

Eduardo Gomes
Salgado¹

Carlos Eduardo
Sanches da Silva

Carlos Henrique
Pereira Mello

Elizabete Ribeiro
Sanches da Silva

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DIFFICULTIES ENCOUNTERED IN ISO 9001:2008 IMPLEMENTATION PROJECTS IN INCUBATED TECHNOLOGY-BASED COMPANIES

Abstract: *Quality Management Systems (QMS) are designed to continuously improve the performance of organizations aiming to constantly improve their services seeking to overcome their results.*

Thus, for the services and/or products offered to transmit confidence and credibility, they should be designed within appropriate norms and standards. This research aims to assess the difficulties encountered by the incubated companies participating in the PRIME-FINEP project and developing projects for certification of their QMS in accordance with ISO 9001:2008. An exploratory survey was performed in nine incubated technology-based companies (TBC), through a questionnaire with 21 questions totaling the opinion of 20 respondents. After analyzing the data it is concluded, with statistical meaning, that the TBC's with little incubation time present difficulties in implementing the quality policy (5.3), difficulty not identified in other studies conducted in large companies. However difficulties similar to those of the large companies are present in the incubated TBC, and are the following: documentation requirements (4.2) present in all incubated companies (regardless of incubation time), and design and development (7.3) present in companies with little incubation time. The difficulty in implementing the quality policy (5.3) is reflected in the achievement of the QMS certification project in accordance with ISO 9001:2008.

Keywords: *Quality Management System (QMS), ISO 9001:2008, Technology-based Company*

1. Research Context

The government has developed several actions to reduce technological dependence and promote local and regional development (e.g. technology parks, business incubators,

research incentive laws). This research addresses one of these incentives, the PRIME program developed by FINEP which allocated investments of US\$ 100,000,000.00 in technology-based companies.

In Brazil, 2000 technology-based companies obtained US\$ 54.000,00 to invest in market and management advisory services. The projects funded by FINEP started their

¹ Corresponding author: Eduardo Gome Salgado
email: egsalgado@yahoo.com.br

projects in November 2009. Some companies, among the consulting firms hired, opted for certifying their Quality Management System in accordance with ISO 9001:2008, either by requirements of the market or their own initiative.

The norm prescribes the sections that the QMS must have implemented, in this sense several studies have been developed (Magd, 2008; Pokisinska *et al.*, 2006; Tian and Tam, 2007; Bhuiyan and Alam, 2005; Yahya and Goh, 2001) in order to identify which sections the organizations find greater difficulty in implementing. In this respect, this research has the same question, having as object of study incubated technology-based companies. The research method is the same used by studies similar to the exploratory survey. It has as hypothesis:

- H1: there is no difficulty in implementing any of the sections required by the NBR ISO 9001:2008
- H2: the difficulties of implantation depend on the incubation time
- H3: the percentage of project implementation is related to the difficulties of implementation

2. Implementation of Quality Management System according to ISO 9001

For Aggelogiannopoulos *et al.*, (2007), production quality has become the most significant factor of influence in business and economic partnerships nationally and internationally. Quality is one of the factors of competitiveness, obtained through various methodologies and managerial methods, including the Quality Management System based on ISO 9000.

The ISO (International Organization for Standardization) exists to develop and promote standards around the world, aiming to establish technical standards essential in the international context to protect companies, products, services and consumers in business relations and its

requirements are valid for all countries. According to Bhuiyan and Alam (2005), ISO's work results in international agreements which are published as International Standards. The series that addresses the quality management system is the 9000 series, which was created for the development of quality and standardization.

For Aldowaisan and Youssef (2006), the interest in the ISO 9001 certification is increasing, and this certification is no longer the privilege of multinationals and large companies, being accessible to all interested companies. With globalization and the consequent increased competitiveness, there is an increasingly need to obtain sustainable advantage regarding competing organizations. Thus, due to this need, the QMS ceased to be a differential to become a mandatory requirement. In addition, Gómez *et al.* (2009) states that ISO 9001 is, among the models of the QMS, the most influential and most implemented.

According to Bhuiyan and Alam (2004), ISO 9001 is based on process and promotes continuous improvement for all these processes. ISO 9001 specifies requirements for a quality management system which can be used by organizations for internal application, certification or contractual purposes. This norm focuses on the effectiveness of the quality management system. ISO 9001 is the normative reference based on which, the quality system certifications of organizations are made.

The adoption of a QMS should be a strategic decision (Mello *et al.*, 2005). Therefore, the development and implementation of this system should consider the uniqueness of each organization, since it depends on several factors like: Specific objectives; supplied products, and processes used.

Since ISO 9001 gained popularity, several authors try to understand the effects on businesses. Surveys report the benefits, barriers, partnerships, leadership, concerns, tools, techniques, fears, difficulties, the systematic of implementation, the diffusion

of ISO 9001 standard in terms of its certification intensity, the obligations in implementing a QMS, financial performance in different sectors of activity such as (Pascal *et al.*, 2002; Wilkinson and Dale, 2002; Bhuiyan and Alam, 2004; Bhuiyan and Alam 2005; Pokisinska *et al.*, 2006; Aggelogiannopoulos *et al.*, 2007; Jovanovic and Jovanovic, 2008; Benner and Veloso, 2008; Sampaio *et al.*, 2010; Kirsch *et al.*, 2009; Alolayyan *et al.*, 2011; Saizarbitoria *et al.*, 2011; Talib *et al.*, 2011; Dias and Heras, 2013; Souza Junior *et al.*, 2014; Landin *et al.*, 2014; Ali, 2014).

For the implementation of ISO, the organization must satisfactorily contain the necessary requirements which are presented in distinct categories, as described in ISO 9001:2008: General Requirements (Section 4.1); Management Responsibility (item 5); Resource Management (item 6); Product Realization (item 7) and Measurement, analysis and improvement (item 8).

Several studies point out the systematic implementation of the quality management system based on ISO 9001 in various industries like (Burnett *et al.*, 1997; Melloet *et al.*, 2005; Aggelogiannopoulos *et al.*, 2007), Martínez-Pardo and Mariano-Magan, 2008; Kirsch *et al.*, 2009; Sampaioet *et al.*, 2010). But incubated technology-based companies have some features, such as: few employees; product in development process; not marketed product.

3. Incubated Technology-Based Company

According to Jucá Junior (2005) it is a complex task to define a technology-based company, since the parameters for such classification are relative, since measuring a technology does not admit single answers. In this same sense, referencing high technology, in turn, does not relate to the existence of "low technology", but to the use of technologies until then little used, or else little traditional.

For Ng (2006), technology-based companies have the characteristic of using emerging technologies to develop new products, services and solutions. Unlike traditional industries, this kind of company explores the technologies with a continuous development to have the gains for the delivery of new products, services and solutions with high added value to the end customer. In the same line of reasoning, Lindelöf and Löfsten (2003) state that, the role of technology-based companies is to accelerate the diffusion of technology and support their competitiveness.

The National Association of Entities Promoting Innovative Enterprises (ANPROTEC, 2002) defines technology-based company as one that has a process or product that results from scientific research and whose added value comes from advanced technology areas such as: information technology, biotechnology, fine chemicals, precision mechanics, new materials etc., and can even be characterized by the application of scientific knowledge, the mastery of complex techniques and the high technical qualification work.

The incubator for technology-based companies, object of this research, is that which holds companies whose products, processes or services are generated from applied research results, in which the technology represents high added value (MCT, 2000).

Incubated companies have characteristics of small and medium-sized enterprises. According to (Millward and Lewis, 2005; Koufteros *et al.*, 2005; Kumar *et al.*, 2006; Millward *et al.*, 2006; Mu *et al.*, 2007; Mathur *et al.*, 2012) the small and medium-sized enterprises represent a key element in national economies around the world. Most of the literature of PDP focuses on the activities of large known companies or within the context of well-developed economies, but the literature within the small and medium-sized companies located in developing countries is more limited.

This research has as object of study, incubated TBC that implement ISO 9001:2008 certification projects.

The selection of the technology-based companies (TBC) is justified by the surveys conducted by (Oliva *et al.*, 2011; Jugend and Silva, 2010; Andries and Debackere, 2006; Van Auken, 2001) that show that, these companies have more complex technologies, a factor of competitiveness in the market, and possess a high risk involved in product development and in the creation of this type of company. Moreover, the small and medium-sized TBCs, generally, operate in markets not occupied by large companies.

4. Survey Development

The survey research, according to Fink and Kosecoff (1998) and Forza (2002), is a method of collecting information directly from people about their ideas, feelings, health, plans beliefs and, social, educational and financial background, or about the unit, company or organization they operate. According to Pinsonneault and Kraemer (1993), the Survey research can be classified as to their purpose in explanatory, exploratory or descriptive. Based on the classification proposed by Pinsonneault and Kraemer (1993), as to the purpose, this research is exploratory due to its goal.

This research used steps proposed by Pinsonneault and Kraemer (1993), Fink (1995) and Forza (2002):

4.1 Defining the purpose of the research

Assess the difficulties encountered by the incubated companies participating in the PRIME-FINEP project and developing projects for certification of their Quality

Management System in accordance with ISO 9001:2008.

4.2 Population and Sample: Incubators of the Mineira Innovation Network

According to Malhotra (2006), population is the sum of all the elements that share common characteristics. Population for this research was defined as all the incubated companies in the South of Minas region, participating in the PRIME-FINEP project and developing projects for certification of their Quality Management System in accordance with ISO 9001:2008. Nine companies were identified and all responded to the questionnaire. It is worth mentioning that all the companies planned the project using MSProject and started at the same time.

4.3 Implementation Method

It was decided for the Survey, applied through a questionnaire delivered personally to collaborators of the incubated companies, having its filling been accompanied by the researcher to clarify any doubts.

4.4 Preparation of the instrument

The Bhuiyan and Alam (2005) questionnaire was applied (Table 1). We sought to identify and quantify the 20 sections of ISO 9001:2008, in the form of Likert scale, with five response ranges to choose from, that varied from very (5) to none (1), to collect the opinions of collaborators from the companies participating in the certification project.

Table 1. Sections of ISO 9001:2008 and number of the respective questions in the questionnaire

Question	NBR ISO 9001:2008 Section
1	4.2 - Documentation Requirements
2	5.1 - Management commitment
3	5.2 - Customer focus
4	5.3 - Quality Policy
5	5.4 - Planning
6	5.5 - Responsibility, authority and communication
7	5.6 - Critical analysis by the Management
8	6.1 – Provision of resources
9	6.2 – Human Resources
10	6.3 - Infra-structure
11	6.4 – Work Environment
12	7.1 – Planning of product realization
13	7.2 – Customer-related processes
14	7.3 - Design and development
15	7.4 – Acquisition
16	7.5 - Production and service provision
17	7.6 - Control of monitoring and measuring devices
18	8.2 - Measurement and monitoring
19	8.3 - Control of nonconforming product
20	8.4 - Data Analysis
21	8.5 – Improvements

4.5 Validation of the instrument

To determine the reliability of the questionnaire, the degree of homogeneity of the set of responses by *Cronbach's* alpha was calculated, since it provides internal consistency values, enabling to evaluate the scale used, as Hair Jr. *et al.*, (2005). The internal validity refers to the conditions of application of the instrument, in this case the questionnaire.

Although there is no absolute standard,

Cronbach alpha values equal to or above 0.70 reflect an acceptable reliability (Nunnally and Bernstein, 1994). However, Malhotra (2006) recommends as a decision criterion for "*Cronbach's* alpha to be considered acceptable, indices above 0.6, and the closer to 1, the greater the reliability." In this study, the value of *Cronbach's* alpha was calculated using the software Minitab15 ®. The lowest result obtained for each question was 0.8891 which meets the recommended conditions. Thus

obtaining, the validation the questionnaire used.

All companies responded, yielding more than two questionnaires per company, totaling 20 respondents. One questionnaire was eliminated for answering the 21 questions in the same degree of difficulty (rated 2), when analyzing the respondent's profile it was found that the same took little participation in the certification project. The author believes that these rates have no statistical basis and that honesty in the responses has a far greater importance than a high response rate. As we reached 100% of the companies, the questionnaire was personally applied and 95% of the questionnaires were validated, it is considered the appropriate external validity.

4.6. Data Collection

The questionnaires were individually and personally applied, seeking to clarify any doubts. The questionnaires were answered in the period of April 20 to May 10. It was considered as participating in the certification project the owners and employee involved with the certification, proven via documental analysis (e.g.: meeting minutes, training records, quality handbook). Due to the small number of companies, size of the questionnaire, the researchers knowing the collaborators of the companies and the spatial proximity of the incubators, the data collection showed no difficulties.

4.7. Preliminary analysis of the data

Data *boxplot* was carried out (Figures 1 and 2), being the *outliers* kept in subsequent analyzes.

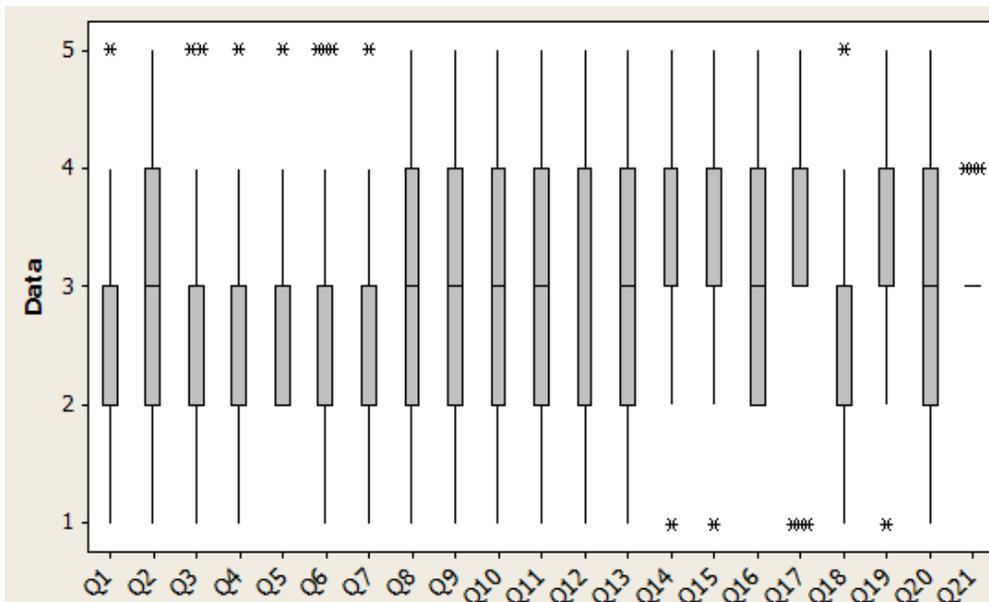


Figure 1. Box Plot of the opinions on difficulty of implementation.

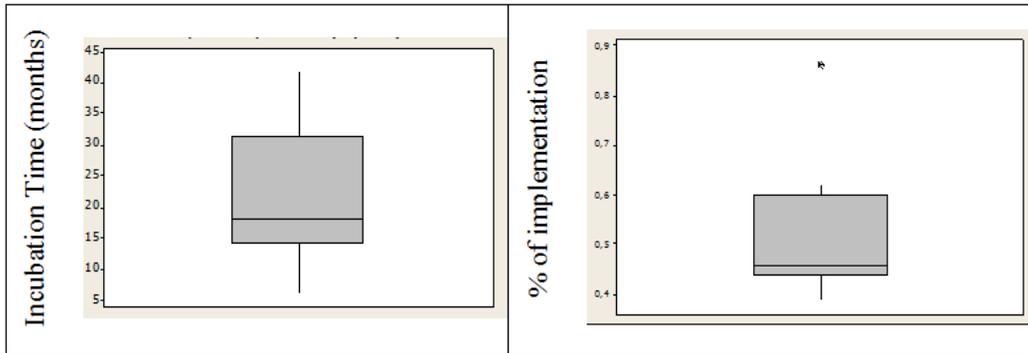


Figure 2. Box Plot of incubation time and the % of implementation

There is a wide dispersion in the difficulties in the implementation of the sections (Figure 1), being it less accentuated in question 21 (8.5 - improvements).

In Figure 2 the median incubation time is 18 months, being the minimum 6 months and the maximum 42 months. For the implemented percentage the median is 46%, the maximum being 86% and the minimum 39%. The company that has 86% of the project implemented is the one that has been incubated for the longest time and the certification is a market demand.

Subsequently, the T test (Figure 3) in the software Minitab15 ® for the perception of difficulties in the implementation of the section, considering a statistical difference of 5% (P Value lower or equal to 0.05).

The sections perceived as being difficult to implement with statistical significance (hypothesis H1) are: quality policy (5.3), design and development (7.3) and documentation requirements (4.2). The result regarding the difficulty of implementing the section "design and development (7.3) and documentation requirements (4.2)" was also identified in the researches, via survey, of Yahya and Goh (2001) conducted in Asian companies and Bhuiyan and Alam (2005) held in Canadian companies. But the difficulties identified in the researches of Yahya and Goh (2001), and Bhuiyan and Alam (2005), with statistical significance, were: continuous improvement (8.5) and Critical analysis by the Management (5.6).

Variable	N	Mean	StDev	SE Mean	95% CI	T	P
Q1	19	2,421	1,121	0,257	(1,881; 2,962)	-2,25	0,037
Q2	19	3,000	1,202	0,276	(2,421; 3,579)	0,00	1,000
Q3	19	2,842	1,068	0,245	(2,327; 3,357)	-0,64	0,527
Q4	19	2,368	1,065	0,244	(1,855; 2,882)	-2,58	0,019
Q5	19	2,789	0,855	0,196	(2,377; 3,202)	-1,07	0,297
Q6	19	2,842	1,214	0,279	(2,257; 3,427)	-0,57	0,578
Q7	19	2,632	1,012	0,232	(2,144; 3,119)	-1,59	0,130
Q8	19	3,053	1,177	0,270	(2,485; 3,620)	0,19	0,848
Q9	19	3,105	1,100	0,252	(2,575; 3,636)	0,42	0,682
Q10	19	3,105	1,049	0,241	(2,600; 3,611)	0,44	0,667
Q11	19	3,053	1,177	0,270	(2,485; 3,620)	0,19	0,848
Q12	19	3,263	1,046	0,240	(2,759; 3,767)	1,10	0,287
Q13	19	3,211	1,134	0,260	(2,664; 3,757)	0,81	0,429
Q14	19	3,474	0,964	0,221	(3,009; 3,938)	2,14	0,046
Q15	19	3,316	1,003	0,230	(2,832; 3,799)	1,37	0,187
Q16	19	3,105	0,937	0,215	(2,654; 3,557)	0,49	0,630
Q17	19	3,105	1,100	0,252	(2,575; 3,636)	0,42	0,682
Q18	19	2,895	0,994	0,228	(2,416; 3,374)	-0,46	0,650
Q19	19	3,263	0,991	0,227	(2,785; 3,741)	1,16	0,262
Q20	19	3,158	1,015	0,233	(2,669; 3,647)	0,68	0,506
Q21	19	3,1579	0,3746	0,0859	(2,9773; 3,3385)	1,84	0,083

Figure 3. Test T difficulty of implementing the sections of ISO 9001:2008

Subsequently, It was used the method of regression "Partial Least Squares" or PLS that applies when there are: multiple dependent variables, highly correlated predictors; more predictors than observations (Yacoub and MacGregor, 2003; Helland 1988). The PLS method reduces the number of predictors to a set of components. Therefore, PLS is a method which seeks to form components that capture the maximum information from the variables X and that is useful for predicting Y_i , while reducing the dimensionality of the problem of regression by using a smaller number of components than original variables. In this research, there are twenty section-questions of ISO 9001:2008 (variables X), being identified that they are correlated, besides the existence of more predictors than observations (20 questions variables X against 2 Y_i : incubation time and percentage of certification project developed).

The correlation analysis using the PLS, calculated through the *software* Minitab 15 ®, that uses the algorithm NIPALS (Nonlinear Iterative Partial Least Squares).

All the results showed relation with the incubation time and percentage of the certification project implemented for a confidence interval of 95% (pvalue <0.05), obtaining values of pValue: 0,000. As well as the analysis of residues, it resulted in data normality.

One major issue that arises in the Major Component Analysis is the criterion for choosing the number of components to retain. Kim and Mueller (1978) report that the most popular methods are: Kaiser, which proposes to consider only the eigenvalues greater than one, demonstrating that these values would be the statistically significant. But this condition is not sufficient. Not all eigenvalues greater than one correspond to components with apparent significance, and the Eigenvalues Diagram: consists of observing the diagram of eigenvalues and conserving the ones situated above the break point of the fall of the curve of the function

that relates the order and the eigenvalues. Thus, if two factors are associated with almost equal eigenvalues, they represent the same proportion of variability and there is no reason, a priori, to keep one and not the other. However, a strong decrease between two successive eigenvalues follows in conserving the predecessor factors in the interpretation.

For Johnson and Wichern (1992) the first components must absorb from 80 to 90% of the total variation, to be used as substitutes for the original data and, in accordance with the Kaiser criteria, the components whose eigenvalues are smaller than one should be excluded. In this research, it will be adopted, predominantly, the diagram of eigenvalues in which the main components absorb at least 80% of the total variation. For the response time of incubation, seven main components were selected, with the explanation rate of 96.24% and PValue equal to 0.000. As for the percentage of the certification project concluded, 7 major components were obtained, explanation rate of 93.47% and Pvalue of 0.000.

Analyzing Figure 4. it is noted that the difficulties present in companies with greater time of incubation and greater percentage of implementation for the ISO 9001:2008 project are the same for: 16 - Production and service provision (7.5); 2 - Management commitment (5.1); and 18 - Measurement and monitoring (8.2). Yet the difficulties for companies with lower incubation time and a lower percentage of the project implementation are: 5 - Planning (5.4); 20 - Data Analysis (8.4); 4 - Quality Policy (5.3); 19 - Control of nonconforming product (8.3). It is worth noting that question 3 - Customer focus (5.2) is a difficulty that does not depend on the company's incubation time and the percentage of the certification project implemented.

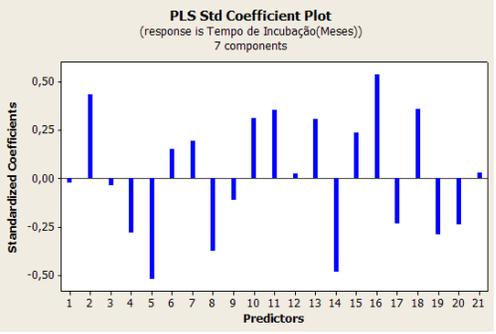
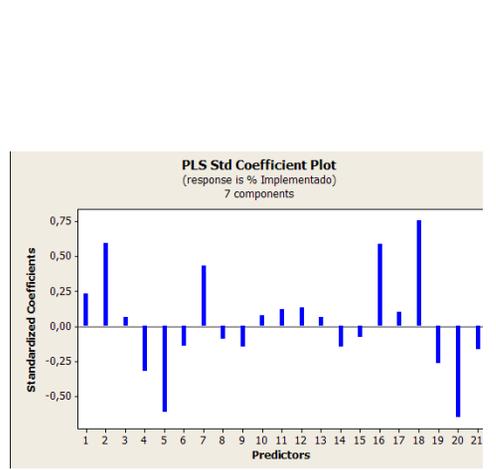
	<p>Difficulties present in companies with greater time of incubation (Hypothesis H2):</p> <ul style="list-style-type: none"> 16 - Production and service provision (7.5) 2 - Management commitment (5.1) 18 - Measurement and monitoring (8.2) 11 - Work Environment (6.4) 10 - Infra-structure (6.3) 13 - Acquisition (7.4)
	<p>Difficulties that do not depend on the incubation time (hypothesis H2):</p> <ul style="list-style-type: none"> 1 - Documentation Requirements (4.2) 3 - Customer focus (5.2) 21 - Improvements (8.5) 12 - Planning of product realization (7.1)
	<p>Difficulties present in the companies with the highest percentage of implementation of QMS ISO 9001:2008 project (hypothesis H3):</p> <ul style="list-style-type: none"> 18 - Measurement and monitoring (8.2) 2 - Management commitment (5.1) 16 - Production and service provision (7.5) 7 - Critical analysis by the Management (5.6)
	<p>Difficulties that do not depend on the implementation percentage of QMS ISO 9001:2008 project (hypothesis H3):</p> <ul style="list-style-type: none"> 3 - Customer focus (5.2) 10 - Infra-structure (6.3) 13 - Customer-related processes (7.2)
	<p>Difficulties present in the companies with the lowest percentage of implementation of QMS ISO 9001:2008 project (hypothesis H3):</p> <ul style="list-style-type: none"> 5 - Planning (5.4) 20 - Data Analysis (8.4) 4 - Quality Policy (5.3) 19 - Control of nonconforming product (8.3)

Figure 4. Difficulty to implement the sections of ISO 9001:2008 and the value of its respective PLS coefficient for the analyzed results.

Presenting the results for the research participants, the comments are reinforced:

"...companies which longer incubation time are starting to market their products thus requiring collect data for measuring and monitoring, as well as identifying the need for management commitment."

"...companies with shorter incubation time are still in the product development stage, being it their focus; in this context data are scarce and the planning is suppressed by the need to obtain the prototype and subsequently validate the product, as well as define what is expected of the QMS."

"...customer focus is our major concern, as we seek to identify and incorporate the needs of the market for our products. The higher the technology we incorporate in our products, greater the work to obtain the trust of customers".

5. Conclusion

After analyzing the data, it is concluded with statistical meaning that the TBC's with little incubation time present difficulties in

implementing the quality policy (5.3), difficulty not identified in other studies conducted in large companies. However the same difficulties encountered in large companies are present in the incubated TBC, and are the following: documentation requirements (4.2) present in all incubated companies (regardless of incubation time) and design and development (7.3) present in companies with little incubation time. The difficulty in implementing the quality policy (5.3) is reflected in the achievement of the QMS certification project in accordance with ISO 9001:2008.

It is recommended, as continuity to this research, to identify the causes of the difficulties identified, thus enabling to improve the implementation of QMS, as well as analyze the reasons that led the TBCs to get certified.

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Eduardo Gome Salgado

Federal University of
Alfenas
Brasil
egsalgado@yahoo.com.br

**Carlos Eduardo Sanches
da Silva**

Federal University of Itajubá
Brasil
sanches@unifei.edu.br

**Carlos Henrique Pereira
Mello**

Federal University of Itajubá
Brasil
carlos.mello@unifei.edu.br

**Elizabete Ribeiro
Sanches da Silva**

Federal University of Itajubá
Brasil
beriberio@uol.com.br
