARD

ISO
9002

First edition
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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Quality systems — Model for quality assurance in production and installation

Systèmes qualité — Modèle pour l'assurance de la qualité en production et installation

Reference num
ISO 9002 : 1987

4.1.2 Organization

4.1.2.1 Responsibility and authority

The responsibility, authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined; particularly for personnel who need the organizational freedom and authority to

a) initiate action to prevent the occurrence of product nonconformity;

b) identify and record any product quality problems;

c) initiate, recommend or provide solutions through designated channels;

d) verify the implementation of solutions;

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.2 Verification resources and personnel

The supplier shall identify in-house verification requirements, provide adequate resources and assign trained personnel for verification activities (see 4.17).

Verification activities shall include inspection, test and monitoring of the production and installation processes and/or product; audits of the quality system, process and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.

4.1.2.3 Management representative

The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of this International Standard are implemented and maintained.

4.1.3 Management review

The quality system adopted to satisfy the requirements of this International Standard shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained (see 4.16).

NOTE — Management reviews normally include assessment of the results of internal quality audits, but are carried out by, or on behalf of, the supplier's management, *viz* management personnel having direct responsibility for the system. (See 4.16.)

4.2 Quality system

The supplier shall establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements. This shall include

a) the preparation of documented quality system procedures and instructions in accordance with the requirements of this International Standard;

b) the effective implementation of the documented quality system procedures and instructions.

NOTE — In meeting specified requirements, timely consideration needs to be given to the following activities :

a) the preparation of quality plans and a quality manual in accordance with the specified requirements;

b) the identification and acquisition of any controls, processes, inspection equipment, fixtures, total production resources and skills that may be needed to achieve the required quality;

c) the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation;

d) the identification of any measurement requirement involving capability that exceeds the known state of the art in sufficient time for the needed capability to be developed;

e) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

f) the compatibility of the production process, installation, inspection and test procedures and the applicable documentation;

g) the identification and preparation of quality records (see 4.15).

4.3 Contract review

The supplier shall establish and maintain procedures for contract review and for the coordination of these activities.

Each contract shall be reviewed by the supplier to ensure that

a) the requirements are adequately defined and documented;

b) any requirements differing from those in the tender are resolved;

c) the supplier has the capability to meet contractual requirements;

Records of such contract reviews shall be maintained (see 4.15).

NOTE — The contract review activities, interfaces and communication within the supplier's organization should be coordinated with the purchaser's organization, as appropriate.

4.4 Document control

4.4.1 Document approval and issue

The supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of this International Standard. These documents shall be reviewed and approved for adequacy by authorized personnel prior to issue. This control shall ensure that

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b) obsolete documents are promptly removed from points of issue or use.

4.8.2 Special processes

These are processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met. These processes shall be qualified and shall also comply with the requirements of 4.8.1.

Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

4.9 Inspection and testing

4.9.1 Receiving inspection and testing

4.9.1.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.9.1.2) until it has been inspected or otherwise verified as conforming to specified requirements. Verification shall be in accordance with the quality plan or documented procedures.

4.9.1.2 Where incoming product is released for urgent production purposes, it shall be positively identified and recorded (see 4.15) in order to permit immediate recall and replacement in the event of nonconformance to specified requirements.

NOTE — In determining the amount and nature of receiving inspection, consideration should be given to the control exercised at source and documented evidence of quality conformance provided.

4.9.2 In-process inspection and testing

The supplier shall

a) inspect, test and identify product as required by the quality plan or documented procedures;

b) establish product conformance to specified requirements by use of process monitoring and control methods;

c) hold product until the required inspections and tests have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (see 4.9.1). Release under positive recall procedures shall not preclude the activities outlined in 4.9.2a);

d) identify nonconforming product.

4.9.3 Final inspection and testing

The quality plan or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the data meets specified requirements.

The supplier shall carry out all final inspection and testing in accordance with the quality plan or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

No product shall be despatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation is available and authorized.

4.9.4 Inspection and test records

The supplier shall establish and maintain records which give evidence that the product has passed inspection and/or test with defined acceptance criteria (see 4.15).

4.10 Inspection, measuring and test equipment

The supplier shall control, calibrate and maintain inspection, measuring and test equipment, whether owned by the supplier, on loan, or provided by the purchaser, to demonstrate the conformance of product to the specified requirements. Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

The supplier shall

a) identify the measurements to be made, the accuracy required and select the appropriate inspection, measuring and test equipment;

b) identify, calibrate and adjust all inspection, measuring and test equipment and devices that can affect product quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards — where no such standards exist, the basis used for calibration shall be documented;

c) establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory;

d) ensure that the inspection, measuring and test equipment is capable of the accuracy and precision necessary;

e) identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status;

f) maintain calibration records for inspection, measuring and test equipment (see 4.15);

g) assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration;

h) ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out;

i) ensure that the handling, preservation and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use is maintained;

j) safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent sub-contractor quality records shall be an element of these data.

All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss. Retention times of quality records shall be established in writing. Where agreed contractually, quality records shall be made available for evaluation by the purchaser or his representative for an agreed period.

4.16 Internal quality audits

The supplier shall carry out internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

Audits shall be scheduled on the basis of the status and importance of the activity.

The audits and follow-up actions shall be carried out in accordance with documented procedures.

The results of the audits shall be documented and brought the attention of the personnel having responsibility in the ar audited. The management personnel responsible for the a shall take timely corrective action on the deficiencies found the audit (see 4.1.3).

4.17 Training

The supplier shall establish and maintain procedures for iden fying the training needs and provide for the training of personnel activities affecting quality during production a installation. Personnel performing specific assigned tasks sh be qualified on the basis of appropriate education, train and/or experience, as required. Appropriate records of train shall be maintained (see 4.15).

4.18 Statistical techniques

Where appropriate, the supplier shall establish procedures identifying adequate statistical techniques required for verify the acceptability of process capability and product charac istics.

GLOSSARY

Assessment An estimate or determination of the significance, importance or value of something.

Audit A planned, independent and documented assessment to determine whether agreed upon requirements are met.

Blocking Grouping runs for efficiency, generality and safety.

Calibration A comparison of two instruments or measuring devices, one of which is a standard of known accuracy traceable to national standards, to detect, report or eliminate by adjustment any discrepancy in accuracy of the measuring device.

Conformance An affirmative indication or judgement that a product or has met the requirements of the relevant specifications, contract, or regulation.

Corrective Action Action taken to eliminate the root(s) cause(s) and symptom(s) of an existing undesirable deviation or nonconformity to prevent recurrence.

Factors Controllable process or product characteristics whose influence on the response is to be studied.

Inspection Activities -such as measuring, examining, testing- that

	gauge one or more characteristics of a product or service and the comparison of these with specified requirements to determine conformity.
Levels	Specific settings of the chosen factors to be studied during the experiment.
Procedure	A document that specifies the way to perform an activity.
Quality	To exceed customer's expectations at the lowest cost possible
Quality Assurance	All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given quality requirements.
Quality Control	The operational techniques and activities that are used to fulfill requirements for quality.
Quality Manual	A document stating the quality policy, quality system and quality practices of an organization.
Response	The process and/or quality characteristic to be optimized.
Replication	Independent repetition of runs to ensure reliable conclusions.

Elvira S. Perez

Born in Caracas, Venezuela, the 2nd of April 1960.

Obtained her High School Diploma at Colegio Sta. Teresa, San Bernardino Caracas in 1977. Four years of her regular school were done at P.S. 151-Queens, New York City, USA.

Obtained her Manufacturing Engineering Degree at the Universidad Simon Bolivar- Sartenejas, Venezuela in 1982. Second of her graduation group.

Worked over six years in the Venezuelan oil industry in Inspection, QA audits, standardization. One year on-the-job training in British Petroleum, United Kingdom in the QA/QC department.

Up to 1992, a QA/QC consultant in Produtec, S.A. for manufacturer's who are suppliers to the Venezuelan oil industry and individuals.

In 1993 obtains a scholarship from the Venezuelan government to pursue her Master of Applied Science at Concordia University, Montreal.

She will reincorporate to her consulting job and as an industrial instructor in areas related to quality control, expanding the range of application to the iron and aluminum industry.