Title: Success Factors in ISO 9000 Registration

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Abstract: When trying to achieve ISO 9000 registration, where the key successful factors? After reviewing the literature the authors developed 14 different items that were stated to be critical. Out of those fourteen, which are the 4 most important? These items are ranked by people working with ISO 9000.

SUCCESS FACTORS IN ISO 9000 REGISTRATION

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SUCCESS FACTORS IN ISO 9000 REGISTRATION

A PROJECT SUBMITTED TO

DRAGAN MILOSEVIC

EMGT 560 - ENGINEERING MANAGEMENT SYNTHESIS

ENGINEERING MANAGEMENT

BY

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ABSTRACT: When trying to achieve ISO 9000 Registration, what are the key success factors to achieve ISO 9000 registration? After reviewing the literature we developed 14 different items that were stated to be critical. Out of those 14, which are the 4 most important? These items are ranked by people working with ISO 9000.

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PREFACE

Success Factors in ISO 9000 Registration is the product of an eight week course, Engineering Management Synthesis. This is the "Capstone course in the Engineering management Program, synthesizing the concepts and methodologies of engineering and technology management into an individual or group project."[1] The objective of the course is to solve a real world problem with the tools we have acquired in the engineering management program.

In choosing a project, we strove to study an area that was new to us, relevant to our current and future activities, demonstrate a wide variety of skills developed in the engineering management program, and attainable within the time allowed. We are thankful that we have achieved these goals.

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INTRODUCTION

In 1993 a resource directory was published by the Oregon Quality Initiative. [2] The directory listed eleven companies that had attained ISO 9000 Registration in Oregon. If you talk to many of the manufacturing companies around Oregon, they will tell you how they are on the road toward ISO 9000 registration. Many seek the path, but few have found the way.

In a November, 1993, a survey of 20 registration organizations representing over 8600 registered companies, only 58.5% of the assessed companies were gaining immediate registration.[3] This may not seem great, but it was a vast improvement over 1992's 30% first time registration rate for American companies. Multiply the high failure rate time the endless internal meetings, the work involved in detailed process manuals, and the $25,000 direct external cost[4] and you will agree there is a need to discover the key elements to ISO 9000 registration.

What are the critical success factors to achieve ISO 9000 registration?

If you are familiar with ISO 9000 you may wish to skip chapter 1 and go to page 10.

CONDENSED SUMMARY

What factors must be emphasized for the successful ISO 9000 registration? To uncover these pearls of wisdom, we started with a literature search of ISO 9000 references for the last four years. This produced over 200 citations from journals, magazines, and books. Of the 200 citations, we were only interested in those that looked at the strategic elements of implementation. From this we developed fourteen elements that could be called key to a successful ISO 9000 registration.

Now that we had a list, how do we validate what a writer claimed as important or are some items more important than others? We developed a survey and presented it to 25 people in industry that know what ISO 9000 registration is. We also wanted to know if experienced people have a better grasp on what items are important, so we could focus on their replies.

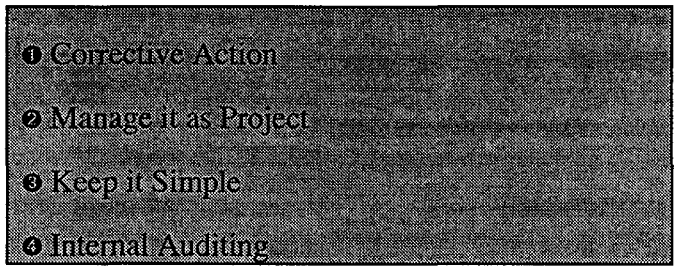

Table 1 - Four Top Success Factors

All fourteen items were viewed as important to success and four of the items were consistently at the top, these items are listed in Table 1. We also discovered that the novice group was very close in ranking the items, but had a much larger deviation within the group.

CHAPTER 1

ISO 9000 Background

Where Did It Come From?

ISO 9000 has evolved for over forty years starting with its first incarnation as MIL-Q 9858A. MIL-Q 9858A was developed out of hard lessons learned in World War II ordnance production. Reliance on suppliers in the ordnance field is a life or death matter.

Next, Europe joined in the evolutionary development with the NATO A.Q.A.P. documents which were then published as DEF STANS by the Procurement Executive of the Ministry of Defense in England. In the 60's, many private companies started looking at these military standards as a way of improving their own quality. The benefits of quality were starting to catch on.

A big international milestone was in 1972 when the British Standards Institution, trying to attain some degree of standardization around quality, produced BS 4891 - A Guide to Quality Assurance. This document is written in general terms to guide companies in the development of a quality system. BSI later published BS 5179, and finally, in 1979, produced BS 5750. BS 5750 closely resembled its military forefathers, but was written to apply to industry.

The importance of these developments were not lost on The International Standards Organization (ISO); and in 1987 the ISO 9000 series were created. Since that time BS 5750 has been modified to be identical with ISO 9000. You can find identical replaces of ISO 9000 published throughout the world called by the names ANSI/ASQC Q90, NZS 5600, AS3900, etc. It is truly an international standard that has evolved for over 50 years.

STRUCTURE OF THE ISO 9000 STANDARDS

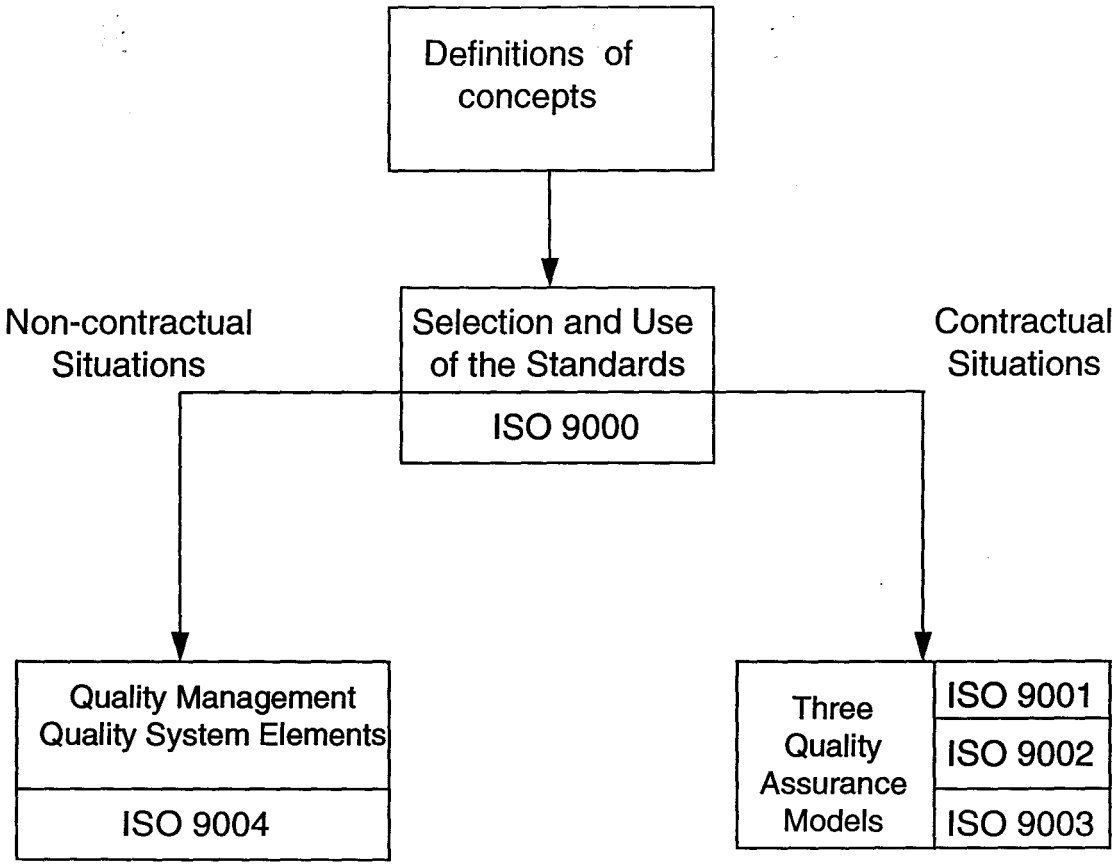

Figure 1 - ISO 9000 Family of Standards

These standards are intended to be used in contractual and non-contractual situations. "In both contractual and non-contractual situations, an organization wants to install and maintain a quality system to strengthen its competitiveness and to achieve the needed product quality in a cost effective way. In addition to this, however, in the contractual situation, the purchaser wants to know whether this supplier can produce products and services that consistently meet necessary requirements." [5] According to the ISO 9000 series, in a contractual situation, both supplier and customer must agree on what is acceptable.

The ISO 9000 standard is presented in five documents: ISO 9000, ISO 9001, ISO 9002, ISO 9003, and ISO 9004. The standards ISO 9001 through ISO 9003 apply to companies according to the scope of their activities. ISO 9000 and ISO 9004 are documents that provide guidelines for specific industrial applications.

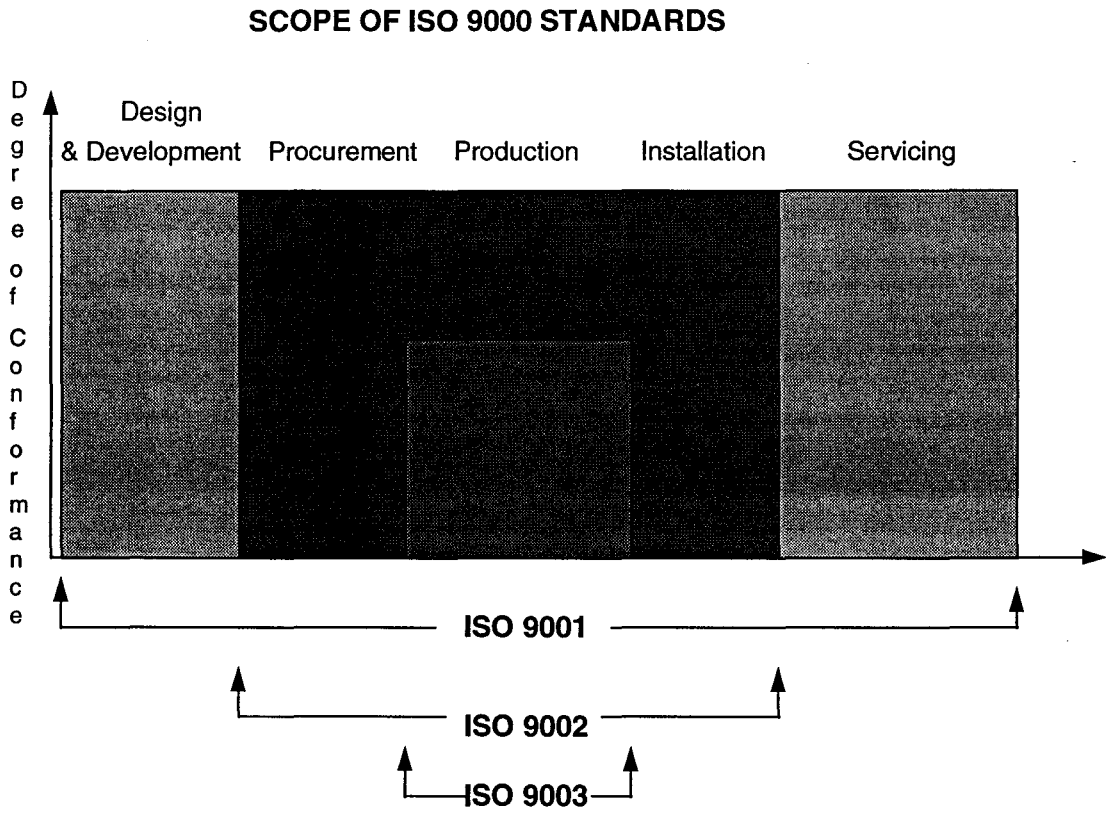

Figure 2 - ISO 9000 Graph

ISO 9000

Quality Management and Quality Assurance Standards, guidelines for selection and use: It explains fundamental quality concepts, and defines key terms and guidance of selecting, using as well as tailoring ISO 9001, ISO 9002, and ISO 9003 for external quality assurance purposes. It also provides guidance on using ISO 9004 for internal purposes.

ISO 9001

Quality Systems: model for quality assurance in design/development, production, procurement, installation, and servicing. It is the most comprehensive conformation standards. ISO 9001 is used when a company must ensure product conformance to the entire product cycle. It is generally used in manufacturing and processing industries.

ISO 9002

Quality Systems: model for quality assurance in procurement, production, and installation. It is designed for products that do not involve design aspect.

ISO 9003

Quality Systems: model for quality assurance in final inspection and test. It is generally used for the companies whose products are not complex. These products can be assessed by testing and inspection in a production line.

> ***Note:*** *There is inconsistency in the literature in regard to the contents of ISO 9002 and ISO 9003. We think that they are intentionally vague in certain ways, so that it can accommodate different business operations.*

ISO 9004

Quality Management and Quality Systems Elements Guidelines: It guides all organizations for internal quality management purposes without considering contractual requirements of quality assurance. ISO 9004 covers most of the quality system elements contained in ISO 9001 through ISO 9003 in detail. It helps the organization determine which quality systems to choose. [6]

The ISO 9000 standard focuses on 20 aspects of a quality program that are subject to a audit during the registration process.

These are:

1. Management responsibility
2. Quality system
3. Contract review
4. Design control
5. Document control
6. Purchasing
7. Purchaser supplied product
8. Product identification and tractability
9. Process control
10. Inspection and testing
11. Inspection, measuring, and test equipment
12. Inspection and test status
13. Control of non-conforming product
14. Corrective action
15. Handling, storage, packaging, and delivery
16. Quality records
17. Internal quality audits
18. Training
19. Servicing
20. Statistical Techniques [6]

Table 2 - Twenty Aspects of a Quality Program

The ISO 9001 through ISO 9003 are not designed for any specific industry. Although some industries such as chemical industries, have issued their own set of guidelines, these guidelines do not provide additional information.

Is ISO 9000 Needed? [7]

What drives a company to pursue ISO 9000 is a cost benefit decision with a plethora of reasons. Bill Houser and Ken Somers[7] developed a framework to help view the often complex motivation in such a decision.

MANAGEMENT

		ISO Required: Yes	ISO Required: No
NO ISO		Disaster Lost Market Share to Those Who Are Registered	No Effect
YES ISO		Opportunity Increase Market Share From Non-Registrants	Improve Quality Good Quality System and Platform for TQM

Table 3 - Is ISO 9000 Necessary?

Table 3 shows a two dimensional matrix between the management decision and pressure from customers. The table is not concerned with what reasons drive the decision, but it shows what consequences can occur. When presented in this format, it is easy to choose to avoid the 'Disaster' scenario. It can also make sense to not pursue ISO 9000 if there is not market pressure and the management is not behind TQM. Should your company pursue ISO 9000? That is much to large a topic for this paper, but as we pointed out in the introduction, there are hundreds of articles and books that address this topic.

CHAPTER 2

HYPOTHESES

In this term project, our group concentrated on the topic of *"Success Criteria for ISO 9000 Registration."* The project consists of a literature research to develop a list of success criteria and a survey of people who are in industry at the different experience levels of the ISO 9000 registration process. The respondents are asked to weigh the importance of each success criteria from their personal experience. Our goal is to analyze three hypotheses for this project.

These are:

1. Validate the importance of collected success criteria for ISO 9000 registration as discovered in our literature research. Here, the survey will be used to validate or reject the success criteria.
2. Show that the importance of the success criteria will be different for the people who are at the beginning of ISO 9000 registration, and the people who are registered. This way, we will show that there is a learning curve for the people who are involved in ISO 9000 registration process. Our assumption is that the people who are through the registration process know the importance of success criteria, since they have a thorough experience with the process.
3. Show there is a higher variation in responses within the novice group than the experienced group. The purpose here is to prove that there is more of an inconsistency among the novice group concerning the importance of the success criteria are. On the other hand, we also would like to prove that experienced people are more consistent.

CHAPTER 3

METHODOLOGY

Our group reviewed the literature in order to find the success criteria for ISO 9000 registration. Also, we conducted a survey to validate our literature findings. Along with survey results, we tested our hypotheses (See Hypotheses section) and provided our analysis and results.

Literature Search

When we first started out project, we were confident that there would be a large body of literature describing success factors in the registration process. The bulk of the literature described why it was important to follow the road to ISO 9000 or a step by step guide, but very little was written from the strategic perspective we were looking for.

1. Keep the Process Simple[8]

This is also known as KISS (Keep It Simple Stupid). How important is it to avoid complicated quality management processes (All the processes' subject to the ISO 9000 registration mentioned in the ISO clauses)? Keep a focus on the system elements that can make a difference. "People understand focus."[7] Keeping any process simple is always a difficult task.

2. Treat Registration Process as a Project [8,9]

Do not try to achieve ISO 9000 by committee. First, appoint a project team. Second, appoint a project manager to plan, organize, and control. Third, establish a steering team to provide leadership and guidance to the project manager. Set milestones and stick with them.[7]

3. Training Staff/Management About ISO 9000 Rules and Procedures [8,10]

Everyone needs to be singing out of the "same hymn book", so the same training needs to be given from the bottom to the top of the company.

4. Internal Auditing [8,11,10]

Internal auditing provides you with visibility into the current state of your business. It can not correct problems, but it will expose areas needing work.

5. Employee Involvement [12]

Can management, even with outside consultants, obtain and keep ISO 9000 registration without employee involvement?

6. Partnering With ISO 9000 Certified Companies [13]

A good example of this is the creation of an ISO 9000 user group designed to exchange information about auditors, consultants, techniques, and even frustrations.

7. Viewing the Registrar as a Supplier [8]

Use the same criteria for selection of a registrar as you would do for selecting any critical supplier. Interview potential firms and seek input from their other clients.

8. Which is More Appropriate, Proactive or Reactive Approach **Error! Bookmark not defined.**[14]

Are you far sighted, "Do you anticipate your customers' needs of ISO 9000 registration" or are you customer driven, "Do you wait for your customer to require you to pursue registration of ISO 9000?"

9. Inspection/Testing Methodology [15]

How important is it to have a well-defined methodology for testing at receiving, in process, and final inspection? Many company errors can be attributed to questionable inspection and testing methodology.

10. Follow Through in Corrective Action Procedures [15]

When you find a problem with a product, is there a corrective action procedure to insure it does not happen again? Is it important to follow through and implement the corrective action procedure quickly?

11. Regular Supplier Review Process [15]

Many production problems can be caused by materials provided by your suppliers. Just as all procedures must be reviewed and kept up to date, so must the supplier relationship be reviewed and evaluated on a regular basis.

12. Supplier Alliance Program [16]

This program captures the benefits that can be derived from a group of excellent suppliers integrated into your organization.

13. Automated Document Control System [17]

Imagine trying to do all the ISO 9000 documentation through a manual process.

14. Adapting ISO 9000 Documentation to Fit the Needs of Your Company [8]

Do not change the way your company does its job to fit someone's idea of how ISO 9000 works. ISO 9000 is a very flexible system and can be molded to fit your company's needs.

Survey

The survey is a vehicle by which we can validate and rank the factors we discovered in the literature search. The format is a simple design that presents each factor and asks the survey participant to rank the importance from his or her personal experience. We emphasized personal experience; wanting to avoid the corporate answer to the questions. [The actual survey is presented in APPENDIX A at the end of the paper.]

Who Took the Survey

We had a very good response rate considering the short period of time we had to administer the survey. We classified the respondents into two groups. Experienced respondents, who indicated that they had personal experience with ISO 9000 in any one company that had achieved registration; or novice respondents, who indicated less than that level of experience. This differentiation will come up throughout the paper. Respondents were all from the greater Portland area. (See Table 4)

Number of surveys distributed	25
Number returned	21
Number of different companies	18
Experienced	12
Novice	9
ISO 9000 level	
9003	1
9002	5
9001	14
No Level Indicated	2

Table 4 - Demographics of Respondents

Note: Some respondents indicated experience in more than one level.

Problems With the Survey

The biggest problem is with question #8 *"Which is More Appropriate, Proactive or Reactive."* We should have treated this as two questions, but we were trying to save space, so we could keep the number of pages down. Page wise question foolish, I guess you could say. It confused people and skewed the data. After discussing this with our mentor, we dropped the question. Could one of these items have been the most important factor to achieve ISO 9000 registration? We doubt it. The responses were middle of the scale.

We did have one glaring mistake pointed out to us several times. We used the term ISO 9000 certification instead of ISO 9000 registration. It reflects our level of inexperience in this area.

Other Certified Companies' ranked lowest with an average importance 3.05. We can also see that the variance for success criteria increases as their importance decreases.

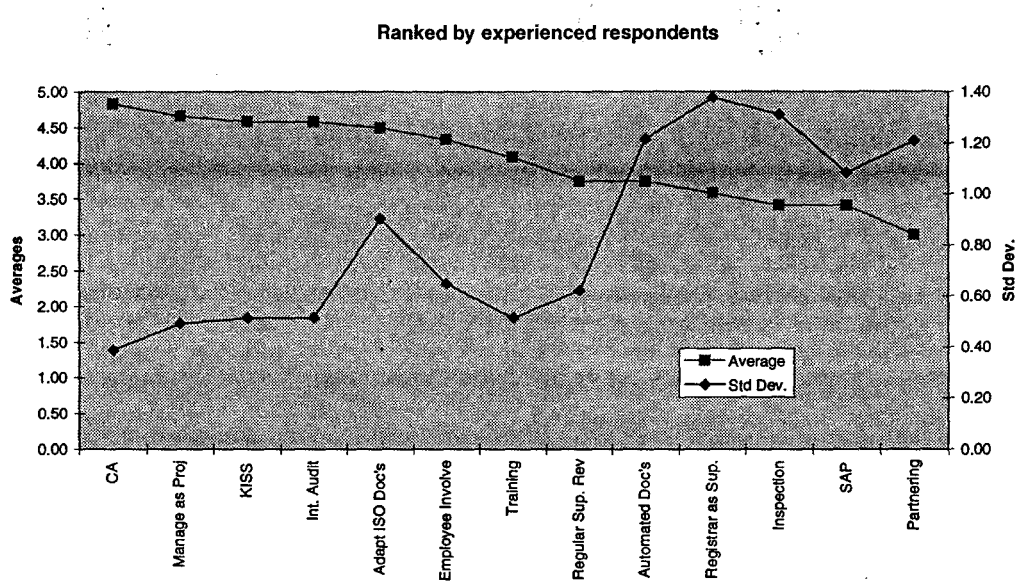

Figure 4 - Ranked by Experienced Respondents

Figure 4 shows the ranking of 13 success criteria according to all 12 experienced respondents. When the success criteria are ranked by the respondents' averages, there is more consistency in the first four success criteria.

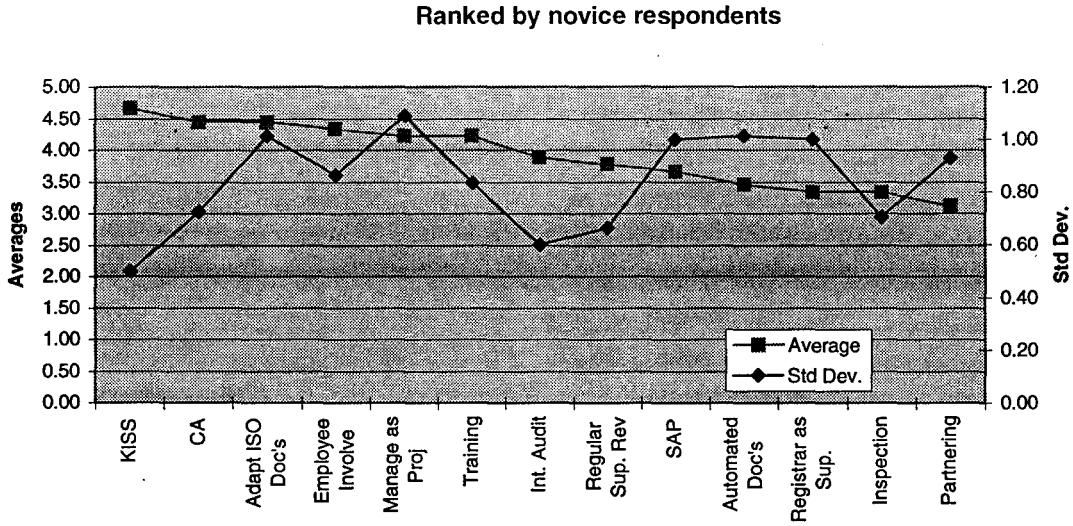

Figure 5 - Ranked by Novice Respondents

Figure 5 shows the ranking of 13 success criteria according to the 8 novice respondents. This time we ranked the success criteria by novice respondents' averages. Although experienced respondents concurred on ranking the first four success criteria, novice respondents did not show consistency in their rankings.

What Did We Forget?

As one of the last items on our survey, we asked respondents what we forgot. Eight people responded with the following list.

1. Management commitment
2. Time for staff to work on ISO 9000
3. Select consultant and auditor that works in your industry
4. Tied to #10, Accurate "Root Cause" analysis (Many don't agree on what root cause analysis is)
5. Budget/resource allocation e.g. Hire part time clerical help
6. Write your own manual
7. Create a quality culture
8. Management review of the system status must be well defined, documented and practiced
9. Management involvement/continued involvement

Items 1, 2, 5, 8, and 9 we had intended to be covered by question #2. Treat Registration Process as a Project [8], but we did not communicate the item well or we had different viewpoints on the results of treating the process as a project. We felt that item 6 should have been covered by #14. Adapting ISO 9000 Documentation to Fit the Needs of Your Company [8].

CHAPTER 5

ANALYSIS

In this section, we are going to test our hypotheses against the survey results.

Hypothesis-1: **Verification of the success criteria.** We assumed that experienced respondents will verify the success criteria identified by the literature research. There is a consistency among the experienced respondents that the following are very important success criteria for ISO 9000 registration:

❶ Corrective Action

❷ Manage it as Project

❸ Keep it Simple

❹ Internal Auditing

These criteria have been marked in the top 90% of the importance scale, and have the lowest deviation among the experienced respondents. Both experienced and novice respondents averages for all success criteria ranked above 3.00 on a scale of 0 - 5.00 (0 being the least important and 5.00 being the most important). This validates the importance of success criteria found in the literature research.

Hypothesis-2: **Ranking the importance of success criteria for experienced and novice respondents.** We know from the Table 5 section that experienced respondents and novice respondents had different importance ranking for success criteria. In order to determine the difference of importance, we applied a regression analysis between experienced and novice respondents' averages for all corresponding success criteria.

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.89
R Square	0.78
Adjusted R Square	0.76
Standard Error	0.29
Observations	13.00

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1.00	3.25	3.25	39.82	0.00
Residual	11.00	0.90	0.08		
Total	12.00	4.15			

	Coefficient	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.000%*	*Upper 95.000%*
Intercept	0.04	0.64	0.06	0.95	-1.37	1.45	-1.37	1.45
Novice	1.02	0.16	6.31	0.00	0.67	1.38	0.67	1.38

Table 6 - Regression Results

The t-statistics shows a relation between means when the t-value is outside the range of -2 and +2. R-square statistics shows a perfect correlation when R-square value is 1.00. Since in the Table 6, t-statistics is 6.31 , and R-square is 0.78, we can conclude that there is a strong relationship between the averages; indicated by experienced and novice respondents for all success criteria. However, if we look at some of the higher importance criteria, there are some significant differences of averages which cause the different ranking between experienced and novice respondents.

Section III - Further Explanation

1. **Keep the Process Simple**
   This is also known as KISS (Keep It Simple Stupid). How important is it to avoid complicated quality management processes (All the processes' subject to the ISO 9000 certification mentioned in the ISO clauses)?

2. **Treat Registration Process as a Project**
   Do not try to achieve ISO 9000 by committee. First, appoint a project team. Second, appoint a project manager to plan, organize, and control. Third, establish a steering team to provide leadership and guidance to the project manager.

3. **Training of Staff and Management About ISO 9000 Rules and Procedures**
   Everyone needs to be singing out of the same hymn book so the same training needs to be given from the bottom to the top of the company.

4. **Internal Auditing**
   Internal auditing provides you with visibility into the current state of your business. It can not correct problems, but it will expose areas that you need to work on.

5. **Employee Involvement**
   Can management, even with outside consultants, obtain and keep ISO 9000 certification without employee involvement?

6. **Partnering with ISO 9000 Certified Companies**
   A good example of this is creation of an ISO 9000 user group so you can exchange information about auditors, consultants, techniques, and even frustrations.

7. **Viewing the Registrar as a Supplier**
   Use the same criteria for selection of a registrar as you do for selecting any critical supplier. Interview potential firms, seek input from their other clients.

8. **Which is More Appropriate, Proactive or Reactive Approach**
   Far sighted, "Do you anticipate your customers' needs of ISO 9000 certification" or customer driven, "Do you wait for your customer to require you to pursue certification of ISO 9000?"

9. **Inspection/Testing Methodology**
   How important is it to have a well-defined methodology for testing at receiving, in process, and final inspection? Many company errors can be attributed to questionable inspection and testing methodology.

10. **Follow Through in Corrective Action Procedures**
    When you find a problem with a product, is there a corrective action procedure to insuring it does not happen again? Is it important to follow through and implement the corrective action procedure quickly?

11. **Regular Supplier Review Process**
    Many production problems can be caused by materials provided by your suppliers. Just as all procedures must be reviewed and kept up to date, so must the relationship to your suppliers must be reviewed and evaluated on a regular basis.

12. **Supplier Alliance Program**
    This program captures the benefits that can be derived from a group of excellent suppliers integrated into your organization.

13. **Automated Document Control System**
    Imagine trying to do all the ISO 9000 documentation thorough a manual process.

14. **Adapting ISO 9000 Documentation to Fit the Needs of Your Company**
    Do not change the way your company does its job to fit someone's idea of how ISO 9000 works. ISO 9000 is a very flexible system and can be molded to fit your companies needs.