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DEVELOPING A MODEL TO MEASURE AUDIT PROCESS EFFECTIVENESS IN A MEDICAL DEVICE ORGANIZATION

By

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CERTIFICATION OF DISSERTATION APPROVAL

The dissertation of Liz B. Machado was reviewed and approved by the members of the Dissertation Committee. The Doctoral Academics Requirements Compliance form, signed by the committee members, has been deposited in the Register Office and at the Graduate Studies & Research Center at the *Universidad del Turabo*.

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ABSTRACT

This research focuses in the compliance and quality audits in the regulated environment of a medical device organization. Due to the scarce literature in this area, other audit types in accounting and financial were reviewed to understand variables, indicators or opportunity areas related to audit's effectiveness. The main objective of the investigation is to measure the effect of different factors, found in the literature, which may have an effect with audit's effectiveness. The investigation is an exploratory research that measured variables that may affect the audit's effectiveness. The framework established was developed based on the literature review and researcher's expertise. The investigational model assessed the audit's effectiveness in terms of the audit process elements and risk management. The tool used to gather the data was developed and verified for validity and reliability. In a second stage, the tool gathered data from fifty (50) audits to explore the effect of the variables previously identified on audit's effectiveness.

The results showed that there are variables in the audit process that could affect the audit's effectiveness. However, other relations, identified during the literature review, could not be corroborated. For example, relationship between audit plan and audit effort, relationship between audit plan and audit's effectiveness, and connection between operational/business risks and audit planning could not be confirmed. Other type of indicators or audits elements may be studied to verify these relationships. Meanwhile, the study revealed that the auditor's knowledge is an important factor in the planning phase of the audit process. Other important variables that affect the effectiveness were monitoring and audit report. A secondary relation was observed for audit effort with audit report and corrective action with monitoring. Finally, the study obtained significance evidence that strategic risk had an effect on audit effort in the audit process. This relationship was included since an opportunity was identified during the literature review, because no studies had been completed evaluating the relationship between risks and the audit process, per Glover et al. (2000), Wright and Bedard, (2000), and Johnstone and Bedard (2001).

DEDICATION

First, this investigation is dedicated to God. He opened all the doors necessary to reach this personal goal. In addition, He was present in all phases, gave me the courage and wisdom, guided me in my darkest hours, and gave me hope to continue the journey. One of the lessons learned from God was to have patience and serenity to handle unexpected difficult situations, and know that at the end an answer will arrive.

To my wonderful family, Abraham Machado, Noelia Matos and Noel A. Machado, for your love and unconditional support during this process. In addition, I want to thank you for believing in me, be the source of my happiness and inspiration, and for your understanding for a long time where I was in my "world" as you said.

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CHAPTER I

INTRODUCTION

The medical devices companies must comply with external and internal regulations and standards. They need to implement processes to ensure compliance to these requirements. The companies are responsible to adapt their processes depending on the type of product and commensurate to risk. In that way, they provide best in class quality products, intended for human use, while complying with pre-established regulatory requirements.

In this industry, internal or external parties perform audits to ensure that these quality and compliance expectations are met. Medical devices manufacturers have typically two or more audits during the year. Most of them are expected and scheduled ahead. But some are without notification. Companies need to be prepared for these audits. Products are approved to the market once external regulatory bodies certify the processes and confirm compliance to the regulatory standards.

Two of these external bodies are known as FDA (Food Drug Administration) (FDA, 2014) and ISO (International Organization for Standardization) (ISO, 2013). ISO has listed 1,129,446 companies in 2013 for ISO 9001 standard and 25,666 for ISO 13485 standard (ISO, 2013), as an example. Meanwhile, FDA has listed 1,261 companies (FDA, 2014). These regulatory bodies require companies to implement quality systems that comply with their regulations and standards and lead to better product quality.

Product quality and compliance are very important in the medical devices manufacturing environment. They are not only the expectation from the aforementioned regulators and corporate, but they represent a competitive advantage among companies in

the same environment. This importance leads management to look for tools or programs that increase their organization effectiveness and efficacy. One of these programs is the internal audit. The main goal of an audit is to collect reliable and verifiable evidence, which allows conformity with particular requirements (Maruszewska & Bialy, 2013). In addition, it is required by federal governments and other foreign governments (e.g. Korea) to have an internal audit program to check if they are in compliance with their procedures, regulations and standards.

This study focuses on the effectiveness of these internal audits but also takes into consideration an organization that have a Total Quality Management (TQM) program. TQM integrates humanistic principles as well as scientific methodologies for the purpose of continuous process improvement (Parzinger & Nath, 2000). Internal Audits support TQM programs by assuring that company is in compliance with regulations and standards. In addition, this study focuses on quality internal audits in a medical device company within a regulated environment. Accounting and financial audits were also reviewed to understand the variables that may influence the audit's effectiveness, but they are out of the scope of this research. These other audits were evaluated since there is not much literature related to quality audits.

1.1 Problem Definition

The internal audit process is a program in many organizations to verify if they are in compliance with their policies, procedures and execution's objectives. The internal audit function evaluates data received from customers, problems in product and processes, and the environment where the product is being manufactured, among other systems. These data can be reviewed as part of other audits' types (e.g. internal and

external) or can be taken into consideration as part of the audit planning (Davidson & Gist, 1996). The literature shows a linear path between the elements, starting with audit planning, continue with execution, communication and ending with reporting. There is only one direction, which has inputs from previous audit and assessment results. It was found little information related to the fix-it/corrective action and monitoring elements (Jeroncic, 2010 and Agbejule & Jokipii, 2009). These activities are executed by the auditee and not by the auditor that execute the audit process. Most of the information found indicates that the audit process ended with the reporting element and that the effectiveness is only measured as compliance to schedule (reporting element).

The problem is that compliance to schedule not necessarily evaluates elements that could affect the audit results. This only measures timelines from the planning to the report. Besides, there other elements that are found in the literature that could affect the effectiveness of the audit results that are not taken into consideration within the measure compliance to schedule. This study will demonstrate that there are other elements in the audit that affect the effectiveness results. In addition, the linear path presented by the literature will be study to corroborate these relations and verify if they exist in the quality audit process.

1.2 Justification

The internal audit program is part of the performance evaluation in companies. Soh and Martino-Bennie (2011) indicate that there is an increasing involvement in operational and value-added activities as part of the internal audit. This is important for the company to understand if this program is effective or not and to know which variables affect the results to take them into consideration as part of the audit planning and through

the elements of the program. Audit effectiveness is improved as part of the performance of the company and then customer satisfaction also increases (Shanin, Attafar, & Samea, 2012). This is critical for competitive advantage.

In this study, the variables related to audit effectiveness will be put to the test with data from a company. This analysis identifies the elements in a linear path based on the literature review. Nevertheless, there are other variables and indicators that could affect the audit effectiveness results based on auditor's experience. The elements to be studied are audit effectiveness, audit planning, audit effort, audit report, corrective action and monitoring. However, the literature mentioned relationships in elements, from audit planning to audit report. Karapetrovic and Willborn (2000) indicate that research and development of an audit risk model for auditing would be a worthy exercise and the study includes risk factors in the model proposed. Finally, the corrective action and monitoring elements were not included as part of the audit process (Hernandez, 2010; Karapetrovic & Willborn, 2000; and Soh & Mantirnov-Bennie, 2011) and this study will corroborates if a relation exist.

1.3 Research questions and hypothesis

The principal objective of this investigation is to measure the effect of audit planning, audit effort, audit report, corrective action, monitoring and risk (business, operational, and strategic), and auditor's knowledge and to develop a model for predicting effectiveness of an audit in a medical device organization. This study pretends to answer the investigation questions and the hypothesis developed based on these questions:

Question 1: Is there a relation between audit planning and audit effort, and if this relation affects the audit effectiveness?

Hi1 There is a relation between audit planning and the audit effort.

H01 No relation exists between audit planning and the audit effort.

Question 2: Is there a relation between audit effort and audit report, and if this relation affects the audit effectiveness?

Hi2 There is a relation between audit effort and audit report.

H02 No relation exists between audit effort and audit report.

Question 3: Is there a relation between audit report and corrective action, and if this relation affects the audit effectiveness?

Hi3 There is a relation between audit report and corrective action.

H03 No relation exists between audit report and corrective action.

Question 4: Is there a relation between corrective action and monitoring and if this relation affects the audit effectiveness?

Hi4 There is a relation between corrective action and monitoring.

H04 No relation exists between corrective action and monitoring.

Question 5: Is there a relation between audit planning and the audit effectiveness?

Hi5 There is a relation between audit planning and the audit effectiveness.

H05 No relation exists between audit planning and the audit effectiveness.

Question 6: Is there a relation between audit effort and audit effectiveness?

Hi6 There is a relation between audit effort and audit effectiveness.

H06 No relation exists between audit effort and audit effectiveness.

Question 7: Is there a relation between audit report and audit effectiveness?

Hi7 There is a relation between audit report and audit effectiveness.

H07 No relation exists between audit report and audit effectiveness.

Question 8: Is there a relation between corrective action and audit effectiveness?

Hi8 There is a relation between corrective action and audit effectiveness.

H08 No relation exists between corrective action and audit effectiveness.

Question 9: Is there a relation between monitoring and audit effectiveness?

Hi9 There is a relation between monitoring and audit effectiveness

H09 No relation exists between monitoring and audit effectiveness.

Question 10: Are there relation between business risk, and audit planning and if they affect audit effectiveness?

Hi10 There are relation between business risk and audit planning.

H010 No relations exist between business risk and audit planning.

Question 11: Are there relation between operational risk and audit planning and if they affect audit effectiveness?

Hi11 There are relation between operational risk and audit planning.

H011 No relations exist between operational risk and audit planning.

Question 12: Are there relation between auditor's knowledge and audit planning and if they affect audit effectiveness?

Hi12 There are relation between auditor's knowledge and audit planning.

H012 No relations exist between auditor's knowledge and audit planning.

Question 13 Are there relation between strategic risk and audit effort and if they affect audit effectiveness?

Hi13 There are relation between strategic risk and audit effort.

H013 No relations exist between strategic risk and audit effort.

1.4 Model framework

This study will explore different variables relationships and how they can affect the effectiveness result. From the literature review, a framework was established using the audit process and the risk based approach. This framework was defined in Figure 1. Using this framework, this research seeks to establish a model between audit effectiveness and each element in the audit process including the different risk variables.

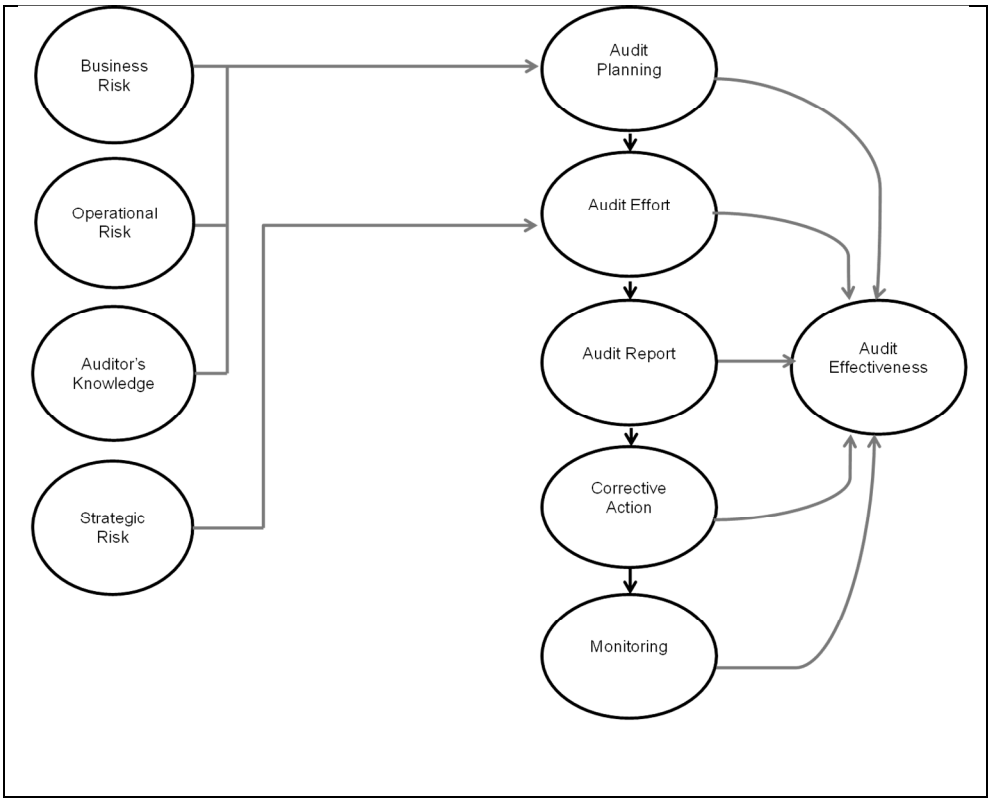


Figure 1. Audits Effectiveness – Framework.

In addition, this research pretends to assess whether the risks influence the audit planning and audit effort. In developing the model for audit's effectiveness, relations among the elements in the audit process will be assessed. By identifying the significant influences of audit effectiveness on quality aspects, this research will enable managers to obtain maximum benefits from audit programs.

This chapter describes the impact of the audit program in the literature review. It explains the internal audit process as part of the TQM program in the companies. The importance of the internal audit and external audits were reviewed during the literature review. The literature shows a linear path for the audit process while other authors suggest about other elements like risk and auditor's education. The definition of the

problem and the framework was developed and the importance of this study for the medical device organization and for research.

Chapter II presents the literature review or the studies and support evidence about the variables presented in Chapter I. In addition, in Chapter II, the literature shows the linearity of the audit process while other opportunities were presented related to this process and the importance in an organization. In addition, the literature shows many dimensions that could affect the audit effectiveness. The variables' relationship was discussed using the framework and literature review. The audit effectiveness relation with other variables like audit planning, audit effort, audit report, corrective action, and monitoring will be evaluated. In addition, this research studies the relation of business risk, operational risk, and auditor's knowledge with audit planning. Finally, the relation of strategic risk and audit effort is examined.

1.5 Limitations

There are some limitations about the study. The questionnaire will be submitted only to one company with three sites in Puerto Rico. In addition, after the validation of the instrument, only the principal researcher will use the instrument as observation and gathering data process. Future research may consider submitting this questionnaire to other medical device companies in Puerto Rico or outside of Puerto Rico or to other industries where audits are important. The results of this investigation could not be generalized to any type of companies. In addition, other element considered as an indicator that could be evaluated as a construct is statistical sampling techniques in auditing. This study used it to define one of the construct. Future research could

consider the incorporation of other elements of the TQM program as part of the model and study the effects of them in the audit process.

CHAPTER II

REVIEW OF LITERATURE

The manufacturing companies needs to have flexible systems and organizational structures to adapt to external environment that may influence the competitive advantage and quality effort. A system is a set of interrelated and interdependent parts arranged in a manner that produces a unified whole (Robbins & Coulter, Management, 2009). A company to be flexible or sensitive to its environment needs to be opened to receive feedback of the external sources and cannot be closed. Closed systems are not influenced by and do not interact with their environment. In contrast, open systems are influenced by and do interact with their environment (Robbins & Coulter, Management, 2009). The organization is "open" to and interacts with its environment.

An open system will have inputs and transformation processes and outputs. In these processes the environment may influence the input and outputs while the inputs receive feedback from the outputs. The organization is being made up of interdependent factors, including individuals, groups, attitudes, motives, formal structure, interactions, goals, status, and authority (Robbins, 1997). This needs to be taken into consideration since no organization can survive in the long term if it ignores government regulations, supplier relations, or the varied external constituencies on which it depends (Robbins & Coulter, Management, 2009). The Figure 2 shows the interactions of an organization as an open system.

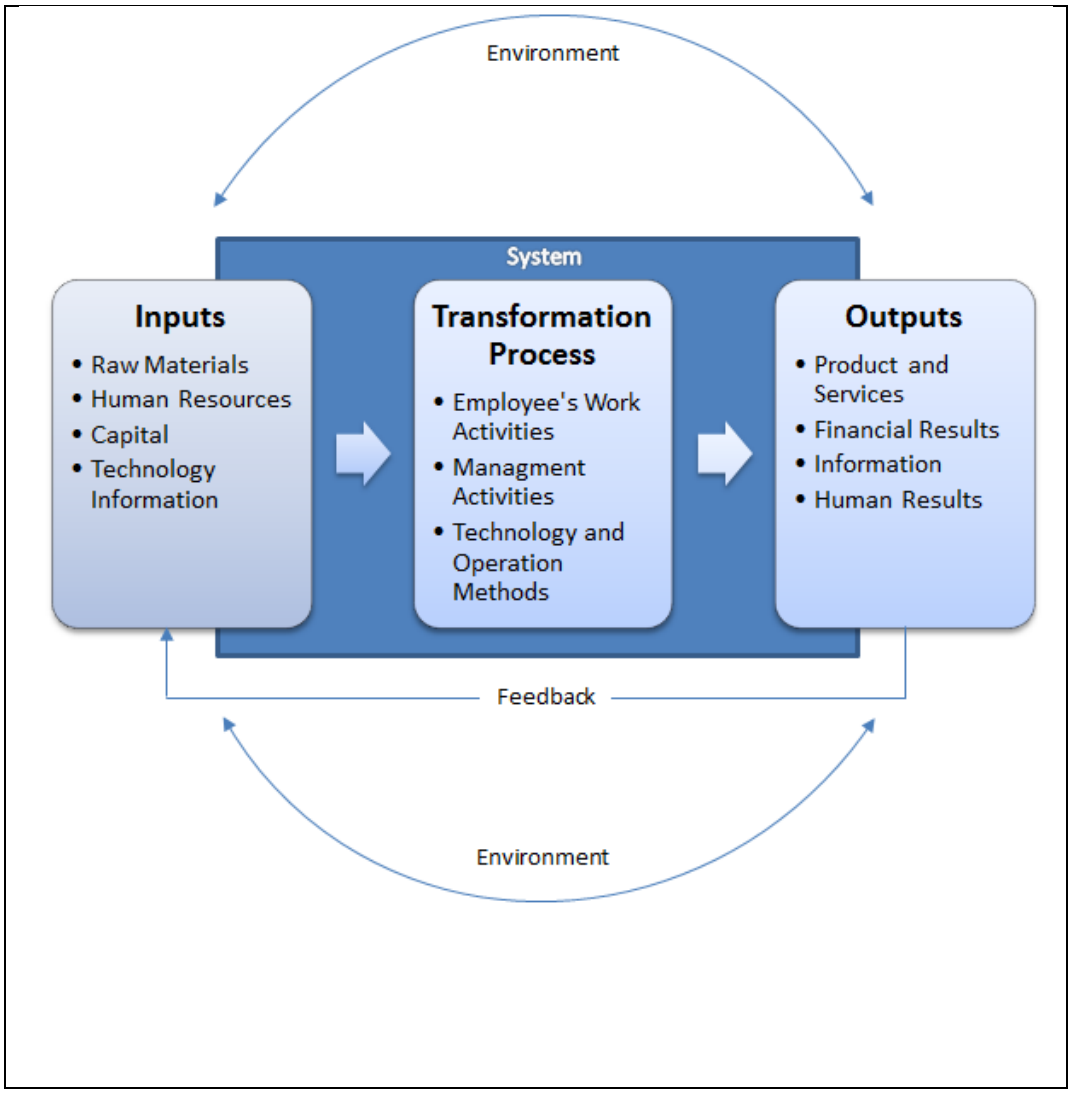


Figure 2. Organization as an Open System. Open systems that used TMQ philosophy to identified continuous improvements process and responding customer needs. Adapted from Management, by S. Robbin and M. Coulter, Pearson. Copyright 2009 by Pearson.

Managers who adopt this open system ensure that all parts of the organization are coordinated internally so the organization's goal can be achieved. They rely on their environment for life-sustaining inputs and as outlets to absorb their outputs (Robbins, Managing Today, 1997). The decisions in the organization take into consideration the internal environment (resources, processes, etc.), but also the external environment for effective decision making. The quantitative approach is used to improve decision

making. It involves applying statistics, optimization models, computer simulations and other quantitative techniques to management activities. Work scheduling, as an example, can be more efficient as a result of critical-path scheduling analysis. One area where quantitative techniques are being used is known as total quality management (Robbins & Coulter, 2009).

There was a quality revolution during the 1980s through 1990s where quality experts like W. Edwards Deming and Joseph M. Juran brought ideas and techniques that Japanese organizations embraced. Japanese manufacturers increased their quality compared with United States (U.S.) competitors. Managers in the U.S. started to assess and use the quality perspective, like Deming and Juran, which are the basis for the Total Quality Management programs (TQM). TQM is a management philosophy devoted to continual improvement and responding to customer needs and expectations (Robbins & Coulter, 2009). TQM was a departure from earliest management approaches that were based on the belief that keeping costs low was the only way to increase productivity. In addition, the literature shows that W. Edwards Deming must have realized that maintaining or controlling a process was not good enough. He developed, back in the 1920s, a quality tool known as the plan-do-check-act (Gupta, 2006). The plan-do-check-act (PDCA) cycle has been an integral part of quality management for several decades. Today, the ISO (International Standard Organization) 9001 quality management standard specifies the use of the PDCA model for managing processes and creating process oriented thinking (Gupta, 2006). PDCA is a continuous feedback loop to identify and change process elements to reduce variation. The objective of PDCA is to plan to do something, manufacture or do it, verify or check it for meeting requirements, and correct

the process to maintain the acceptable output performance (Gupta, 2006). ISO 9001 is based on the PDCA model in which the input is customer requirements and the deliverable is process output meeting customer requirements. Figure 3 shows the use of PDCA for product management.

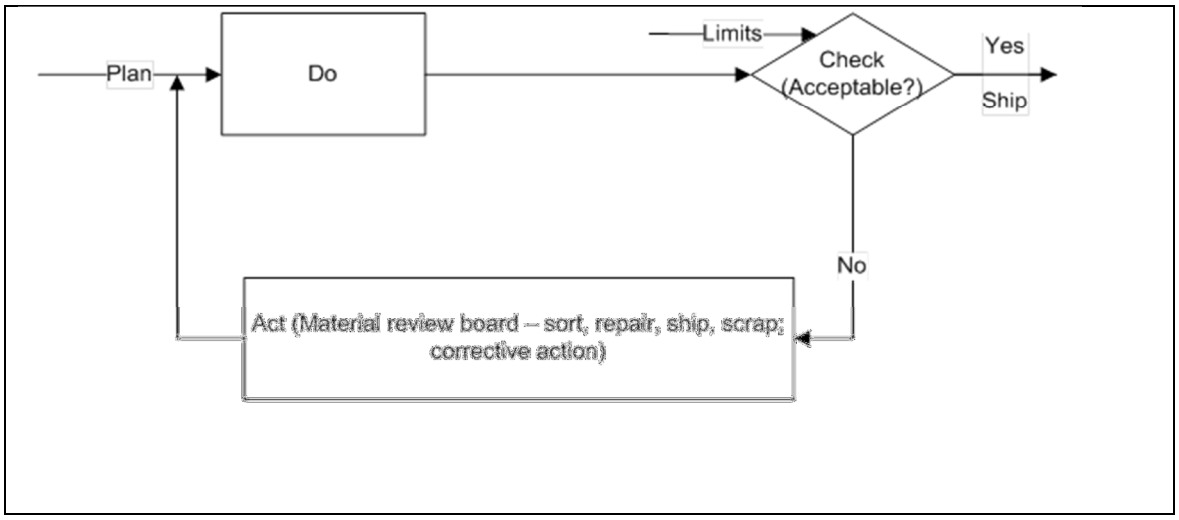


Figure 3. Use of the Deming Cycle (PDCA) for product management. Verification and monitor occur as part of the check step of the Deming cycle. Adapted from Beyond PDCA-A New Process Management Model, by P. Gupta, 2006, Quality Progress, 39, p.46. Copyright 2006 by Quality Progress.

ISO 9001defines PDCA elements (Gupta, 2006) starting with the plan stage that establishes the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies. The do stage is the step to implement the process. Check is used to monitor and measure processes and product against policies, objectives and requirements for product, and report the results. Finally, act is the stage where the actions are taken to continually improve the process. This study is assessing the effectiveness of a program that act as the check stage definition provided by ISO 9001 in the manufacturing companies. This program is known as audit. Audits can be let to control and check the quality assurance system. This includes lessons

acquired from previous corrective actions from other similar processes including preventive actions. In addition, the literature explains how the results from the corrective and preventive actions can become inputs in the system for the act stage (Mizuno, 1988).

Audit is a formal verification of an organization's accounts, records, operating activities, or performance. Audits can generally be characterized as either external or internal (Robbins, 1997). An external audit for the financial area is a verification of an organization's financial statements by an outside and independent accounting firm. This is similar to the process that occurs in the quality or compliance area where an external organization or agency will check the compliance to the regulation and standards. The external auditor's job is reviewing the various accounts on the financial statements with respect to their accuracy and conformity with generally accepted accounting practices. The external audit's value to management, in terms of a control device, is generally indirect because the audits are meant only to verify what management already knows. They are an indirect control device, however, in the sense that their existence serves as a deterrent against abuses or misrepresentation by those who develop the financial statements. The internal audit is done by members of the organization. It encompasses verifying the financial statements, just as the external audit does, but additionally includes an evaluation of the organization's operations, procedures, and policies, plus recommendations for improvement. So, in terms of control, the internal audit is a more comprehensive evaluation. It goes beyond merely verifying financial statements, seeks to uncover inefficiencies, and offer suggested actions for their correction (Robbins, Managing Today, 1997).

As the literature indicates, the audit is a control device that indicates managers how their systems are performing against different requirements. All managers should control, even if they think their units are performing as planned. They can't really know how units are performing unless they've evaluated what activities have been done and compared actual performance against the desired standard. Effective controls ensure that activities are completed in ways that lead to the attainment of goals. Where controls are effective is determined by how well they help employees and managers achieve their goals. Planning can be done, an organizational structure can be created, employees can be motivated through effective leadership, but there's no assurance that activities are going as planned. Control is important and it can be seen through specific areas: planning, empowering employees, and protecting the workplace (Robbins & Coulter, 2009). The control process is defined by three steps: measuring, comparing, and managerial actions. Measuring is used to determine what actual performance is, comparing is the step to determine the variation between actual performance and a standard, and management can do nothing, correct the actual performance, or revise the standard. In summary, the control process is a three-step process of measuring actual performance, comparing actual performance against a standard, and taking managerial action to correct deviations or inadequate standards (Robbins & Coulter, 2009). The interest in this process is that management has an active participation and decisions to make corrective activities or to do nothing, including changing the standard. An audit could be an indirect or direct control process. It may needs to include similar steps like the controlling process in its methodology. The controlling process could include measure, comparing process and requirements, and action. Quality improvement

initiatives are not possible without a mean for monitoring and evaluating their progress, as the audit does. Robbins (2009) indicates that many worldwide organizations have pursued challenging quality goals to publicly demonstrate their quality commitment. One of the best organizations to challenge these quality goals is known as ISO 9000. ISO 9000 is a series of international quality management standards established by the International Organization for Standardization, which sets uniform guidelines for processes to ensure that products conform to customer requirements. The ISO 9000 standards have become the internationally recognized standard for evaluating and comparing companies in the global market place. In fact, this type of certification can be a prerequisite for doing business globally. Achieving ISO 9000 certification provides proof that quality operation systems are in place (Robbins & Coulter, 2009). An organization with European business, for example needs to be certified in ISO standards by an external contractor that corroborate the compliance with these standards if the foreign countries allow. The contracted agency compares the company's quality system against ISO standards and identify if there is a gap or area for improvement.

Historical perspectives and philosophies relative to audit process lay the groundwork for model development. Recent studies attempted to identify which factors are critical to the audit process and its effectiveness. The interest of this research is to identify factors and create a model to improve the internal audit process and the external audit outcome in a regulated company. In this direction, the literature review establishes that there are different audit types that are part of the continuous improvement mechanism in the quality system of an organization. Some audits' scopes are in the financial statements, accounting area, quality system, compliance, among other areas.

The scope is established by the organization management or by the regulation/certification requirements. The literature review suggested that audits have similar process steps regarding if they are internal, external or an assessment (Hernandez, 2010; Karapetrovic & Willborn, 2000; and Soh & Martinov-Bennie, 2011). Audit in this study, refers to a general audit process, which includes internal and external, unless it is specified otherwise.

This research focuses in the audit process steps like audit planning (Davidson & Gist, 1996; American Institute of Certified Public Accountants, 1982; Agbejule & Jokipii, 2009; Hughes, 1977) audit effort (Asare, Davidson, & Gramling, 2008; Davidson & Gist, 1996), and audit report (Soh & Martinov-Bennie, 2011). In addition, other steps were evaluated like corrective action (Jeroncic, 2010) and monitoring (Agbejule & Jokipii, 2009). The audit effectiveness was other element reviewed. The literature referred to it as changes in the degree of adherence to procedures (Hughes, 1977). The effectiveness could be interchanged by efficiency, but they are not equals. Efficiency means doing things right and effectiveness means doing the right thing. Doing things right means minimizing the cost of resources needed to achieve goals. Doing the right thing means selecting appropriate goals and the achieving them (Robbins, 1997). One of the effectiveness criteria by common stakeholders for government regulators is legal compliance (Robbins, 1997). This means that to be effective for an organization is to be in compliance with legal regulations.

The literature review suggested other factors that are part of the audit process that may influence the steps and the audit effectiveness. This research describes some of these factors as business risk (Sahnoun & Zarai, 2009), operational risk (Odoyo,

Omwono, & Okinyi, 2014), auditor's knowledge (Fukukawa & Mock, 2011; Hawkes & Adams, 1994; Soh & Martinov-Bennie, 2011) and strategic risk (Odoyo, Omwono, & Okinyi, 2014). For this reason, the risk management approach is an element this research will take into account from the beginning of the audit process. Based on this, the risk management was assessed to identify a link to audit effectiveness and improve the audit's outcome. Lastly, a few studies evaluated the internal and external data sources (Odoyo, Omwono, & Okinyi, 2014) and linked them to the audit process. The following literature review addresses each of these areas in detail.

There was little literature about these elements and audit effectiveness. There was a paper from 1977 that is taken into consideration (Hughes, 1977). The literature review includes external systems that consider the PDCA cycle (e.g. ISO organization) that could submit feedback to an organization using the audit system. The literature indicates that the certification of international standards (e.g. International Organization for Standardization (1SO) 9001) has become an obligatory requirement since its original released in 1987 (Hernandez, 2010). The ISO 9000 internal auditing methodology is a proactive process for identifying whether the procedures created by the organizations are being followed and are effective (Taormina, 2000). The Internal Audit is a standard clause that is part of the ISO standards, such as ISO 9001: 2000, standard clause 8.2.2 – Internal Audit, ISO 13485, standard clause 8.2.2 – Internal Audit, ISO 14001, standard clause 4.5.5 – Internal Audit (Kausek, 2007). This includes ISO 19011 that is the guideline for auditing management systems. In addition to international standards, there are regulations that establish requirements in the audit area. One of them is a requirement established by the Food and Drug Administration (FDA). The Food and Drug

Administration is the oldest comprehensive consumer protection agency in the U. S. federal government. Its origins can be traced back to the appointment of Lewis Caleb Beck in the Patent Office around 1848 to carry out chemical analyses of agricultural products, a function that the newly created Department of Agriculture inherited in 1862. Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law that prohibited interstate commerce in adulterated and misbranded food and drugs (FDA, 2015). Manufacturing regulations are based in the FDA Good Manufacturing Practices (GMP's) formally introduced in the 1970s (FDA, 2015). These regulations are applied to the different quality systems in the manufacturing companies. The audit is part of the Code of Federal Regulations (CFR) Title 21 in Part 820, Subpart B, Section 820.22 – Audit (FDA, 2015). The previous regulations and standards are some examples about what the companies need to comply in their current environment. In addition, those are the baselines of this study since the regulatory controls have become more stringent ensuring that what was acceptable in the past is not acceptable now (Psomas & Fotopoulos, 2009).

Management is involved as part of the implementation of these regulations through the risk based approach (Pluta & Poska, 2010, p. 73). In August 2002, United States Food and Drug Administration announced a new initiative, Pharmaceutical Current Good Manufacturing Practices (cGMP) for the 21st Century. This initiative, coupled with the publication of the International Conference on Harmonization (ICH) Q8 Pharmaceutical Development, 2006, ICH Q9 Risk Management, 2007, ICH Q10 Pharmaceutical Quality Systems, 2007, ICH Q11 Concept Paper, 2011 (2-5), and the long

awaited FDA Guidance for Industry on Process Validation: General Principles and Practices, 2011, represented a significant shift of regulatory requirements from the traditional "test to compliance" to the current "quality by design" (Yang, 2012).

However, ISO standards that were mentioned early in this study are used in companies as guidelines to setup their quality systems (Psomas & Fotopoulos, 2009), similar to the ICH Q8, Q9, Q10 and Q11. ISO as an organization does not perform certification to its standards, does not issue certificates and does not control certification performed independently of ISO by other organizations. It receives requests for information on the number of certificates and this led the organization to undertake "The ISO Survey" every year (Psomas & Fotopoulos, 2009). This survey can be found in the ISO webpage. Figure 4 through Figure 9 are graphs related to this survey. The information available is from 1993 to 2013. Figure 4 shows that for 2013 there are 1,129,446 worldwide companies certified in ISO 9001 while in 1993 there were 37968. Figure 5 shows that in 2013, 101057 companies from North America and Central and South America were certified in ISO 9001 and 2,753 were certified in 1993. Finally, related to ISO 9001, in Puerto Rico, sixty-five (65) companies were certified in this ISO while two (2) were certified in 1993 (Figure 6). There is a significant difference in quantity of certified companies within the years. In addition, this means that there has been an increment of companies that implement ISO standards to comply with customer's request, quality image, efficiency and control improvement, market-share increase, quality of products and services, and corporation level decision.

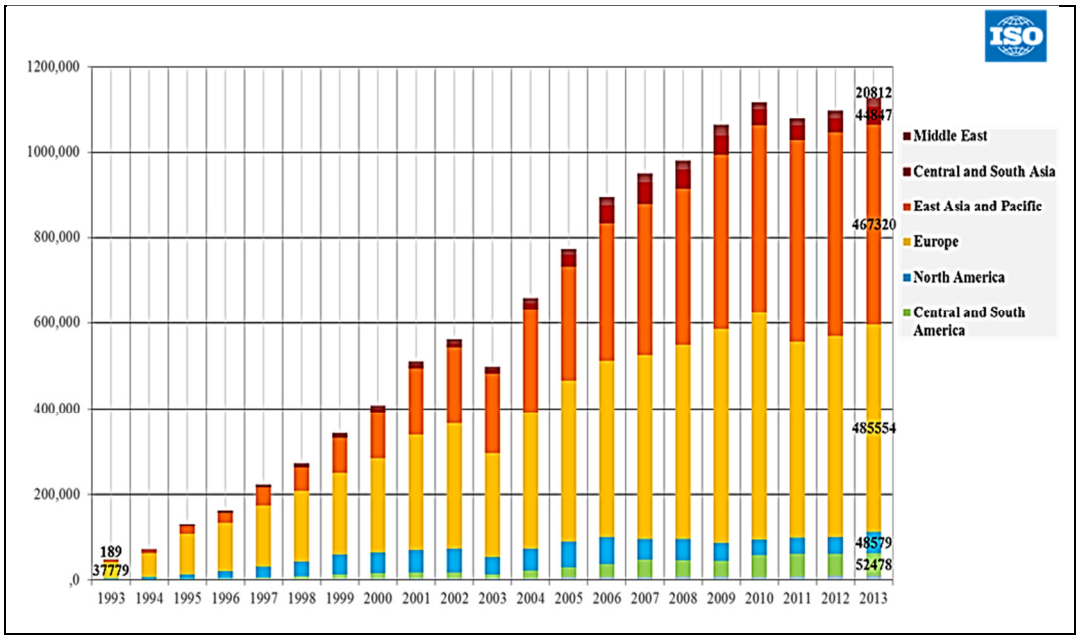


Figure 4. Companies certified by ISO 9001 standard – Worldwide (ISO, 2013).

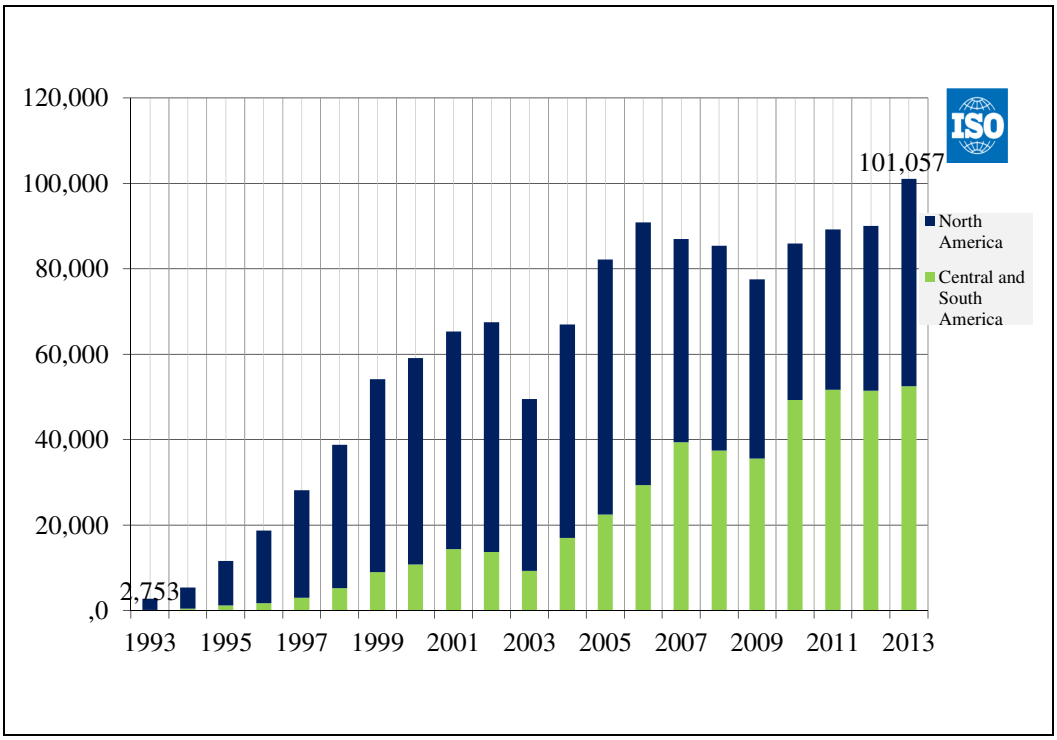


Figure 5. Companies certified by ISO 9001 standard – North, Central and South America (ISO, 2013).

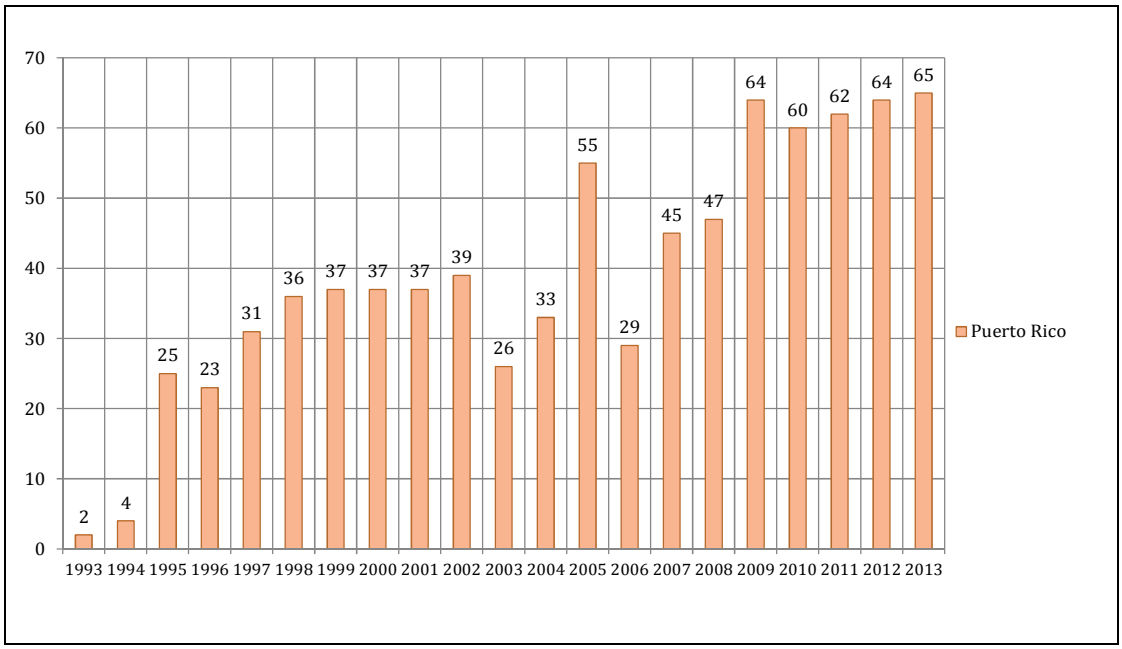


Figure 6. Companies certified by ISO 9001 standard – Puerto Rico (ISO, 2013).

In addition to ISO 9001, there are other standards like ISO 14583. Figure 7 shows that 25,666 worldwide companies were certified on ISO 13485 in 2013 while 2,403 were certified in 2004.

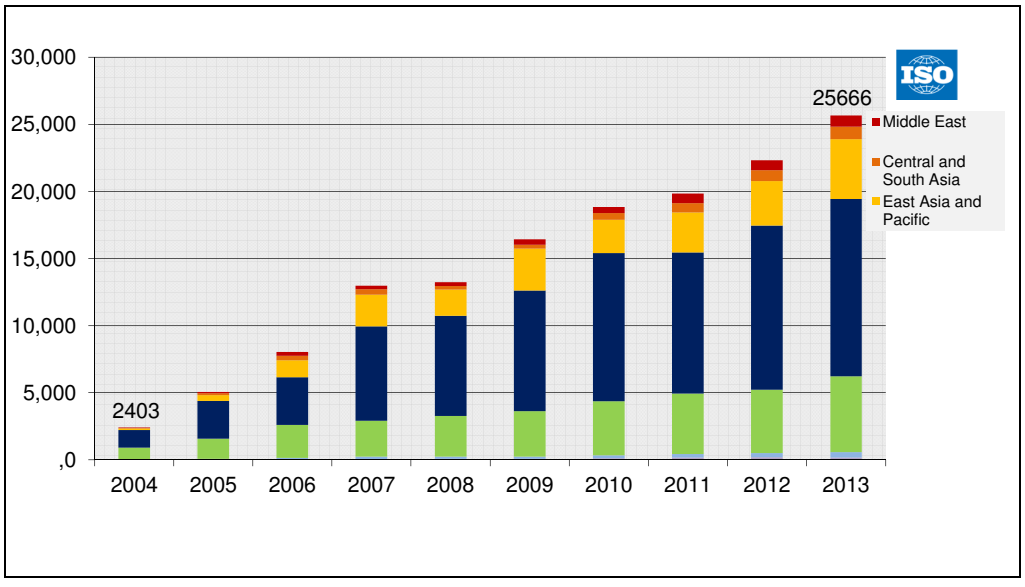


Figure 7. Companies certified by ISO 13485 standard - Worldwide (ISO, 2013). For companies in North America and Central and South America, 6,062 in Figure 8 were certified on ISO 13,485 companies by 2013 and 873 in 2004.

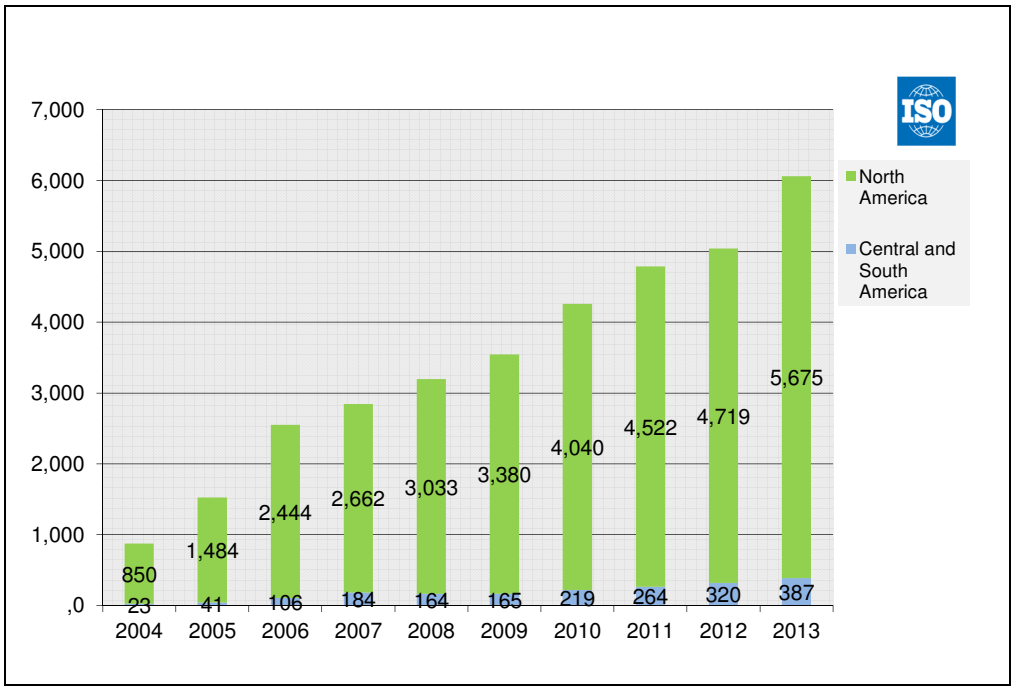


Figure 8. Companies certified by ISO 13485 standards – North, Central and South America (ISO, 2013).

Finally, Figure 9 shows Puerto Rico's companies in ISO 13485. In 2013 thirty-six (36) companies were certified in ISO 13485 and only 873 in 2004. All graphs shows an increment in certified companies through the years in the different zones identify by ISO.

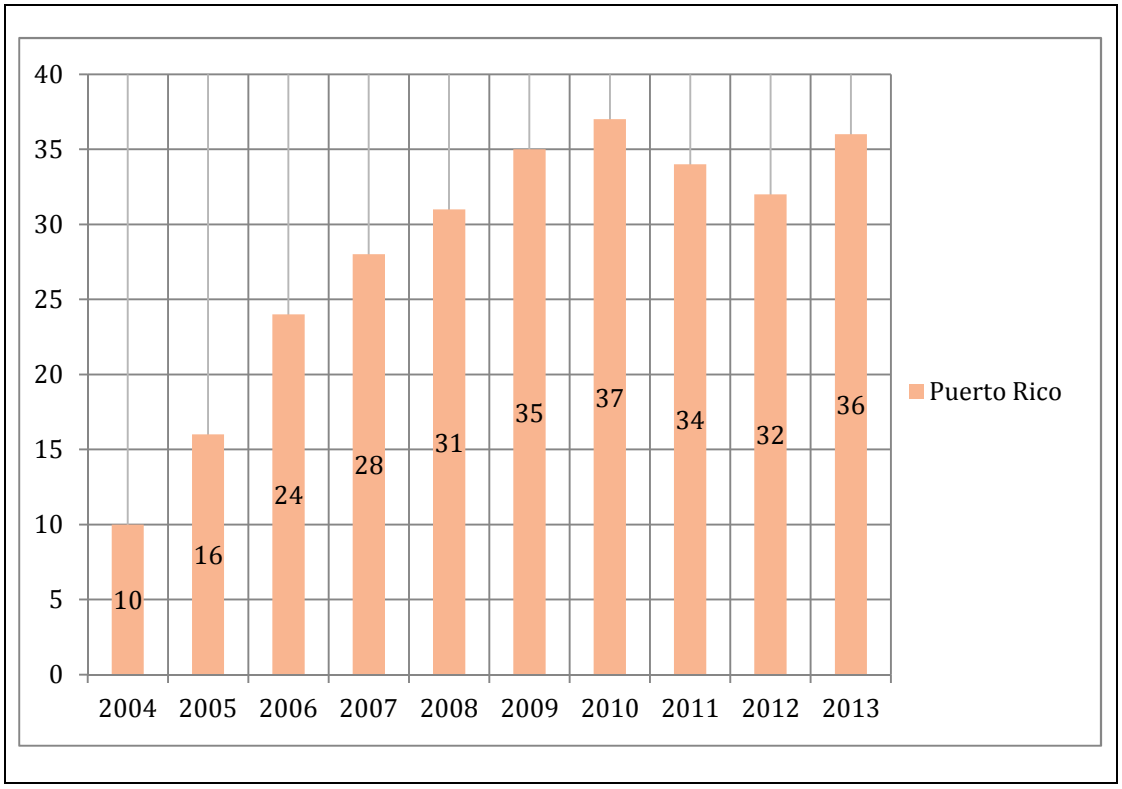


Figure 9. Companies certified by ISO 13485 standards – Puerto Rico (ISO, 2013).

In addition, the literature review revealed that many studies have already been done and concluded that the standard helps companies improve their operational performance meaning their internal procedures, productivity documentation, structure, order in the work, and so on (Psomas & Fotopoulos, 2009).

The companies that implement these standards and regulations need to ensure compliance in their processes and procedures before an external audit or inspection is performed. In the same direction, the company needs to be ready to comply with these requirements. One of the mechanisms to assess that the company is in compliance is through the audits' program. Audits have gained prominence in the last 20 years as a tool for assessing the effectiveness of quality assurance efforts and, more recently, for the

evaluation of compliance with applicable quality standards, such as ISO 9000 (Karapetrovic & Willborn, 2000). Auditing is not the criticism of coworkers; it is the assessment of the processes (Hernandez, 2010). However, it is reported that in many organizations audits are performed by external agencies rather than by internal audit units. Such a situation could reflect the lack of quality assurance expertise among auditors (Hernandez, 2010).

The audit systems pursue that the company comply with the implemented procedure, regulation, and standards. Audits are not only meant for checking the systems for their compliance with quality system (QS) standards, they can also be used for exercising continuous quality improvement (CQI) and reaching the benchmarks of total quality management (TQM) (Rajendran & Devadasan, 2005). In some cases the auditing exercises are applied under pressure to comply with the certification. In these cases, the agenda of audits are not realized in the majority of today's organizations and as a result, its authentic benefits are not fully nourished. One of the reasons that can explain why this happens is that the management views auditing as a checkpoint to obtain a quality system certification. The literature indicates that a suitably timed and properly organized quality-auditing program will lead to continuous quality improvement (CQI) process in the organization (Rajendran & Devadasan, 2005).

Audits performed to the quality system are part of the company's quality organization structure. These audits evaluate the compliance of the applicable quality standards. Auditors examine, in several stages, whether or not quality processes, resources and objectives are in compliance. The evaluation of the system effectiveness can be a powerful management tool for quality improvement (Karapetrovic & Willborn,

2000). An audit is viewed as a set of interdependent processes, using human material, infrastructural, financial, information and technical resources to achieve objectives related to the continuous improvement of performance (Karapetrovic & Willborn, 2000). The purpose of an internal audit is to check on how well a system and processes are doing (Markovitz, 2011). Also, these audits tell management whether the established procedures are being followed and seek to ensure that quality management systems are effective in achieving quality objectives laid down in the ISO 9000 series (Hawkes & Adams, 1994).

Moreover, the audit system must be continuously able to meet changing audit policy and objectives to be effective (Karapetrovic & Willborn, 2000). That implies that the audits exist in the organization to provide administrative management with reasonable assurances that financial or quality information is accurate and reliable: that the organization complies with policies, plans, procedures, laws, regulations and contracts (Agbejule & Jokipii, 2009).

There are three objectives per Committee of Sponsoring Organizations of the Treadway Commission (COSO) framework: effectiveness and efficiency of activities, reliability of financial information, and compliance with applicable laws and regulations (Agbejule & Jokipii, 2009). When these three are achieved, the internal control is effective. There are other components that other research indicates that are part of the COSO 1994 framework. Those are control environment, risk assessment, control activities, information and communication, and monitoring (Agbejule & Jokipii, 2009). COSO suggests that the components are interrelated, but it offers little guidance on how these components interact.

Furthermore, there are various mechanisms that ensure that an organization is in compliance. Internal and external audit help enhance audit committee effectiveness by serving as a resource to the Boards of Directors. The linkages between internal and external audit mechanisms are generally under research (Mihret & Admassu, 2011). External auditors assess internal audits work to determine the extent of their reliance on internal audit (Mihret & Admassu, 2011). The external auditors are required under International Standards on Auditing (ISA) to consider various aspects of corporate governance, including the internal audit function's objectivity (IAF) and quality when assessing an entity's control environment and/or potential reliance of the work of the IAF (Soh & Martinov-Bennie, 2011). It is hoped that the findings will prompt further consideration of current evaluation practices. In that way, the stakeholder expectations are maintained through a quality assurance and improvement program that covers all aspects of the internal audit's activity and continuously monitors its effectiveness.

The audit system, much like a chain that always fails at its weakest link, is only as good (meaning as reliable, available and maintainable) as its weakest element. Organizations that utilize their audits in a kaizen-like manner, focusing on small, but steady improvements, will benefit from a structured quality assurance (QA) approach (Karapetrovic & Willborn, 2000). Kaizen philosophy covers improvement and a participative process (Hawkes & Adams, 1994). The Kaizen concept stresses the need for a supportive and leadership role for management to encourage people to improve everything they do in their work environment (Hawkes & Adams, 1994). They will manage the audit system by concentrating first on the global auditing policy and objectives, and transforming them into a meaningful framework of different audit

programs (quality, environmental, safety, etc.), which will be brought to fruition by conducting individual audits (assessments). Individual audit plans are prepared, audits are executed, and audit reports are provided to the client (Karapetrovic & Willborn, 2000). After several cycles of audits are performed, the people responsible for the management of the audit system may analyze the performance of the system, and prepare a report on the overall system efficiency and effectiveness. As an input into the analysis, results of the internal quality system should be taken into account by the top management, who should review it and attempt to find possibilities for improvement (Karapetrovic & Willborn, 2000).

In the introduction of this study, it was established that the scope is the audit process and effectiveness in companies with regulated environment. Then, the standards and regulations were defined and later the audit process was defined according to literature review. Other element reviewed was the audit effectiveness, which is defined as changes in the degree of adherence to procedure. This means that audit effectiveness can be measured in terms of the adherence to procedure in an organization. The effectiveness depends of the audit impact to in the internal control system (procedures). In addition, effectiveness is defined as the results of obtained objective evidence against the acceptance criteria (Hughes, 1977). The effectiveness variable is the effect of audit planning on audit efficiency. Effectiveness can be measured using total audit effort required to achieve a successful audit (Hughes, 1977). In the literature, the audit effort refers to effectiveness in terms of probability that a system will fulfill a set objective within a given time frame under specified conditions and scope (Karapetrovic & Willborn, 2000). Also, effectiveness was defined, according to literature, as reliability,

availability and suitability in this study. Other studies used other variables like time pressure (TP), task complexity (TC), and audit effectiveness (AE) to examine the relationships among them (Bowrin & King, 2010). The time pressure (TP) was defined on Bowrin & King's paper (2010) as an individual's perception regarding her/his ability to perform and assigned task within a specified time limit, given that timely task completion is an important dimension of task performance. TC was defined as the manner in which task elements are interrelated and the extent to which task requirements are specified. In that study, TC was operationalized by asking auditors to perform two independent tasks that have been shown to exhibit different levels of complexity, but are usually performed by auditors with similar levels of experience. Finally, AE was operationally defined as the extent to which the auditor achieved the stated objective. The results show a negative interactional relationship among TP, TC, and AE. One of the limitations concerns the non-random procedure used to recruit public accounting firms and auditors (Bowrin & King, 2010). Findings suggest that the firms may need to resist the urge to reduce the time allowed for performing compliance tests (Bowrin & King, 2010). In addition, the results show that the rate of change in AE, in response in TP, is different for the two audit tasks studied. It suggests that it may not be appropriate for audit planner to assume a uniform TP effect across the various tasks involved in an audit (Bowrin & King, 2010). Future research may examine whether other variables that have been suggested as moderators/mediators of the TP-AE relationship (such as locus of control) have an effect on the relationship in the auditing context (Bowrin & King, 2010).

Another study related to audit effectiveness indicated that Ernst & Young (2007) reports that the top two metrics used in the measurement of internal audit effectiveness

are the completion of audits against to an internal audit plan and the length of time for issuing the internal audit reports (Soh & Martinov-Bennie, 2011). Soh and Maritnov-Bennie (2011) looked for what are the roles and responsibilities of the internal audit function, what are the key factors to Internal Audit Function (IAF) effectiveness and how is the effectiveness of the internal audit function evaluated. Bennie (2011) indicates that for this purpose evidence was collected through semi-structured interviews. A non-directional style of questioning was employed in order to mitigate interviewer bias. A protocol was developed for recording and analyzing the data from the interviews. In order to validate the data collected, the combined interview summary, categorized by target issues, was emailed to each interviewee for approval (Soh & Martinov-Bennie, 2011). Some findings of this study indicate that IAF has experienced and expansion and refocus of its roles and that the performance evaluation mechanisms of IAF have not evolved contemporaneously with its roles (Soh & Martinov-Bennie, 2011). In addition, the study presents the limitations of the use of a qualitative approach to collecting data, in that the findings are limited in terms of their generalizability. Future research may consider investigating similar issues in other regulatory contexts and national settings, development of more appropriate performance evaluation of the IAF in view of its increasing involvement in operational and value-added activities (Soh & Martinov-Bennie, 2011).

In some studies, like the one by Agbejule & Jokipi (2009), effectiveness has been presented as a necessary dependent variable in contingency research as it provides the means to determine the appropriate fit between control and organizational variables (Langfield-Smith, 1997). The effectiveness of internal control is defined in terms of

management's perceptions of how well the internal control objectives are achieved (Agbejule & Jokipii, 2009). Improving effectiveness as an indicator of performance and increasing customer satisfaction are critically significant for organizations that seek a greater competitive advantage (Shanin, Attafar, & Samea, 2012). For 2007, overall administrative effectiveness (OAE) was proposed as: availability (A), quality (Q) and efficiency (E) (Shanin et al., 2012).

The first step considered in this study as part of the audit process was the audit planning. Usually, the planning phase starts with a schedule that indicates the focus of the audit. Then, the audit generates a plan that establishes the acceptance criteria against the audit that will be performed. Later, the auditor through interviews, and record reviews will check the current state of the organization against the requirements. Lastly, the auditor generates the report with the results. (Hernandez, 2010). Figure 10 shows linear path for the audit process.

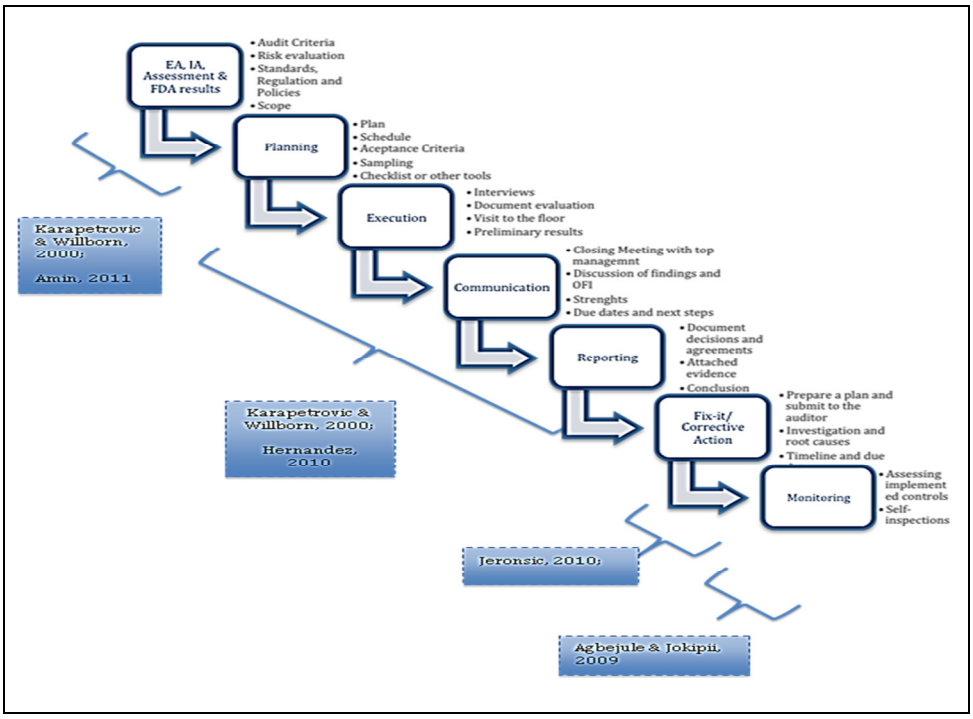


Figure 10. Audit Process – Based on Literature Review.

The audit-implementation process is effective in the case that there are strict restrictions in the matter of timeframe for implementing a quality management system (QMS), and there is very few or no experience in the organization in the implementation of this type of system. The documentation process needs to be driven by a proved subject matter expert (SME) due to the time restrictions (Hernandez, 2010). Davidson & Gist (1996) indicated that professional standards require that during the planning phase of the engagement, the auditor assess the risks like inherent risk, control risk, and detection risk in addition to making a preliminary judgment of materiality to select an audit strategy (Davidson & Gist, 1996). The detection risk in the paper was used as a basis for audit planning decisions on the nature, timing, and extent of audit procedures. Also, the American Institute of Certified Public Accountants (AICPA, 1982) defined detection risk

as the risk that the procedures performed by the auditor to reduce audit risk of noncompliance to an acceptably low level will not detect noncompliance that exists and that could be material, either individually or when aggregated with other instances of noncompliance (American Institute of Certified Public Accountants, 1982). The inherent risk is a factor that was not clearly defined, but these authors assumed the level of inherent risk as minimal for their samples. The auditor will accept greater detection risk when inherent and control risks are low. The control risk is related to certain information in analytical procedures required under standards. The AICPA defined it as the risk that noncompliance with a compliance requirement that could occur and that could be material, either individually or when aggregated with other instances of noncompliance, will not be prevented, or detected and corrected, on a timely basis by the entity's internal control over compliance. Another definition by Agbjule & Jokipii (2009) was that the control risk refers to policies, procedures, and practices that assure management that the objectives are achieved and risk mitigation strategies are carried out effectively.

The time constraint was studied as part of audit planning that could affect the amount of effort needed to achieve a successful audit. An increase in audit planning hours should result in a more than equal decrease in verification hours, so the total audit execution hour's decrease. The study of Hughes (1977) concentrated on the informational aspects of internal audits, with practical attention being given to audit timing. In this study, the time constraint is a factor that will be analyzed as part of the audit planning and in corrective action. However, the importance of Hughes' study is that internal audits in an organization typically are scheduled at relatively infrequent intervals of time and, thus, the timeliness dimension of information takes on added significance.

Also, he stated in his study that the level of effectiveness of the internal control system in maintaining production efficiency as the focal point of the auditing timing problem is seems to be appropriate. That is, the decision to audit is to be dependent upon the impact, which the audit can be expected to have on the effectiveness of the internal control system (Hughes, 1977). The audit sampling is part of the audit planning. Audit sampling is one of the most fundamental testing procedures used to gather audit evidence, and it has undergone significant change during the history of modern auditing. Audit sampling is a pervasive audit testing technique (Elder, Akresh, Higgs, & Liljegren, 2013). If the auditor used a smaller sample size than required, which resulted in a questionable acceptance of the quality system compliance, a corrective action may require an adequate determination of the sample size and confidence level in the audit (Karapetrovic & Willborn, 2000).

Asare, Davidson & Gramlin (2008) defined the audit effort as total budgeted hours as part of the audit process step. The audit effort decisions might be reflected in ways other than the total number of budgeted hours. For example, more hours may be spent in a particular audit area, while fewer hours may be spent in another audit area (Asare, Davidson, & Gramling, 2008). Besides audit effort, another variable defined by the same authors was audit report. Audit report is the completion of audits in comparison to an IAF plan, and includes the length of time for issuing IAF reports (Soh & Martinov-Bennie, 2011). As stated previously, the variable timeliness definition will be taken into consideration, even though finance audits are out of the scope of this study. Timeliness definition was taken into consideration and it was defined as the number of days that elapses between a company's financial year-end and the day on which its audited

financial statement is received by the Indonesian Stock Exchange (IDX) (Siti & Mohd Ghazali, 2012). Multivariate regression analysis was performed to analyze the relationship between audit committee effectiveness and timeliness of reporting (Siti & Mohd Ghazali, 2012). The findings suggest that audit committee effectiveness is a significant factor ensuring timely submission of audited financial statements (Siti & Mohd Ghazali, 2012).

Two audit process factors that this study considered are not necessary in the literature but are included as part of the organization systems. These two factors are Fix It or Corrective Action and Monitoring. The Fix-it or Corrective or preventive action eliminates the cause(s) of an existing or potential nonconformity or an undesirable situation in order to prevent recurrence or occurrence. For corrective actions, tools for root cause analysis can be used to identify the cause(s) of the issue. For the potential issues, the prevention can include FMEA (Failure Mode and Effect Analysis) or FTA (Fault Tree Analysis) analysis to determine potential risk associated with the identified issue. The workload and resource management needs to be focus on those areas within the quality system that present higher risk to the quality of a product. One of the limitations that an audit program can face is the lack of resources since they are competing with other business priorities (Hernandez, 2010). This occurs when the auditors or assigned resources perform the audit activities in parallel with their current activities. Management expects that all the activities be completed on time and with good results. The other factor is the time restriction-requirement set by the customer and the number of people involved (Hernandez, 2010). Also, the timing affects the adequate response to audit results. For this, it is necessary to determine the type of actions

determining the timeframe for the implementation and assessing the associate risks (Jeroncic, 2010). Meanwhile, the monitoring component refers to a process of assessing the quality of controls. It covers ongoing and periodical evaluations of the external supervision of internal controls by management or other parties outside the process. Monitoring ensures that controls are operating as intended and that they are modified appropriately to cater for changes in conditions. Objective criteria to be used for acceptance should be included as part of the verification.

There is a key element in the audit process that needs to be assessed. This important element is the auditor's knowledge and/or competences. Auditors need some competencies to be qualified to participate in an audit. In some cases, the quality assurance of auditing activities rests solely with the adequate qualification and competence of auditors, and conformance of the auditing process to the existing audit guidelines (Karapetrovic & Willborn, 2000). Literature shows that audit suitability needs to be taken into consideration and that it depends on many audit elements; the onus is usually on the auditor (or the auditor team) and their qualifications and competence (Karapetrovic & Willborn, 2000). Competence may be defined as the demonstrated and recognized ability of a qualified auditor to consistently achieve audit objectives to the satisfaction of client and auditee, while qualifications refer to the auditor's education, training and experience (Karapetrovic & Willborn, 2000).

The auditors need to understand and know how the process for quality systems is in order to perform the audit based on current procedures, processes, standards and regulations. That means the verification of the compliance and conformance of the established processes – to the standard; to assure that their coworkers are following

documented processes (Hernandez, 2010). Also, auditors must objectively and independently collect and verify audit evidence, evaluate it against audit criteria and report their findings. Objectivity and independence are two separate fundamental principles of auditing. Objectivity relates to the consistency of the auditing process and results, materiality of evidence, the use of appropriate methodology (e.g. statistical sampling, flowcharts, and checklists), the application of a systematic approach to auditing, and being free from bias (Karapetrovic & Willborn, 2000). Independence refers to auditors' organizational position and their state of mind. They are subject to quality assurance department instead of rendered services to management team organization (Karapetrovic & Willborn, 2000).

Another element in the audit process is the risk management approach, mentioned earlier in this literature review. The risk management is part of the quality system and it is included as an element in the audit process. ICH Q9 lists benefits of an effective risk management approach within the quality systems. Some of them include ensuring high quality of product by identifying and controlling potential quality issues, improving decision making, and facilitation of better and more informed decisions (Jeroncic, 2010). The quality risk management includes seven elements: risk assessment, risk identification, risk analysis, risk evaluation, risk control/treatment, risk communication, and risk review and monitoring. Risk assessment is the process of risk identification, analysis, and evaluation. The risk identification purpose is to identify the causes and sources of hazards, events, situations or circumstances that could have an impact upon the quality of the product, the quality objectives, and the nature of that impact. Risk identification identifies the causes and sources of hazards, events, situations or

circumstances that could have an impact upon the quality of the product, the quality objectives, and the nature of that impact. Risk analysis is an estimate of the risk associate with an identified hazard. It consists of linking the consequences and their likelihoods for the identified hazard (can also link detectability of the hazard) to determine the level of risk (Jeroncic, 2010). Risk evaluation involves comparing the identified and analyzed risks against established risk criteria to determine their significance. Risk control/treatment is the process of decision making in order to reduce and/or accept risks, identify risk control/treatment solutions and implement these solutions aiming to reduce the risk to an acceptable level. Risk communication refers to information sharing regarding risks and risk management between stakeholders. It is important that this information is accurately communicated through reporting channels established by the organization in order to ensure the success and effectiveness of the quality risk management process. Lastly, risk review and monitoring is a regular review of the quality risk management ensuring that any new knowledge and experience is taken into account (Jeroncic, 2010).

For a risk-based auditing, the effort is prioritized in the areas carrying the largest risk of non-compliance with the audit criteria or where not enough information is available to ensure a correct finding (Karapetrovic & Willborn, 2000). It is important to understand and take into consideration the risks as part of an audit. Amin (2011) indicated that most auditors do not revise their audit planning (no additional test, for instance) when analytical procedures provide unexpected significant fluctuation. Also, the auditors do not take into consideration the client's risk factor that affects various audit planning tasks, such as effectiveness of audit program and justification of audit

investigation (Amin, 2011). Furthermore, Hawkes and Adams (1999) indicated that internal audits frequently lose credibility with operational managers because they are so risk-averse, and do not provide much support when risky decisions have to be made (Hawkes & Adams, 1994). Conventional approaches to internal audit tend to focus on how things are done, rather than the reasons why they are done (Hawkes & Adams, 1994). Nevertheless, the risk in this study is related to the client risks and how affects the planning, but other research indicates that risk is a characteristic that can affect auditor judgments and impact audit quality (Agoglia, Brazel, Hatfield, & Jackson, 2010). While recent field research has not found a link between client risk and the extent of audit review, it is possible that reviewers will weigh the relative advantages/disadvantages of electronic and face-to-face interaction differently depending on the level of client risk (Agoglia, Brazel, Hatfield, & Jackson, 2010).

Some of the components of the risk that is in the literature are business risk, operational risk and strategic risk. Those are presents in the audit process. Business risk refers to the risks that an auditee's economic condition will deteriorate over time (either in the short or long term) to such an extent that the auditee cannot achieve its earnings targets and/or fulfill its obligations on debt covenants (Sahnoun & Zarai, 2009). Operational risk is the risk of direct or indirect loss resulting from inadequate or failed internal processes, people, and systems or from external events. Strategic risk may arise from regulatory, political impediments or technological innovation. This means that the strategic risk is dependent on external sources like government, corporate standards, and technology changes, among other external factors. Strategic risk is part of the audit strategy that will result in an acceptable level of audit risk.

The concepts of risk, uncertainty, materiality, statistical sampling, reliability of findings, and audit errors were assessed even though, accounting audits are out of the scope of this study. These concepts were well known and continuously researched in the accounting literature based on literature (Karapetrovic & Willborn, 2000). They are crucial for proper understanding and application of audits, regardless of the particular discipline addressed. However, they are not given appropriate recognition in the auditing literature (Karapetrovic & Willborn, 2000). One example that was mentioned in the literature is that the American Society for Quality (ASQ) does not reference audit risk, materiality, reliability, maintainability, and quality assurance of auditing activities (Karapetrovic & Willborn, 2000). Another concept that the literature mentioned that has poor recognition in the auditing process is cost. Cost-effectiveness relates to the ability of the audit to achieve objectives while minimizing the associated spending. When an audit is designed and conducted in a manner that ensures its suitability, availability and reliability, reduction of costs comes as a natural consequence (i.e. profit) (Karapetrovic & Willborn, 2000). Future research suggests investigating the cost of effectiveness and the domain of statistical sampling techniques in auditing, modeling of audit maintainability and sustainability, as well as the use of quality assurance schemes for auditing smaller companies (Karapetrovic & Willborn, 2000). Research and development of an audit risk model for auditing would be a worthy exercise (Karapetrovic & Willborn, 2000). The development of a quantitative method for assessing audit effectiveness through reliability, availability, and suitability measures needs particular attention (Karapetrovic & Willborn, 2000). Also, the intent to localize the most important factors that influence audit reliability, availability and suitability, and test their effects for a variety of settings (e.g.

using design of experiments (DOE)) (Karapetrovic & Willborn, 2000) could be performed. Finally, an empirical study addressing these issues in further detail is suggested, and would contribute to the research not only in auditing, but also in other areas of auditing practice (Karapetrovic & Willborn, 2000).

The literature review defines the factors that were included in the model framework (Figure 1) in Chapter 1. Each of these constructs and other variables definitions are in Table 1 for the use of this investigation.

Table 1

Definition of Variables based on Literature Review

Variable	Literature Review	Definition	Indicators
Audit Effectiveness	Hughes, J. S. (1977). Optimal Internal Audit Timing. *Accounting Review*, *52*(1), 56	a. Changes in the degree of adherence to procedure b. Depends on audit impact to the effectiveness of internal control system (procedures). c. Result of obtain objectively and evaluate evidence against acceptance criteria. Function of internal auditing: degree of correspondence between procedures, which should have been followed as implied by, actually was taken. d. Audit quality encompasses audit effectiveness: the achievement of a desired level of assurance that material client errors have been detected. e. The effectiveness constant: effect of audit planning on audit efficiency. It can be measure using Total audit effort required to achieve a successful audit. f. COSO framework: (1) Effectiveness and efficiency of activities; (2) Reliability of financial information; and (3) Compliance with applicable laws and regulations.	Not following procedure events External data source: FDA observations (e.g. 483, warning letters), Adverse effect, MDR
	Agbejule, A., & Jokipii, A. (2009). Strategy, control activities, monitoring and effectiveness. *Managerial Auditing Journal, 24*(6), 500-522.	When these three objectives are properly achieved, internal control should be deemed effective. In this study, internal control effectiveness is defined on the basis of how well these three objectives are achieved in the organizations studied. *Note*. In this study reliability of financial will not take into consideration.	

Variable	Literature Review	Definition	Indicators
Audit Planning	a. Davidson, R. A., & Gist, W. E. (1996). Empirical Evidence on the Functional Relation between Audit Planning and Total Audit Effort. Journal Of Accounting Research, 34(1), 111-124. b. American Institute of Certified Public Accountants. Auditing Standards Board. (1982). AICPA Codification of Statements on Auditing Standards. American Institute of Certified Public Accountants. c. Agbejule, A., & Jokipii, A. (2009). Strategy, control activities, monitoring and effectiveness. Managerial Auditing Journal, 24(6), 500-522.audit	a. Professional standards require that during the planning phase of the engagement, the auditor assess inherent risk, control risk, and detection risk in addition to making a preliminary judgment of materiality to select an audit strategy. Detection risk a. is used as a basis for audit planning decisions on the nature, timing, and extent of audit procedures. b. The risk that the procedures performed by the auditor to reduce audit risk of noncompliance to an acceptably low level will not detect noncompliance that exists and that could be material, either individually or when aggregated with other instances of noncompliance. Inherent risk: a. is a factor that was not clearly defined, but these authors assumed the level of inherent risk as minimal for their samples. The auditor will accept greater detection risk when inherent and control risks are low. b. The susceptibility of a compliance requirement to noncompliance that could be material, either individually or when aggregated with other instances of noncompliance, before consideration of any related controls over compliance. Control risk: a. is related to certain information in analytical procedures required under standards. b. The risk that noncompliance with a compliance requirement that could occur and that could be material, either individually or when aggregated with other instances of noncompliance, will not be prevented, or detected and corrected, on a timely basis by the entity's internal control over compliance. c. Refer to policies, procedures and practices that assure management that objectives are achieved and risk mitigation strategies are carried out effectively.	Detection risk Inherent risk Control risk

Variable	Literature Review	Definition	Indicators
Audit Planning (Continue)	Hughes, J. S. (1977). Optimal Internal Audit Timing. *Accounting Review*, *52*(1), 56-68.	Audit planning affects the amount of effort needed to achieve a successful audit. An increase in audit planning hours should result in more than equal decrease in verification hours, so the total audit execution hour's decrease.	Time constraints
	Elder, R. J., Akresh, A. D., Glover, S. M., Higgs, J. L., & Liljegren, J. (2013). Audit Sampling Research: A Synthesis and Implications for Future Research. Auditing: *A Journal Of Practice & Theory, 32 (1),* 99-129	Audit sampling is one of the most fundamental testing procedures used to gather audit evidence, and it has undergone significant change during the history of modern auditing. Audit sampling is a pervasive audit testing technique.	Audit Sampling
Audit effort	Asare, Stephen Kwaku, Ronald A. Davidson, and Audrey A. Gramling. 2008. "Internal Auditors' Evaluation of Fraud Factors in Planning an Audit: The Importance of Audit Committee Quality and Management Incentives." *International Journal Of Auditing* 12, no. 3: 181-203.	Audit effort is total budgeted hours. The audit effort decisions might be reflected in ways other than the total number of budgeted hours. For example, more hours may be spent in a particular audit area, while fewer hours may be spent in another audit area.	Time to prepare the plan Time to execute the plan Time to report
Audit Report Timeliness	Soh, D. S., & Martinov-Bennie, N. (2001). The Internal Audit Function – Perceptions of Internal Audit Roles, Effectiveness, and Evaluation, *Managerial Accounting Journal*, 26(7), 602-622.	IAF (Internal Audit Function) effectiveness is the completion of audits in comparison to an IAF plan, and the length of time for issuing IAF reports.	Audit Delay (Audit report timeliness)

Variable	Literature Review	Definition	Indicators
Fix It/Corrective Action	Jeroncic, B. (2010). Improved utilization of self-inspection programs within the GMP environment-A quality risk management approach. *Journal of GXP Compliance, 14*(3), 84-96.	Corrective or preventive action eliminating the cause(s) of an existing or potential non- conformity or undesirable situation in order to prevent recurrence or occurrence. For corrective actions, tools for root cause analysis can be used to identify the cause(s) of the issue. For the potential issues, the prevention can include FMEA (Failure Mode and Effect Analysis) or FTA (Fault Tree Analysis) analysis to determine potential risk associated with the identified issue. The workload and resource management needs to be focus on those areas within the quality system that present higher risk to the quality of product. Adequate response to audit results – determining the type of action for the issues identified within the audits, determining the timeframe for the implementation of actions and assessing the associate risks.	Actions Resources workload Time constraints
Monitoring (for effectiveness)	Agbejule, A., & Jokipii, A. (2009). Strategy, control activities, monitoring and effectiveness. *Managerial Auditing Journal, 24*(6), 500-522.audit Blodea, G. (2007), How to Set Up a CAPA Program from Scratch. *Journal of GXP Compliance*, 11(3), 64-82.	The monitoring component refers to a process of assessing the quality of controls. It covers ongoing and periodical evaluations of the external supervision of internal controls by management or other parties outside the process. Monitoring ensures that controls are operating as intended and that they are modified appropriately to cater for changes in conditions. Objective criteria to be used for acceptance should be included as part of the verification.	Assessment Activities Acceptance Criteria

Variable	Literature Review	Definition	Indicators
Auditor's knowledge	Hironori Fukukawa and Theodore J. Mock. Audit Risk Assessments Using Belief versus Probability. *Auditing: A Journal of Practice & Theory*, 30 (1), 75-99.	The evaluation of audit evidence to determine the quality and meaning of that evidence and to assess the need for additional evidence based on the process.	Training and certifications
	Hawkes, L. C., & Adams, M. B. (1994). Total Quality Management: Implication for Internal Audit. *Managerial Auditing Journal*, 9(4), 11-18.	Staff needs to be continuously trained in how to do their job. Change is an integral part of today's business environment and staff has to be properly equipped to cope with it.	
	Wedemeyer, P. D. (2010). A discussion of auditor judgment as the critical component in audit quality - A practitioner's perspective. *International Journal Of Disclosure & Governance*, 7(4), 320-333.	A natural tendency as auditors gain experience is for them to rely heavily on their earlier experience in making judgments. This is a proper and useful approach but suffers from the risk that the auditor will encounter situations that are not comparable to earlier experience or that the auditor will not observe a change in conditions that affects audit risk. Although competent professionals take responsibility for their own continuing education, the processes and procedures of an audit firm must include provisions for keeping personnel informed of new developments, particularly changes in conditions that may affect audit judgments.	Experience
Business risk	Sahnoun, Manel Hadriche and Zarai, Mohamed Ali, Auditor-Auditee Negotiation Outcome: Effects of Auditee Business Risk, Audit Risk, and Auditor Business Risk in Tunisian Context. Corporate Governance: An International Review. Sep2009, Vol. 17 Issue 5, p559-572.	In general, the term "auditee business risks" refers to the risks that an auditee's economic condition will deteriorate over time (either short or long term); to such an extent that the auditee cannot achieve its earnings targets and/or fulfill its obligations on debt covenants.	Quantity of objective and/or goals

Variable	Literature Review	Definition	Indicators
Operational Risk	Odoyo, F. S., Omwono, G. A., & Okinyi, N. O. (2014). An analysis of the role of internal audit in implementing risk management- a study of state corporations in Kenya. *International Journal of Business and Social Science, 5*(6).	a. Risk of direct or indirect loss resulting from inadequate or failed internal processes, people, and systems or from external events.	External data source: FDA observations (e.g. 483, warning letters), Adverse effect, MDR Internal data source: equipment mal-function, internal audit findings, supplier control, process assessment (compliance, manufacturing, and self-inspection)
	21CFR820.3 (2014). Food and Drugs Administration Department of Health and Human Services, Subchapter H – Medical Devices. 820.3 (b).	Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.	External data source: Complaints
	21CFR820.3 (2014). Food and Drugs Administration Department of Health and Human Services, Subchapter H – Medical Devices. 820.3 (q).	Nonconformity means the nonfulfillment of a specified requirement.	Internal data source: Nonconformity
Strategic Risk	Odoyo, F. S., Omwono, G. A., & Okinyi, N. O. (2014). An analysis of the role of internal audit in implementing risk management- a study of state corporations in Kenya. *International Journal of Business and Social Science, 5*(6).	This risk may arise from regulatory, political impediments or technological innovation. This means that the strategic risk is dependent on external sources like government, corporate standards, and technology changes, among other external factors.	Acceptance Criteria External Governance
		Strategic risk is part of the audit strategy that will result in an acceptable level of audit risk. Meaning that establishes the criteria to demonstrate the risk acceptance level of the auditee.	Audit strategy

The questionnaire developed in this study used the previous variables listed in Table 1. This questionnaire needs to be valid before use in secondary data that are described in Chapter III. The content validity used, as indicated in the literature, to measure the degree to which an instrument has an appropriate sample of items for the construct being measured (Polit & Beck, 2006). There are different types of content validity used by researchers of educational and other psychological methodologies to demonstrate the criterion-related or contract validity of the questionnaires.

Nevertheless, Lynn (1986) advocated a two-stages process for estimating content validity in new instruments with a 4-Likert rating scale and minimum experts equals to five (5). Lynn (1986) indicates that a minimum of five experts would provide a sufficient level of control for chance agreement. However, in some content areas it may be difficult to locate this many content/domain experts and to obtain their cooperation (Lynn, 1986). This could be true depending on the type of study that will be performed. In this case, the study is one exploratory and will include experts from the three sites previously mentioned.

However, Lynn (1986) establishes in the article that the maximum number of judges which might be used has not been established, but is in unlikely to exceed 10. In the other hand, Lynn (1986) recommends a CVI that utilizes proportion agreement, which has been criticized by researchers and statisticians over the past decades (Wynd, Schmidt, & Atkins, 2003). The critique is related to 4-Likert ordinal scale recommended by Lynn, where the respondent can select between 1 and 2 for not relevant and somewhat relevant, and 3 and 4 for quite relevant and very relevant, respectively. Using this approach, the result can be considered content valid or content invalid. In that way, the scale becomes a

two-category nominal scale. This is one of the reasons that this approach to calculate the content validity will not be used in this study. To avoid the two-category nominal scale, a 5-Likert ordinal scale will be used.

The other reason to not use the recommended content validity by Lynn (1986) is the sample size for the judges or experts. In this study, the questionnaire will be sent to 200 resources identified as an expert and is expected to receive more than 10 complete responses. That is, that Lynn recommended process used a maximum of 10 raters, while this study will use more than 10.

As previously discussed, there are many content validity methodologies and one of the popular methods is Lawshe (1975). This methodology used experts with the objective to identify if the question is relevant or not. It consists of a Content Validity Ratio (CVR) using the following formula:

$$CVR = \frac{n_e - (N/2)}{N/2}$$

CVR is defined by n_e (the subject matter expert (SME) quantity) and N (the total of SMEs) (Wilson, Pan & Schumsky, 2012). Lawshe's approach called for the assembly of a set of SMEs who rated each of an instrument's items on a 3-point scale ("essential", "useful, but not essential", and "not necessary") (Lawshe, 1975). This study differs since the scale used is a 5-point scale ("Extremely Well" to "Not at all Well"). Lawshe's take into consideration SMEs answered with "essential". This study will use other type of content validity methodology (describe in the Validity Test section) since the scales differ from the one that Lawshe suggested.

CHAPTER III

METHODOLOGY

3.1 Introduction

In Chapter I the investigation problem, justifications about the study, investigation problems, research questions and hypothesis were presented. . A summary of the research question are as follow:

1. Which variables contribute to predict the audit effectiveness in a medical device organization?
2. Which variables do not contribute to predict the audit effectiveness in a medical device organization?
3. Which variables (if any) must be added or deleted to the audit effectiveness proposed model for the scope of medical device organization in P.R?

Chapter II details the literature review about the variables included in this investigation. This chapter describes the methodology that will be used to gathering data through hypothesis tests. To comply with the objective of this study, this chapter includes the investigation design, the description and sample selection, the description of the instrument, the gathering of data and the statistical analysis. The investigation design which will be applied to a medical device organization in Puerto Rico will develop, measure, and propose the framework and put the hypotheses made to the test

3.2 Research Design

The investigation design needs to comply with the study of the objectives while the hypotheses are tested and answer the investigation questions presented in Chapter I. The purpose of this study is to determine if there is a relation between audit planning,

audit efforts, audit report, corrective action, and various risk elements and the audit effectiveness. This study is a quantitative research that uses different indicators to measure the variables. The results will be used for the hypotheses tests using a statistical methodology. The evaluation of these variables contributes to the audit process, practice and could improve the effectiveness of it. The design of this research is non-experimental since the data will not be manipulated and it will be observed in the current environment and then it will be analyzed.

The indicators of each variable will be used to measure: the relation between them: audit effectiveness (external data source and not following procedure), audit planning (detection risk, control risk, time constraint, inherent risk, audit sampling), audit effort (time in audit preparation, time in audit execution, time in audit report), audit report (audit delay), corrective action (resources workload, actions, and time constraints), monitoring (assessment activities and acceptance criteria), business risk (quantity of objectives/goals), operational risk (external data source and internal data source), auditor's knowledge (experience and training and certifications), and strategic risk (external governance, acceptance criteria, and audit strategy). The scope of this study is to create a model to correlate the variables that affect the audit effectiveness results. This relation will be analyzed objectively for the transversal data at hand.

3.3 Participants and general characteristics

The methodology process was divided in two stages. The phase one (1) used primary data to develop, validate and test for reliability the instrument. The phase two (2) used the instrument (validated and tested for reliability) with secondary data to evaluate the relations between the variables. In the phase one, the variables were

operationalized based on the literature review and researcher's expertise. The questionnaire developed by the researcher was validated using a sample of subject matter experts (SMEs) from a medical device organization with three sites in Puerto Rico. They confirmed that the variables were operationalized and that there was no additional information need to add or delete in the instrument. The details of the process, including instrument administration, sampling selection, and IRB approvals are in the following sections.

In the second phase, the data source was audits reports from the medical device organization. The timeframe were from April 2011 to May 2016. The organization has minimum 3 internal audits per site yearly and external audits are not unannounced. This data are difficult to gather and obtain the permission to review. The organization provided a written authorization to the researcher to allow the use of the audit reports and other supporting data for the investigation purpose. The data gathering and evaluation are described in the following sections.

3.4 Description and Sampling Selection

The phase one (1) of this study consists in a selection or auditors or resources (SMEs) from a medical device organization in Puerto Rico, that has audit experience for the validity and reliability of the instrument used (questionnaire). The SMEs will be used as part of the validation and reliability of the questionnaire created. The population is part of an organization located in Puerto Rico and it has three sites in the Island with a total of 2,655 employees in Puerto Rico as of October 2015. There are 1,205 employees for Site 1, 534 employees for Site 2, and 916 employees for Site 3. This only includes permanent employees for these companies and does not include temporary employees

and contractors. There are 418 resources that will be part of the scope and sampling selection. The population for this study will be 418 and 200 random sample resources will be selected to guarantee at least 25 returns to evaluate the maximum rater's response and the content validity using Aiken (1980). Nevertheless, the content validity methodology that will be used take into consideration small and large rater's quantities to calculate the validity index. The selected resources that participated in the survey for this verification were subject matter experts, auditors or the area owners. The roles selected were Engineering, Manager, Directors, Supervisor, Compliance (include Audit), and Specialist.

Human resources department from the medical device organization provided a list of the employees that has the previous roles listed. Two hundred (200) random sample resources were selected to guarantee that at least 30 questionnaires return to validate the instrument. Minitab 16 was used to select the sample. The first column is the identification number that is from 1 to 418. The second column had the resource's name. The first and second column selected using Random Data/Sample from Columns command. The command requires enter the number of rows to sample (200) and the columns to sample selection. This will give the identifications with the name of the resources sample.

The questionnaire scope involves auditors that will evaluate if the identified measurement question describes or it's related to the variable's indicators. The participants should be people with auditing experience or lead auditor experience. People must have at least 5 years of experience. The sampling must be at least 30 resources with this requirement. This information will be gathered through the questionnaire; this will

not be asked before delivery of the instrument to the target audience. This was taken into consideration during the questionnaire design where a screening question was included. The purpose of this question is to ensure that only participants that meet the 5 years or more experience as auditor or auditing activities complete the survey. This restriction is to include the information provided by experts and to be aligned with the subject matter experts (SME) definition (minimum five years of work experience or a combination of education, training and experience).

The second phase used audit reports and supporting documents after validate and reliability test were completed during phase 1. The sampling selection was determined using the recommended by Hair, Hult., Ringle, & Saerstedt (2014). The PLS-SEM is the methodology used to analyze the data from the questionnaire using audits report from a medical device organization. The methodology was used since this is an exploratory study, small samples can be used, and data distribution is not taken in consideration using PLS-SEM. The PLS-SEM is discussed in detail through the Methodology for Data Analysis section in this chapter. The sample size recommended for this study using PLS-SEM for a commonly used statistical power of 80% is 45 for a significance level of .05 (Hair, Hult, Ringle, & Saerstedt, 2014). Nevertheless, for exploratory research a significance level of 0.10 is allowed. The difference between the significance level for 5% and 10% is the sample size: 45 and 37, respectively. The sampling size used in this study was 50 audits and comply with both sampling size requirement for each significance level. The R^2 is 0.50, the significance level is 5% and the maximum number of arrows pointing at a construct is 5 (for the model in this study). Table 2 details the Sample Size Recommendation in PLS-SEM for a Statistical Power of 80%.

Table 2

Sample Size Recommendation in PLS-SEM for a Statistical Power of 80%

Maximum Number of Arrows Pointing at a Construct	Significance Level 1% Minimum R^2				5% Minimum R^2				10% Minimum R^2			
	0.10	0.25	0.50	0.75	0.10	0.25	0.50	0.75	0.10	0.25	0.50	0.75
2	158	75	47	38	110	52	33	26	88	41	26	21
3	176	84	53	42	124	59	38	30	100	48	30	25
4	191	91	58	46	137	65	42	33	111	53	34	27
5	205	98	62	50	147	70	45	36	120	58	37	30
6	217	103	66	53	157	75	48	39	128	62	40	32
7	228	109	69	56	166	80	51	41	136	66	42	35
8	238	114	73	69	174	84	54	44	143	69	45	37
9	247	119	76	62	181	88	57	46	150	73	47	39
10	256	123	79	64	189	91	59	48	156	76	49	41

Note. Adapted from "A primer on partial least squares structural equation modeling (PLS-SEM)", by Hair, Hult, Ringle, & Saerstedt, 2014. *SAGE Publications*, 2, p. 21. Copyright 2014 by SAGE Publications, Inc.

In summary, for the phase 1, the questionnaire was distributed to 200 SMEs with the Informative Letter and after approval by the IRB. For the phase 2, at least 45 audit reports and supporting documents from the medical device organization need to be used to evaluate the relations in the model proposed.

3.5 Informative letter, participant confidentiality, and privacy rights (Phase 1 only)

During this process, the researcher delivered the questionnaire using an email with the following link: https://www.surveymonkey.com/r/auditeffective with an Informative Letter. The Informative Letter had the information of the questionnaire, benefits, risks (if any), what to expect if the subject decides to participate, and researcher's contact information. The BCC field in the email was used. This did not allow the email's recipient to know who receives the same email. Also, the email's "From" had a generic name provided by the IT Department (RS_CompanyName_Department). This means that the email did not have the

researcher's name, only in the "Informative Letter". The questionnaire was self-administered to not pressure the participants. Once the participants completed the questionnaire, the results were collected through the SurveyMonkey and no IP address or information from the respondent was collected.

This investigation have not any risk for the participant or the organization. At the contrary, the organization can benefit with the results, since the information can contribute to its improvement. This research not only contributes to organizations in the medical devices industry, but also the auditing literature. In other words, the audit effectiveness model will help to predict the audit effectiveness in an organization of medical devices. This is a model that will evaluate various variables, their relations and their effects on the audit effectiveness. There was not incentive for the participation in this investigation.

The identity of participants will be protected and will be managed in private and in a confidential way. All identifiable information or data will be managed confidentially as established by the HIPAA law. To comply with this statement, the following security measures were taken in account, including data codification to protect any sensitive information. Only the researcher and her mentor have access to data and information. The data will be stored for a period of 5 years in the researcher's apartment. Once the study is completed, the documents will be destroyed and shredded after five (5) years. The participation in this study was voluntary. The resource may choose not to participate without any penalty. If the person decided to participate, he/she can withdraw from the study at any time without penalty or loss of benefits.

3.6 Instrument

The participation in this investigation will consist on filling a questionnaire about the audit effectiveness. This questionnaire was developed by the researcher and approved by the IRB Board of Turabo University. It has two parts for a total of 30 questions. The first part consists of the analysis demographic information and the second part is related to the variables and the indicators data analysis. The participants will select the best answer that describes his/her perceptions about the topic presented.

The questionnaire uses the questions to operationalize the constructs with their indicators. Table 3 shows this information for the purpose of this study based on definitions established in Table 1 of Chapter II.

Table 3

Operationalization of Variables

Variable	Indicators	How is measured?
Audit Effectiveness	Not following procedure events	How many investigations were opened due to not following procedures?
		How many complaint investigations indicate that the cause was not following procedure?
	External data source: FDA observations (e.g. 483, warning letters), Adverse effect, MDR	How many FDA observations does your company have during the last year?
		How many Warning Letters does your company have during the last year?
		How many MDR report did your company fill in the last year?
		How many external audit findings do you receive in the last year?
Audit Planning	Detection risk	How many years of previous audits were assessed to prepare the audit plan?
		How many tools exist? Tools are documents with guidelines or a requirements list from a procedure. Some examples are checklist, report, guidelines, tables, lists, and templates.
		In how many meetings the issues (events that may affect a process, product, system, or client) are discussed.
		How many complaints does your company receive in one year?
		How many defects in process or product does the company acknowledge in one year?

Variable	Indicators	How is measured?
Audit Planning (Continue)	Inherent risk	How many sub-systems data or input sources (data used to identify risk for the quality system area) are used to prepare the plan? How many assessment results are used to prepare the plan? How many previous audits (internal/external) results are assessed by the auditor's team or by the auditor alone?
	Control risk	How many procedures exist for audit/assessment? Has acceptance criteria been defined? Is there a plan before an audit start?
	Time constraints	How much time is dedicated audit activities? How much time is dedicated to audit activities? How much time is dedicated to corrective actions activities?
	Audit Sampling	How much time is required to be prepared before an audit? How many audits do you participate during a year? How much do you dedicate to prepare a plan? How much time is dedicated for approval of the plan?
Audit effort	Time to prepare the plan	How much time do you spend preparing the plan?
	Time to execute the plan	How much time is required to execute an audit plan? How much time do you spend executing an audit plan?
	Time to report	How much time do you spend preparing the report? How much time is necessary (desired by management) to approve the report? How much time is required to approve the report? How much time, since the report was approved, the results were communicated to management? How much time took to discuss the results to management? How much time took to discuss the results to affected population and subject matter experts?

Variable	Indicators	How is measured?
Audit Report Timeliness	Audit Delay (Audit report timeliness)	How much time takes to prepare an audit report since the plan?
		How much time takes to prepare a report after execution?
		What is the approval date of the most recent audit plan?
		What is the approval date of the audit report of that audit plan?
Fix It/Corrective Action	Actions	What is the project scope? (E.g. Narrow (to one site) or broader (two or more sites))
		How many corrective actions were created during current year?
	Resources workload	How many projects do you have?
		How many sites do you support?
		How many audits do you perform in a year?
	Time constraints	What is the lead-time of the longest project?
		How much time is dedicated to audit activities?
		How much time is dedicated to corrective actions activities?
Monitoring (for effectiveness)	Assessment Activities	How many effectiveness tasks were created for the last years?
		How many of these effectiveness tasks were effective for the last years?
		How is the frequency to evaluate the monitoring data?
		How much time is the monitoring period?
	Acceptance Criteria	Is the audit acceptance criteria established?
		What is the level of confidence level desired by your firm?
		Is there an area that the goal was not met?
		How many audits met the acceptance criteria?

Variable	Indicators	How is measured?
Auditor's knowledge	Training and certifications	How many training is required to perform the audit (e.g. procedures, trainings (not certification), etc.)? How many certificates are required as an auditor? How much time (hours) is required as an auditor in a year? Is/Are the auditor(s) trained in sampling techniques?
	Experience	How many years of experience do you have as an auditor? How many years of experience do you have in a regulated environment? How much time (hours) do you have as an auditor in a year? How many audits do you complete in a year? How many reports do you prepare in a year? How many audits do you lead in a year?
Business risk	Quantity of objective and/or goals	If your company has division or business unit: How many business areas are with more than three non-conformances? If your company has division or business unit: How many business areas the goal was not met? Total of business areas that are measured during last year. How many of long-term planning does your company established? How many strategic projects does your company have?
Operational Risk	External data source: FDA observations (e.g. 483, warning letters), Adverse effect, MDR	How many FDA observations does your company have during the last year? How many Warning Letters does your company have during the last year? How many MDR (Medical Device Reports) report did your company fill in the last year?

Variable	Indicators	How is measured?
Operational Risk (Continue)	Internal data source: equipment mal-function, internal audit findings, supplier control, process assessment (compliance, manufacturing, and self-inspection)	How many internal audit findings do you receive in the last year?
		How many equipment nonconformities affect or cause a nonconformity product?
		How many investigations are related to assessments (e.g. compliance, manufacturing, and self-inspection)?
		How many assessment processes (e.g. compliance, manufacturing, and self-inspection) your company performs in a year?
	External data source: Complaints	How many complaint procedures does your company have?
		How many confirmed external nonconforming items and complaints (situation or issue that not conform to a procedure, regulation or standard identified by an external agency or external audit company) were received during last years?
	Internal data source: Nonconformity	Does internal audit plan use nonconformance sources as part of the plan?
		How many internal nonconformities (situation or issue that not conform to a procedure, regulation or standard identified by your company)) were found in the last years?
Strategic Risk	Acceptance Criteria	Is the audit acceptance criteria established?
		What is the level of confidence level desired by your firm?
		Is there an area that the goal was not met?
		How many audits met the acceptance criteria?
	External Governance	How many standards changed during the last year?
		How many governance regulations changed during the last year?
		How many corporate policies changed during the last year?
		How many new products were introduced or transfer in the last year?

Variable	Indicators	How is measured?
Strategic Risk (Continue)	Audit strategy	How many documents are planned to assess? How many documents in an audit do you evaluate? How many document were left without assess due to time constraints? How many requests documents did the auditee not deliver? How many findings the auditor found?

The questionnaire was design with a 5-Likert scale. The nominal and ordinal scale is used in the first part of the survey to gather some information (e.g. gender, years of experience, etc.), about the respondent and to exclude respondents to less than five years of experience in audits. This type of scale assigns numbers that can be used to identify and classify objects. The second scale used is ordinal. This is used in the rest of the questionnaire where the respondents answer as "Extremely Well" to "Not at all Well" for questions describing an indicator and variable.

3.7 Instrument administration during phase 1

The questionnaire for the phase one (1) was submitted using the website Survey Monkey to facilitate the distribution, collection and guarantee the participant's anonymity. For that reason, the questionnaire was designed in such a way that the respondents can go back to previous pages in the survey and update existing responses until the survey is finished or until they have exited the survey. Also, some considerations were made in the design of the questionnaire related to the missing data.

The Survey Monkey webpage provides a mechanism to require answering all questions before the participant move to the next page. The webpage will alert if a question is left in blank and will not allow continuing with the survey until answered. This will not occur with optional questions and for this survey only two questions were optional. After submitting the survey, the respondent will not be able to update existing responses. The website respondent data will be anonymous. The website will use SSL to encrypt the survey and the results as they are sent between the respondents and SurveyMonkey. A password is set to restrict access to the survey. Only the participants will have the password that will be sent with the invitation to participate in the survey.

In the questionnaire the scale used was coding using a 5-Likert scale. Where Extremely well is 5, Very well is 4, Moderately Well is 3, Slightly Well is 2 and Not at all well is 1. This scale demonstrates symmetry of Likert items since it has a middle category, "Moderately Well l". The scale used is perceived as symmetric with equidistant attributes, where the neutral category is in the middle ("Moderately Well") and the distance between categories 1 and 2 is the same as 3 and 4. The coding of this is very important, since using the 5-Likert as described will behave more like an interval scale.

The validity of the questionnaire occurred during first phase after gathering the data through Survey Monkey, meaning that the second phase will not start until this phase is completed. During the second phase, the researcher used the instrument to gather the audit data report from a medical device organization. The researcher used the questionnaire to gather data from audit reports that contains investigations, complaints and other sources related to the audit. This data will be from a company of the medical device industry with sites in Puerto Rico. The data will be quantities and will not include

any name, information from patient, organizations, auditors, leaders, branch, products, or any information that will reveal the Medical Devices Company in the study including any branch, name or brands.

3.8 Reliability and Validity Test for phase 1

There are various procedures to calculate the reliability of the questionnaire. The one that will be used in this study is the Cronbach alpha and factor analysis for reliability and validity of scale. Coefficient alpha (Cronbach, 1951) is often used as a point estimate of reliability in practice (Paek, 2015). It's recommended that the Cronbach alpha (also known as coefficient alpha) needs to be near to 1 to use the questionnaire for this investigation (Fernandez, 2010). An alpha value greater than 0.90 indicates that the questionnaire is excellent; the questionnaire is good between 0.89 and 0.80, is acceptable between 0.79 and 0.70, is weak between 0.69 and 0.60, and, finally, is poor if less than 0.50 (George & Mallery, 2009). SPSS software will be used for this analysis or similar software.

The data is collected and subject to validation. The methodology to be used is the recommended by Aiken (1985). The formula to calculate the V (validity) coefficient contains the ratings (judgments or responses), of a single item by n raters (judges or experts) or the ratings of m items by a single rater (Aiken, 1985). The scale used is named as c. The formula is described as: $V = S/[m(c-1)]$. The range of both V coefficients is 0 to 1, a high value indicates that an item has high content validity or that a set of items has high content validity in the judgment of a single rater (Aiken, 1985).

This methodology is used since the raters are expected to be more than 10 (as recommended by Lynn (1986)) and the central limit theorem can be applied to determine

the statistical significance of the mean value of V. The central limit theorem formula is: z = .2(Ṽ - .5)$\sqrt{3mn(c-1/(c+1)}$, where Ṽ is the mean of V, m is the items provided by a single rater, n are the raters, and c is the scale rating categories. If z is greater than 1.645 (.05 level) or 2.33 (.01 level), it is concluded that the set of items, and hence the entire scale or questionnaire, has significant content validity (Aiken, 1985).

3.9 Instrument administration during phase 2

Once the phase 1 was completed and the instrument is valid and reliability test is completed with satisfactory results, the instrument is used with secondary data (real data) using audit reports and other supporting reports from the medical device organization. Table 4 summarizes the data sources from each variable in the model evaluated.

Table 4

Data sources used during the second phase

INDICATOR NAME	INDICATOR DESCRIPTION	SOURCE
DR_PrAu	DETECTION RISK YEARS OF PREVIOUS AUDIT	Audit Report
DR_T	DETECTION RISK TOOLS	Audit Risk Report
DR_F	DETECTION RISK FORUM	Business and quality report
DR_D	DETECTION RISKQTY OF DEFECTS	Business and quality report
IR_AuRes	INHERENT RISK - AUDITS USED FOR PLAN	Audit Report
CR_P	CONTROL RISK PROCEDURES	Audit Report
TC_AQ	TIME CONTRAINTS AUDIT YEARLY	Audit Report
TC_TAP	TIME CONTRAINTS PLAN APPROVAL	Audit Report
AS_ST	AUDIT SAMPLING - SAMPLING TECHNIQUES	Audit Report

INDICATOR NAME	INDICATOR DESCRIPTION	SOURCE
T_Tr	AUDIT TRAINING - TRAINING QTY	Audit Report and Human Resources Report
T_Ce	AUDIT TRAINING - CERTIFICATION QTY	Audit Report and Human Resources Report
AE_E	AUDITOR'S EXPERIENCE IN AUDIT	Audit Report and Human Resources Report
AE_ReEn	AUDITOR'S EXPERIENCE IN A REGULATED ENVIRONMENT	Audit Report and Human Resources Report
AE_Ayr	AUDITORS EXPERIENCE - AUDIT COMPLETED IN A YEAR	Audit Report and Human Resources Report
EDS_FDA	EXTERNAL DATA SOURCE - FDA OBS LAST YEAR	Audit Report and Audit Risk Report
EAS_EA	EXTERNAL DATA SOURCE - EXTERNAL AUDIT IN LAST YEAR	Audit Report and Audit Risk Report
IAS_IA	INTERNAL DATA SOURCE - INTERNAL AUDIT IN LAST YEAR	Audit Report and Audit Risk Report
IAS_ENC	INTERNAL DATA SOURCE - EQUPMENT NC THAT AFFECT PRODUCT	Audit Report and Audit Risk Report
IAS_AP	INTERNAL DATA SOURCE - ASSESSMENT PROCESS	Audit Report and Audit Risk Report
IAS_Sinv	INTERNAL DATA SOURCE - SUPPLIER INVESTIGATION	Audit Report and Audit Risk Report
NC_AP_Nc	NC- INTERNAL AUDIT PLAN USED NC SOURCE	Audit Report
NC_IA_NC	NC- QTY OF INTERNAL NC	Audit Report
AC_Gnot	AC-GOAL NOT MET	Audit Report
AC_Acm	AC-AUDIT MET AC	Audit Report
EG_STD	EXTERNAL GOVERNANCE - STANDARDS CHANGE	Audit Risk Report
EG_REG	EXTERNAL GOVERNANCE - REGULATIONS CHANGE	Audit Risk Report
EG_POL	EXTERNAL GOVERNANCE - CORPORATE POLICIES CHANGES	Audit Risk Report
EG_NEWp	EXTERNAL GOVERNANCE - NEW PROD INTRODUCTION	Audit Risk Report

INDICATOR NAME	INDICATOR DESCRIPTION	SOURCE
AS_EVAL	AUDIT STRATEGY - QTY OF DOCUMENTS TO ASSESS	Audit Report
AS_DOC	AUDIT SOURCE - EXTERNAL FINDINGS DOCUMENTS RECEIVE IN LAST YEAR	Audit Report
NFP_INV	NOT FOLLOWING PROCEDURE - INVESTIGATION DUE TO NOT FOLLOWING PROCEDURE	Audit Report
NC_IA	NC-INTERNAL AUDIT FINDING	Audit Report
AD_TRaP	AUDIT DELAY-TIME TO RERPORT AFTER PLAN	Audit Report
AD_TRaE	AUDIT DELAY-TIME TO REPORT AFTER EXECUTION	Audit Report
A_CA	ACTIONS - CORRECTIVE ACTIONS IN A YEAR	Audit Report
RW_Pa	RW_AUDIT PERFORMED IN A YEAR	Audit Reports in a Year
TC_TCA	TIME CONSTRAINTS - TIME FOR CORRECTIVE ACTION	Audit Report
AA_TQTY	ASSESSMENT ACTIVITY - QTY OF EFFECTIVENESS TASK	Audit Report
AA_EFF	ASSESSMENT ACTIVITY- EFFECTIVENESS OF EFFECTIVENESS TASK	Audit Report
AA_MT	ASSESSMENT ACTIVITY - FREQUENCY OF MONITORING TASKS	Audit Report
AA_MP	ASSESSMENT ACTIVITY - MONITORING PERIOD	Audit Report
AC_AnM	ACCEPTANCE CRITERIA - AREAS NOT MET	Audit Report
AC_AM	ACCEPTANCE CRITERIA - AREAS MET AC	Audit Report
TP_TpP	TIME TO PREPARE THE PLAN	Audit Report
TR_TrRA	TIME TO REPORT - TIME REQUIRED TO REPORT APPROVAL	Audit Report and Audit Procedure

INDICATOR NAME	INDICATOR DESCRIPTION	SOURCE
TR_TC	TIME TO REPORT - TIME TO COMMUNICATE	Audit Report and Audit Procedure
TR_TdRES	TIME TO REPORT - TIME TO DISCUSS RESULTS WITH MGT	Audit Report and Audit Procedure
TR_TdPOP	TIME TO REPORT - TIME TO DISCUSS WITH POPULATION	Audit Report and Audit Procedure
QOG_LTP	QTY OF OBJECTIVES_GOALS - LONG-TERMS PLANS	Business and quality report
QOG_SP	QTY OF OBJECTIVES_GOALS - QTY OF STRATEGIC PLANS	Business and quality report
NC_E_FIND	NC - FINDINGS OT EQUAL TO EXT FINDINGS	Business and quality report
QOG_BU_NC	QOG - BU WITH MORE THAN 3 NC	Business and quality report

3.10 Methodology for Data Analysis

The multivariate analysis will be used when second phase is completed. This analysis involves the application of statistical methods that simultaneously analyze multiple variables. The variables typically represent measurements associated with individuals, companies, events, activities, situations, and so forth (Hair, Black, Babin, & Anderson, 2013).

The statistical methods often used by social scientists are typically called first-generation techniques (Hair, Hult, Ringle, & Saerstedt, 2014). These techniques include regression-based approaches such as multiple regression, logistic regression, and analysis of variance, but also techniques such as exploratory factor analysis, cluster analysis, and multidimensional scaling (Hair, Hult, Ringle, & Saerstedt, 2014). They are used in research problem as confirmatory of hypotheses testing of existing theories and concepts and as exploratory when in search for latent patterns in the data in case there is no or only

little prior knowledge on how the variables are related. Also, these techniques can examine only a single relationship at a time (Hair, Black, Babin, & Anderson, 2013). On the other hand, other researchers used the second generation techniques to overcome weaknesses of first-generation methods. The second generation technique, structural equation modeling (SEM), enables researchers to incorporate unobservable variables measured indirectly by indicator variables. They also facilitate accounting for measurement error in observed variables (Hair, Hult, Ringle, & Saerstedt, 2014). In addition, this technique can examine a series of dependence relationships simultaneously and it's particularly useful in testing theories that contain multiple equations involving dependence relationships (Hair, Black, Babin, & Anderson, 2013).

SEM foundation lies in two multivariate techniques: factor analysis and multiple regression analysis. Factor analysis uses mathematical procedures for the simplication of interrelated measures to discover patterns in a asset of variables. To perform a factor analysis, there has to be univariate and multivariate normality within the data (Yong & Pearce, 2013). The data for this study is expected to be non-normal because of it is a nature and the small sample size to be collected in the second phase of the data collection. The recommended sample size for factor analysis is at least 300 participants and the variables that are subjected to factor analysis each should have at least 5 to 10 observations (Yong & Pearce, 2013). In addition is recommended that the variables should be at least 10:1; in this case to perform a factor analysis, the sample should be 100 (proposed model has 10 variables). However, this is an exploratory study and the relations between the variables are unknown. Therefore, for the purpose of this research the PLS-SEM (Partial Least Square – Structural Equation Modeling) will be used since

this is an exploratory research to develop a model that will explain the audit effectiveness in a specific company.

PLS-SEM is a nonparametric statistical method from a maximum likelihood (ML) and used as based CB SEM methodology (Hair, Hult, Ringle, & Saerstedt, 2014). This means that does not require the data to be normally distributed. Nevertheless, it is necessary to understand if the data is normal or non-normal, since extremely non-normal data prove problematic evaluation in the assessment of the parameter's significances. To use this technique three characteristics need to be presented in the model (see Figure 3): estimation of multiple and interrelated dependence relationships, an ability to represent unobserved concepts in these relationships and account for measurement error in the estimation process and a model needs to be defined to explain the entire set of relationships (Hair, Black, Babin, & Anderson, 2013).

This research use the PLS-SEM since the theory of the framework proposed is less developed (Hair, Hult, Ringle, & Saerstedt, 2014) for the type of industry of interest. PLS-SEM uses available data to estimate the path relationships in the model with the objective of minimizing the error terms of the endogenous constructs. PLS-SEM is the preferred method when the research objective is theory development and explanation of variance; prediction of the constructs which is the scope of this study (Hair, Hult, Ringle, & Saerstedt, 2014). PLS-SEM works efficiently with small sample sizes and complex models and makes practically no assumptions about the underlying data (Hair, Hult, Ringle, & Saerstedt, 2014). Also, this method works with multi-item measures, incorporate reflective and formative measurement models, handle complex models with many structural model relations including larger numbers of indicators that help in

reducing the PLS-SEM bias, among other characteristics (Hair, Hult, Ringle, & Saerstedt, 2014). The overall complexity of a structural model has little influence on the sample size requirements for this methodology. The reason is that the algorithm does not compute all relationships in the structural model at the same time. Instead, it uses PLS regressions to estimate the model's partial regression relationships. A simulation study by Reinartz (2009) indicated that PLS-SEM is a good choice when the sample size is small (Hair, Hult, Ringle, & Saerstedt, 2014).

The structural equation modeling or SEM has five elements that needs to be considered before used this multivariate analysis methods, besides the three characteristics mention previously. First, the variate is a linear combination of several variables that are chosen based on the research problem. This will combine a set of weights times the associated data observation for the variables (e.g. $x_1w_1+ x_2w_2+\ldots+ x_5w_5$; where x is individual variables and w is the weights). In this research the Figure 1 shows the framework that will be used to develop this. The second element is the measurement and is the process of assigning numbers based on a set of rules. The rules are used to assign the numbers to variable in a way that accurately represents the variable. In the framework proposed, shown in Figure 1, the variables are difficult to measure and a set of indicators will represent them. In that way the variable will be measured combining them to form a single composite score (i.e. the score of the variate (Hair, Hult, Ringle, & Saerstedt, 2014)). This approach involves reducing measurement error, which is the difference between the true value of a variable and the value obtained by a measurement (Hair, Hult, Ringle, & Saerstedt, 2014). The measurement error could occur due to poorly worded questions on the survey, misunderstanding of the scaling,

incorrect application of a statistical method. Based on Hair, Hult, Ringle, & Saerstedt, 2014, all measurements used in a multivariate analysis are likely to contain some measurement error and the objective is to reduce this measurement error.

The third element of the SEM is the measurement scale. The second phase uses secondary data from real audit report and supporting documents (e.g. audit risk reports). Hair et. al (2014) indicates that PLS-SEM works with metric data like the one used from the audit reports. Finally, the fifth element of SEM is the data distribution. Researchers working with SEM only need to distinguish normal from non-normal distributions (Hair, Hult, Ringle, & Saerstedt, 2014). PLS-SEM generally makes no assumptions about the data distributions. The statistical test that will be used after received the results is Shapiro-Wilk or other similar normality test. Skewness and kurtosis will be used to examine and determine the deviate extent of the data from normality, if the data distribution is non-normal (Hair, Hult, Ringle, & Saerstedt, 2014).

The path model used for this survey is described in Figure 11. This path is composed of two elements that are the structural model and measurement model. The structural model displays the relationship between the constructs (Ys) and the measurement model displays the relationship between the constructs and the indicators (Ys and Xs). Figure 11 shows the exogenous latent variables which are those constructs that explain other constructs (Y7 thru Y10) in the model and the endogenous which are those constructs that are being explained in the model (Y1 thru Y6). In the path model Y2 through Y6 have a direct effect on Y1 while Y7 thru Y10 have an indirect effect in Y1.

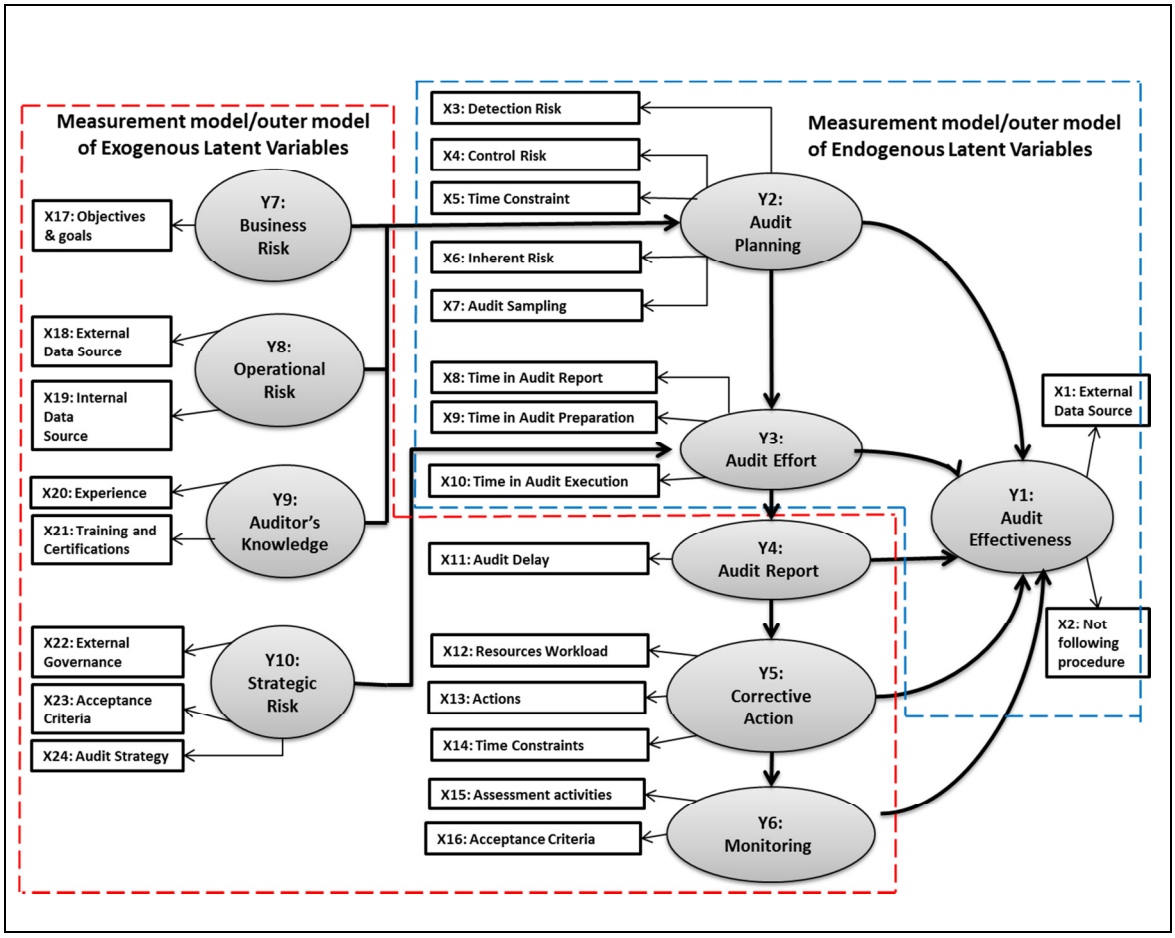


Figure 11. SEM Path Model based on proposed framework.

Figure 12 shows the relationship and relation based on the developed framework. The developed path model in Figure 11 shows the relationship of the dependent constructs, each related to others as well as to the independent constructs. Separate equations are required for each dependent construct. The need for a method that can estimate all the equations simultaneously is met by PLS-SEM (Hair, Black, Babin, & Anderson, 2013). PLS-SEM is the methodology that will be used in this study based on the evaluation made and path model proposed.

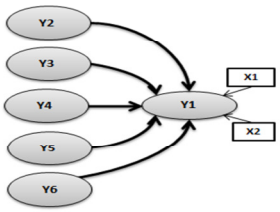
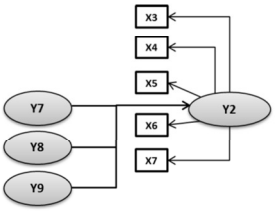
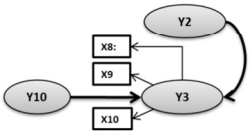
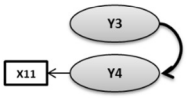
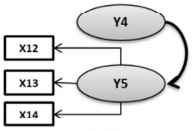
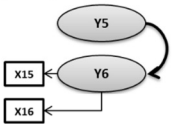
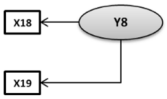
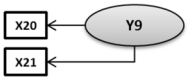
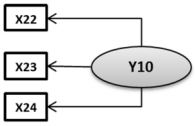
Causal Relationships Independent Variables		Dependent Variables	Path Diagram
X1, X2, Y2, Y3, Y4, Y5, Y6	→	Y1	
X3, X4, X5, X6, X7, Y7, Y8, Y9	→	Y2	
X9, X9, X10, Y2, Y10	→	Y3	
X11, Y3	→	Y4	
X12, X13, X14, Y4	→	Y5	
X15, X16, Y5	→	Y6	
X17	→	Y7	
X18, X19	→	Y8	
X20, X21	→	Y9	
X22, X23, X24	→	Y10	

Figure 12. Dependence and relationships through path diagrams based on framework.

CHAPTER IV

DATA ANALYSIS AND RESULTS DISCUSSION

4.1 Introduction

This investigation has the purpose to analyze if the effectiveness audit has other factors that influence the results besides the timeliness from planning, planning to report, and compliance to schedule. In this chapter, the data analysis used was obtained from the survey completed by experts in the audit area in a particular medical device organization. After the content validity and reliability of the questionnaire, data from audits of the medical device organization were evaluated and analyzed with the model proposed and its constructs for relation.

This chapter starts with the distribution of the questionnaire and the process to administrate and receive the survey results through Survey Monkey. Then, it will discuss the content validity methodology (Aiken's V) used and the reliability results (Cronbach Alpha) of the questionnaire. The descriptive analysis will be discussed along with the statistics test to analyze the data. Later, the chapter includes the proposed model and the PLS-SEM evaluation after obtaining the audit data from the medical device organization. Finally, this chapter discusses the results and conclusion about the established hypothesis in previous chapter.

4.2 Questionnaire Results

The questionnaire and the Informative Letter, among other requirements were developed and submitted to the Institutional Review Board (IRB) and approved in 2015. This included a Support Letter from the selected medical device organization to the IRB to allow the distribution of the questionnaire using the company email and access to the

survey's link. The questionnaire was distributed using an email with the following link, https://www.surveymonkey.com/r/auditeffective, with the Information Letter. In chapter 3, the Informative Letter and the questionnaire were described and they were not changed since the approval until the distribution. The selection of the resources was through company's human resources report and randomly selected using Minitab 16. The email was sent to 200 random sample resources from a population of 418 identified experts in the selected medical device organization. The experts did not know who is copied in the email since the BCC field was used to send the information. The "From" field had a generic name provided by the IT Department (RS_CompanyName_Department). The name of the researcher will be only in the Informative Letter as required by the IRB. The questionnaire was self-administered and was the decision of the expert to complete it or not. The expert was allowed to stop the survey without any pressure. The identity of the participant was protected through survey monkey and their IP address was not requested.

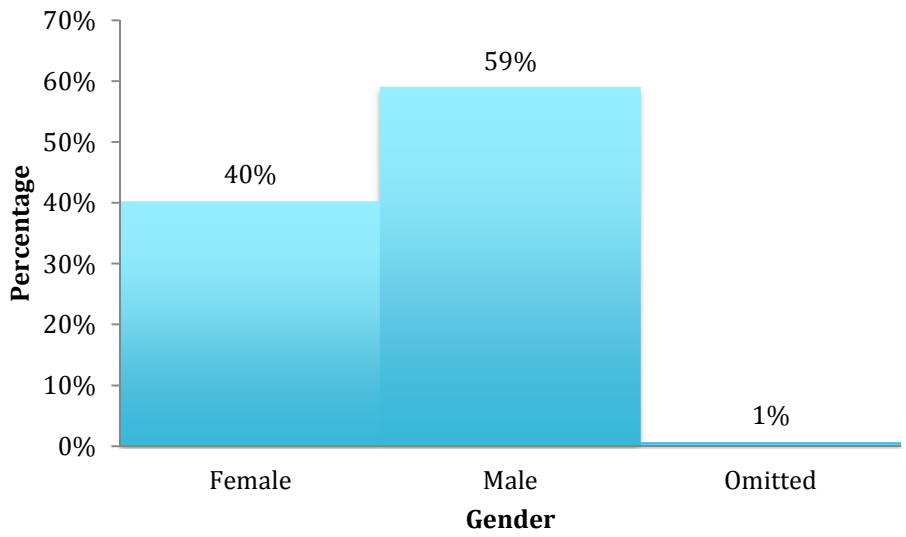
The emails sent to 200 experts returned 139 respondents that access the survey and started to answer it. This means that 70% of the identified expert accessed the survey. The auditors profile accessed the questionnaire included resources with high school graduate, diploma or equivalent (1%), associate degree (1%), bachelor degree (63%), master degree (34%), and doctorate (1%). Also, the resources had different years of experience as auditor: 59% had less than or equal 4 years, 22% had 5-9 years, 13% had 10-14 years, 4% had 15-19 years, and 2% had 20 years or more. From the 139 questionnaires, 40% were accessed by female, 59% by male, and only 1% did not response. The ages from these experts were: 28% in a range from 25 to 34, 48% in a range from 35 to 44, 17% in a range from 45 to 54, 4% in a range from 55 to 64, 1% had

65 or older, and 2% did not response. The responses from these experts (auditors) were evaluated to check if the questionnaire was completely answered and if the quantity of respondents complied with the criteria of 5 years or more of experience as auditor. However, only 33 of them were completed and complied with the criteria used of 5 years or more of experience as an auditor. It could be that the expert does not have enough time to answer it since the email was received to the email's work and may have to answer it with other priorities of the day. Also, the questionnaire has 30 questions, but 97 items (indicators) to evaluate, adding complexity and time to complete the instrument. Nevertheless, 33 responses are acceptable for the content validity and reliability methodology that are used in this chapter to confirm if the questionnaire is valid and reliable. The information was arranged to allow the calculation of content validity using Excel. Appendix D shows a print screen of the file used to assess the information (raw data) from the Survey Monkey site. Appendix D shows that the IP Address, Email Address, First Name, Last Name and Custom Data columns are in blank. The columns with the information are related to the answers from the respondent (experts) and the identification provided by the Survey Monkey site (Respondent Id column).

4.3 Descriptive Analysis

The questionnaire has two parts: general information (including demographic information), and the second part that is related to the constructs and indicators. The percentage of participation of the respondents, described in this chapter as experts, can be graphed as in Figure 13. This section describes demographic variables. Two of those questions are optional like the gender (nominal result) and age (ordinal scale). *The age*

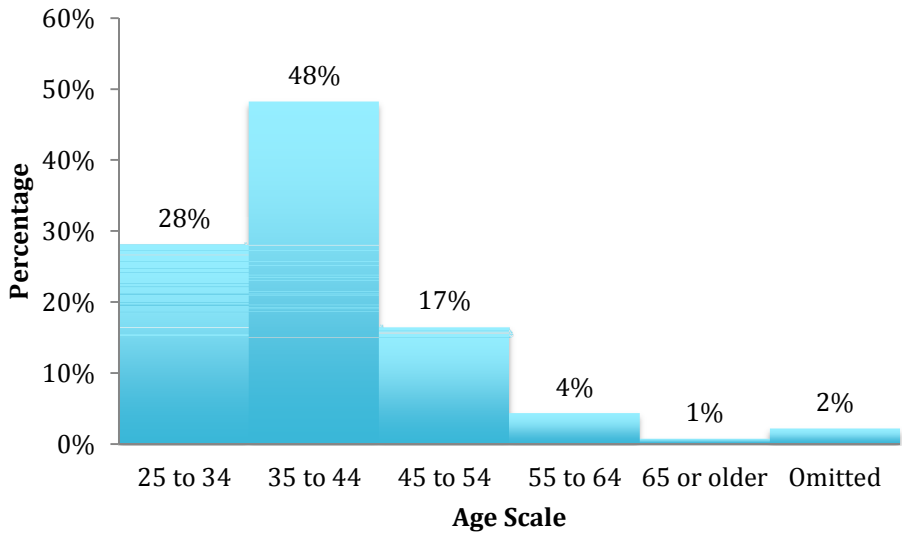
was requested in the survey using ordinals scale even though it is quantitative. The other two questions were required to participate in the questionnaire.



(This question was optional for the participants in the questionnaire).

Figure 13. Expert Gender – Histogram.

Figure 13 shows that the experts' participation in the survey included 59% males and 40% females, 1% omitted this question. The completed questionnaires (with exception of two optional questions related to gender and age) were taken into consideration even though this question was optional.



(The age is quantitative. The survey requested in an ordinal scale).

Figure 14. Expert Age – Histogram.

In the other hand, Figure 14 shows the expert participation with ages range from 25 to 65. The experts with more participation were around 35 to 44 age next to 45 to 54. Also, Figures 15 and 16 graphs the expert education and experience. Both categories are important in the study since the experience and education (like training) also is part of the model's construct. Also, the experience question was the one to discriminate for the participation in the survey with expert of 5 or more years of experience.

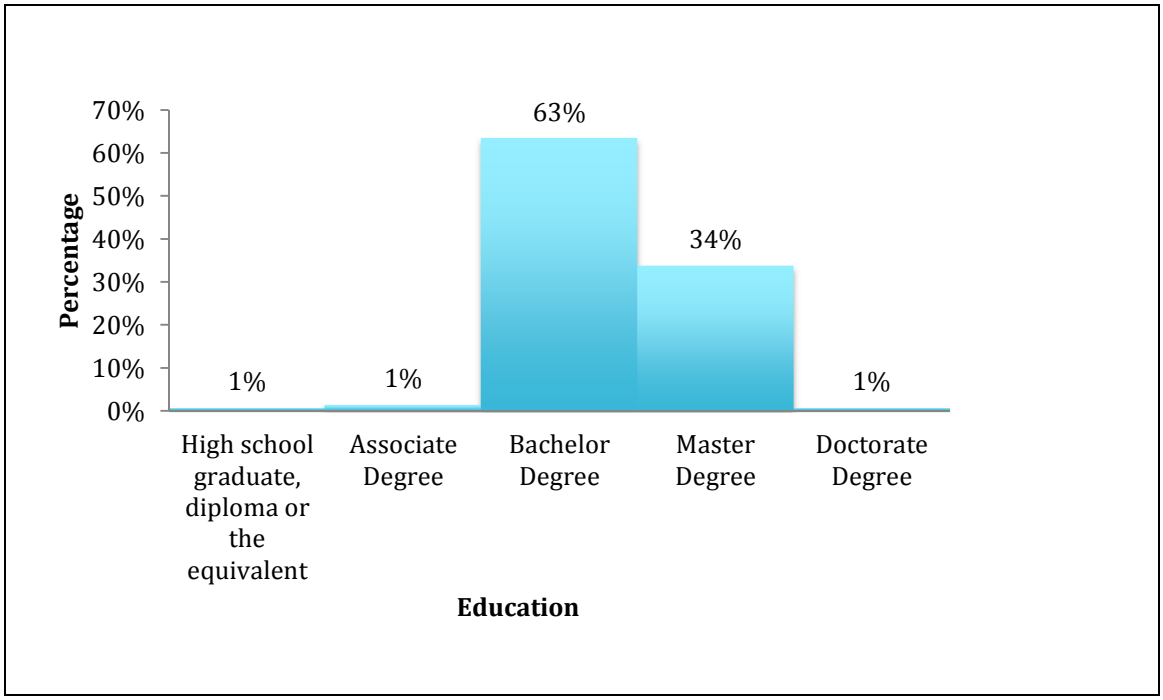


Figure 15. Expert Education – Histogram.

Figure 15 shows that the highest expert's education had Bachelor Degree (63%) next to the 34% with a Master Degree. Only 3% of participant has a Doctorate Degree or an Associate Degree.

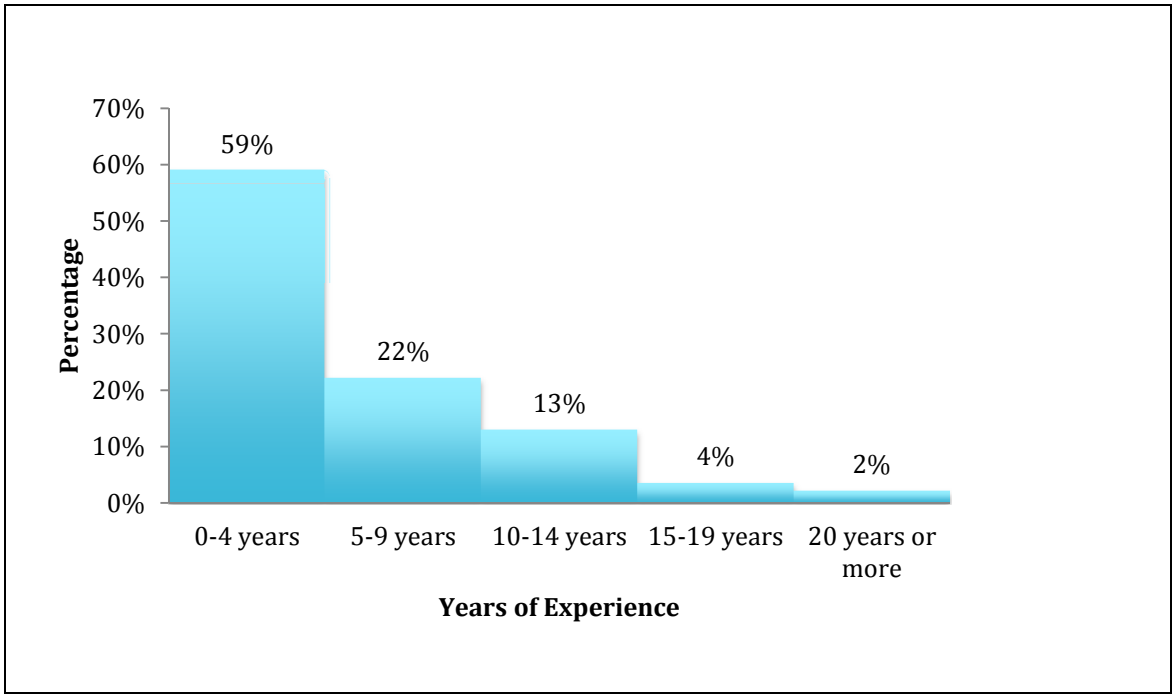


Figure 16. Expert Experience as Auditor Charts - Histogram

The 22% of experts that participated in the survey had between 5-9 years of auditor's experience next to 13% with 10-14 years, the 4% with 15-19 years, and, finally, 20 years or more has 2% of the participants. These results are graphed in Figure 18, which also describes the participants with less than 5 years of experience with the major participation (59%). This range of the scale was not used since the focus for this study was experts with 5 years or more of experience in audits. The following sections describe the analysis performed to the survey results from the 33 experts to determine the validity and reliability tests.

4.4 Content Validity Analysis Results

The Content Validity methodology used was the Aiken's V (1985) that was explained in Chapter 3. The use of this methodology allows the analysis for experts

greater than 10 (recommended by Lynn (1986)) and a 5 Likert ordinal scale instead of 4-Likert ordinal scale recommended by Lynn (1986) and 3-Likert scale used by Lawshe (1975). Also, Aiken's V (1985) uses the central limit theorem for large sample (more than 25 raters or experts).

The responses received were organized to calculate the content validity index using the formula from Aiken that establishes V = S/[m(c-1)], where S is equal to a single item by n raters (or experts), c is the scale used, and m is the items number by a single rater. The range of V coefficient is 0 to 1; a high value indicates that an item has high content validity or that a set of items has high content validity in the judgment of a single rater (Aiken, 1985). Appendix E shows the table with all the responses and results for S and V in the Excel file used. Table 5 summarizes the results of the content validity index for this study.

Table 5

Content Validity Index (n = 33): Aiken's V (1985)

ITEM#	INDICATOR	S	V
Item 1	DR_YRS_PREV_AUDIT	94	0.712121
Item 2	DR_TOOLS_QTY	100	0.757576
Item 3	DR_FORUM	91	0.689394
Item 4	DR_COMPLAINTS	96	0.727273
Item 5	DR_DEFECTS	98	0.742424
Item 6	IR_INPUTS	110	0.833333
Item 7	IR_ASSESSMENTS	95	0.719697
Item 8	IR_AUDIT	94	0.712121
Item 9	CR_PROCEDURES	93	0.704545
Item 10	CR_ACCEPTCRIT	108	0.818182
Item 11	CR_PREVIOUS_PLAN	114	0.863636
Item 12	TC_BEFO_AUDIT	108	0.818182
Item 13	TC_AUDITS	88	0.666667
Item 14	TC_TIME_PLAN	96	0.727273
Item 15	TC_PLAN_APPROVAL	90	0.681818
Item 16	AS_SAMPLING	96	0.727273
Item 17	AS_ST	85	0.643939

ITEM#	INDICATOR	S	V
Item 18	AS_SP	83	0.628788
Item 19	AS_ST_USED	78	0.590909
Item 20	AT_TRAINING_QTY	109	0.825758
Item 21	AT_CERT_QTY	104	0.787879
Item 22	AT_AUDIT_HRS	98	0.742424
Item 23	AT_ST	86	0.651515
Item 24	AE_EXP_AUDIT	98	0.742424
Item 25	AE_EXP_REG_ENV	110	0.833333
Item 26	AE_AUD_T	83	0.628788
Item 27	AE_AUD_COMPL	89	0.674242
Item 28	AE_R	79	0.598485
Item 29	AE_LeadA	78	0.590909
Item 30	EXTDS_FDA	94	0.712121
Item 31	EXTDS_WL	89	0.674242
Item 32	EXTDS_MDR	87	0.659091
Item 33	EXTDS_EXT_AUDIT	98	0.742424
Item 34	INTDS_IA	94	0.712121
Item 35	INTDS_EQUIP_NC	96	0.727273
Item 36	INTDS_INV_ASSESS	105	0.795455
Item 37	INTDS_ASSESS_PROC	101	0.765152
Item 38	INTDS_SUPPLIER_INV	102	0.772727
Item 39	C_COMPLAINT_PROC	92	0.69697
Item 40	C_NC_COMPLAINTS	107	0.810606
Item 41	NC_IA_PLAN_NC	101	0.765152
Item 42	NC_INT_NC	103	0.780303
Item 43	AC_AUDIT_CRIT	117	0.886364
Item 44	AC_CONF_LEVEL	104	0.787879
Item 45	AC_G_NOT_MET	97	0.734848
Item 46	AC_AUDIT_MET	98	0.742424
Item 47	EG_STD	86	0.651515
Item 48	EG_REG	88	0.666667
Item 49	EG_CORP	90	0.681818
Item 50	EG_NEW_PROD	88	0.666667
Item 51	AS_DOC_ASSESS	90	0.681818
Item 52	AS_DOC_EVAL	89	0.674242
Item 53	AS_NO_DOC	80	0.606061
Item 54	AS_REQ_NOT_DEL	85	0.643939
Item 55	AS_FIND_RES	82	0.621212
Item 56	NFP_INV	105	0.795455
Item 57	NFP_COMPLAINT	103	0.780303
Item 58	NFP_FDA	81	0.613636
Item 59	NFP_MDR	89	0.674242
Item 60	NFP_EA	86	0.651515

ITEM#	INDICATOR	S	V
Item 61	NFP_NOT_OBS	79	0.598485
Item 62	NC_COMPLAINT	92	0.69697
Item 63	NC_IA_FINDINGS	101	0.765152
Item 64	AD_TIME_REPORT_PLAN	96	0.727273
Item 65	AD_TIME_REPORT_EXEC	103	0.780303
Item 66	AD_PL_APP_DATE	86	0.651515
Item 67	AD_AR_APP_DATE	93	0.704545
Item 68	ACTIONS_PROJ_SCOPE	91	0.689394
Item 69	ACTIONS_CA	105	0.795455
Item 70	RW_PROJ_ASSIGN	112	0.848485
Item 71	RW_SITES_SUPPORT	97	0.734848
Item 72	RW_AUD_COMPL	95	0.719697
Item 73	TC_LT_LONG_PROJ	87	0.659091
Item 74	TC_AUDIT_TIME	96	0.727273
Item 75	TC_CA_TIME	105	0.795455
Item 76	AA_EFF_TASK	99	0.75
Item 77	AA_EFFEC_EFF_TASK	108	0.818182
Item 78	AA_FREQ_MONIT	103	0.780303
Item 79	AA_MONIT_PERIOD	105	0.795455
Item 80	AC_AC_ESTABLISHED	110	0.833333
Item 81	AC_CONFID_LEVEL	103	0.780303
Item 82	AC_AREAS_NOT_MET	102	0.772727
Item 83	AC_AREAS_MET	103	0.780303
Item 84	TME_PREP_PLAN	96	0.727273
Item 85	TE_REQ_TO_EXEC	93	0.704545
Item 86	TE_TIME_TO_EXEC	89	0.674242
Item 87	TR_PREP_REPORT	90	0.681818
Item 88	TR_REPORT_APPR	93	0.704545
Item 89	TR_REQ_REPORT_APPR	97	0.734848
Item 90	TR_TO_COMM	90	0.681818
Item 91	TR_DISC_MGT	91	0.689394
Item 92	TR_DISC_POPUL	92	0.69697
Item 93	QOG_NC	82	0.621212
Item 94	QOG_BU_MET	87	0.659091
Item 95	QOG_BU_MEAUS	91	0.689394
Item 96	QOG_LOMG_PLANS	97	0.734848
Item 97	QOG_STRAT_PLANS	106	0.80303

Aiken's V (1985) indicates that for a sample 25 raters (experts) and a 5-Likert scale V need to be more than 0.63. The results from Table 5 were evaluated, even though, the raters are 33. The items with less than 0.63 are in Table 6.

Table 6

Content Validity Index (V < .63): Aiken's V (1985)

ITEM#	INDICATOR	V
Item 18	AS_SP	0.628788
Item 19	AS_ST_USED	0.590909
Item 26	AE_AUD_T	0.628788
Item 28	AE_R	0.598485
Item 29	AE_LeadA	0.590909
Item 53	AS_NO_DOC	0.606061
Item 55	AS_FIND_RES	0.621212
Item 58	NFP_FDA	0.613636
Item 61	NFP_NOT_OBS	0.598485
Item 93	QOG_NC	0.621212

The reason for this evaluation is to confirm if there are indicators with low validity index (<0.63) similar as a sampling with 25 experts and to consider to eliminate them from the study. The Content Validity for the entire questionnaire using the Central Limit Theorem (z) was used and this study compares the questionnaire with the 97 items and without the items identified with less 0.63. Table 7 summarizes the Central Limit Theorem calculation results for large sample (raters > 25). The theorem formula used for this calculation is $z = .2(\tilde{V} - .5)\sqrt{3mn(c - 1/(c + 1)}$, where $\tilde{V}$ is the mean of V, m is the items provided by a single rater, n is the raters, and c is the scale rating categories. If z is greater than 1.645 (.05 level) or 2.33 (.01 level), it is concluded that the set of items, and hence the entire scale or questionnaire, has significant content validity (Aiken, 1985).

Table 7

Central Limit Theorem (n = 33): Aiken (1985)

Items Quantity	$\tilde{V}$	z
97	0.72	3.55
87*	0.73	3.56

**Quantity without items with less than 0.63.*

It can be observed after the z results with the items with less than 0.63 and with the all items that z and $\tilde{V}$ are similar. The z result is greater than 2.33 (.01 level) and it is concluded that the set of items and the entire questionnaire have significant content validity. The 97 items were taken into consideration for the Reliability test calculation. This is discussed in the Cronbach Alpha Analysis Results section.

4.5 Cronbach Alpha Analysis Results

The reliability test used in this investigation was discussed in Chapter 4. Cronbach Alpha was used to calculate the reliability of the questionnaire. The value of Cronbach alpha near 1 indicates that the internal consistency of the questionnaire items is higher (Fernandez, 2010). An alpha value greater than 0.90 indicates that the questionnaire is excellent; the questionnaire is good between 0.89 and 0.80, is acceptable between 0.79 and 0.70, is weak between 0.69 and 0.60 and finally is poor less than 0.50 (George & Mallery, 2009).

IBM SPSS Statistics Version21 software was used for reliability analysis of the questionnaire. The test was performed to the 33 responses and 97 items in the questionnaire. The Cronbach alpha resulted on 0.983. This alpha result indicates that the questionnaire is excellent to perform the investigation. Table 8 summarizes the alpha results and in Appendix G is the report from SPSS with the calculation details.

Table 8

Cronbach's Alpha (33 responses)

Reliability Statistics	
Cronbach's Alpha	N of Items
.983	97

4.6 Statistical Analysis and PLS-SEM Results

This investigation used the PLS-SEM (Partial Least Square – Structural Equation Modeling) since this is an exploratory research to develop a model that will explain the audit effectiveness in a specific company. PLS-SEM is a nonparametric statistical method from maximum likelihood (ML) and based on CB SEM (Hair, Hult, Ringle, & Saerstedt, 2014). This means that does not require the data to be normally distributed. However, extremely non-normal data prove problematic evaluation in the assessment of the parameter's significances.

In Chapter 3, the considerations to use PLS-SEM were examined. The use of PLS-SEM in a study needs to have a linear combination of several variables that are chosen based on the research problem. This is known as then variate and it was established in Figure 10. Other consideration is the process of assigning numbers based on a set of rules. The rules are used to assign the numbers to variable in a way that accurately represents the variable. Figure 1 shows the framework for this study and the variables chosen are difficult to measure and a set of indicators was used to represent them. Two additional considerations were the measurement scale and the coding. The questionnaire submitted to the experts used both: a 5-Likert ordinal scale and a coding from 1-5. Nevertheless, in the second part of the analysis the scale and the coding are not

necessary since the data obtained were variable and not attribute. Finally, to work with PLS-SEM the data distribution need to distinguish normal from non-normal distributions (Hair, Hult, Ringle, & Saerstedt, 2014). However, PLS-SEM generally makes no assumptions about the data distributions. The statistical test used after the results were Kolmogorov-Smirnov and Shapiro-Wilk and, to confirm the deviate extend from normality, skewness and kurtosis were used (Hair, Hult, Ringle, & Saerstedt, 2014).

This second stage used the questionnaire with a sampling of 50 audits from a medical device organization. The audits were performed from fiscal year 12 to fiscal year 16 (Fiscal Year starts in May and ends in April next year) and include external and internal audits. During the data gathering, the researcher found that some of the data are constant for some items (indicators). In addition, the data was evaluated for missing data and any observation exceeding the 15% level was removed. This is recommended before running a PLS-SEM analysis (Hair, Hult., Ringle, & Saerstedt, 2014). Also, it is recommended to verify the data for straight lining and inconsistent results patterns. The variables were assessed and it was found constant observations in the results and straight line (35 indicators). Those indicators were removed from the data set and will not be used for the purpose of this study since when a variable is a constant has zero variance and PLS-SEM cannot estimate the model. However, it was verified during the analysis that all the constructs had indicators that describe them. A total of 62 items will be used in the PLS-SEM analysis. The 35 indicators that were removed with constant results are summarized on Appendix H.

(Normality Test)

The questionnaire results were verified for normality before the statistical analysis. The tests used were Kolmogorov-Smirnov and Shapiro-Wilk using the SPSS software. For this test the null-hypothesis is that the data has a normal distribution. From Table 9, the tests result show that almost all the variables (except AS_DOC) had p-values equals or near to 0.000 showing evidence of non-normality distribution.

Table 9

Test for Normality using IBM SPSS Software

Variables	Kolmogorov-Smirnov[1]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
DR_PrAu	.397	50	.000	.645	50	.000
DR_T	.491	50	.000	.373	50	.000
DR_F	.536	50	.000	.125	50	.000
DR_C	.304	50	.000	.695	50	.000
DR_D	.180	50	.000	.836	50	.000
IR_I	.523	50	.000	.+205	50	.000
IR_AuRes	.288	50	.000	.838	50	.000
CR_P	.453	50	.000	.446	50	.000
TC_AQ	.175	50	.001	.930	50	.006
TC_TPL	.166	50	.001	.903	50	.001
TC_TAP	.310	50	.000	.495	50	.000
AS_ST	.180	50	.000	.927	50	.004
T_Tr	.376	50	.000	.631	50	.000
T_Ce	.364	50	.000	.600	50	.000
T_ST	.539	50	.000	.255	50	.000
AE_E	.365	50	.000	.794	50	.000
AE_ReEn	.257	50	.000	.828	50	.000
AE_Ayr	.175	50	.001	.930	50	.006
EDS_FDA	.435	50	.000	.616	50	.000
EAS_EA	.465	50	.000	.562	50	.000
IAS_IA	.270	50	.000	.802	50	.000
IAS_ENC	.395	50	.000	.690	50	.000
IAS_InAS	.539	50	.000	.255	50	.000
IAS_AP	.322	50	.000	.674	50	.000

Variables	Kolmogorov-Smirnov[1]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
IAS_Sinv	.161	50	.002	.897	50	.000
C_C	.199	50	.000	.838	50	.000
NC_AP_Nc	.499	50	.000	.467	50	.000
NC_IA_Nc	.285	50	.000	.788	50	.000
AC_Gnot	.492	50	.000	.314	50	.000
AC_Acm	.181	50	.000	.835	50	.000
EG_STD	.390	50	.000	.689	50	.000
EG_REG	.290	50	.000	.708	50	.000
EG_POL	.228	50	.000	.819	50	.000
EG_NEWp	.499	50	.000	.467	50	.000
AS_EVAL	.125	50	.050	.896	50	.000
AS_NO_DOC	.540	50	.000	.198	50	.000
AS_DOC	.120	50	.068	.960	50	.085
NFP_INV	.267	50	.000	.673	50	.000
NC_C	.298	50	.000	.586	50	.000
NC_IA	.218	50	.000	.812	50	.000
NC_E_FIND	.431	50	.000	.583	50	.000
AD_TRaP	.271	50	.000	.641	50	.000
AD_TRaE	.166	50	.001	.890	50	.000
A_CA	.203	50	.000	.840	50	.000
RW_Pa	.499	50	.000	.467	50	.000
TC_TCA	.163	50	.002	.843	50	.000
AA_TQTY	.279	50	.000	.632	50	.000
AA_EFF	.278	50	.000	.635	50	.000
AA_MT	.349	50	.000	.636	50	.000
AA_MP	.294	50	.000	.772	50	.000
AC_AnM	.156	50	.004	.873	50	.000
AC_AM	.529	50	.000	.344	50	.000
TP_TpP	.164	50	.002	.916	50	.002
TE_TReP	.461	50	.000	.578	50	.000
TE_TeP	.153	50	.005	.854	50	.000
TR_TpR	.292	50	.000	.419	50	.000
TR_TC	.507	50	.000	.316	50	.000
TR_TdRES	.540	50	.000	.201	50	.000
TR_TdPOP	.494	50	.000	.280	50	.000
QOG_BU_NC	.209	50	.000	.878	50	.000

Variables	Kolmogorov-Smirnov[1]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
QOG_LTP	.305	50	.000	.811	50	.000
QOG_SP	.284	50	.000	.798	50	.000

Note. 1. Lilliefors Significance Correction

Nevertheless, AS_DOC had 0.68 in the Kolmogorov-Smirnov test and 0.085 in the Shapiro-Wilk test. In this case, AS_DOC had a p-value >0.05 and the null-hypothesis cannot be rejected. This is the only variable that has a normal distribution. In this situation, skewness and kurtosis test were performed to determine the deviate extent of the data from normality.

The skewness and kurtosis test were performed to the data and it is observed in Table 10, that the skewness and kurtosis results show that the variables has results greater and lower than -1 and +1, respectively. In the case of skewness if the variables has results greater than +1 and lower than -1, this is an indication of a substantially skewed distribution (Hair, Hult., Ringle, & Saerstedt, 2014).

Table 10

Test for Normality using SmartPLS Software

Variable	No.	Missing	Mean	Median	Min	Max	Standard Deviation	Excess Kurtosis	Skewness
DR_PrAu	1	0	0.98	1	0	2	0.469	1.836	-0.068
DR_T	2	0	21.68	20	20	50	4.99	20.424	4.127
DR_F	3	0	1.02	1	1	2	0.14	50	7.071
DR_C	4	0	3.6	2	0	20	5.004	3.279	1.967
DR_D	5	0	10.18	8	0	27	8.492	-0.252	0.997
IR_I	6	0	1.68	1	0	30	4.249	40.838	6.251
IR_AuRes	7	0	1.44	1	0	5	1.003	2.391	1.212
CR_P	8	0	1.3	1	1	5	0.755	13.364	3.451
TC_AQ	9	0	8	10	1	18	4.354	-0.669	-0.024
TC_TPL	10	0	124.14	90	0	365	105.286	-0.796	0.643
TC_TAP	11	0	21.9	7	0	223	43.662	12.084	3.464
AS_ST	12	0	7.8	9	1	18	4.162	-0.424	0.027

Variable	No.	Missing	Mean	Median	Min	Max	Standard Deviation	Excess Kurtosis	Skewness
T_Tr	13	0	3.72	3	3	6	1.132	0.204	1.349
T_Ce	14	0	1.9	1	1	5	1.5	0.536	1.496
T_ST	15	0	0.94	1	0	1	0.237	13.124	-3.821
AE_E	16	0	11.7	15	1	21	5.464	-1.262	-0.588
AE_ReEn	17	0	17.44	21	1	33	9.356	-1.384	-0.416
AE_Ayr	18	0	8	10	1	18	4.354	-0.669	-0.024
EDS_FDA	19	0	1.26	0	0	7	2.198	1.153	1.556
EAS_EA	20	0	1.4	0	0	7	2.577	0.387	1.464
IAS_IA	21	0	8.84	3	0	31	9.416	0.322	1.135
IAS_ENC	22	0	101.9	16	0	297	122.999	-1.476	0.679
IAS_InAS	23	0	0.06	0	0	1	0.237	13.124	3.821
IAS_AP	24	0	0.98	1	0	2	0.969	-2.013	0.041
IAS_Sinv	25	0	18.9	19	9	29	6.175	-0.567	0.126
C_C	26	0	25.52	24	15	39	9.227	-1.539	0.294
NC_AP_Nc	27	0	0.82	1	0	1	0.384	0.989	-1.718
NC_IA_Nc	28	0	4.2	1	0	18	5.257	-0.137	1.011
AC_Gnot	29	0	0.98	1	0	2	0.244	15.064	-1.163
AC_Acm	30	0	7.86	8	0	38	6.702	6.889	1.967
EG_STD	31	0	3.42	1	0	12	4.332	-0.617	1.076
EG_REG	32	0	1.74	1	0	5	2.134	-1.256	0.746
EG_POL	33	0	6.3	7	2	10	3.176	-1.629	-0.233
EG_NEWp	34	0	2.98	1	1	12	4.226	0.989	1.718
AS_EVAL	35	0	21.88	21	8	57	9.365	2.126	0.873
AS_NO_DOC	36	0	0.04	0	0	1	0.196	22.331	4.841
AS_DOC	37	0	17.06	15	1	42	10.063	-0.586	0.248
NFP_INV	38	0	0.86	0	0	7	1.281	9.71	2.627
NC_C	39	0	22.82	8	0	161	39.518	6.861	2.638
NC_IA	40	0	9	5	0	31	9.321	0.363	1.136
NC_E_FIND	41	0	1.44	0	0	7	2.562	0.365	1.447
AD_TRaP	42	0	64.38	40	2	400	73.104	9.997	2.977
AD_TRaE	43	0	15.16	10	0	57	14.185	0.072	0.879
A_CA	44	0	18.2	10	0	64	19.319	-0.048	1.018
RW_Pa	45	0	1.18	1	1	2	0.384	0.989	1.718
TC_TCA	46	0	193.62	149	0	1,015.00	195.322	4.751	1.675
AA_TQTY	47	0	2.92	1	0	22	4.939	6.601	2.536
AA_EFF	48	0	2.94	1	0	22	4.937	6.571	2.526
AA_MT	49	0	0.52	1	0	1	0.5	-2.078	-0.083
AA_MP	50	0	80.16	90	0	365	88.877	0.037	0.763
AC_AnM	51	0	3.86	4	0	16	3.774	1.673	1.194
AC_AM	52	0	0.1	0	0	1	0.3	5.792	2.75

Variable	No.	Missing	Mean	Median	Min	Max	Standard Deviation	Excess Kurtosis	Skewness
TP_TpP	53	0	129.66	91	0	365	104.022	-0.874	0.554
TE_TReP	54	0	8.44	5	0	38	9.458	2.865	2.037
TE_TeP	55	0	23.18	21	2	92	17.258	4.427	1.716
TR_TpR	56	0	19.58	10	0	251	35.469	36.992	5.695
TR_TC	57	0	1.16	1	0	8	1.332	20.458	4.461
TR_TdRES	58	0	1.26	1	1	8	1.278	22.991	4.889
TR_TdPOP	59	0	34.32	30	0	365	49.985	39.441	6.02
QOG_BU_NC	60	0	2.12	2	0	6	1.645	-0.559	0.33
QOG_LTP	61	0	26.88	17	2	68	18.125	0.476	1.208
QOG_SP	62	0	12.64	13	3	40	8.802	3.464	1.745

In the last column (named Skewness) of Table 10, the results are presented and show that 41 of 62 variables are skewed distribution. In the other case, kurtosis test shows that if the number is greater than +1, the distribution is too peaked, but if it is less than -1, the distribution is too flat (Hair, Hult., Ringle, & Saerstedt, 2014). Finally, there are 30 variables that the distribution is too peaked and 8 were the distribution is too flat. In general, this confirmed the previous tests that the data distribution is considered non-normal.

4.7 Partial Least Square – Structural Equation Modeling Results (PLS-SEM)

The objective of this investigation is to measure multidimensional concepts for an audit effectiveness model described in Chapter 3. Also, the focus of this study lies in identifying and exploring relationships on the constructs and model paths proposed. The use of PLS-SEM is justified from the literature. The literature suggests that the PLS is advantageous when the researcher is trying to explore, rather than confirm, theory. It is useful when the phenomenon being investigated is relatively new and that is the case of this research as detailed in Chapter 1 and 3 (Do Valle & Assaker, 2015). The data in this study is non-normal as previous demonstrated, but PSL modeling can be used to examine structural models in cases of small samples and when the multivariate normality of the

data cannot be supported (Do Valle & Assaker, 2015). Also, in PLS-SEM, complexity is not problematic, as long as the sample is of sufficient size (Ritchter, Sinkovics, Ringle, & Schlagel, 2016). The sample size for this study is 50 audits that complied with the previous sample sized established in Chapter 3 of a minimum of 45 with a Power of 80%, minimum R^2 equals to 0.50 and 5 maximum indicators for a construct. Appendix I shows a table from Ritchter et al. (2016) that summarizes the PLS-SEM benefits that needs to take in consideration when use this methodology. From that information, the collection of a variety of data with constructs that are theoretically less-clearly defined can be supported by PLS-SEM, including non-normal data. Additional, PLS-SEM relies on a nonparametric bootstrap procedure (Efron & Tibshirani (1993) and Davidson & Hinkley (1997)) to test the significance of estimated path coefficients in PLS-SEM.

The data from the 50 audits for the 62 indicators were entered in PLS-SEM software and the path model was drawn. Figure 17 shows the path model created in SmartPLS and Figure 18 the path coefficients with R^2. Path coefficients are always standardized path coefficients. Given standardization, path weights therefore vary from -1 to +1. Weights closest to absolute 1 reflect the strongest paths.

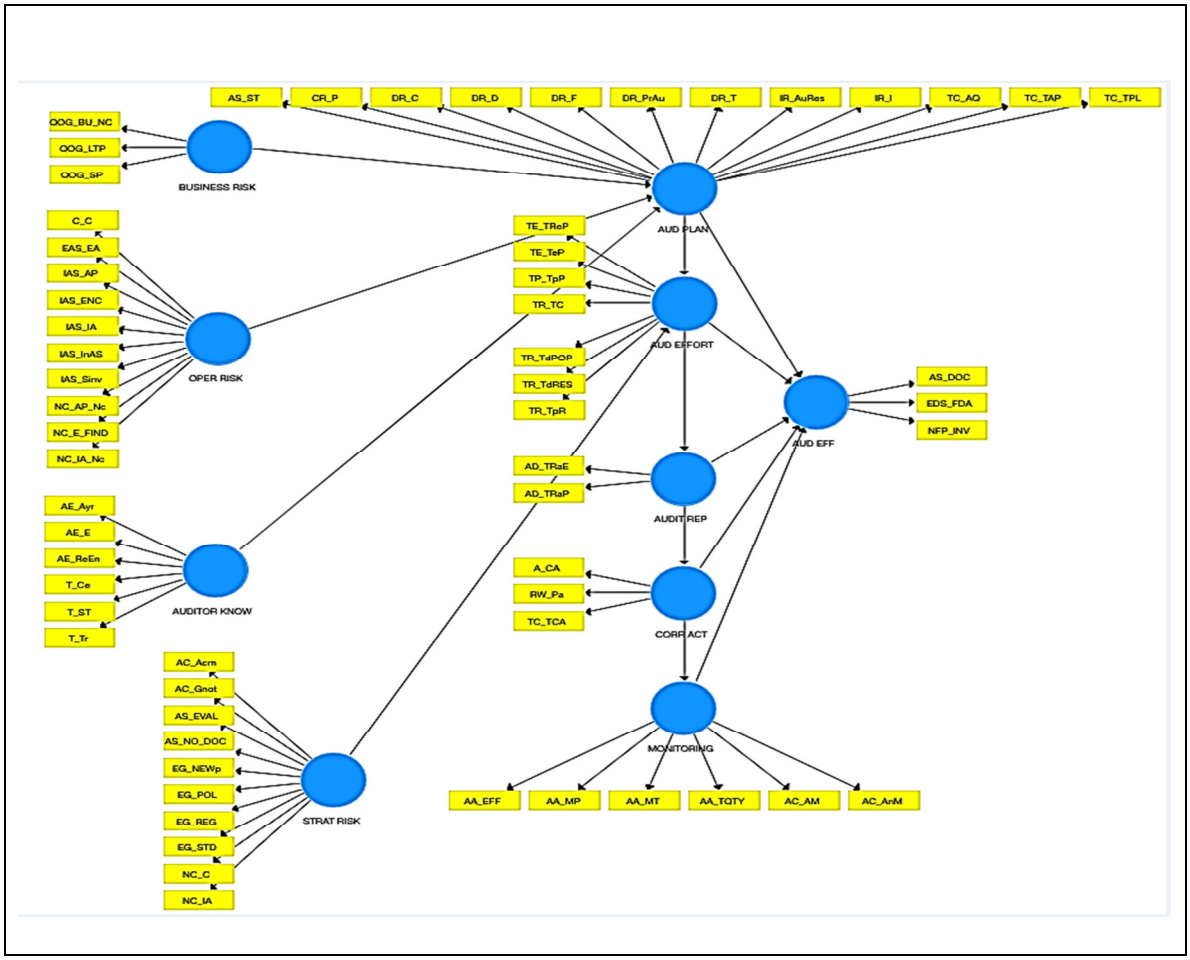


Figure 17. Path Modeling created in SmartPLS.

Figure 18 shows the model created in SmartPLS and the analysis results. The analysis includes the results from the indicators, paths, and the R-squared of the latent variables proposed for this study.

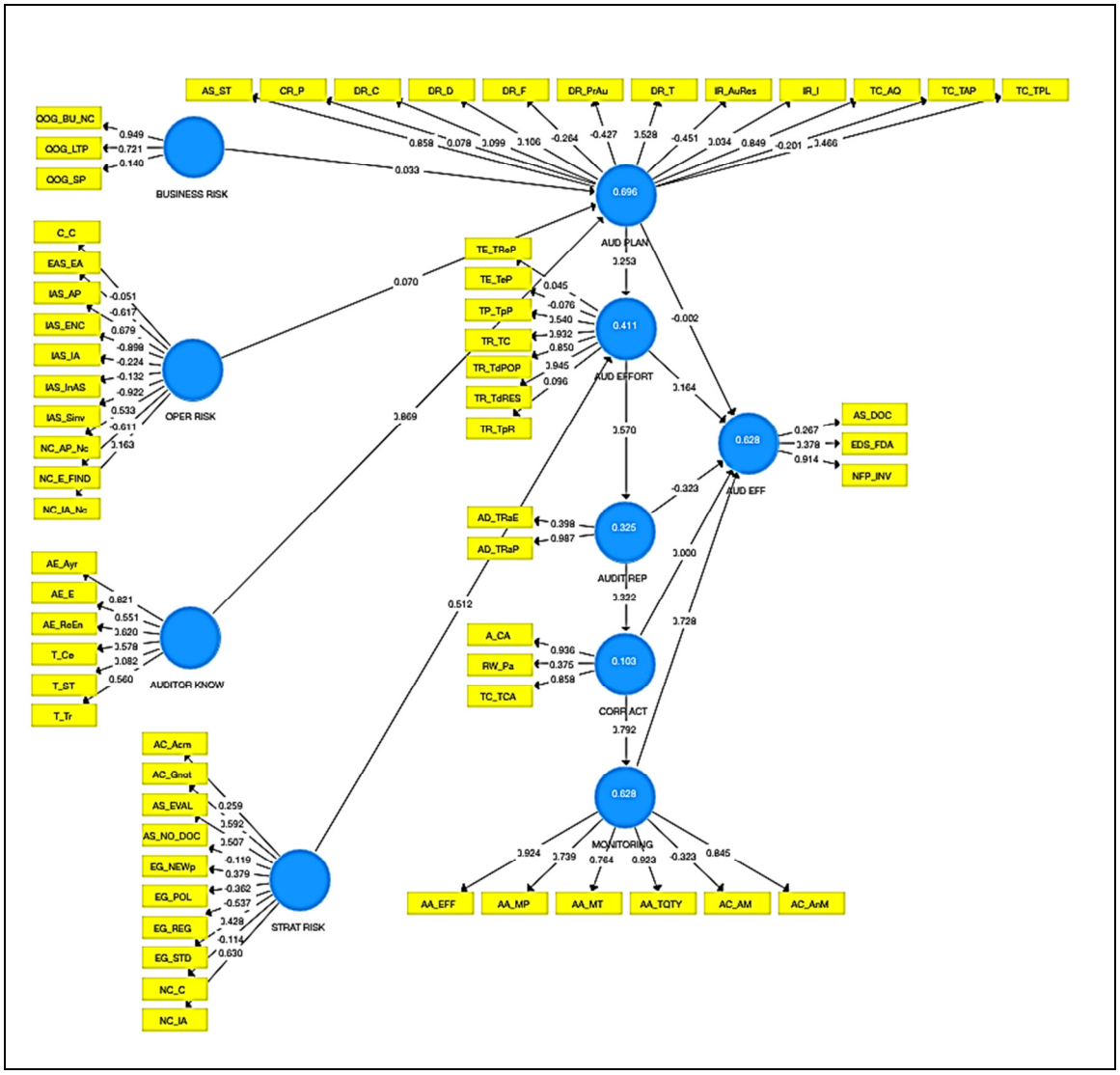


Figure 18. Path Modeling Results using PLS-SEM.

Before the analysis, the convergence was checked, even though convergence is not often a problem in PLS-SEM (Garson, 2016). Appendix J has a "print screen" of the iteration lists. If the number of listed iterations is below the maximum (in this case is 300), the solution converged. From Appendix J, convergence was reached in 34 iterations.

The R-square results show in Table 11 indicates that Audit Effectiveness, Audit Planning and Monitoring are 63%, 70%, 63%, respectively, explained by the model. This

is considered between moderate to substantial according to Garson, 2016. Also, 0.25 can be considered as high depending on the given subject that is study. R-square adjusted was calculated and were slightly lower, as an example Audit Effectiveness was 59%. The resulting R^2 coefficients are considered as moderate to describe the variables already discussed.

Table 11

R-Square Results

	R Square	R Square Adjusted
AUDIT EFFECTIVENESS	0.628	0.586
AUDIT EFFORT	0.411	0.386
AUDIT PLANNING	0.696	0.676
AUDIT REPORT	0.325	0.311
CORRECTIVE ACTION	0.103	0.085
MONITORING	0.628	0.620

It is recommended by Garson (2016) that for a reflective model, the composite reliability is a preferred alternative to Cronbach's alpha as a test of convergent validity in a reflective model since estimate better the internal consistency reliability. Appendix K shows the results for Cronbach's Alpha, rho A, Composite Reliability and Average Variance Extracted (AVE) from SmartPLS. Table 12 shows the Composite Reliability and Average Variance Extracted (AVE) results.

Table 12

Construct Reliability and Validity Results

	COMPOSITE RELIABILITY	AVERAGE VARIANCE EXTRACTED (AVE)
AUDIT EFFECTIVENESS	0.555	0.350
AUDIT EFFORT	0.725	0.399
AUDIT PLANNING	0.228	0.206
AUDIT REPORT	0.689	0.567
AUDITOR KNOWLEGDE	0.721	0.336
BUSINESS RISK	0.678	0.480
CORRECTIVE ACTION	0.790	0.584
MONITORING	0.865	0.609
OPERATIONAL RISK	0.390	0.325
STRATEGIC RISK	0.253	0.185

Composite reliability varies from 0 to 1, with 1 being perfect estimated reliability. In a model adequate for exploratory purposes, composite reliabilities should be equal to or greater than 0.60; equal to or greater than 0.70 for an adequate model for confirmatory purposes and equal to or greater than 0.80 is considered good for confirmatory research (Garson, 2016). From Table 12, the variables Audit Effort, Auditor Knowledge, Audit Report, Business Risk, Corrective Action, and Monitoring have composite reliability greater than the recommended of 0.6. Not that far is Audit Effectiveness with 0.555, but with less than 0.4; Audit Planning, Operational Risk and Strategic Risk. In this study the Cronbach's Alpha is not applicable since according to Garson, 2016, it is biased against short scales. Also, Cronbach's Alpha is sensitive to the number of items in the scale and generally tends to underestimate the internal inconsistency reliability (Hair, Hult., Ringle, & Saerstedt, 2014). Nevertheless, the variable with highest results is Monitoring, which

had a higher result in Composite reliability test and the lowest was Strategic Risk that had a low result in Composite reliability test.

The convergent validity is other test that measures the relation with alternative measures for the same construct. According to Hair et al., 2014, to establish convergent validity is necessary to consider the outer loadings of the indicators, as well the average variance extracted (AVE). As explained early, Appendix K shows Average Variance Extracted (AVE) resulted from SmartPLS Software. The AVE establishes the convergent validity at the construct level. The literature indicates that AVE is equivalent to the communality of a construct (Hair, Hult., Ringle, & Saerstedt, 2014). For this test, an AVE values higher than 0.50 indicates that the construct explains more than half of the variance of its indicators. If it is less than 0.50 indicates that more error remains in the items than the variance explained by the construct. Table 11 shows the results of the AVE test. The result indicates that three variables (Audit Report, Corrective Action and Monitoring) are greater than 0.50, meaning that they explain more than half of the variance of its indicators. In the other hand, the other variables (e.g. Strategic Risk) have less than 0.50 meaning that more errors remain in the items, even though some variables has results near to 0.50; e.g., Business Risk.

Other measure for convergent validity is the Outer Loadings results of the indicators from the PLS-SEM. The results are in Appendix L as reported by SmartPLS. Latent variables should explain part of the indicator's variance. The result should indicate that an indicator's outer loading is considered acceptable above 0.70 (Hair, Hult., Ringle, & Saerstedt, 2014). In addition, it is necessary to consider if indicators with values between 0.40 and 0.70 are necessary to eliminate. There are occasions that the

indicator remains since they contribute or affect the content validity if it is removed. Indicators below 0.40 should be removed (Hair, Hult., Ringle, & Saerstedt, 2014). These results are shown in Figure 18 and Appendix L. However, also the literature indicates that 0.70 standards is a high one and real-life data may well not meet this criterion, which is why some researchers, particularly for exploratory purposes, will use a lower level such as 0.40 for the central factor and 0.25 for other factors (Raubenheimer, 2004). This is summarized in Table 13.

The model evaluation criteria assessment was discussed in previous paragraphs to determine the reliability and validity. The summary of the results previously discussed are in Table 13. This table shows the reliability, composite, AVE and loading of 62 items.

Table 13

Summary Results for the Model Evaluation Criteria

LATENT VARIABLE	INDICATORS	OUTER LOADINGS (>0.40)	COMPOSITE RELIABILITY (>0.70)	AVE (>0.50)
AUDIT EFFECTIVENESS	AS_DOC	0.267		
AUDIT EFFECTIVENESS	EDS_FDA	0.378	0.555	0.350
AUDIT EFFECTIVENESS	NFP_INV	0.914		
AUDIT EFFORT	TE_TReP	0.045		
AUDIT EFFORT	TE_TeP	-0.076		
AUDIT EFFORT	TP_TpP	0.540	0.725	0.399
AUDIT EFFORT	TR_TC	0.932		
AUDIT EFFORT	TR_TdPOP	0.850		
AUDIT EFFORT	TR_TdRES	0.945		

LATENT VARIABLE	INDICATORS	OUTER LOADINGS (>0.40)	COMPOSITE RELIABILITY (>0.70)	AVE (>0.50)
AUDIT EFFORT	TR_TpR	0.096		
AUDIT PLANNING	AS_ST	0.858		
AUDIT PLANNING	CR_P	0.078		
AUDIT PLANNING	DR_C	0.099		
AUDIT PLANNING	DR_D	0.106		
AUDIT PLANNING	DR_F	-0.264		
AUDIT PLANNING	DR_PrAu	-0.427		
AUDIT PLANNING	DR_T	0.528	0.228	0.206
AUDIT PLANNING	IR_AuRes	-0.451		
AUDIT PLANNING	IR_I	0.034		
AUDIT PLANNING	TC_AQ	0.849		
AUDIT PLANNING	TC_TAP	-0.201		
AUDIT PLANNING	TC_TPL	0.466		
AUDIT REPORT	AD_TRaE	0.398	0.689	0.567
AUDIT REPORT	AD_TRaP	0.987		
AUDITOR KNOWLEGDE	AE_Ayr	0.821	0.721	0.336
AUDITOR KNOWLEGDE	AE_E	0.551		

LATENT VARIABLE	INDICATORS	OUTER LOADINGS (>0.40)	COMPOSITE RELIABILITY (>0.70)	AVE (>0.50)
AUDITOR KNOWLEGDE	AE_ReEn	0.620		
AUDITOR KNOWLEGDE	T_Ce	0.578		
AUDITOR KNOWLEGDE	T_ST	0.082		
AUDITOR KNOWLEGDE	T_Tr	0.560		
BUSINESS RISK	QOG_BU_NC	0.949		
BUSINESS RISK	QOG_LTP	0.721	0.678	0.480
BUSINESS RISK	QOG_SP	0.140		
CORRECTIVE ACTION	A_CA	0.936		
CORRECTIVE ACTION	RW_Pa	0.375	0.790	0.584
CORRECTIVE ACTION	TC_TCA	0.858		
MONITORING	AA_EFF	0.924		
MONITORING	AA_MP	0.739		
MONITORING	AA_MT	0.764	0.865	0.609
MONITORING	AA_TQTY	0.923		
MONITORING	AC_AM	-0.323		
MONITORING	AC_AnM	0.845		
OPERATIONAL RISK	C_C	-0.051		
OPERATIONAL RISK	EAS_EA	-0.617	0.390	0.325
OPERATIONAL RISK	IAS_AP	0.679		

LATENT VARIABLE	INDICATORS	OUTER LOADINGS (>0.40)	COMPOSITE RELIABILITY (>0.70)	AVE (>0.50)
OPERATIONAL RISK	IAS_ENC	-0.898		
OPERATIONAL RISK	IAS_IA	-0.224		
OPERATIONAL RISK	IAS_InAS	-0.132		
OPERATIONAL RISK	IAS_Sinv	-0.922		
OPERATIONAL RISK	NC_AP_Nc	0.533		
OPERATIONAL RISK	NC_E_FIND	-0.611		
OPERATIONAL RISK	NC_IA_Nc	0.163		
STRATEGIC RISK	AC_Acm	0.259		
STRATEGIC RISK	AC_Gnot	0.592		
STRATEGIC RISK	AS_EVAL	0.507		
STRATEGIC RISK	AS_NO_DOC	-0.119		
STRATEGIC RISK	EG_NEWp	0.379	0.253	0.185
STRATEGIC RISK	EG_POL	-0.362		
STRATEGIC RISK	EG_REG	-0.537		
STRATEGIC RISK	EG_STD	0.428		
STRATEGIC RISK	NC_C	-0.114		
STRATEGIC RISK	NC_IA	0.630		

These results indicate that is necessary to assess the indicators with lower than 0.4 for central factor and 0.25 for other factors in the loading test. In that direction, the

validity and reliability and errors are minimized. After this modification to the path model and confirmation of the validity and reliability of the measures, the path will be evaluated in parallel with the relation. Finally, the acceptance or rejection of the hypothesis will be assessed and confirmed. The following paragraphs explain which variables indicated a lower loading with less than 0.25 and if they are justified to remain in the variable's list.

In this study, there were indicators that should be eliminated like in Audit Effort: TE_Tep, TE_TReP, and TR_TpR with -0.076, 0.045, and 0.096, respectively. A summary of these indicators are in Table 14.

Table 14

Construct Reliability and Validity Results of items to be removed

Construct	Indicator	Outer Loadings Results
AUDIT EFFORT	TE_TReP	-0.076
	TE_TeP	0.045
	TR_TpR	0.096
AUDIT PLANNING	CR_P	0.078
	DR_C	0.099
	IR_I	0.034
AUDITOR KNOWLEGDE	T_ST	0.082
OPERATIONAL RISK	C_C	-0.051
	IAS_InAS	-0.132
STRATEGIC RISK	AS_NO_DOC	-0.119
	NC_C	-0.114

The indicators from Table 14 were removed from the model and the path model was re-calculated without the indicators from Table 14. Also, the distribution test was analyzed and it was confirmed that the data has a non-normal distribution. The results for normality test for 51 variables are in Appendix M. The following paragraphs explain

these results and Figure 19 shows the path model modified using SmartPLS. Also, Figure 19 includes the results for the path and the construct's relation.

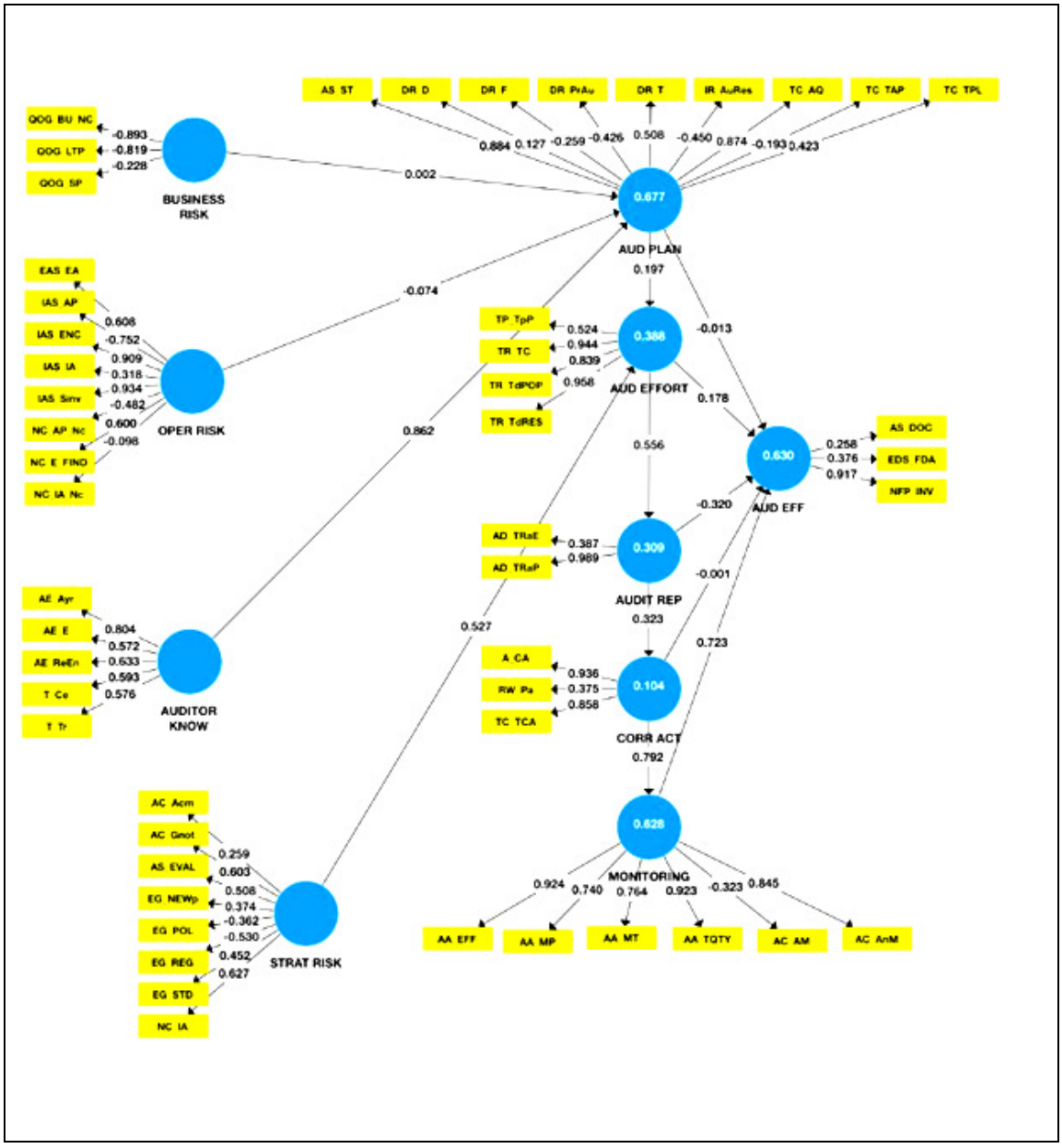


Figure 19. Modified Path Modeling created in SmartPLS. There were indicators that will remain as part of the model after the PLS-SEM analysis because according to Hair et al. (2014), the indicator can be retained if when they are removed does not increase measures above threshold (results below 0.25) and if they are elimination may improve the reliability or discriminant validity but at the same time decrease the measurement's

content validity. In addition, factors can be identified by the largest loadings, but it is also important to examine the zero and low loadings in order to confirm the identification of the factors. Depending on the design of the study, the variable can be retained with the assumption that it is the latent nature of the variable can be dropped when the interpretation is difficult as indicating by Yong and Pearce (2013).

The results for the latent variable and indicators for the loadings, indicator reliability, composite reliability and AVE criteria were examined after the removal of the indicators with lower outer loading. The results show that the construct measures are valid and reliable.

The discriminant validity is used in addition to the AVE and outer loadings (convergent validity). This measurement implies that a construct is unique and captures phenomena not represented by other constructs in the model (Hair et al., 2014). The Fornell-Lacker criterion is recommended to evaluate this measure. The results established or not this criterion between the constructs. If the criterion is not established, there is an alternative to remove the indicator from a specific construct to attempt to meet the criteria. However, removing indicators could improve the reliability or discriminant validity but at the same time decrease the measurement's content validity. The discriminant validity was assessed and results indicated that monitoring's relation are higher than audit effectiveness. The cross loading were assessed to verify which indicator or indicators could affect this results. The monitoring indicators (e.g. 0.789) are less than the high indicator (e.g. 0.917) of audit effectiveness. Also, the effect of omitting these indicators was checked and resulted to decrease the convergent validity. These indicators will remain as part of the model based on cross loading verification. These same approach occurred with corrective action, where monitoring is a little higher. When the cross loadings were checked the corrective action's indicator (e.g. 0.936) is higher

than monitoring (e.g. 0.736). The PLS-SEM results for discriminant validity are in Appendix P.

A summary from the PLS-SEM measurements for the Modified Path Model is in Table 15 and the SmartPLS reports were included from Appendix N to Appendix R.

Table 15

Results for the Model Evaluation Criteria for Modified Path Model

Variable	Indicators	Outer loadings	Composite Reliability	AVE
Audit Effectiveness	AS_DOC	0.258	0.552	0.350
	EDS_FDA	0.389		
	NFP_INV	0.941		
Audit Effort	TP_TpP	0.524	0.898	0.697
	TR_TC	0.944		
	TR_TdPOP	0.839		
	TR_TdRES	0.958		
Audit Planning	AS_ST	0.884	0.253	0.276
	DR_D	0.127		
	DR_F	-0.259		
	DR_PrAu	-0.426		
	DR_T	0.508		
	IR_AuRes	-0.450		
	TC_AQ	0.874		
	TC_TAP	-0.193		
	TC_TPL	0.423		
Audit Report	AD_TRaE	0.387	0.685	0.564
	AD_TRaP	0.989		
Auditor Knowledge	AE_Ayr	0.804	0.774	0.411
	AE_E	0.572		
	AE_ReEn	0.633		
	T_Ce	0.593		
	T_Tr	0.576		
Business Risk	QOG_BU_	-0.893	0.718	0.507

Variable	Indicators	Outer loadings	Composite Reliability	AVE
	NC			
	QOG_LTP	-0.819		
	QOG_SP	-0.228		
Corrective Action	A_CA	0.936	0.790	0.584
	RW_Pa	0.375		
	TC_TCA	0.858		
Monitoring	AA_EFF	0.924	0.865	0.609
	AA_MP	0.740		
	AA_MT	0.764		
	AA_TQTY	0.923		
	AC_AM	-0.323		
	AC_AnM	0.845		
Operation Risk	EAS_EA	0.608	0.470	0.417
	IAS_AP	-0.752		
	IAS_ENC	0.909		
	IAS_IA	0.318		
	IAS_Sinv	0.934		
	NC_AP_Nc	-0.482		
	NC_E_FIND	0.600		
	NC_IA_Nc	-0.098		
Strategic Risk	AC_Acm	0.259	0.377	0.230
	AC_Gnot	0.603		
	AS_EVAL	0.508		
	EG_NEWp	0.374		
	EG_POL	-0.362		
	EG_REG	-0.530		
	EG_STD	0.452		
	NC_IA	0.627		

There were indicators that will remain as part of the model after the PLS-SEM analysis since they were considered important for this exploratory research. According to Hair (2014), the indicator can be retained if when they are removed does not increase measures above threshold. In this case, they were not increasing significantly the

measure but their removal from the model decrease the convergent validity. Also, the outer loading was verified and the values presented in Table 15 and Appendix R.

4.8 Assessment of the PLS-SEM Model

An assessment of the structural model results is recommended after confirmation that the construct measures are reliable and valid. Hair et al. (2014) suggested assessing the structural model using five (5) steps: Collinearity, Significance and Relevance, R^2, Effect Sizes (f^2), and Predictive Relevance (Q^2). The following sections of this chapter cover these assessments.

- Step 1 - Collinearity

The collinearity assessment is used to identify significance levels among the predictor constructs. The path coefficients might be biased, if this is not identified. PLS algorithm using SmartPLS that used variance inflation factor (VIF) that is the reciprocal of the tolerance. VIF is the degree to which the standard error has been increased due to the presence of collinearity. A VIF value of 4.00 implies that the standard error has been doubled due to collinearity. In PLS-SEM a VIF value of 5 and higher indicates a potential collinearity problem (Hair et al., 2014). The PLS-SEM results indicated that there is no collinearity between the constructs of the path model. The collinearity results were from 1.000 to 2.968 for the constructs. The results details are in Appendix V

- Step 2 - Significance and Relevance and Step 3 - R^2

The hypothesized relationships in this investigation were represented using the structural model relationships among the constructs. The bootstrapping procedure was used to assess the t-values to analyze the significance and relevance. Also, the R^2 was assessed to determine the predictive accuracy. The next sections, analyze the path model,

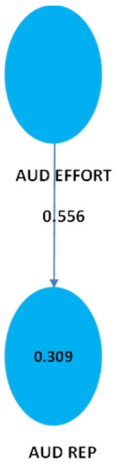
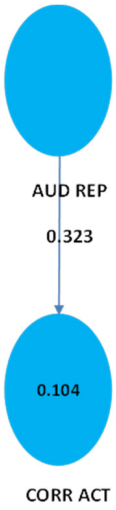
the construct's relation and the hypotheses. The literature suggests that a path with more than 0.20 are usually significant and those with values below 0.10 are usually not significant (Hair, Hult., Ringle, & Saerstedt, 2014). PLS aims at maximizing the R^2 values of the endogenous latent variable in the path model. The objective is high R^2 but this depends on the particular model and research discipline. The R^2 near 0.75 is considered substantial, near 0.50 is considered moderate, and weak is considered near 0.25. The R^2 is discussed in Table 16 with other criteria for the path model including the verification of the hypotheses.

Table 16

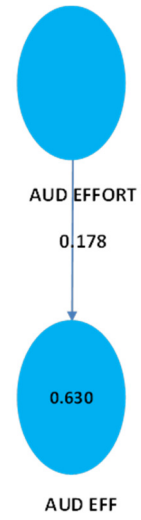
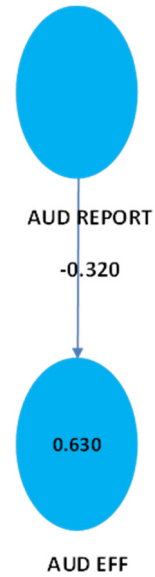
Significance and Relevance Results for Modified Path Model

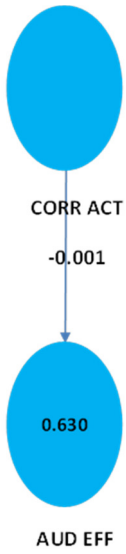
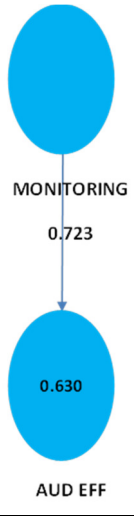
H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details
Hi1	There is a relation between audit planning and the audit effort.		$R^{2:}$ The model shows a path with a result of 0.197 and R^2 of 0.338 for AUD EFFORT variable (Audit Effort). This means that AUD PLAN explains 39% of AUD EFFORT variance. This means that the 39% is considered moderate describing the latent variable. Path Coefficients: In the other hand, the path result of 0.197 is no significant since is less than the recommended 0.20. Nonetheless, it is near to0.20 and even greater than 0.10 meaning that can be considered. t-Value (from Bootstrapping Analysis): t-value for this path is 0.806 with p-value of 0.421. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of .05 (p=0.05). Hypothesis result: H01 is not rejected.
H01	No relation exists between audit planning and the audit effort.		

H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details

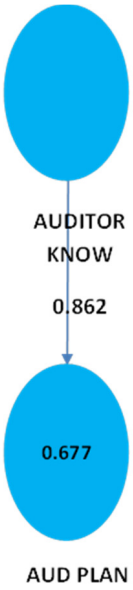
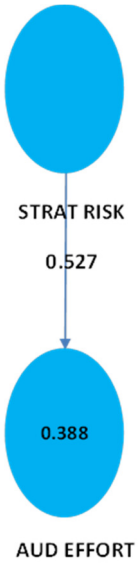
Hi2	There is a relation between audit effort and audit report.		$R^{2:}$ The model shows a path with a result of 0.556 and R^2 of 0.309 for AUD REP variable (Audit Report). This means that AUD EFFORT explains 31% of AUD REP variance. This means that R^2 between 0.50 and 0.25 is considered moderate describing the latent variable. Path Coefficients: In the other hand, the path result of 0.556 is significant since is greater than the recommended 0.20. t-Value (from Bootstrapping Analysis): t-value for this path is 1.776 with p-value of 0.078. This means that the path is not significant since t-value needs to be more than 1.65 for a significance of 10% (p=0.10) for an exploratory research (Hair et al., 2014). This hypothesis will be considered for a significance level of 0.10. Hypothesis result: H02 is rejected.
H02	No relation exists between audit effort and audit report.		
Hi3	There is a relation between audit report and corrective action.		R^2: The model shows a path with a result of 0.323 and R^2 of 0.104 for CORR ACT variable (Corrective Action). This means that AUD REP explains 10.4% of AUD REP variance. This R^2 is below 0.25 and near to 0 and it is considered weak relation to describe the latent variable. Path Coefficients: In the other hand, the path result of 0.323 is significant since is greater than the recommended 0.20. t-Value (from Bootstrapping Analysis): t-value for this path is 1.176 with p-value of 0.240. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of 10 (p=0.10). Hypothesis result: H03 is not rejected.
H03	No relation exists between audit report and corrective action.		

H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details
Hi4	There is a relation between corrective action and monitoring.		R^2: The model shows a path with a result of 0.792 and $R^2$of 0.628 for MONITORING variable. This means that CORR ACT explains 63% of MONITORING variance. This means that the 63% is considered moderate to describe the latent variable since it is between 0.75 and 0.50. Path Coefficients: In the other hand, the path result of 0.792 is significant since is greater than the recommended 0.20. t-Value (from Bootstrapping Analysis): t-value for this path is 13.432 with p-value of 0.000. This means that the path is significant for a p=.05, the t statistic has to be greater than 1.96. Hypothesis result: H04 is rejected.
H04	No relation exists between corrective action and monitoring.		
Hi5	There is a relation between audit planning and the audit effectiveness .		$R^{2:}$ The model shows a path with a result of 0.-0.013 and R^2 of 0.630 for AUD EFF variable (Audit Effectiveness). Also, this variable (AUD EFF) is described by AUD PLAN jointly with AUD EFFORT, AUD REP, CORR ACT, and MONITORING. All these variables explain the 63% of the variance of AUD EFF. Also, it means that the 63% is considered moderate to describe the latent variable since it is between 0.75 and 0.50. Path Coefficients: In the other hand, the path result of -0.013 is not significant since is below than the recommended 0.10 (for path between 0.10 and 0.20 depends on the research type). t-Value (from Bootstrapping Analysis): t-value for this path is 0.077 with p-value of 0.938. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of 10 (p=0.05). Hypothesis result: H05 is not rejected.
H05	No relation exists between audit planning and the audit effectiveness		

H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details
Hi6	There is a relation between audit effort and audit effectiveness .		$R^{2:}$ The model shows a path with a result of 0.178 and R^2 of 0.630 for AUD EFF variable (Audit Effectiveness). Also, this variable (AUD EFF) is described by AUD PLAN jointly with AUD EFFORT, AUD REP, CORR ACT, and MONITORING. All these variables explain the 63% of the variance of AUD EFF. Also, it means that the 63% is considered moderate to describe the latent variable since it is between 0.75 and 0.50. Path Coefficients: In the other hand, the path result of 0.178 is no significant since is less than the recommended 0.20 but it is near to, even is greater than 0.10 meaning that can be considered. t-Value (from Bootstrapping Analysis): t-value for this path is 0.639 with p-value of 0.523. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of 0.05 (p=0.05). Hypothesis result: H06 is not rejected.
H06	No relation exists between audit effort and audit effectiveness .		
Hi7	There is a relation between audit report and audit effectiveness.		$R^{2:}$ The model shows a path with a result of -0.320 and R^2 of 0.630 for AUD EFF variable (Audit Effectiveness). Also, this variable (AUD EFF) is described by AUD PLAN jointly with AUD EFFORT, AUD REP, CORR ACT, and MONITORING. All these variables explain the 63% of the variance of AUD EFF. Also, it means that the 63% is considered moderate to describe the latent variable since it is between 0.75 and 0.50. Path Coefficients: In the other hand, the path result of -0.320. The path resulted with a negative number but this number is greater than 0.20. For that reason, the meaning is that AUD EFF is predicted to decrease and, the value will be considered significant. t-Value (from Bootstrapping Analysis): t-value for this path is 1.703 with p-value of 0.089. This means that the path is not significant since t-value needs to be more than 1.65 for a significance of 10% (p=0.10) for an exploratory research (Hair et al., 2014). This hypothesis will be considered for a significance level of 10%. Hypothesis result: H07 is rejected.
H07	No relation exists between audit report and audit effectiveness.		

H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details
Hi8	There is a relation between corrective action and audit effectiveness.		$R^{2:}$ The model shows a path with a result of -0.001 and R^2 of 0.63 for AUD EFF variable (Audit Effectiveness). Also, this variable (AUD EFF) is described by AUD PLAN jointly with AUD EFFORT, AUD REP, CORR ACT, and MONITORING. All these variables explain the 63% of the variance of AUD EFF. Also, it means that the 63% is considered moderate to describe the latent variable since it is between 0.75 and 0.50. Path Coefficients: In the other hand, the path result of -0.001 is not significant since is below than the recommended 0.10 (for path between 0.10 and 0.20 depends on the research type). t-Value (from Bootstrapping Analysis): t-value for this path is 0.004 with p-value of 0.997. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of 0.05 (p=0.05). Hypothesis result: H08 is not rejected.
H08	No relation exists between corrective action and audit effectiveness		
Hi9	There is a relation between monitoring and audit effectiveness		R^2: The model shows a path with a result of 0.723 and $R^2$of 0.630 for MONITORING variable. This means that CORR ACT explains 63% of MONITORING variance. This means that the 63% that is above for R^2 between 0.75 and 0.50 is considered moderate describing the latent variable. Path Coefficients: In the other hand, the path result of 0.723 is significant since is greater than the recommended 0.20. t-Value (from Bootstrapping Analysis): t-value for this path is 1.996 with p-value of 0.046. This means that the path is significant for a p=0.05, t statistic has to be greater than 1.96. Hypothesis result: H09 is rejected.
H09	No relation exists between monitoring and audit effectiveness.		

H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details
Hi10	There is relation between business risk and audit planning.		R^2: The model shows a path with a result of 0.002 and R^2 of 0.677 for AUD PLAN (Audit Plan) variable. This means that BUSINESS RISK jointly with OPER RISK, and AUDITOR KNOW explains 68% of AUD PLAN variance. This means that the 68% is considered moderate describing the latent variable. Path Coefficients: In the other hand, the path result of 0.002 is not significant since is below than the recommended 0.10. t-Value (from Bootstrapping Analysis): t-value for this path is 0.014 with p-value of 0.989. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of o.05 (p=0.05). Hypothesis result: H010 is not rejected.
010	No relations exist between business risk and audit planning.		
Hi11	There is relation between operational risk and audit planning.		R^2: The model shows a path with a result of -0.074 and $R^2$of 0.677 for AUD PLAN (Audit Plan) variable. This means that BUSINESS RISK jointly with OPER RISK, and AUDITOR KNOW explains 68% of AUD PLAN variance. This means that the 68% is considered moderate describing the latent variable. Path Coefficients: In the other hand, the path result of -0.074 is not significant since is below than the recommended 0.10. The negative symbol means that that AUD PLAN is predicted to decrease 7.4% influenced by OPER RISK. t-Value (from Bootstrapping Analysis): t-value for this path is 0.342 with p-value of 0.733. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of 0.05 (p=0.05). Hypothesis result: H011 is not rejected.
H011	No relations exist between operational risk and audit planning.		

H id	Hypotheses description	Path Model Coefficients and R^2 values	Results Details
Hi12	There is relation between auditor's knowledge and audit planning.		R^2: The model shows a path with a result of 0.862 and R^2 of 0.677 for AUD PLAN (Audit Plan) variable. This means that BUSINESS RISK jointly with OPER RISK, and AUDITOR KNOW explains 68% of AUD PLAN variance. This means that the 68% considered moderate describing the latent variable. Path Coefficients: In the other hand, the path result of 0.862 is significant since is greater than the recommended 0.20. t-Value (from Bootstrapping Analysis): t-value for this path is 3.561 with p-value of 0.000. This means that the path is significant for a p=0.05, t statistic has to be greater than 1.96. Hypothesis result: H012 is rejected.
H012	No relations exist between auditor's knowledge and audit planning.		
Hi13	There is relation between strategic risk and audit effort.		R^2: The model shows a path with a result of 0.527 and $R^2$of 0.388 for AUD EFFORT (Audit Effort) variable. This means that STRAT RISK explains 39% of AUD EFFORT variance. This means that the 39% is considered a weak in described the latent variable. Path Coefficients: In the other hand, the path result of 0.527 is significant since it greater than .20. t-Value (from Bootstrapping Analysis): t-value for this path is 2.928 with p-value of 0.004. This means that the path is not significant since t-value needs to be more than 1.96 for a significance of 0.05 (p=0.05). Hypothesis result: H013 is rejected.
H013	No relations exist between strategic risk and audit effort.		

The objective of this study was to reject or no reject the null-hypothesis proposed in Chapter 1 and 3. The rejection or no rejection of the null-hypothesis was performed using the results of PLS-SEM and bootstrapping procedures. The criteria used were path

values, R^2, t-values and p-values. The details of this analysis are in Table 16. The summary of the hypothesis and the result of rejection are in Table 17.

Table 17

Hypotheses Summary Results

H id	Hypothesis description	Decision	t-value	p-value (significance level)
Hi1	There is a relation between audit planning and the audit effort.	Not Rejected	0.806	0.421
H01	No relation exists between audit planning and the audit effort.			
Hi2	There is a relation between audit effort and audit report.	Rejected	1.776	0.078
H02	No relation exists between audit effort and audit report.			
Hi3	There is a relation between audit report and corrective action.	Not Rejected	1.176	0.240
H03	No relation exists between audit report and corrective action.			
Hi4	There is a relation between corrective action and monitoring.	Reject	13.432	0.000
H04	No relation exists between corrective action and monitoring.			
Hi5	There is a relation between audit planning and the audit effectiveness.	Not Rejected	0.077	0.938
H05	No relation exists between audit planning and the audit effectiveness			
Hi6	There is a relation between audit effort and audit effectiveness.	Not Rejected	0.639	0.523
H06	No relation exists between audit effort and audit effectiveness.			
Hi7	There is a relation between audit report and audit effectiveness.	Rejected	1.703	0.089
H07	No relation exists between audit report and audit effectiveness.			

H id	Hypothesis description	Decision	t-value	p-value (significance level)
Hi8	There is a relation between corrective action and audit effectiveness.	Not Rejected	0.004	0.997
H08	No relation exists between corrective action and audit effectiveness.			
Hi9	There is a relation between monitoring and audit effectiveness.	Rejected	1.996	0.046
H09	No relation exists between monitoring and audit effectiveness.			
Hi10	There is relation between business risk and audit planning.	Not Rejected	0.014	0.989
H010	No relations exist between business risk and audit planning.			
Hi11	There is relation between operational risk and audit planning.	Not Rejected	0.342	0.733
H011	No relations exist between operational risk and audit planning.			
Hi12	There is relation between auditor's knowledge and audit planning.	Rejected	3.561	0.000
H012	No relations exist between auditor's knowledge and audit planning.			
Hi13	There is relation between strategic risk and audit effort.	Rejected	2.928	0.004
H013	No relations exist between strategic risk and audit effort.			

The analysis concluded that there is significant evidence to reject null-hypotheses H02, H04, H07, H09, H012, and H013. This means that those variables correlate between them in the proposed model. Also, the results verified some of the assumptions made in Chapter 1 and 3 from other business areas. The comparison with the literature will be discussed in Chapter 5. Some of the relations for this study confirmed that a relation exists between corrective action and monitoring, between monitoring and audit effectiveness, and finally, between auditors' knowledge and audit planning.

Nevertheless, it was not expected that H01 was rejected, since literature indicates that the audit plan may affect the audit effort in terms of time constrains. Also, H03, H05, and H06 were expected to be rejected even though there is little literature about these factors in the areas assessed. The study shows that audit plan, audit effort, and corrective action did not influence or correlate with the variable audit effectiveness. As a matter of fact, the path values results were less than 0.20 and even some were less than 0.10 to consider. Other results indicated that there is no significance evidence to corroborate that the relation of business risk and audit plan and the relation between operation risk and audit exist.

There are other criteria that need to be examined besides the R^2 and start the analysis to reject or not reject the null-hypothesis. It is observed from Figure 19 that the structural model has high and low paths coefficients values. This relationship needs to be evaluated to verify if they are significant. The bootstrapping procedure was used to examine this paths value. This was performed using SmartPLS software. The bootstrapping results used for this study are in Appendix Q and S. Appendix Q shows the t-values, p-values, and confidence intervals (C.I.) for the latent variables. The t-values and p-values results are summarized in Table 16 along with the verification of the null-hypothesis. The outer loadings for the constructors and its constructors are in Appendix S with t-values and p-values. The critical values for a two-tailed test are 1.65 (alpha = 0.10%), 1.96 (alpha = 5%), and 2.57 (alpha = 1%) (Hair, Hult., Ringle, & Saerstedt, 2014). The t-values results established that some of the indicators are not significant for the construct (e.g. AC_Gnot) since they had t-values below 1.65 for $p<0.01$ (as recommended for an exploratory study according with Hair et al., 2014). A summary of

the indicators and construct t-values that are significant based on the above discussed criteria are in Table 18.

Table 18

Significant Indicator-Latent Variable

Indicator<-Latent Variable	t-values	p-values
AA_EFF <- MONITORING	61.664	0.000
AA_MP <- MONITORING	9.259	0.000
AA_MT <- MONITORING	15.598	0.000
AA_TQTY <- MONITORING	60.843	0.000
AC_AM <- MONITORING	3.657	0.000
AC_AnM <- MONITORING	16.028	0.000
AC_Gnot <- STRATEGIC RISK	1.954	0.051
AD_TRaP <- AUDIT REPORT	3.261	0.001
AE_Ayr <- AUDITOR KNOWLEGDE	4.068	0.000
AE_E <- AUDITOR KNOWLEGDE	2.460	0.014
AE_ReEn <- AUDITOR KNOWLEGDE	2.970	0.003
AS_ST <- AUDIT PLANNING	4.296	0.000
A_CA <- CORRECTIVE ACTION	36.151	0.000
EG_REG <- STRATEGIC RISK	1.986	0.048
NC_IA <- STRATEGIC RISK	2.215	0.027
NFP_INV <- AUDIT EFFECTIVENESS	4.468	0.000
TC_AQ <- AUDIT PLANNING	4.231	0.000
TC_TCA <- CORRECTIVE ACTION	11.851	0.000
TP_TpP <- AUDIT EFFORT	2.242	0.025
TR_TC <- AUDIT EFFORT	2.602	0.010
TR_TdPOP <- AUDIT EFFORT	2.634	0.009
TR_TdRES <- AUDIT EFFORT	2.840	0.005

The results show that the indicators that are not significant for the construct of the path model created could be removed or may be significant to other construct like NC_IA (Nonconformance form Internal Audits). This could describe AUD EFF (Audit Effort) directly instead indirectly through the STRAT RISK (Strategic Risk). In summary, the path coefficients that are above the t-value of 1.65 for an exploratory study and result that do not reject the null-hypotheses are summarized in Table 19.

Table 19

Path Coefficients significant for the model

Path Model Constructs	t-values	p-values
AUDIT EFFORT -> AUDIT REPORT	1.766	0.078
AUDIT REPORT -> AUDIT EFFECTIVENESS	1.703	0.089
AUDITOR KNOWLEGDE -> AUDIT PLANNING	3.561	0.000
CORRECTIVE ACTION -> MONITORING	13.432	0.000
MONITORING -> AUDIT EFFECTIVENESS	1.996	0.046
STRATEGIC RISK -> AUDIT EFFORT	2.928	0.004

- Step 4 Effect sizes, f^2

The previous steps evaluated the significance and relevance of the structural model relationships, including the level of R^2. This step examined the effects of omitting an exogenous construct from model. This assessment used the R^2 values of all endogenous constructs and evaluated the change in the R^2 of them when the exogenous construct was removed. The effect values are assessed where 0.02, 0.15, and 0.35, represent small, medium, and large effects of the exogenous latent variables as recommended by Hair et al. (2014). Table 20 summarizes the omitted exogenous latent variable and their effect on the endogenous latent variable.

Table 20

Effect (f2) of the exogenous latent variable on endogenous latent variable

Endogenous Latent Variable	Exogenous Latent Variable	R^2 included	R^2 excluded	$1-R^2$ included	f^2	f^2 effect of the exogenous latent variable
Audit Plan	Business Risk	0.677	0.677	0.323	0.000	small
Audit Plan	Oper Risk	0.677	0.659	0.323	0.056	small
Audit Plan	Auditor Knowledge	0.677	0.353	0.323	1.003	large
Audit Effort	Strategic Risk	0.388	0.158	0.612	0.376	large
Audit Effectiveness	Audit Report	0.630	0.564	0.37	0.178	medium
Audit Effectiveness	Corrective Action	0.630	0.641	0.37	-0.030	small
Audit Effectiveness	Monitoring	0.630	0.485	0.37	0.392	large

The formula to calculate the effect size is $f^2 = (R^2_{included} - R^2_{excluded}) / (1- R^2_{included})$. Audit Planning (Audit Plan) had small effect when Business Risk and Operational Risk were removed. This is aligned with the significance analysis performed using t-value (no significant evidence to reject the null-hypothesis). Also, Audit Effectiveness had small effect when Corrective Action was omitted from the model. The Corrective Action had an indirect effect (t value = 1.945) thru Monitoring that had a large effect on Audit Planning when is omitted. The model resulted that audit planning had no effect or relation in Audit Effectiveness (f^2 and t-values results). This variable was removed from the model with its exogenous variables. The final model was evaluated after the blindfolding and predictive relevance assessment.

- Step 5 Blindfolding and Predictive Relevance, Q2

It suggested by Hair et al. (2014) that the blindfolding and predictive relevance is used to predicts the data points of indicators in reflective measurement models of endogenous constructs. Blindfolding is an iterative process that repeats until each data point has been omitted. The audit planning (Audit Plan) was removed because t-value indicates there was no relation with audit effectiveness and PLS-SEM indicated that the sample size could be too small for the degree of freedom causing that the matrix of moments is not invertible and the *Q2* could not be calculated. After this, PLS-SEM results indicated that for the endogenous variables (Aud Eff, Aud Effort, Corr Act, and Monitoring) the modified path model predicted relevance for each particular construct. It was expected that the model did not predict relevance for Audit Rep and Aud Plan (removed from the model) because t-values and significance and, relevance assessments indicated that there is no relation with Aud Eff. The blindfolding and predictive relevance, Q2, results are in Appendix W.

4.9 Modified Model Assessment Summary

This investigation presented the methodology and analysis to show the variables that affects the effectiveness of an audit process in a medical device organization. The results obtained using the five steps of PLS-SEM structural model assessment procedure allow conclusions and recommendations to the organization researched by this study. It is necessary to remark that this study found evidence supporting that the auditor knowledge influences the audit plan, that the audit effort influences the audit report, the audit report influences the audit effectiveness, corrective actions influence the monitoring process, and that the monitoring influences the audit effectiveness. This supports the principal

objective of this investigation and corroborates which factors influence or not audit effectiveness. The final model is discussed in the next section prior to summarize the results, arrive to conclusions and provide the recommendations.

4.10 Final Model PLS-SEM Analysis

The final model includes the relations that are significant for this study. The path and relations results were analyzed. Also, the PLS-SEM results demonstrated that the relations, the paths coefficient, and other tests results corroborated the hypothesis discussed in previous section. Figure 20 and 21 show the corroborated relations between the studied variables.

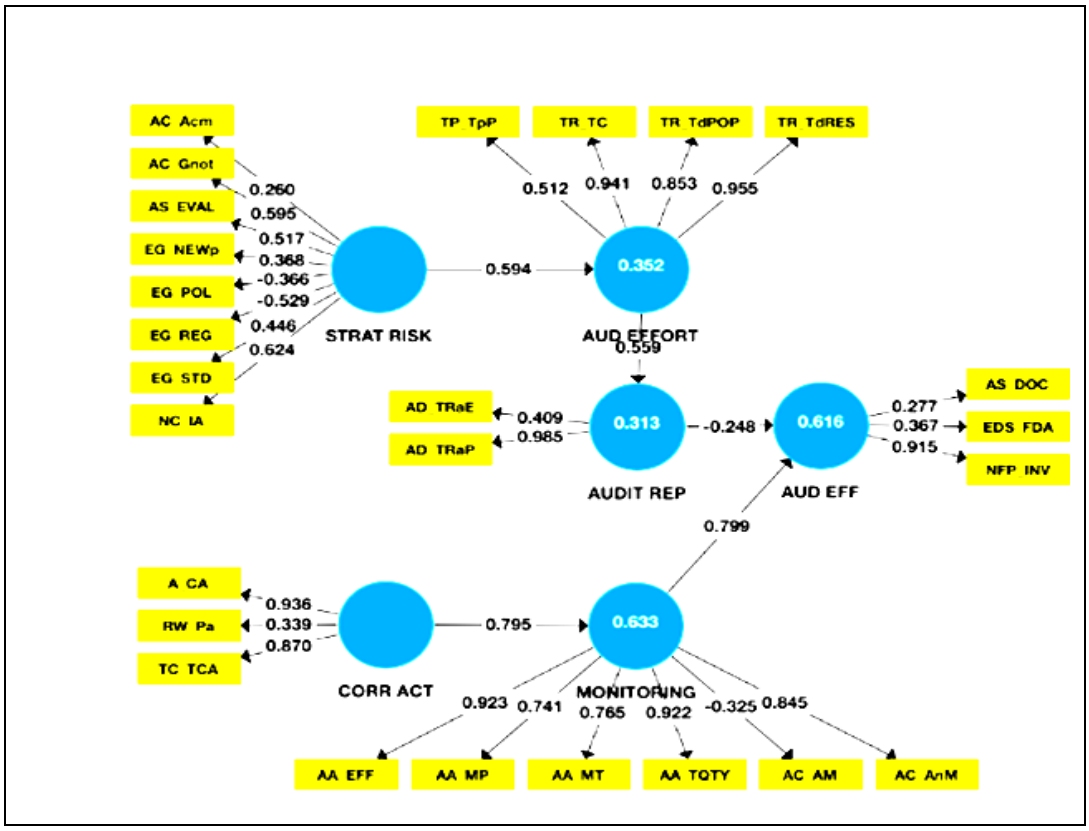


Figure 20. Final Path Modeling: Audit Effectiveness.

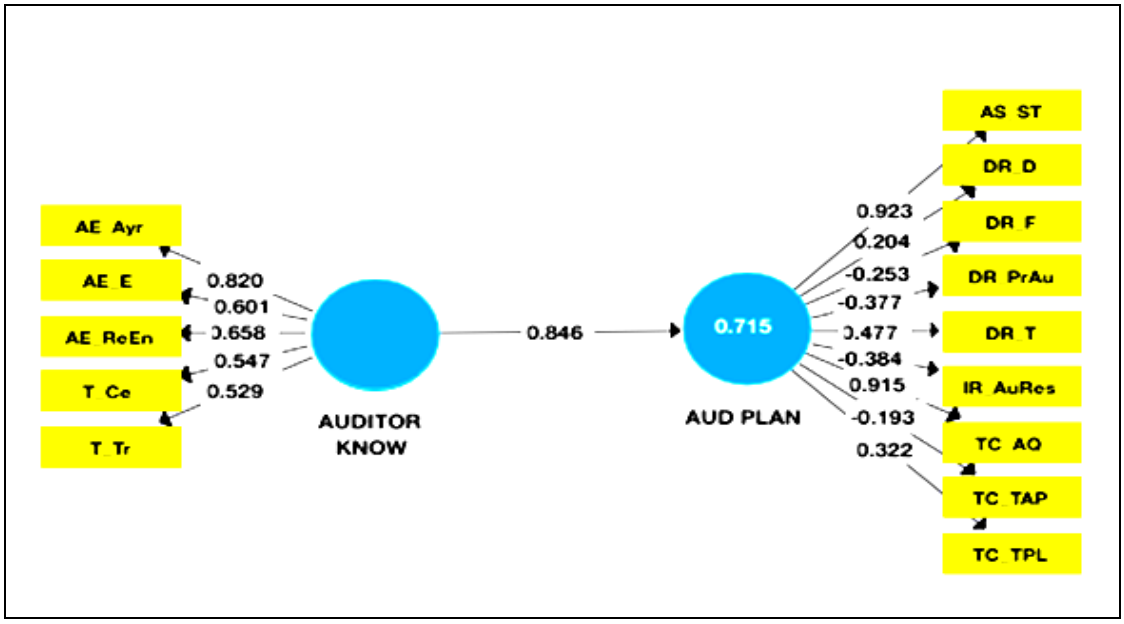


Figure 21. Final Path Modeling: Audit Planning and Auditor Knowledge.

The audit planning is not shown in the same figure since the results indicated that there is not significant evidence to reject the null-hypothesis (there is no relation between audit planning and audit effectiveness or audit effort). This could be possible since the audit planning data used includes internal, external, and self-inspections audits. The planning of these audits are different, for example, the requirements source could be receive from client complaint's, certifications expired, management requests, increase in a defect, trends, among others. The planning will be different depends on the audit type and the requirements. This study used internal, external, and self-inspection as equivalent and did not make any difference. These relationships could be study in future research and determine if they have any individual relationship in the audit planning and audit effectiveness or audit effort.

Figure 20 shows that audit report and monitoring explained 62% of audit effectiveness. The final model analysis results are from Appendix U to Appendix BB.

The normality test was performed again to record the results of the variables in the final model. The results were similar to previous result for normality test. The variables had non-normal distribution. The composite reliability and Cronbach's alpha are in Appendix U. The results for these tests were greater than 0.50, except for strategic risk (0.373) and audit planning (0.290). The indicators convergent validity had similar results as the modified path model. The results are in Appendix Y and Appendix AA. The t-values for the latent variables are in Appendix Z. The results show that all variables are above 1.65. The Corrective Actions variable has an indirect effects to Audit Effectiveness with 7.174 (t-value) through the Monitoring variable. No other variable has an indirect effect to Audit Effectiveness.

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

In previous chapters, the purpose of the study was established based on the literature review, different data sources, and experience of the researcher. Different research approaches related to the topic of interest were assessed. There was limited literature available to formulate the investigation problem and objectives related to the quality internal audits. Most of the literature explained the audit process from the accounting perspective. However, from the literature review, it was possible to detail the problem, the framework, and the opportunities areas related to the quality internal audit and how the researchers explored the variables impacting the audit process.

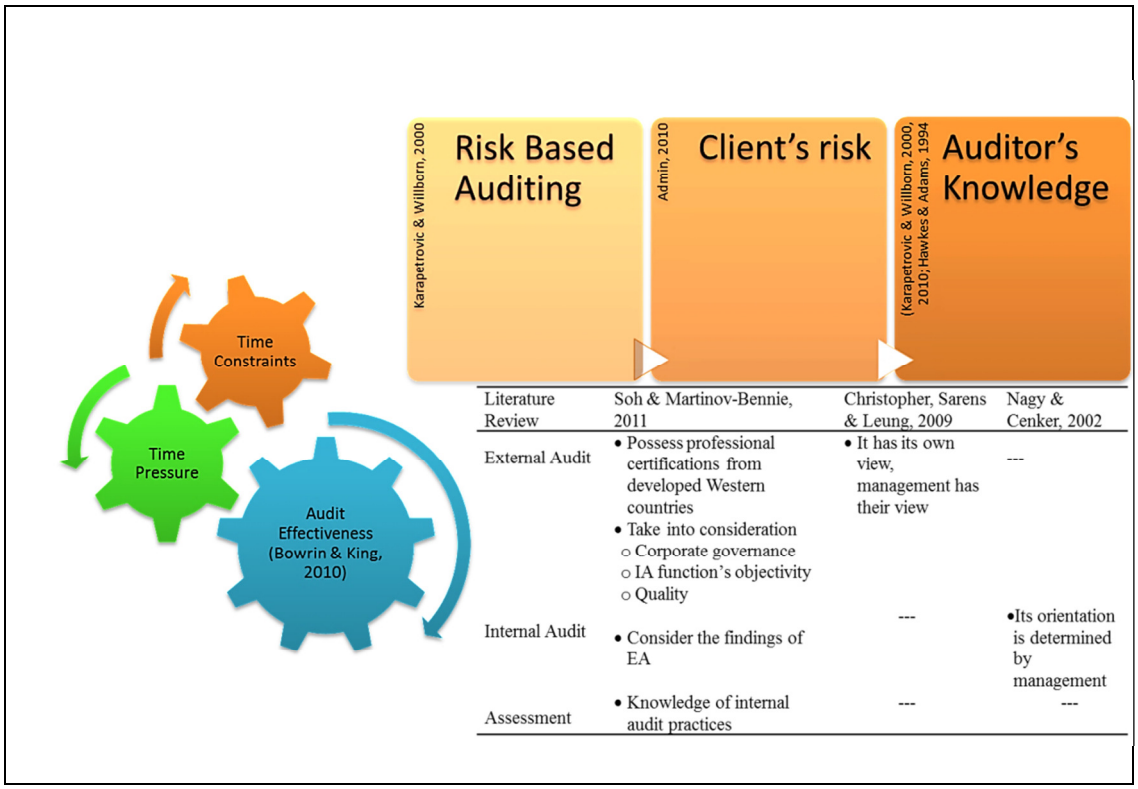
The investigation also used the open systems in management as a source of the framework established. The open systems receive feedback and are sensitive to its environment. Robbins (1997) indicated that the organization with open systems take into consideration internal and external process for decision making. In the open systems, the quantitative approach is use to improve the decision making process. Meanwhile, the organizations with TQM (Total Quality Management) program have a philosophy for continuous improvement and responding to customer needs and expectations (Robbins, 1997). The organizations with open systems take into consideration internal and external processes for decision making using the quantitative approach in an organization with a TQM program. One of the tools in the TQM program is the PDCA cycle (Plan-Do-Check-Act Cycle) and it is recommended by the ISO (International Standard Organization) to use among the organization since it takes into consideration external

elements and has a continuous feedback loop (Gupta, 2006). Each of the elements of PDCA cycle was reviewed through the literature review and Check is the element into consideration. The element check verifies the current process against the requirement (Gupta, 2006) and check the quality assurance system (Gitlow, 1995). The interest of the check element is that the audit process is part of the quality system approach and is the check element in a quality system organization.

The purpose of this investigation was to explore and identify factors that influence the audit's effectiveness in a medical device organization. The literature review established that there should be a linear relationship between the results of external audits (i.e. FDA audit results) and internal audits (Karapetrovic & Willborn, 2000 and Amin, 2011). Other elements were established like planning, execution, communication, and reporting (Karapetrovic & Willborn, 2000 and Hernandez, 2010). In addition, other authors include fix-it or corrective action and monitoring as part of the audit process (Agbejule & Jokipii, 2009). Most of the information found indicates that the audit process ended with the reporting element and that the effectiveness is measured as compliance to schedule (reporting element) (Karapetrovic & Willborn, 2000). The factors found to describe the elements of the audit process were from management, risk management, quality, finance and accounting areas. Those different disciplines were used since the audit process is generally used in all businesses type, even though the area of interest was the quality audits in the medical devices companies. The finance and accounting areas were explored further to establish the process and the factors of interests since there was few literature reviews to assess the quality internal audit process. In the

medical devices area, there was not found literature related to the quality audit process, except by the external sources of the organization (e.g. ISO).

The special interest in this investigation is the effectiveness of the audit process. The effectiveness in the audit process was defined similar to other elements and factors from literature of different disciplines. Nevertheless, the factors and elements were found in the literature to justify the proposed model studied in this investigation. The Figure 22 establishes some of the basis used for this study.



Literature Review	Soh & Martinov-Bennie, 2011	Christopher, Sarens & Leung, 2009	Nagy & Cenker, 2002
External Audit	• Possess professional certifications from developed Western countries • Take into consideration o Corporate governance o IA function's objectivity o Quality	• It has its own view, management has their view	---
Internal Audit	• Consider the findings of EA	---	•Its orientation is determined by management
Assessment	• Knowledge of internal audit practices	---	---

Figure 22. Literature Review.

The importance of this study is that the risk was one of the variables studied in the investigation since it was identified as a gap in terms of audit effectiveness according to Glover et al., 2000; Wright and Bedard, 2000; and Johnstone and Bedard, 2001. Other

variables not found in the literature, but taken into consideration were summarized in Table 21.

Table 21

Variables included in the model found in the literature review

Variables	Literature Review
Audit effectiveness, Time Pressure, Time Constraints	Bowrin and King's paper (2010) Hughes, J. S., 1977
Audit plan time against of time for issuing the audit reports	Soh and Maritnov-Bennie (2011)
Audit timing execution	Hughes (1977)
Audit sampling as part of the audit planning	Elder, Akresh, Higgs, and Liljegren (2013)

In addition, the investigation added two additional elements (Corrective Action and Monitoring) since the literature described them separately. In general, this investigation found variables studied in different disciplines that influence the audit effectiveness and incorporate them in a model. This research used auditors as experts from a medical device organization to confirm the reliability and validity of the questionnaire. Data from 50 audits, executed from 2013 to 2016 was used to analyze the model. Based on that, the researcher addressed the research questions related to the audit's effectiveness. This investigation found variables that can predict the audit effectiveness in a medical device organization and variables that did not contribute. In addition, it examined the variables to be deleted in the proposed model for the scope of the investigation.

The principal objective of this investigation was to measure the audit planning, audit effort, audit report, corrective action, monitoring and risk (business, operational, and strategic), and auditor's knowledge in relation to the effectiveness of an audit in a

medical device organization. A questionnaire was created and tested based on the model proposed with each variable defined. The model was created using the audit process and the risk based approach. The investigation reached the objective and measured each of the variables described with data from a medical device organization. The following sections in this Chapter discuss the results and establish the conclusions, the study contributions and limitations found during the process. Finally, the recommendations are discussed.

5.2 Discussion of the Results

The results were obtained using a questionnaire as an instrument previously validated with experts in the audit process field. The experts were from a medical device organization and 33 questionnaires were received. The data from this questionnaire was to validate the instrument. Once this was completed, the instrument was used with a sampling of 50 audits from the same medical device organization.

The data was assessed for missing values, constant values, and other factors as required in the PLS-SEM procedure. The studied model was examined using PLS-SEM for each variable and their paths. The data was analyzed for reliability and validity and some of the indicators to improve the reliability and validity of the measurements and minimize errors. The model was modified after removing those variables. The results for reliability and validity were acceptable after this modification.

1. Modified Path Model

   The study had 13 hypotheses and all of them were tested. The t-values (two-tails) were examined for p-value of 0.05 ($t > 1.96$ per (Hair et al. (2014)) and depending on the construct and information available, since this

research is exploratory, the significance level of 10% was used. The first hypothesis was related to audit planning and audit effort and their relation. There was not significant evidence to reject the null-hypothesis. This means that there is no relation between audit planning and audit effort. Hughes (1977) indicated that audit planning affects the amount of effort needed to achieve a successful audit. An increase in audit planning hours should result in more than equal decrease in verification hours, so the total audit execution hours' decrease. The study reflected that there is no significance evidence to reject the null-hypotheses (t-value equals 1.536) meaning that there is a no relation between audit planning and the audit effort.

The next hypothesis was related to audit effort and audit report and their relation. The results showed that there is significant evidence to reject the null-hypothesis (t = 1.766). This means that there is relation between audit effort and audit report. In the literature, there is no evidence that these two variables influence one over the other, even though the same authors Asare, Davidson & Gramlin (2008), defined both of them. Audit effort for example, was defined as total budgeted hours, total hours (time), and audit report as completion of audits and includes the length of times for issuance a report (time). The researcher studied these two variables since in the literature shows linearity in the process (audit effort and then report) and it was understood that one process could influence the other in terms of time. Also, the researcher has noticed this relation, in the medical device organization,

where time constrains or timeliness during execution could affect (positively or not) the reporting stage.

The relation between audit report and corrective action was tested. This hypothesis has no significant evidence to reject the null-hypothesis (t = 1.176). This means that there is no relation between audit report and corrective action. In the literature, there is no evidence that these two variables influence one over the other. The reason is that the variable for corrective action was added as part of this study to explore the influence over the other variables in the path model. However, the results reflected that there is no significant evidence to reject the null-hypothesis.

Similar to one of the previous variables, corrective action and monitoring were not part of the literature model for the audit effectiveness or audit process. They were defined using the literature but any research was found measuring their relation. In this case, the results indicate that there is significant evidence to reject the null-hypothesis. This means that there is a relation between corrective actions and monitoring (t-value equals 13.432). This means that both variables need to be considered during the audit process and effectiveness. However, this depends on the industry and other variables that may be not take into consideration as part of the model, since only one type of organization was chosen as part of the study.

The variables audit planning and audit effectiveness was assessed for existent relation. There was not significant evidence to reject the null-hypothesis (t = 0.077). This means that there is not a relation between audit

planning and audit effectiveness. In the literature, Hughes (1977) establishes that exist an effect of audit planning on audit effectiveness. The effectiveness constant is the effect of audit planning on audit efficiency. From the study, the indirect effects in each variable were calculated using SmartPLS. The results indicate that the t-value for the relation between audit effort and audit effectiveness is 0.530. This means that the relation with indirect effects (that includes the audit planning) does not exist in this particular study. The results for the indirect effects are in Appendix S. This confirms that, contrary to Hughes (1977) observations, there is no a relation between these variables.

The relation between audit report and audit effectiveness was also studied. The results from Chapter 4 show that there is significant evidence to reject the null-hypothesis, revealing that no relation exists between these variables. The t-value was 1.703. However, this results and analysis were made for a significance level of 0.05 with a t-value > 1.96. Hair et al. (2014), establishes that for exploratory investigations, the significance level is 0.10 with t-value > 1.65. This could explain the evidence from the literature stated by Soh, D. S., & Martinov-Bennie, N. (2001) that Internal Audit Function effectiveness is the completion of audits in comparison to an IAF plan, and the length of time for issuing IAF reports. This study take into consideration this relation, since for a significance level of 10% (t-value > 1.65), R2 equals 0.50 and 5 arrows pointing at a construct for a statistical power of 80%, there is evidence to reject the null-hypothesis for the relation between audit report and audit effectiveness.

The next relation investigated was the one between corrective action and audit effectiveness. The results showed that there is not significance evidence to reject the null-hypothesis (t-value equals 0.0423). This relation was exploratory, since the literature did not establish this relation or if, at least, an influence to audit effectiveness exist. However, the indirect effects in the Appendix S indicated that there is a relation between corrective action and audit effectiveness with t-value equals to 1.945. This need to be taken into consideration since this variable was included for exploratory purpose and evidence from the literature was not found. The following results showed that exist a relation between monitoring and audit effectiveness. Similar as corrective action, the literature did not establish a relation between monitoring and audit effectiveness. Nevertheless, this relation was of particular interest by the researcher since in the literature Hernandez (2010), Karapetrovic and Willborn (2000), and Soh and Mantirnov-Bennie (2011) indicated that the corrective action and monitoring elements are not included as part of the audit process. The null-hypothesis was rejected since the t-value was 3.253 for monitoring and audit effectiveness.

The risks management approach was one of the opportunity areas to study based on the literature. Karapetrovic and Willborn (2000) indicated that research and development of an audit risk model for auditing would be a worthy exercise. The risk variables selected were defined through the literature using the studies by Sahnoun et al. (2009). Business risk and operational risk were verified for relation with audit planning. The literature

suggested that professional standards require that during the planning phase of the engagement, the auditor assess different type of risks in addition to making a preliminary judgment of materiality to select an audit strategy (Davidson & Gist, 1996). The relation with strategic risk was established with audit effort. The relation between business risk and audit planning was tested. The results revealed that there is not significant evidence to reject the null-hypothesis. This means that there is no a relation between business risk and audit planning (t-value 0.014). The same occurred with operational risk and audit planning, the null-hypothesis was not rejected since there was not significant evidence (t value equals to 0.342). However, for strategic risk the result indicated that the null-hypothesis can be rejected since the t-value is 2.928. Strategic risk has a relation with audit effort based on these results.

Finally, but not less important, the relation between auditor's knowledge and audit planning was verified. The results demonstrated that there is sufficient evidence to reject the null-hypothesis (t-value equals 3.561). Davidson and Gist (1996) indicated that the auditor assess risks and review the material to be assessed during the planning. This is related to the result that the auditor's knowledge has a relation with the audit planning.

2. Final Path Model

The study resulted in a model for audit effectiveness with no relation between audit planning and auditor's knowledge. This model was retested using PLS-SEM methodology to confirm the results found in the modified model. Also, audit planning and auditor's knowledge was retested. The other

variables were not considered based on the hypothesis results discussed in Chapter 4. All results were similar for the final path model and the modified one (previously discussed) and the SmartPLS outputs are in the Appendices, referenced in the following results analysis. The following sections explained the endogenous and exogenous variables with the indicators, and their relations implications according to the final model.

3. Audit Planning and Auditor's Knowledge

The audit planning resulted out of the model because the study cannot corroborate the relation between the audit planning and audit effectiveness (Figure 21). This could occur since this study used the different type of audit's data (e.g. external, internal, self-inspection audits, etc.). The differences between these audits types were out of the scope for this study but it may influence in the relations result for audit planning and audit effectiveness. These audits depend on different external sources to start the planning stage. Those sources could be standards certification expired, client's complaints, procedural or governance requirements, and product issues, among others. Nevertheless, the study demonstrated a relation between the strategic risk and the audit planning.

The auditor' knowledge was defined as the auditor experience (e.g. audits lead, experience in a regulated environment, and experience in audits) and training (e.g. certifications and auditor's training). All indicators had a moderate to a strong relationship with auditor's knowledge. The auditor's training and certifications influenced the audit planning in terms of audit

sampling, detection risks, inherent risks, and time constraints. The audit sampling techniques, for example, could be influenced by the auditor's trainings, certifications or experience that he/she had. PLS-SEM results indicated that the audit experience has a positive result (0.658). This resulted in an influence to increase the use of sampling techniques (positive signs) by the auditor.

Wedemeyer, P. D. (2010) explained that the auditors gain experience and rely in earlier experience in making judgments but competent professionals took continue education and be informed if any changes occurred. The model explained that the auditor's experience and trainings affected the audit planning in the used of sampling techniques, tools, documents to assess (e.g. previous audits, defects), and time to prepare and approve the plan. This relationship could vary in terms of the requirement by the organizations and external requirements. These two variables were not part of the objectives of this study but it could take in consideration in other future investigations.

In the other hand, the detection and inherent risks were defined as forum quantities, year of previous audit to take in consideration, previous audit results, and the time to approve the plan decreased the audit plan but the influence is weak for some of them. These indicators like the time to approve the plan is negative for the audit planning, since if the audit is not approved, it could not be taken into consideration for the planning. Other indicator that is particular important in the audit planning is the audit quantity for the plan

development. This corroborates if in the audit planning is considered high quantity of previous audits, audit planning will increase, too. In terms of audit planning and the auditor's knowledge relation corroborates Davidson and Gist (1996) that explained that when the auditors assess risks and reviews the material to be assessed is influenced by the experience and training during the planning stage.

4. Audit Strategy and Audit Effort

The audit strategy was defined as acceptance criteria results (e.g. met or not met) established by standards, procedures or other requirements. Also it was defined as document assessed quantity and external governance that involved new products changes, internal audit findings, changes in policies, regulations, and standards. The audit strategy used these elements to influence the audit effort (execution) that will take during the audit process. In terms of audit effort, the time constrains indicator was used to define the execution process (e.g. time to prepare the plan, time to report, time to communicate (management and population). The results showed that the internal audit findings from previous audits used as part of the strategic risk influences in how to proceed in the audit effort (execution). The study showed that the time constrains in audit effort could affect the execution of the plan, report, and communication by the changes in standards, changes in policies and other requirements. Those indicators are no controlled by the auditors and it is a constraint during this process. This corroborated Odoyo et al. (2014) who indicated that the risk may arise from regulatory, political

impediments or technological innovation. One indicator that could influence the time to complete the audit effort is the documents to evaluate during the process. The auditor could increase the time to report and communicate if they are not received the documentation on time or is not familiar with the process. This result is in accordance with Asare et al. (2008) who indicated that the auditor may spend more hours in a particular area and fewer in other audit area affecting the audit effort.

5. Audit Effort and Audit Report

The audit effort was described during the relationship with strategic risk in terms of time constraints. The audit effort was defined for this study in terms of audit delay for report after the plan and after the execution. The results showed that the report approval is delayed when the audit report after the execution completion increased since there is a positive relation between the latent variables. This was defined by Soh and Martinov-Bennie (2001) who explained that the report timeliness is the length of time of issuing the audit reports.

6. Corrective Action and Monitoring

The corrective action is defined as the actions created to correct the findings documented in the report. Also, the resource workload and the time constraints to complete the action tasks are part of the corrective action. The results showed that the time constrains influence the monitoring process that could result in an increase in monitoring period or frequency. Other indicators like the corrective action and resource workload influence in combination

with the time constrains the monitoring assessment activities including the tasks, period, frequency, and results (acceptance criteria met or not).

7. Audit Effectiveness, Audit Report, and Monitoring

The audit effectiveness was defined as external data sources that include external findings, FDA observations and investigations related to procedure not follow. Monitoring and audit report were described previously and they were defined as audit delays and assessment activities, respectively. The audit is effectiveness is degree of correspondence between procedures, which should have been followed (Hughes, 1977). The audit is effective if in the organization there are procedure not follow and the auditor detected these events. In the study resulted that the not following procedure indicator (0.915) and indicator is strong enough to describe the dependent variable (audit effectiveness). This result is explained in the literature where Hughes (1977) pointed out that the audit quality encompasses audit effectiveness when the achievement of a desired level of assurance that the material client errors have been detected. Meanwhile, the other indicators are not that strong like FDA observation and external finding documentation but support the definition of audit effectiveness in the literature. It was expected that those indicators (external findings and FDA observations) decrease the audit effectiveness and the result was expected as negative. The model described that the audit report when increase the audit delay decreased the audit effectiveness because there is a negative sign in the path -0.248). This relationship had a t-value of 2.067 in the final model analysis with a

significance level of 0.05 (Appendix Z). In the other hand, when the effectiveness assessment activities exists and the acceptance criteria used to assess the quality controls during the action activities are presented in monitoring increased the audit effectiveness. The audit acceptance criteria met decreased the monitoring when there were audits that found findings against the acceptance criteria. Nevertheless, the areas that did not met the acceptance criteria in previous audit increased the monitoring period to assess the controls implemented in the current audits.

5.3 Conclusions

The final path model resulted in a reflective measurement model where the measures represent the effects of an underlying construct (Hair et al., 2014). The reflective indicators were a sample of all the possible items available within the conceptual of the construct. This means other items could be available and need to explore in future investigations. The indicators studied were related to the constructs for the purpose of this investigation's objective, which was exploration of audit process and risk management variables relations. The investigation reveals the relations with audit effectiveness and audit planning in two separate paths. These two constructs did not correlate based on the results found. Nevertheless, other considerations could be increased the sampling size and study additional indicators to found low relations for the exogenous latent variables related to audit planning and audit effort and endogenous latent variables related to audit effectiveness.

The endogenous latent variables that describe or influences audit effectiveness in quality audit process were audit report and monitoring with an indirect relation with the

exogenous latent variable corrective action. The relation is indirect since corrective action is an exogenous latent variable and influences monitoring, that receives its input and translate it to audit effectiveness. Similar occurred with audit effort that is influences audit report, where the strategic risks is an exogenous latent construct that use the audit effort and audit report to translate its inputs into an output audit effectiveness. These are the cases that could be studied with an increase in sampling to found those lower relations that can describe the endogenous variables.

The investigation verified that the audit planning as endogenous variable receive the inputs from auditor's knowledge. The study results corroborates how this relation affects the audit planning in terms of detection risks, tools used, time constraints in plan development and approval, previous audits results, among other indicators based on the auditor's experience and training. The audit planning is one of the endogenous that with an increased in sampling size could corroborate the relation with audit effectiveness and audit effort according to the literature and the original model proposed in this study. Other consideration is to verify the audit type's relation and differences to influences the planning in a quality audit process.

5.4 Study Contributions

This exploratory research verified different variables relationships and how they affect the effectiveness result in an audit process for a medical device organization. The framework was established from literature review using the open systems as a baseline through the quality system approach that integrate the PDCA cycle, specifically the check element that use the audit process and the risk based approach. The audit and the risk based approach were found important techniques in the verification of the current state of

an organization against standards, regulations and requirements. The research found variables that correlate and some that did not correlate with the audit effectiveness. This research made the following contributions:

1. During the study a model was created based on the established framework to explore the relationships between existing and new variables impacting the audit effectiveness.
2. This model was used to create the questionnaire to measure known components (e.g. planning, audit effort, and report) and new components (corrective action, monitoring, risk management, and auditor' knowledge) that according to literature and experience, should influence the audit effectiveness result. It was verified which of the components influence the audit effectiveness and which were not based on an established confidence level.
3. The integration of the corrective action in the audit process indicated that there is an indirect (t-value = 7.174 in the final path model) influence with the audit effectiveness. However, the direct relation was not confirmed. This was one of the objectives in this research.
4. In addition, the monitoring was integrated in the audit process indicating that there is a direct (t-value = 9.380 in the final path model) influence with the audit effectiveness. This was one of the objectives to be explored in this research.
5. The study verified the auditor's knowledge and the relation with the audit planning and demonstrated that there is a relation between them (t-value = 3.459 in the final path model).

6. In term of risks, the investigation results indicated that strategy risk correlate with audit effort (t-value = 3.475 in the final path model).
7. Audit effort influences audit report which influences the audit effectiveness. This path is very interesting since the stage of execution and the stage of reporting could affect the audit effectiveness results in terms of time constraints, resource workload, actions, and the time to prepare and approve the report.

5.5 Study Limitations

The researched was focus on quality audits in medical devices manufacturing environment. Audits related to other environments like financial, accounting, among others, were out of the scope of this research. However, these areas were evaluated during the literature review. It was noticed during the literature review that this area has scarce studies, specifically the effectiveness of the audit process. The definition about effectiveness that is compliance to schedule was used and proposed in other environments during the literature review. This was not the approach of this investigation. For this reason, it was difficult to operationalize the audit process and risk management variables. At the end, all the constructs were based on existing literature review and were operationalized.

The researcher acknowledges that there are other factors that could influence the audit effectiveness results in other types of organizations. Other the risks factors affecting the relation between the audit planning and audit effort need to be taken into consideration. The scope of the study was a medical device organization and no other type of organization was explored. The medical device organization was selected since it had many of audits performed in a year and the effectiveness of them is constantly a

challenge. For this reason, not all the outcomes and findings of this investigation may apply to other type of organizations or components in the audit process. Other limitation using one organization was the sampling size even though PLS-SEM methodology support the use of small sampling size and increase in this could found low relations in endogenous variables.

5.6 Recommendations

The results and findings in this investigation suggest the following recommendations to managers in organizations and universities:

1. The managers need to be aware of the factors that impact effectiveness in the audit process when planning strategies related to actions and trainings. It is recommended to take special attention to the training departments and increase the availability of other training tools to the auditors in the organization.
2. Other recommendations are related to check the strategic risk during execution stage and audit reporting. These two stages in the audit process could influence the audit effectiveness results in terms of time constrains, criteria used, requirements (internal and external), and other previous audits.
3. This study revealed two factors that correlate with audit effectiveness. The corrective action and monitoring stages showed an influence to the dependent variable and need to be considered as two elements in the management decisions. The oversight of corrective actions during the decisions taken could be an issue during an audit or time constraints. Time constrains is one of the indicators that influence the actions and the monitoring activities. This affects directly the

monitoring process and indirectly the audit effectiveness and needs to be taken into consideration as part of the objectives of the quality area.

4. In addition, an oversight to factors related to the monitoring activities that influence the audit effectiveness, could be taken in consideration when establishing the audit strategy or the actions to correct the audit findings.
5. It is recommended to the universities to include courses or seminars related to the quality audit process and its effectiveness. A 63% of the experts that access the questionnaire had at least bachelor degrees and 59% has 4 years or less of experience. This could be an opportunity to bring courses and seminars to the students in preparation to their work environment. The different types of audits (e.g. quality, compliance and accountant) will continue to increase in the organizations to assure that the organization meet the standards, regulations and other requirement as established in the literature (Gupta, 2006).
6. It is recommended to review the audit process and how the objectives and tactics goal in an organization support the effectiveness of the audit, specifically the assessments, self-inspections and other strategies tools that are performed since they could influence the audit effectiveness results.

5.7 Future Investigations

This investigation developed a framework based on the audit process and risk management. Also, it included the risk factors, auditor's knowledge and two new variables (corrective action and monitoring). There are standards that indicate the expectations from regulatory bodies and guide the organization in the audit process; however, limited current research evidence exists on the factors that influence the audit

process effectiveness. Some questions arose during the study that were not addressed and can be used for further research:

1. Additional studies could evaluate different risk factors to verify the relationship between the audit planning and audit effectiveness. This could not be found in this study, but there is literature review that indicates that suggest an important relationship.
2. The effect of corrective actions in audit effectiveness needs additional research since this study show that indirectly they have an influence of the audit effectiveness. Additional, research may need to look into other factors in business management and compliance areas to include other factors that could verify this relationship.
3. The audit sampling was one of the factors identified in the literature review that may influence the audit planning but little information was found that corroborate the relationships established in this study. The use of non-statistical and statistical sampling techniques to determine the audit sampling by the auditor could affect the audit effectiveness results.
4. The literature review indicated that the audit planning affects the amount of effort needed to achieve a successful audit. In addition, if the time of the planning hours increases there should be decreased in the verification hours in the audit effort. There was no evidence that could corroborate this in the study and further research is necessary.

5. This study could be expanded to other medical device organizations or manufacturing sectors that have open systems with quality management systems and audit programs in place.
6. The audit effectiveness could be evaluated in other similar programs and the research could take into consideration other factors in the audit process. Other line of research could incorporate other elements of the TQM program (e.g. customer-focused, strategic and systematic approach, process-centered, among others) as part of the model and study the effects of them in audit process.
7. Other consideration for future investigation is to define the audit types (e.g. internal, external and self-inspections) as a variable and identify the effects in audit planning and audit effectiveness. This was out of the scope in this investigation.
8. Future research may consider investigating similar issues in other regulatory contexts and national settings.
9. Finally, this study can be replicated with a larger sample size so the researcher could detect smaller R^2 values (less than 0.50) in any of the endogenous constructs in the structural model.

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APPENDIX A

INFORMATIVE LETTER

Sistema Universitario Ana G. Méndez
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Información para participar en un estudio/investigación
Carta Informativa

Desarrollo de un modelo para medir la efectividad del proceso de auditorías en una empresa de manufactura en el área de dispositivos médicos

Descripción del estudio/investigación y tu participación en el mismo

La investigadora principal, Liz B. Machado Matos, en conjunto con su mentor, el Dr. Victor Mojica, le invita a formar parte de un estudio de investigación sobre el tema de la efectividad de las auditorías en una industria de dispositivos médicos. El propósito de esta investigación es identificar un modelo para medir la efectividad de auditorías en este sector de manufactura. El estudio analizará varias variables para diseñar un modelo que prediga la efectividad en las auditorías.

La participación en esta investigación consiste en llenar un cuestionario sobre la efectividad de la auditorías. El mismo contiene 30 preguntas. Los participantes elegirán la contestación que mejor describa su percepción sobre el tema de estudio. Su participación validará el instrumento que será utilizado por la invesigadora principal para obtener datos de una compañía de dispositivos médicos. Durante el proceso usted recibirá un correo electrónico por la investigadora principal con un enlace ("link") que lo llevará a la página web (SurveyMonkey) que contiene el cuestionario. El mismo será auto administrado para no ejercer ningún tipo de presión en los participantes. En adición, usted obtendrá un "password" para poder acceder al mismo y así controlar el acceso al instrumento. Una vez haya completado el cuestionario los resultados serán almacenados en la página "web" SurveyMonkey.

Le tomará aproximadamente 30 a 45 minutos participar de esta investigación.

Riesgos e Incomodidad

Esta investigación no conlleva ningún riesgo para usted o su organización. Por el contrario, su organización podra beneficiarse de los resultados, en la medida en que obtendrá y podrá aplicar prácticas que contribuyan al mejoramiento de la organización.

Posibles Beneficios

Los resultados de esta investigación no conllevan ningún beneficio personal, pero serán de beneficio para la organización que usted representa. Los resultados de efectividad de las auditorías permitirán aportar a la literatura tener un modelo que ayude a predecir la efectividad de la auditoría en una organización de dispositivos médicos. Este es un modelo el cual evaluará varias variables y sus relaciones no lineares y su efecto en la efectividad de las auditorías.

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Incentivos

No hay incentivos para participar en esta investigación.

Protección de la Privacidad y Confidencialidad

Toda información relacionada a la identidad del participante será manejada de manera privada y confidencial y será protegida en todo momento. Se utilizará el sitio "web" MonkeySurvey para suministrar el cuestionario y recopilar los resultados. Además, se utilizará una lista de distribución existente en la compañía a estudiar, que agrupa a empleados de tres facilidades. La lista de distribución se compone como "Lista de Distribución_Nombre de la Facilidad_Grupo de Usuarios". El IP addresss no será colectado y una vez entrado al website la colección de las respuestas será entre el participante y el SurveyMonkey. Un "password" será añadido y enviado a cada participante para que sólo los que reciban el correo electrónico puedan participar. Así otras personas que puedan encontrar el estudio (cuestionario) no participen, ya que el alcance es sólo una compañía con facilidades en Puerto Rico. Toda información relacionada a la identidad del participante será manejada de manera privada y confidencial y será protegida en todo momento. Los resultados serán recopilados entre el participante y Survey Monkey. La investigadora ni su mentor tendrán alguna interacción con el participante durante el proceso. Sólo el investigador enviará el enlace ("link") utilizando el correo electrónico ("email") a una lista de distribución utilizando el campo "BCC". El campo "BCC" no permite que los que reciben el correo electrónico sepan quien recibió la invitación. El enlace ("link") será: https://www.surveymonkey.com/r/auditeffective. Bajo ninguna circunstancia se compartirá información del participante con terceros. Los datos o documentos recopilados se guardarán en un archivo en el lugar de residencia de la investigadora principal. Los mismos serán almacenados por un periodo de cinco (5) años y estarán bajo la tutela del investigador principal, Liz B. Machado Matos. Solamente la investigadora principal y su mentor tendrán acceso a los datos. Después de los 5 años los documentos se destruirán, triturarán y botarán.

Decisión sobre su participación en este estudio

Su participación en este estudio es totalmente voluntaria. Usted tiene todo el derecho de decidir participar o no de este estudio. Si usted decide participar en este estudio tiene el derecho de retirarse en cualquier momento sin penalidad alguna.

Información contacto

Si usted tiene alguna duda o inquietud correspondiente a este estudio de investigación o si surge alguna situación durante el periodo de estudio, por favor contacte a Liz B. Machado Matos al 787-216-3622 o al correo electrónico machal0502@gmail.com. Si usted tiene preguntas sobre sus derechos como sujeto de investigación por favor comuníquese con la Oficina de Cumplimiento en la Investigación del SUAGM al 787-751-3120 o compliance@suagm.edu.

APPENDIX B

INSTRUMENT: QUESTIONNAIRE: DEVELOPING A MODEL TO MEASURE AUDIT EFFECTIVENESS IN A MEDICAL DEVICE ORGANIZATION

Investigation Title: Developing a model to measure audit effectiveness in a medical device organization
This questionnaire consists of two parts with a total of 30 questions. The identity of the person that answers this survey is anonymous.

I. General Information

In this section you will select the best answer with the information that describes you.

1. What is your gender? (Optional)
☐ Feminine ☐ Men

2. What is your age? Select the range based on the rounded to the nearest year. (Optional)
☐ 25-34 years
☐ 35-44 years
☐ 45-54 years
☐ 55-64 years
☐ 65 or older

3. Education. What is the highest degree or level of school you have completed?
☐ High school graduate, diploma or the equivalent
☐ Associate Degree
☐ Bachelor Degree
☐ Master Degree
☐ Doctorate Degree

4. How many years of auditor's experience do you have?
☐ 0-4 years ☐ 5-9 years ☐ 10-14 years ☐ 15-19 years
☐ 20 years or more

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II. **The following questions include variables that describe the audit effectiveness: Audit Planning**

This section consists of variables and questions related to Audit Planning.

The questions to evaluate could describe each variable. You will select the importance or relevance of each question. Preceding each question, the variables are defined to help you answer this questionnaire

5. **Detection risk is used as a basis for audit planning decisions on the nature, timing, and extent of audit procedures.**

Based on the definition above, how well the following questions describe detection risk?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many years of previous audits were assessed to prepare the audit plan?					
How many tools exist? Tools are documents with guidelines or a requirements list from a procedure. Some examples are checklist, report, guidelines, tables, lists, and templates.					
In how many meetings the issues (events that may affect a process, product, system, or client) are discussed.					
How many complaints does your company receive in one year?					
How many defects in process or product does the company acknowledge in one year?					
Add another question that you may think describes this variable:					

6. Inherent risk – The susceptibility of a compliance requirement to noncompliance that could be material, either individually or when aggregated with other instances of noncompliance, before consideration of any related controls over compliance.

Based on the definition above, how well the following questions describe inherent risk?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many sub-systems data or input sources (data used to identify risk for the quality system area) are used to prepare the plan?					
How many assessment results are used to prepare the plan?					
How many previous audits (internal/external) results are assessed by the auditor's team or by the auditor alone?					
Add another question that you may think describes this variable:					

7. Control risk –Refer to policies, procedures and practices that assure management that objectives are achieved and risk mitigation strategies are carried out effectively.

Based on the definition above, how well the following questions describe control risk?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many procedures exist for audit/assessment?					
Has acceptance criteria been defined?					
Is there a plan before an audit start?					
Add another question that you may think describes this variable:					

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8. Time Constraint – Audit planning affects the amount of effort needed to achieve a successful audit. This time affects by different factors (external: management decisions, due dates, other audits, etc…).

Based on the definition above, how well the following questions describe time constraint?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much time is required to be prepared before an audit?					
How many audits do you participate during a year?					
How much do you dedicate to prepare a plan?					
How much time is dedicated for approval of the plan?					
Add another question that you may think describes this variable:					

9. Audit sampling is one of the most fundamental testing procedures used to gather audit evidence, and it has undergone significant change during the history of modern auditing. Audit sampling is a pervasive audit testing technique.

Based on the definition above, how well the following questions describe audit sampling?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much time is required to be prepared before an audit?					
How many audits do you participate during a year?					
How much do you dedicate to prepare a plan?					
How much time is dedicated for approval of the plan?					
Add another question that you may think describes this variable:					

3. The following questions include variables that describe the audit effectiveness: Auditor's Knowledge

This section consists of variables and questions related to Auditor's Knowledge. The questions to evaluate could describe each variable. You will select the importance or relevance of each question.

Auditor's Knowledge: The evaluation of audit evidence to determine the quality and meaning of that evidence and to assess the need for additional evidence based on the process.

10. How well the following questions describe Auditor's Training and Certifications?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many training is required to perform the audit (e.g. procedures, trainings (not certification), etc.)?					
How many certificates are required as an auditor?					
How much time (hours) is required as an auditor in a year?					
Is/Are the auditor(s) trained in sampling techniques?					
Add another question that you may think describes this variable:					

11. How well the following questions describe Auditor's Experience?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many years of experience do you have as an auditor?					
How many years of experience do you have in a regulated environment?					
How much time (hours) do you have as an auditor in a year?					
How many audits do you complete in a year?					
How many reports do you prepare in a year?					
How many audits do you lead in a year?					
Add another question that you may think describes this variable:					

4. The following questions include variables that describe the audit effectiveness: Operational Risk

This section consists of variables and questions related to Operational Risk. The questions to evaluate could describe each variable. You will select the importance or relevance of each question.

Operational Risk: Risk of direct or indirect loss resulting from inadequate or failed internal processes, people, and systems or from external events.

12. How well the following questions describe external data source: FDA observations (e.g. 483, warning letters), Adverse effect, MDR?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many FDA observations does your company have during the last year?					
How many Warning Letters does your company have during the last year?					
How many MDR (Medical Device Reports) report did your company fill in the last year?					
How many external audit findings do you receive in the last year?					
Add another question that you may think describes this variable:					

13. How well the following questions describe internal data source: equipment malfunction, internal audit findings, supplier control, process assessment (compliance, manufacturing, and self-inspection)?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many internal audit findings do you receive in the last year?					
How many equipment nonconformities affect or cause a nonconformity product?					
How many investigations are related to assessments (e.g. compliance, manufacturing, and self-inspection)?					
How many assessment processes (e.g. compliance, manufacturing, self-inspection) your company performs in a year?					
How many supplier investigations were opened?					
Add another question that you may think describes this variable:					

14. How well the following questions describe external data source: Complaints?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many complaint procedures does your company have?					
How many confirmed external nonconforming items and complaints (situation or issue that not conform to a procedure, regulation or standard identified by an external agency or external audit company) were received during the last year?					
Add another question that you may think describes this variable:					

15. How well the following questions describe internal data source: Nonconformity?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
Does internal audit plan use nonconformance sources as part of the plan?					
How many internal nonconformities (situation or issue that not conform to a procedure, regulation or standard identified by your company)) were found in the last years?					
Add another question that you may think describes this variable:					

5. The following questions include variables that describe the audit effectiveness and strategic risk

This section consists of variables and questions related to Strategic Risk. The questions to evaluate could describe each variable. You will select the importance or relevance of each question.

Audit Effectiveness: Changes in the degree of adherence to procedure. Result of obtain objectively and evaluate evidence against acceptance criteria.
Strategic Risk: This risk may arise from regulatory, political impediments or technological innovation. This means that the strategic risk is dependent on external sources like government, corporate standards, and technology changes, among other external factors.

16. How well the following questions describe acceptance criteria?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
Is the audit acceptance criteria established?					
What is the level of confidence level desired by your firm?					
Is there an area that the goal was not met?					
How many audits met the acceptance criteria?					
Add another question that you may think describes this variable:					

17. How well the following questions describe external governance?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many standards changed during the last year?					
How many governance regulations changed during the last year?					
How many corporate policies changed during the last year?					
How many new products were introduced or transferred in the last year?					
Add another question that you may think describes this variable:					

18. How well the following questions describe audit strategy?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much documents are planned to assess?					
How many documents in an audit do you evaluate?					
How many document were left without assess due to time constraints?					
How many requests documents did the auditee not deliver?					
How many findings the auditor found?					
Add another question that you may think describes this variable:					

19. How well the following questions describe not following procedure events?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many investigations were opened due to not following procedures?					
How many complaint investigations indicate that the cause was not following procedure?					
Add another question that you may think describes this variable:					

20. How well the following questions describe internal data source: Nonconformity?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many FDA observations does your company have during the last year?					
How many MDR (Medical Device Reports) reports did your company fill in the last year?					
How many external audit findings do you receive in the last year?					
How many findings were not equal to external findings in the last years?					
How many complaint investigations were performed during the last years?					
How many non-conformance internal audits were received in the last years?					
Add another question that you may think describes this variable:					

6. The following questions include variables that describe the audit effectiveness: Various Variables

This section consists of variables and questions related to various variables defined below.
The questions to evaluate could describe each variable. You will select the importance or relevance of each question.

Fix It/Corrective Action: Corrective or preventive action eliminating the cause(s) of an existing or potential non- conformity or undesirable situation
Monitoring: The monitoring component refers to a process of assessing the quality of controls.
Audit Effort: Audit effort is total budgeted hours.
Business risk: In general, the term "auditee business risks" refers to the risks that an auditee's economic condition will deteriorate over time.
Timeliness is the completion of audits in comparison to a plan, and the length of time for issuing reports.

21. How well the following questions describe audit delay (audit report timeliness)?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much time takes to prepare an audit report since the final plan?					
How much time takes to prepare a report after execution?					
What is the approval date of the most recent audit plan?					
What is the approval date of the audit report of that audit plan?					
Add another question that you may think describes this variable:					

22. How well the following questions describe actions?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
What is the project scope? (E.g. Narrow (to one site) or broader (two or more sites))					
How many corrective actions were created during the current year?					
Add another question that you may think describes this variable:					

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23. How well the following questions describe resources workload?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many projects do you have?					
How many sites do you support?					
How many audits do you perform in a year?					
Add another question that you may think describes this variable:					

24. How well the following questions describe time constraints?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
What is the lead-time of the longest project?					
How much time is dedicated to audit activities?					
How much time is dedicated to corrective actions activities?					
Add another question that you may think describes this variable:					

25. How well the following questions describe assessment activities?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How many effectiveness tasks were created for the last years?					
How many of these effectiveness tasks were effective for the last years?					
How is the frequency to evaluate the monitoring data?					
How much time is the monitoring period?					
Add another question that you may think describes this variable:					

26. How well the following questions describe acceptance criteria?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
Is the audit acceptance criteria established?					
What is the level of confidence level desired by your firm?					
Is there an area that the goal was not met?					
How many audits met the acceptance criteria?					
Add another question that you may think describes this variable:					

27. How well the following questions describe time to prepare the plan?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much time do you spend preparing the plan?					
Add another question that you may think describes this variable:					

28. How well the following questions describe time to execute the plan?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much time is required to execute an audit plan?					
How much time do you spend executing an audit plan?					
Add another question that you may think describes this variable:					

29. How well the following questions describe time to report?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
How much time do you spend preparing the report?					
How much time is necessary (desired by management) to approve the report?					
How much time is required to approve the report?					
How much time, since the report was approved, the results were communicated to management?					
How much time took to discuss the results to management?					
How much time took to discuss the results to affected population and subject matter experts?					

Add another question that you may think describes this variable:	

30. How well the following questions describe quantity of objective and/or goals?

Questions	Not at all well	Slightly Well	Moderately Well	Very Well	Extremely Well
If your company has divisions or business units: How many business units are with more than three non-conformances?					
If your company has divisions or business units: How many business units the goal was not met?					
Total of business units that are measured during last year.					
How many long-term plans did your company establish?					
How many strategic projects does your company have?					
Add another question that you may think describes this variable:					

APPENDIX C

APPROVAL LETTER 03-363-15 IRB SUAGM

SISTEMA UNIVERSITARIO ANA G MÉNDEZ
Vicepresidencia de Planificación y Asuntos Académicos
Vicepresidencia Asociada de Recursos Externos y Cumplimiento
Oficina de Cumplimiento

Junta para la Protección de Seres Humanos en la Investigación (IRB)

Fecha	:	8 de octubre de 2015
Investigador principal	:	Sra. Liz B. Machado Matos
Mentor	:	Dr. Victor Mojica
Título del protocolo	:	Modelo para medir la efectividad de auditorías en una empresa de manufactura en el área de dispositivos médico
Número de protocolo	:	03-653-15
Tipo de solicitud	:	Protocolo inicial
Institución, Escuela	:	Universidad del Turabo, Negocios y Empresarismo
Tipo de revisión	:	Exenta
Acción tomada	:	Aprobada
Fecha de revisión	:	5 de octubre de 2015

Certificamos que el estudio/investigación de referencia fue recibido, revisado y aprobado en la Oficina de Cumplimiento por la *Junta para la Protección de Seres Humanos en la Investigación (IRB)*. El mismo fue evaluado y cumple con los criterios establecidos bajo 45 CFR 46.101(b)(1-6) para ser clasificado como **Exento** con un periodo de vigencia del **5 de octubre de 2015 al 4 de octubre de 2016.**

Favor de tener presente lo siguiente:

- La hoja de informativa es un documento que asegura que los sujetos o participantes entienden su participación en el estudio, además de ser un seguro de protección para los mismos. De acuerdo con las Regulaciones Federales se requiere que los participantes reciban copia de la hoja informativa antes de contestar el cuestionario.
- De realizarse algún cambio en los documentos anejados con este estudio deben ser sometidos nuevamente al IRB para su debida revisión y aprobación, utilizando la forma de IRB "Solicitud para Cambios/ Enmiendas".
- Todo evento adverso o no esperado debe ser informado al IRB utilizando la forma de IRB de Solicitud de Eventos Adversos y Problemas Inesperados.

Sra. Liz B. Machado Matos
03-653-15

- Todos los documentos relacionados con la investigación deben ser guardados hasta un término de cinco (5) años. Pasado este término los mismos deben ser eliminados/ triturados, no quemados.

- De no realizar su investigación en el término aprobado deberá someter una solicitud de "Revisión Continua" llenando la forma IRB para "Renovar un Protocolo ya Aprobado" antes de vencerse el mismo.

- Al finalizar su investigación debe someter una solicitud de cierre utilizando la forma de IRB "Solicitud para Cierre de Protocolo Aprobado por el IRB".

De necesitar alguna información adicional, aclarar dudas, notificar algún evento adverso o no anticipado favor de comunicarse con su Coordinador de Cumplimiento Institucional en: Universidad Metropolitana la Srta. Carmen Crespo al (787)766-1717 ext. 6366; Universidad del Turabo la Prof. Josefina Melgar al (787)743-7979 ext. 4126; Universidad del Este la Sra. Natalia Torres al (787) 257-7373 Ext. 2279 y en la Administración Central la Sra. Wanda Vázquez Solá (787) 751-0178 ext. 7195 o puede escribir a:

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APPENDIX D

QUESTIONNAIRE RESULTS: "PRINT SCREEN" FROM THE FILE WITH INFORMATION TABULATED WITH COMPLETED QUESTIONNAIRES RECEIVED

RespondentID	CollectorID	StartDate	EndDate	IP Address	Email Address	First Name	LastName	Custom Data	What is yo	What is yo	What is th	How many	Detection risk is used as a basis for audit p				lanning decisions on the	Inherent ri
									Response	Response	Response	Response	<span style	<span style	<span style	<span style	<span style	Add other	<span style
4481747881	73420320	02/01/2016	02/01/2016						Male	45 to 54	Master De	20 years o	Very well	Extremely	Very well	Very well	Very well		Very well
4481688645	73420320	02/01/2016	02/01/2016						Male	35 to 44	Master De	5-9 years	Moderatel	Not at all	Slightly	Slightly	Very well	How many	Extremely
4481282712	73420320	02/01/2016	02/02/2016						Female	35 to 44	Bachelor D	5-9 years	Moderatel	Very well	Moderatel	Slightly	Moderately well		Very well
4476769001	73420320	01/29/2016	01/29/2016						Female	45 to 54	Master De	10-14 yea	Moderatel	Moderatel	Moderatel	Moderatel	Moderately well		Moderatel
4476499783	73420320	01/29/2016	01/29/2016						Male	35 to 44	Bachelor D	5-9 years	Very well	Very well	Slightly	Moderatel	Slightly well		Very well
4476186466	73420320	01/29/2016	01/29/2016						Male	35 to 44	Master De	5-9 years	Very well	Very well	Very well	Very well	Very well		Very well
4476182853	73420320	01/29/2016	01/29/2016						Male	35 to 44	Bachelor D	15-19 yea	Moderatel	Moderatel	Moderatel	Moderatel	Moderately well		Moderatel
4476181297	73420320	01/29/2016	01/29/2016						Female	45 to 54	Master De	5-9 years	Moderatel	Moderatel	Very well	Extremely	Extremely well		Very well
4476049710	73420320	01/29/2016	01/29/2016						Male	25 to 34	Associate	5-9 years	Moderatel	Very well	Moderatel	Very well	Very well		Very well
4475995986	73420320	01/29/2016	01/29/2016						Male	35 to 44	Bachelor D	15-19 yea	Moderatel	Slightly	Moderatel	Slightly	Very well		Moderatel
4468526685	73420320	01/26/2016	01/26/2016						Female	35 to 44	Bachelor D	15-19 yea	Moderatel	Extremely	Extremely	Extremely	Extremely well		Not at all
4467092696	73420320	01/25/2016	01/25/2016						Male	35 to 44	Bachelor D	10-14 yea	Very well	Moderatel	Moderatel	Very well	Very well		Extremely
4466827961	73420320	01/25/2016	01/25/2016						Male	35 to 44	Bachelor D	5-9 years	Moderatel	Slightly	Not at all	Moderatel	Moderately well		Very well
4466775763	73420320	01/25/2016	01/25/2016						Female	25 to 34	Master De	5-9 years	Moderatel	Slightly	Slightly	Slightly	Slightly well		Moderatel
4466666113	73420320	01/25/2016	01/25/2016						Female	35 to 44	Master De	10-14 yea	Very well	Very well	Very well	Moderatel	Moderately well		Moderatel
4466663557	73420320	01/25/2016	01/25/2016						Female	35 to 44	Master De	10-14 yea	Extremely	Extremely	Extremely	Extremely	Extremely well		Extremely
4466661288	73420320	01/25/2016	01/25/2016						Female	35 to 44	Bachelor D	10-14 yea	Moderatel	Very well	Moderatel	Very well	Very well		Moderatel
4466646536	73420320	01/25/2016	01/25/2016						Female	35 to 44	Bachelor D	10-14 yea	Moderatel	Moderatel	Moderatel	Moderatel	Very well		Very well
4443415906	73420320	01/13/2016	01/13/2016						Male	65 or olde	Bachelor D	5-9 years	Very well	Very well	Very well	Extremely	Extremely well		Very well
4443023575	73420320	01/13/2016	01/13/2016						Male	35 to 44	Bachelor D	5-9 years	Moderatel	Very well	Moderatel	Very well	Moderately well		Very well
4440376465	73420320	01/12/2016	01/12/2016						Female	35 to 44	Bachelor D	5-9 years	Moderatel	Moderatel	Moderatel	Moderatel	Moderately well		Moderatel
4437996258	73420320	01/11/2016	01/11/2016						Female	35 to 44	Master De	10-14 yea	Moderatel	Extremely	Very well	Slightly	Slightly well		Extremely
4437953527	73420320	01/11/2016	01/11/2016						Female	45 to 54	Bachelor D	5-9 years	Very well	Very well	Very well	Very well	Moderately well		Very well
4436082906	73420320	01/09/2016	01/09/2016						Male	55 to 64	Master De	20 years o	Very well	Very well	Very well	Very well	Very well	Is risk cate	Very well
4432839741	73420320	01/07/2016	01/07/2016						Female	35 to 44	Bachelor D	5-9 years	Moderatel	Moderatel	Moderatel	Moderatel	Moderately well		Extremely
4432622918	73420320	01/07/2016	01/07/2016						Female	35 to 44	Doctorate	5-9 years	Very well	Moderatel	Moderatel	Very well	Moderately well		Moderatel
4432248920	73420320	01/07/2016	01/07/2016						Male	45 to 54	Bachelor D	15-19 yea	Extremely	Very well	Very well	Extremely	Very well		Very well
4432143338	73420320	01/07/2016	01/07/2016						Male	25 to 34	Bachelor D	10-14 yea	Very well	Slightly	Very well	Extremely	Extremely well		Very well
4432074713	73420320	01/07/2016	01/07/2016						Male	45 to 54	Master De	5-9 years	Very well	Very well	Extremely	Very well	Very well		Very well
4432046639	73420320	01/07/2016	01/07/2016						Male	35 to 44	Bachelor D	10-14 yea	Moderatel	Very well	Moderatel	Extremely	Extremely well		Moderatel
4432004522	73420320	01/07/2016	01/07/2016						Male	45 to 54	Bachelor D	10-14 yea	Very well	Extremely	Moderatel	Moderatel	Moderately well		Very well
4431929952	73420320	01/07/2016	01/07/2016						Male	55 to 64	Bachelor D	5-9 years	Moderatel	Extremely	Very well	Very well	Very well		Extremely
4431897741	73420320	01/07/2016	01/07/2016						Male	45 to 54	Bachelor D	10-14 yea	Moderatel	Very well	Very well	Slightly	Slightly well		Very well

APPENDIX E

QUESTIONNAIRE RESULTS: CONTENT VALIDITY CALCULATION USING AIKEN'S V (1985) IN EXCEL SOFTWARE

	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	73420320	Aiken's V (1985)	
Var#	4481747881	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.48E+09	4.43E+09	4.43E+09	4.43E+09	4.43E+09	4.43E+09	4.43E+09	4.43E+09	4.43E+09	4431897741	S	V
Items	Respondent 1	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respon	Respondent 33		
Item 1	5	3	3	3	5	5	3	3	3	3	3	3	5	5	5	5	3	5	3	3	3	94	0.712121
Item 2	5	1	5	3	5	5	3	3	5	2	3	3	5	2	5	5	5	5	5	5	5	100	0.757576
Item 3	5	2	3	3	2	5	3	5	3	3	3	3	5	5	5	5	3	3	5	5		91	0.689394
Item 4	5	2	2	3	3	5	3	5	5	2	3	5	5	5	5	5	5	3	5	2		96	0.727273
Item 5	5	5	3	3	2	5	3	5	5	5	3	3	5	5	5	5	5	3	5	2		98	0.742424
Item 6	5	5	5	3	5	5	3	5	5	3	5	3	5	5	5	3	5	5	5	5		110	0.833333
Item 7	5	2	3	3	5	5	3	5	3	2	5	3	5	3	5	5	5	5	5	2		95	0.719697
Item 8	5	2	2	3	5	5	3	5	5	3	5	5	5	2	5	5	3	5	5	2		94	0.712121
Item 9	5	1	2	3	2	5	3	5	5	3	5	5	5	3	5	5	5	5	5	3		93	0.704545
Item 10	5	3	3	3	5	5	3	5	2	2	5	5	5	5	3	5	5	5	5	3		108	0.818182
Item 11	5	1	5	5	5	5	3	5	1	3	5	5	5	5	5	5	5	5	5	3		114	0.863636
Item 12	3	5	5	3	5	5	3	5	2	3	5	5	5	5	3	5	5	5	5	5		108	0.818182
Item 13	5	3	2	3	5	5	3	5	1	3	5	5	3	3	5	5	5	3	3	2		88	0.666667
Item 14	5	1	2	3	5	5	3	5	2	3	5	5	5	5	5	5	5	5	5	5		96	0.727273
Item 15	5	1	3	3	5	5	3	5	1	2	5	5	5	5	5	5	5	3	2	3		90	0.681818
Item 16	5	5	2	3	3	5	3	5	2	2	3	5	5	5	5	5	5	5	3	3		96	0.727273
Item 17	5	2	2	2	3	5	3	3	2	1	1	5	5	5	5	5	5	5	3	3		85	0.643939
Item 18	5	1	2	3	2	5	3	3	5	3	1	3	5	5	3	5	5	5	5	2		83	0.628788
Item 19	5	2	2	3	2	5	3	1	2	3	1	3	5	3	5	5	5	5	3	3		78	0.590909
Item 20	5	2	5	3	2	5	3	5	5	3	3	5	5	5	5	5	5	5	5	5		109	0.825758
Item 21	5	2	5	3	3	5	3	5	5	3	3	5	5	3	5	5	5	5	3	3		104	0.787879
Item 22	5	3	5	3	3	5	3	5	5	3	1	3	5	5	5	5	5	5	2	3		98	0.742424
Item 23	3	2	3	3	3	5	3	5	3	3	1	5	5	5	5	5	5	5	3	2		86	0.651515
Item 24	5	2	3	2	5	5	3	5	3	2	2	5	5	5	5	5	5	5	5	3		98	0.742424
Item 25	5	2	3	3	3	5	3	5	5	2	3	5	5	5	5	5	5	5	5	5		110	0.833333
Item 26	5	5	3	2	3	5	3	5	3	1	1	5	5	3	5	5	5	5	3	2		83	0.628788
Item 27	5	3	2	2	3	5	3	5	2	1	5	5	5	5	5	5	3	5	5	2		89	0.674242
Item 28	5	1	2	2	3	5	3	5	2	2	3	5	5	3	5	5	5	5	2	2		79	0.598485
Item 29	5	3	2	2	3	5	3	5	2	3	1	5	5	5	5	5	5	2	3	2		78	0.590909
Item 30	5	3	2	3	5	5	3	5	2	1	1	5	5	5	5	3	2	5	5			94	0.712121
Item 31	5	3	1	3	5	5	3	5	1	1	1	5	5	5	5	5	2	3	5			89	0.674242
Item 32	5	2	3	3	3	5	3	5	1	1	1	5	5	5	5	5	3	3	5			87	0.659091
Item 33	5	3	2	3	5	5	3	5	1	1	3	5	5	5	5	5	2	5	5			98	0.742424
Item 34	5	5	2	3	5	5	3	5	1	2	3	5	5	5	5	5	3	5	3			94	0.712121
Item 35	5	5	2	3	5	5	3	5	5	1	5	5	5	5	5	5	3	3	3			96	0.727273
Item 36	5	5	3	3	5	5	3	5	5	3	5	3	5	5	5	5	3	5	3			105	0.795455
Item 37	5	2	3	3	5	5	3	5	5	3	5	3	5	5	5	5	3	5	5			101	0.765152
Item 38	5	5	3	3	5	5	3	5	3	2	3	5	5	3	5	5	3	5	5			102	0.772727
Item 39	5	1	2	3	5	5	3	3	2	3	3	5	5	5	5	5	5	2	2			92	0.69697
Item 40	5	5	2	3	5	5	3	5	2	2	2	5	5	5	5	5	3	5	3			107	0.810606
Item 41	5	2	5	3	5	5	3	5	1	3	5	5	5	5	5	5	3	5	3			101	0.765152
Item 42	5	5	5	3	5	5	3	5	1	5	5	3	5	5	5	5	3	5	3			103	0.780303
Item 43	5	3	2	3	5	5	3	5	5	3	5	1	5	5	5	5	5	5	5			117	0.886364
Item 44	5	3	3	3	5	5	3	3	5	2	5	1	5	3	5	5	5	5	3			104	0.787879
Item 45	5	2	2	3	5	5	3	3	5	3	5	2	3	5	5	5	2	5	5			97	0.734848
Item 46	5	2	2	3	5	5	3	5	5	3	3	1	5	5	5	5	5	5	5			98	0.742424
Item 47	5	5	2	3	5	5	3	3	3	3	3	1	5	5	5	5	2	5	2			86	0.651515
Item 48	5	5	2	3	5	5	3	3	3	3	3	1	5	5	5	5	2	5	2			88	0.666667
Item 49	5	5	2	3	5	5	3	3	3	2	5	1	5	3	5	5	2	5	2			90	0.681818
Item 50	5	2	2	2	5	5	3	3	2	3	5	5	5	5	5	5	3	3	2			88	0.666667
Item 51	5	5	3	3	5	5	3	5	3	5	3	1	5	3	5	5	3	3	2			90	0.681818
Item 52	5	1	3	2	5	5	3	3	3	5	5	3	5	2	5	5	3	2	2			89	0.674242
Item 53	5	2	3	3	5	5	3	2	3	3	3	2	5	5	5	5	2	5	3			80	0.606061
Item 54	5	1	3	3	5	5	3	5	1	3	3	1	5	5	5	5	3	5	5			85	0.643939
Item 55	5	1	3	3	5	5	3	3	2	3	5	5	5	5	5	5	3	2	2			82	0.621212
Item 56	5	3	5	3	5	5	3	5	3	3	5	5	5	5	5	5	3	5	5			105	0.795455
Item 57	5	3	3	3	5	5	3	5	3	5	3	5	5	5	5	5	3	5	5			103	0.780303
Item 58	5	1	2	1	5	5	3	3	3	1	1	5	5	5	5	5	2	1	5			81	0.613636
Item 59	5	1	3	3	5	5	3	5	3	1	1	5	5	5	5	5	5	1	5			89	0.674242
Item 60	5	1	2	3	5	5	3	5	3	2	2	5	5	2	5	5	2	3	5			86	0.651515
Item 61	5	1	2	3	5	5	3	5	3	1	3	3	5	2	5	5	2	3	3			79	0.598485
Item 62	5	1	2	3	5	5	3	5	3	3	3	5	5	5	5	5	2	5	3			92	0.69697
Item 63	5	5	2	3	5	5	3	5	3	2	5	5	5	5	5	5	3	5	2			101	0.765152
Item 64	5	3	3	3	3	5	3	5	3	3	5	2	5	5	5	5	5	5	2			96	0.727273
Item 65	5	3	3	3	3	5	3	5	3	5	5	5	5	5	5	5	5	3	2			103	0.780303
Item 66	5	1	3	3	5	5	3	3	3	1	5	2	5	5	5	5	3	5	2			86	0.651515
Item 67	5	1	3	3	5	5	3	5	3	1	5	5	5	5	5	5	5	5	2			93	0.704545
Item 68	5	1	5	3	3	5	3	3	3	3	3	5	5	3	5	5	5	2	2			91	0.689394
Item 69	5	5	5	3	5	5	3	5	3	5	5	3	5	5	5	5	3	5	3			105	0.795455
Item 70	5	5	3	3	3	5	3	5	3	5	5	5	5	5	5	5	3	5	2			112	0.848485
Item 71	5	5	3	3	3	5	3	5	3	2	5	5	5	5	5	5	2	5	2			97	0.734848
Item 72	5	5	3	3	3	5	3	5	3	1	5	5	5	5	5	5	2	5	2			95	0.719697
Item 73	5	1	3	3	2	5	3	5	3	5	5	3	5	3	5	5	5	2	3			87	0.659091
Item 74	5	3	3	3	3	5	3	5	3	5	5	2	5	5	5	5	2	5	3			96	0.727273
Item 75	5	3	3	3	3	5	3	5	3	2	5	5	5	5	5	5	5	5	3			105	0.795455
Item 76	5	5	3	3	5	5	3	5	3	3	5	3	5	5	5	5	5	5	2			99	0.75
Item 77	5	1	3	3	5	5	3	5	3	5	5	3	5	5	5	5	5	5	3			108	0.818182
Item 78	5	5	3	3	5	5	3	5	3	5	5	2	5	3	5	5	5	5	2			103	0.780303
Item 79	5	5	3	3	5	5	3	5	3	3	5	5	5	5	5	5	3	5	3			105	0.795455
Item 80	5	3	3	3	5	5	3	5	3	2	5	2	5	5	5	5	5	5	5			110	0.833333
Item 81	5	3	3	3	5	5	3	5	3	2	5	2	5	5	5	5	5	5	3			103	0.780303
Item 82	5	2	3	3	5	5	3	5	3	2	5	5	5	5	5	5	3	3	5			102	0.772727
Item 83	5	2	3	3	5	5	3	5	3	5	5	3	5	3	5	5	5	5	3			103	0.780303
Item 84	5	5	3	3	3	5	3	5	3	1	5	5	5	3	5	5	5	5	5			96	0.727273
Item 85	5	5	3	3	3	5	3	5	3	1	5	3	5	5	5	5	3	5	3			93	0.704545
Item 86	5	3	3	3	3	5	3	5	3	1	5	3	5	5	5	5	3	2	3			89	0.674242
Item 87	5	2	3	3	3	5	3	5	3	3	5	5	5	5	5	5	3	3	2			90	0.681818
Item 88	5	3	3	3	3	5	3	5	3	3	5	5	5	5	5	5	5	1	2			93	0.704545
Item 89	5	5	3	3	3	5	3	5	3	3	5	3	5	5	5	5	5	5	2			97	0.734848
Item 90	5	2	3	3	3	5	3	5	3	3	5	5	5	3	5	5	2	1	3			90	0.681818
Item 91	5	2	3	3	3	5	3	5	3	3	3	5	5	3	5	5	2	5	3			91	0.689394
Item 92	5	2	3	3	3	5	3	5	3	3	2	3	5	3	5	5	2	5	5			92	0.69697
Item 93	5	1	3	3	5	5	3	5	3	3	3	3	5	5	5	5	2	2	2			82	0.621212
Item 94	5	1	3	3	5	5	3	5	3	2	2	2	5	5	5	5	2	2	3			87	0.659091
Item 95	5	1	3	3	5	5	3	5	3	3	5	2	5	5	5	5	5	1	2			91	0.689394
Item 96	5	5	3	3	5	5	3	5	3	3	5	3	5	3	5	5	5	2	3			97	0.734848
Item 97	5	5	3	3	5	5	3	5	3	3	5	5	5	5	5	5	5	5	3			106	0.80303

APPENDIX F

STUDIED MODEL: INDICATORS NAME AND DESCRIPTION

Item #	Indicator Name	Indicator Description
1	DR_PrAu	DETECTION RISK YEARS OF PREVIOUS AUDIT
2	DR_T	DETECTION RISK TOOLS
3	DR_F	DETECTION RISK FORUM
4	DR_C	DETECTION RISK COMPLAINTS
5	DR_D	DETECTION RISKQTY OF DEFECTS
6	IR_A	INHERENT RISK INPUTS TO PLAN
7	IR_I	INHERENT RISK ASSESSMENT
8	IR_AuRes	INHERENT RISK - AUDITS USED FOR PLAN
9	CR_P	CONTROL RISK PROCEDURES
10	CR_AC	CONTROL RISK ACCEPTANCE CRITERIA
11	CR_PL	CONTROL RISK PREVIOUS PLAN
12	TC_TBA	TIME CONTRAINTS BEFORE AUDIT
13	TC_AQ	TIME CONTRAINTS AUDIT YEARLY
14	TC_TPL	TIME CONTRAINTS FOR PLAN PREPARATION
15	TC_TAP	TIME CONTRAINTS PLAN APPROVAL
16	AS_AS	AUDIT SAMPLING - SAMPLING
17	AS_ST	AUDIT SAMPLING - SAMPLING TECHNIQUES
18	T_Tr	AUDIT TRAINING - TRAINING QTY
19	T_Ce	AUDIT TRAINING - CERTIFICATION QTY
20	T_Ahrs	AUDIT TRIANING - AUDIT HOURS
21	T_ST	AUDIT TRAINING - SAMPLING TECHNIQUES
22	AE_E	AUDITOR'S EXPERIENCE IN AUDIT
23	AE_ReEn	AUDITOR'S EXPERIENCE IN A REGULATED ENVIRONMENT
24	AE_Ayr	AUDITORS EXPERIENCE - AUDIT COMPLETED IN A YEAR
25	EDS_FDA	EXTERNAL DATA SOURCE - FDA OBS LAST YEAR
26	EDS_WL	EXTERNAL DATA SOURCE - WARNING LETTERS IN LAST YEAR
27	EDS_MDR	EXTERNAL DATA SOURCE - MDR LAST YEAR
28	EAS_EA	EXTERNAL DATA SOURCE - EXTERNAL AUDIT IN LAST YEAR
29	IAS_IA	INTERNAL DATA SOURCE - INTERNAL AUDIT IN LAST YEAR
30	IAS_ENC	INTERNAL DATA SOURCE - EQUPMENT NC THAT AFFECT PRODUCT
31	IAS_InAS	INTERNAL DATA SOURCE - INVESTIGATION RELATED TO ASSESSMENT
32	IAS_AP	INTERNAL DATA SOURCE - ASSESSMENT PROCESS
33	IAS_Sinv	INTERNAL DATA SOURCE - SUPPLIER INVESTIGATION
34	C_Cproc	COMPLAINTS - COMPLAINT PROCEDURE QTY
35	C_C	COMPLAINTS - QTY OF EXTERNAL NC AND COMPLAINTS
36	NC_AP_Nc	NC- INTERNAL AUDIT PLAN USED NC SOURCE
37	NC_IA_NC	NC- QTY OF INTERNAL NC
38	AC_ACE	AC-AUDIT CRITERIA
39	AC_CLE	AC-CONFIDENCE LEVEL
40	AC_Gnot	AC-GOAL NOT MET
41	AC_Acm	AC-AUDIT MET AC
42	EG_STD	EXTERNAL GOVERNANCE - STANDARDS CHANGE
43	EG_REG	EXTERNAL GOVERNANCE - REGULATIONS CHANGE
44	EG_POL	EXTERNAL GOVERNANCE - CORPORATE POLICIES CHANGES
45	EG_NEWp	EXTERNAL GOVERNANCE - NEW PROD INTRODUCTION
46	AS_EVAL	AUDIT STRATEGY - QTY OF DOCUMENTS TO ASSESS
47	AS_DOCREQ	AUDIT STRATEGY - DOCUMENT EVALUATION
48	AS_DOC	AUDIT SOURCE - EXTERNAL FINDINGS DOCUMENTS RECEIVE IN LAST YEAR
49	NFP_INV	NOT FOLLOWING PROCEDURE - INVESTIGATION DUE TO NOT FOLLOWING PROCEDURE
50	NFP_C	NOT FOLLOWING PROCEDURE - COMPLAINTS DUE TO NOT FOLLOWING PROCEDURE

Item #	Indicator Name	Indicator Description
51	NFP_MDR	NOT FOLLOWING PROCEDURE - MDR
52	NFP_EA	NOT FOLLOWING PROCEDURE - EXTERNAL AUDIT
53	NC_C	NC - COMPLAINT
54	NC_IA	NC-INTERNAL AUDIT FINDING
55	AD_TRaP	AUDIT DELAY-TIME TO RERPORT AFTER PLAN
56	AD_TRaE	AUDIT DELAY-TIME TO REPORT AFTER EXECUTION
57	AD_PL_APP_DATE	AUDIT DELAY - PLAN APPROVAL DATE
58	AD_AR_APP_DATE	AUDIT DELAY - AUDIT REPORT APPROVAL DATE
59	ACTIONS_PROJ_SCOPE	ACTIONS - PROJECT SCOPE
60	A_CA	ACTIONS - CORRECTIVE ACTIONS IN A YEAR
61	RW_PROJ_ASSIGN	RESOURCES WORKLOAD - PROJECTS ASSIGNED
62	RW_SITES_SUPPORT	RW_SITES_SUPPORT
63	RW_Pa	RW_AUDIT PERFORMED IN A YEAR
64	TC_LtP	TIME CONSTRAINTS-LEAD TIME OF LONGEST PROJECT
65	TC_TA	TIME CONSTRAINSTS - TIME TO AUDIT
66	TC_TCA	TIME CONSTRAINTS - TIME FOR CORRECTIVE ACTION
67	AA_TQTY	ASSESSMENT ACTIVITY - QTY OF EFFECTIVENESS TASK
68	AA_EFF	ASSESSMENT ACTIVITY- EFFECTIVENESS OF EFFECTIVENESS TASK
69	AA_MT	ASSESSMENT ACTIVITY - FREQUENCY OF MONITORING TASKS
70	AA_MP	ASSESSMENT ACTIVITY - MONITORING PERIOD
71	AC_AC	ACCEPTANCE CRITERIA - ACCEPTANCE CRITERIA ESTABLISHED
72	AC_CL	ACCEPTANCE CRITERIA - CONFIDENCE LEVEL
73	AC_AnM	ACCEPTANCE CRITERIA - AREAS NOT MET
74	AC_AM	ACCEPTANCE CRITERIA - AREAS MET AC
75	TP_TpP	TIME TO PREPARE THE PLAN
76	TE_TReP	TIME REQUIRED TO EXECUTE
77	TE_TeP	TIME FOR EXECUTING
78	TR_TpR	TIME TO REPORT - TIME TO PREPARE THE PLAN
79	TR_TRA	TIME TO REPORT - TIME TO REPORT APPROVAL
80	TR_TrRA	TIME TO REPORT - TIME REQUIRED TO REPORT APPROVAL
81	TR_TC	TIME TO REPORT - TIME TO COMMUNICATE
82	TR_TdRES	TIME TO REPORT - TIME TO DISCUSS RESULTS WITH MGT
83	TR_TdPOP	TIME TO REPORT - TIME TO DISCUSS WITH POPULATION
84	QOG_BU_MET	QTY OF OBJ_GOALS - BU MET THE GOALS
85	QOC_BU_MEAUS	QTY OF OBJ_GOALS - BU MEASURED
86	QOG_LTP	QTY OF OBJECTIVES_GOALS - LONG-TERMS PLANS
87	QOG_SP	QTY OF OBJECTIVES_GOALS - QTY OF STRATEGIC PLANS
88	AS_P	AS - SAMPLING PROCEDURES QTY
89	AS_ST_USED	AS - COMPANY SAMPLING TECHNIQUES
90	AE_AUD_T	AE - TIME AS AN AUDITOR
91	AE_R	AE - REPORTS PREPARE
92	AE_LeadA	AE - AUDITS LEAD
93	AS_NO_DOC	AUDIT STRATEGY - DOC NOT ASSESS
94	AS_FIND_RES	AUDIT STRATEGY - FINDINGS FOUND
95	NC_FDA	NC - FDA OBS
96	NC_E_FIND	NC - FINDINGS OT EQUAL TO EXT FINDINGS
97	QOG_BU_NC	QOG - BU WITH MORE THAN 3 NC

APPENDIX G

QUESTIONNAIRE RESULTS: CRONBACH'S ALPHA USING IBM SPSS STATISTICS SOFTWARE

RELIABILITY

```
  /VARIABLES=DR_PrAu DR_T DR_F DR_C DR_D IR_A IR_I IR_AuRes CR_P CR_AC
CR_PL TC_TBA TC_AQ TC_TPL TC_TAP AS_AS AS_ST T_Tr T_Ce T_Ahrs T_ST AE_E
AE_ReEn AE_Ayr EDS_FDA EDS_WL EDS_MDR EAS_EA IAS_IA IAS_ENC IAS_InAS
IAS_AP IAS_Sinv C_Cproc C_C NC_AP_Nc NC_IA_NC AC_ACE AC_CLE AC_Gnot
AC_Acm EG_STD EG_REG EG_POL EG_NEWp AS_EVAL AS_DOCREQ AS_DOC NFP_INV
NFP_C NFP_MDR NFP_EA NC_C NC_IA AD_TRaP AD_TRaE AD_PL_APP_DATE
AD_AR_APP_DATE ACTIONS_PROJ_SCOPE A_CA RW_PROJ_ASSIGN RW_SITES_SUPPORT
RW_Pa TC_LtP TC_TA TC_TCA
AA_TQTY AA_EFF AA_MT AA_MP AC_AC AC_CL AC_AnM AC_AM TP_TpP TE_TReP
TE_TeP TR_TpR TR_TRA TR_TrRA TR_TC TR_TdRES TR_TdPOP QOG_BU_MET
QOC_BU_MEAUS QOG_LTP QOG_SP AS_P AS_ST_USED AE_AUD_T AE_R AE_LeadA
AS_NO_DOC AS_FIND_RES NFP_FDA NC_E_FIND QOG_BU_NC
 /SCALE('ALL VARIABLES') ALL
 /MODEL=ALPHA.
```

Reliability

```
[DataSet1] /Users/shera/Documents/Thesis/CAPITULO 4 - SEPT
2016/Reliability Test 97 vars.sav
```

Scale: ALL VARIABLES

Case Processing Summary

		N	%
Cases	Valid	33	100.0
	Excluded[a]	0	.0
	Total	33	100.0

a. Listwise deletion based on all variables in the procedure.

Reliability Statistics

Cronbach's Alpha	N of Items
.983	97

APPENDIX H

INDICATORS WITH CONSTANT RESULTS REMOVED FROM ANALYSIS

Item #	Indicator Name	Indicator Description
6	IR_A	INHERENT RISK INPUTS TO PLAN
10	CR_AC	CONTROL RISK ACCEPTANCE CRITERIA
11	CR_PL	CONTROL RISK PREVIOUS PLAN
12	TC_TBA	TIME CONTRAINTS BEFORE AUDIT
16	AS_AS	AUDIT SAMPLING - SAMPLING
20	T_Ahrs	AUDIT TRIANING - AUDIT HOURS
26	EDS_WL	EXTERNAL DATA SOURCE - WARNING LETTERS IN LAST YEAR
27	EDS_MDR	EXTERNAL DATA SOURCE - MDR LAST YEAR
34	C_Cproc	COMPLAINTS - COMPLAINT PROCEDURE QTY
38	AC_ACE	AC-AUDIT CRITERIA
39	AC_CLE	AC-CONFIDENCE LEVEL
47	AS_DOCREQ	AUDIT STRATEGY - DOCUMENT EVALUATION
50	NFP_C	NOT FOLLOWING PROCEDURE - COMPLAINTS DUE TO NOT FOLLOWING PROCEDURE
51	NFP_MDR	NOT FOLLOWING PROCEDURE - MDR
52	NFP_EA	NOT FOLLOWING PROCEDURE - EXTERNAL AUDIT
57	AD_PL_APP_DATE	AUDIT DELAY - PLAN APPROVAL DATE
58	AD_AR_APP_DATE	AUDIT DELAY - AUDIT REPORT APPROVAL DATE
59	ACTIONS_PROJ_SCOPE	ACTIONS - PROJECT SCOPE
61	RW_PROJ_ASSIGN	RESOURCES WORKLOAD - PROJECTS ASSIGNED
62	RW_SITES_SUPPORT	RW_SITES_SUPPORT
64	TC_LtP	TIME CONSTRAINTS-LEAD TIME OF LONGEST PROJECT
65	TC_TA	TIME CONSTRAINSTS - TIME TO AUDIT
71	AC_AC	ACCEPTANCE CRITERIA - ACCEPTANCE CRITERIA ESTABLISHED
72	AC_CL	ACCEPTANCE CRITERIA - CONFIDENCE LEVEL
79	TR_TRA	TIME TO REPORT - TIME TO REPORT APPROVAL
80	TR_TrRA	TIME TO REPORT - TIME REQUIRED TO REPORT APPROVAL
84	QOG_BU_MET	QTY OF OBJ_GOALS - BU MET THE GOALS
85	QOC_BU_MEAUS	QTY OF OBJ_GOALS - BU MEASURED
88	AS_P	AS - SAMPLING PROCEDURES QTY
89	AS_ST_USED	AS - COMPANY SAMPLING TECHNIQUES
90	AE_AUD_T	AE - TIME AS AN AUDITOR
91	AE_R	AE - REPORTS PREPARE
92	AE_LeadA	AE - AUDITS LEAD
94	AS_FIND_RES	AUDIT STRATEGY - FINDINGS FOUND
95	NC_FDA	NC - FDA OBS

APPENDIX I

PLS-SEM BENEFITS IN THE PROCESS OF THEORIZING

Stages in empirical research (Churchill, 1995)	Processes peculiar to theorizing … (Weick, 1995)	… might be supported by the following characteristics of PLS-SEM (e.g. see Henseler *et al.*, 2009, 2014; Hair *et al.*, 2011, 2012, 2013, 2014; Sarstedt *et al.*, 2014a, b)
Problem definition and research goal	Generalizing findings to other research areas	(1) Test for the predictive relevance of hypothesized relationships in different research areas (prediction orientation of PLS-SEM, optimal for prediction accuracy, for establishing models with high predictive power, and short distance to practice)
	Selecting from different approaches and synthesizing different approaches Explaining new relationships	The assessment of predictive power allows one to select from competing models, and points to room for improvement in terms of practical relevance (i.e. (2) test and improve existing models by synthesizing different approaches); PLS-SEM's ability to test more complex models can help researchers to explore and (3) uncover new causal relationships that had previously been overlooked
	Relating findings to contextual factors	PLS-SEM tools for multigroup analyses or more explorative or prediction-oriented procedures such as FIMIX-PLS or PLS-POS help to (4) identify relevant contextual factors that define relevant segments or subgroups
Data collection and preparation	Collection a variety of data with constructs that are theoretically less-clearly defined	(5) The data are nonnormal (6) The analysis draws on secondary data
Data analysis	Analysis of a variety of often complex research models	(7) The causal model comprises many constructs, path relationships, and indicators, advanced elements such as moderator variables or hierarchical components, and formatively measured constructs (8) PLS-SEM offers latent variable scores that can be used in subsequent analyses

Table I.
PLS-SEM benefits in the process of theorizing

Source: Ritchter, N. F., Sinkovics, R. R., Ringle, C. M., & Schlagel, C. (2016). A critical look at the use of SEM in international business research. International Business Research, 33(3), 376-404.

APPENDIX J

PLS-SEM: ITERATIONS LIST FOR CONVERGENCE VERIFICATION

Stop Criterion Changes

	AA_EFF	AA_MP	AA_MT	AA_TQTY	AC_AM	AC_Acm	AC_AnM	AC_Gnot	AD_TRaE	AD_TRaP	AE_Ayr	AE_E	AE_ReEn	AS_DOC	AS_EVAL	AS_NO_DOC	AS_ST	A_CA	CR_P
Iteration 0	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
Iteration 1	0.279	0.165	0.169	0.278	-0.040	0.033	0.261	0.414	0.196	0.933	0.504	0.122	0.253	0.221	0.417	0.032	0.399	0.573	0.126
Iteration 2	0.277	0.169	0.177	0.277	-0.062	0.174	0.247	0.358	0.185	0.938	0.553	0.213	0.240	0.234	0.574	0.002	0.368	0.580	0.061
Iteration 3	0.274	0.173	0.180	0.274	-0.069	0.161	0.243	0.339	0.161	0.948	0.556	0.200	0.216	0.238	0.549	0.004	0.360	0.583	0.064
Iteration 4	0.273	0.175	0.181	0.273	-0.071	0.165	0.241	0.335	0.163	0.947	0.551	0.210	0.220	0.240	0.557	0.002	0.360	0.583	0.064
Iteration 5	0.273	0.176	0.182	0.273	-0.072	0.165	0.241	0.332	0.163	0.947	0.550	0.210	0.219	0.241	0.556	0.002	0.358	0.583	0.066
Iteration 6	0.273	0.176	0.182	0.273	-0.072	0.165	0.241	0.332	0.164	0.947	0.548	0.210	0.219	0.242	0.556	0.002	0.357	0.583	0.067
Iteration 7	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.547	0.209	0.219	0.242	0.556	0.002	0.357	0.583	0.067
Iteration 8	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.546	0.209	0.218	0.242	0.556	0.002	0.356	0.583	0.068
Iteration 9	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.546	0.209	0.218	0.242	0.556	0.002	0.356	0.583	0.068
Iteration 10	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.209	0.218	0.242	0.556	0.002	0.356	0.583	0.068
Iteration 11	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.209	0.218	0.242	0.556	0.002	0.356	0.583	0.068
Iteration 12	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.209	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 13	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 14	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 15	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 16	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 17	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 18	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 19	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 20	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 21	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 22	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 23	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 24	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 25	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 26	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 27	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 28	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 29	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 30	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 31	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 32	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 33	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069
Iteration 34	0.273	0.176	0.182	0.273	-0.072	0.166	0.241	0.331	0.164	0.947	0.545	0.208	0.218	0.242	0.556	0.002	0.356	0.583	0.069

APPENDIX K

PLS-SEM: QUALITY CRITERIA RESULTS

	Cronbach's Alpha	rho_A	Composite Reliability	Average Variance Extracted (AVE)
AUDIT EFFECTIVENESS	0.147	0.154	0.555	0.350
AUDIT EFFORT	0.597	0.877	0.725	0.399
AUDIT PLANNING	0.265	0.773	0.241	0.225
AUDIT REPORT	0.397	1.358	0.689	0.567
AUDITOR KNOWLEGDE	0.534	0.727	0.721	0.336
BUSINESS RISK	0.674	0.449	0.688	0.487
CORRECTIVE ACTION	0.611	0.813	0.790	0.584
MONITORING	0.768	0.924	0.865	0.609
OPERATIONAL RISK	0.568	0.887	0.390	0.325
STRATEGIC RISK	0.097	0.476	0.253	0.185

APPENDIX L

CONVERGENT VALIDITY

Outer Loadings

	AUDIT EFFECTIVENESS	AUDIT EFFORT	AUDIT PLANNING	AUDIT REPORT	AUDITOR KNOWLEGDE	BUSINESS RISK	CORRECTIVE ACTION	MONITORING	OPERATIONAL RISK	STRATEGIC RISK
AA_EFF								0.924		
AA_MP								0.739		
AA_MT								0.764		
AA_TQTY								0.923		
AC_AM								-0.323		
AC_Acm										0.259
AC_AnM								0.845		
AC_Gnot										0.592
AD_TRaE				0.398						
AD_TRaP				0.987						
AE_Ayr					0.821					
AE_E					0.551					
AE_ReEn					0.620					
AS_DOC	0.267									
AS_EVAL										0.507
AS_NO_DOC										-0.119
AS_ST			0.858							
A_CA							0.936			
CR_P			0.078							
C_C									-0.051	
DR_C			0.099							
DR_D			0.106							
DR_F			-0.264							
DR_PrAu			-0.427							
DR_T			0.528							
EAS_EA									-0.617	
EDS_FDA	0.378									
EG_NEWp										0.379
EG_POL										-0.362
EG_REG										-0.537
EG_STD										0.428
IAS_AP									0.679	
IAS_ENC									-0.898	
IAS_IA									-0.224	
IAS_InAS									-0.132	
IAS_Sinv									-0.922	
IR_AuRes			-0.451							
IR_I			0.034							
NC_AP_Nc									0.533	
NC_C										-0.114
NC_E_FIND									-0.611	
NC_IA										0.630
NC_IA_Nc									0.163	
NFP_INV	0.914									
QOG_BU_NC						0.949				
QOG_LTP						0.721				
QOG_SP						0.140				
RW_Pa							0.375			
TC_AQ			0.849							
TC_TAP			-0.201							
TC_TCA							0.858			
TC_TPL			0.466							
TE_TReP		0.045								
TE_TeP		-0.076								
TP_TpP		0.540								
TR_TC		0.932								
TR_TdPOP		0.850								
TR_TdRES		0.945								
TR_TpR		0.096								
T_Ce					0.578					
T_ST					0.082					
T_Tr					0.560					

APPENDIX M

NORMALITY TEST FOR MODIFIED MODEL USING IBM SPSS STATISTICS SOFTWARE (51 VARIABLES)

```
EXAMINE VARIABLES=DR_PrAu DR_T DR_F DR_D IR_AuRes TC_AQ
TC_TPL TC_TAP AS_ST T_Tr T_Ce AE_E AE_ReEn AE_Ayr
EDS_FDA EAS_EA IAS_IA IAS_ENC IAS_AP IAS_Sinv NC_AP_Nc
NC_IA_Nc AC_Gnot AC_Acm EG_STD EG_REG EG_POL EG_NEWp
AS_EVAL AS_DOC NFP_INV NC_IA NC_E_FIND AD_TRaP AD_TRaE
A_CA RW_Pa TC_TCA AA_TQTY AA_EFF AA_MT AA_MP AC_AnM
AC_AM TP_TpP TR_TC TR_TdRES TR_TdPOP QOG_BU_NC QOG_LTP
QOG_SP
  /PLOT BOXPLOT STEMLEAF NPPLOT
  /COMPARE GROUPS
  /STATISTICS DESCRIPTIVES
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
DR_PrAu	.397	50	.000	.645	50	.000
DR_T	.491	50	.000	.373	50	.000
DR_F	.536	50	.000	.125	50	.000
DR_D	.180	50	.000	.836	50	.000
IR_AuRes	.288	50	.000	.838	50	.000
TC_AQ	.175	50	.001	.930	50	.006
TC_TPL	.166	50	.001	.903	50	.001
TC_TAP	.310	50	.000	.495	50	.000
AS_ST	.180	50	.000	.927	50	.004
T_Tr	.376	50	.000	.631	50	.000
T_Ce	.364	50	.000	.600	50	.000
AE_E	.365	50	.000	.794	50	.000
AE_ReEn	.257	50	.000	.828	50	.000
AE_Ayr	.175	50	.001	.930	50	.006
EDS_FDA	.435	50	.000	.616	50	.000
EAS_EA	.465	50	.000	.562	50	.000
IAS_IA	.270	50	.000	.802	50	.000

IAS_ENC	.395	50	.000	.690	50	.000
IAS_AP	.322	50	.000	.674	50	.000
IAS_Sinv	.161	50	.002	.897	50	.000
NC_AP_Nc	.499	50	.000	.467	50	.000
NC_IA_Nc	.285	50	.000	.788	50	.000
AC_Gnot	.492	50	.000	.314	50	.000
AC_Acm	.181	50	.000	.835	50	.000
EG_STD	.390	50	.000	.689	50	.000
EG_REG	.290	50	.000	.708	50	.000
EG_POL	.228	50	.000	.819	50	.000
EG_NEWp	.499	50	.000	.467	50	.000
AS_EVAL	.125	50	.050	.896	50	.000
AS_DOC	.120	50	.068	.960	50	.085
NFP_INV	.267	50	.000	.673	50	.000
NC_IA	.218	50	.000	.812	50	.000
NC_E_FIND	.431	50	.000	.583	50	.000
AD_TRaP	.271	50	.000	.641	50	.000
AD_TRaE	.166	50	.001	.890	50	.000
A_CA	.203	50	.000	.840	50	.000
RW_Pa	.499	50	.000	.467	50	.000
TC_TCA	.163	50	.002	.843	50	.000
AA_TQTY	.279	50	.000	.632	50	.000
AA_EFF	.278	50	.000	.635	50	.000
AA_MT	.349	50	.000	.636	50	.000
AA_MP	.294	50	.000	.772	50	.000
AC_AnM	.156	50	.004	.873	50	.000
AC_AM	.529	50	.000	.344	50	.000
TP_TpP	.164	50	.002	.916	50	.002
TR_TC	.507	50	.000	.316	50	.000
TR_TdRES	.540	50	.000	.201	50	.000
TR_TdPOP	.494	50	.000	.280	50	.000
QOG_BU_NC	.209	50	.000	.878	50	.000
QOG_LTP	.305	50	.000	.811	50	.000
QOG_SP	.284	50	.000	.798	50	.000

APPENDIX N

PLS-SEM: QUALITY CRITERIA RESULTS FOR THE MODIFIED PATH MODEL

Construct Reliability and Validity

	Cronbach's Alpha	rho_A	Composite Reliability	Average Variance Extracted (AVE)
AUDIT EFFECTIVENESS	0.147	0.157	0.552	0.350
AUDIT EFFORT	0.839	0.896	0.898	0.697
AUDIT PLANNING	0.232	0.791	0.253	0.276
AUDIT REPORT	0.397	1.483	0.685	0.564
AUDITOR KNOWLEGDE	0.673	0.785	0.774	0.411
BUSINESS RISK	0.674	0.325	0.718	0.507
CORRECTIVE ACTION	0.611	0.813	0.790	0.584
MONITORING	0.768	0.924	0.865	0.609
OPERATIONAL RISK	0.305	0.978	0.470	0.417
STRATEGIC RISK	0.180	0.479	0.377	0.230

APPENDIX O

CONVERGENT VALIDITY FOR THE MODIFIED PATH MODEL

Outer

	AUDIT EFFECTIVENESS	AUDIT EFFORT	AUDIT PLANNING	AUDIT REPORT	AUDITOR KNOWLEGDE	BUSINESS RISK	CORRECTIVE ACTION	MONITORING	OPERATIONAL RISK	STRATEGIC RISK
AA_EFF								0.924		
AA_MP								0.740		
AA_MT								0.764		
AA_TQTY								0.923		
AC_AM								-0.323		
AC_Acm										0.259
AC_AnM								0.845		
AC_Gnot										0.603
AD_TRaE				0.387						
AD_TRaP				0.989						
AE_Ayr					0.804					
AE_E					0.572					
AE_ReEn					0.633					
AS_DOC	0.258									
AS_EVAL										0.508
AS_ST			0.884							
A_CA							0.936			
DR_D			0.127							
DR_F			-0.259							
DR_PrAu			-0.426							
DR_T			0.508							
EAS_EA									0.608	
EDS_FDA	0.376									
EG_NEWp										0.374
EG_POL										-0.362
EG_REG										-0.530
EG_STD										0.452
IAS_AP									-0.752	
IAS_ENC									0.909	
IAS_IA									0.318	
IAS_Sinv									0.934	
IR_AuRes			-0.450							
NC_AP_Nc									-0.482	
NC_E_FIND									0.600	
NC_IA										0.627
NC_IA_Nc									-0.098	
NFP_INV	0.917									
QOG_BU_N						-0.893				
QOG_LTP						-0.819				
QOG_SP						-0.228				
RW_Pa							0.375			
TC_AQ			0.874							
TC_TAP			-0.193							
TC_TCA							0.858			
TC_TPL			0.423							
TP_TpP		0.524								
TR_TC		0.944								
TR_TdPOP		0.839								
TR_TdRES		0.958								
T_Ce					0.593					
T_Tr					0.576					

APPENDIX P

DISCRIMINANT VALIDITY FOR THE MODIFIED PATH MODEL

Fornell-Larcker Criterion

	AUDIT EFFECTIVENESS	AUDIT EFFORT	AUDIT PLANNING	AUDIT REPORT	AUDITOR KNOWLEGDE	BUSINESS RISK	CORRECTIVE ACTION	MONITORING	OPERATIONAL RISK	STRATEGIC RISK
AUDIT EFFECTIVENESS	0.591									
AUDIT EFFORT	0.383	0.835								
AUDIT PLANNING	0.140	0.377	0.526							
AUDIT REPORT	-0.074	0.556	0.288	0.751						
AUDITOR KNOWLEGDE	0.279	0.296	0.821	0.247	0.641					
BUSINESS RISK	-0.588	-0.358	-0.059	-0.127	-0.091	0.712				
CORRECTIVE ACTION	0.566	0.567	0.269	0.323	0.340	-0.498	0.764			
MONITORING	0.747	0.538	0.247	0.211	0.361	-0.570	0.792	0.781		
OPERATIONAL RISK	0.338	0.304	0.405	0.319	0.556	-0.230	0.514	0.389	0.646	
STRATEGIC RISK	0.618	0.595	0.340	0.148	0.345	-0.417	0.609	0.645	0.517	0.479

APPENDIX Q

BOOTSTRAPPING: PATH COEFFICIENTS FOR THE MODIFIED PATH MODEL (T-VALUES, P-VALUES, C.I.)

Mean, STDEV, T-Values, P-Values

	Original Sample	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AUDIT EFFORT -> AUDIT EFFECTIVENESS	0.178	0.183	0.278	0.639	0.523
AUDIT EFFORT -> AUDIT REPORT	0.556	0.439	0.314	1.766	0.078
AUDIT PLANNING -> AUDIT EFFECTIVENESS	-0.013	0.026	0.165	0.077	0.938
AUDIT PLANNING -> AUDIT EFFORT	0.197	0.163	0.245	0.806	0.421
AUDIT REPORT -> AUDIT EFFECTIVENESS	-0.320	-0.254	0.188	1.703	0.089
AUDIT REPORT -> CORRECTIVE ACTION	0.323	0.264	0.275	1.176	0.240
AUDITOR KNOWLEGDE -> AUDIT PLANNING	0.862	0.799	0.242	3.561	0.000
BUSINESS RISK -> AUDIT PLANNING	0.002	0.011	0.121	0.014	0.989
CORRECTIVE ACTION -> AUDIT EFFECTIVENESS	-0.001	0.069	0.362	0.004	0.997
CORRECTIVE ACTION -> MONITORING	0.792	0.795	0.059	13.432	0.000
MONITORING -> AUDIT EFFECTIVENESS	0.723	0.604	0.362	1.996	0.046
OPERATIONAL RISK -> AUDIT PLANNING	-0.074	-0.019	0.217	0.342	0.733
STRATEGIC RISK -> AUDIT EFFORT	0.527	0.552	0.180	2.928	0.004

Confidence Intervals

	2.5%	97.5%
AUDIT EFFORT -> AUDIT EFFECTIVENESS	-0.421	0.658
AUDIT EFFORT -> AUDIT REPORT	-0.102	0.856
AUDIT PLANNING -> AUDIT EFFECTIVENESS	-0.286	0.379
AUDIT PLANNING -> AUDIT EFFORT	-0.569	0.607
AUDIT REPORT -> AUDIT EFFECTIVENESS	-0.617	0.122
AUDIT REPORT -> CORRECTIVE ACTION	-0.279	0.669
AUDITOR KNOWLEGDE -> AUDIT PLANNING	0.061	1.121
BUSINESS RISK -> AUDIT PLANNING	-0.240	0.251
CORRECTIVE ACTION -> AUDIT EFFECTIVENESS	-0.757	0.835
CORRECTIVE ACTION -> MONITORING	0.656	0.890
MONITORING -> AUDIT EFFECTIVENESS	-0.236	1.139
OPERATIONAL RISK -> AUDIT PLANNING	-0.487	0.377
STRATEGIC RISK -> AUDIT EFFORT	0.061	0.865

APPENDIX R

BOOTSTRAPPING: OUTER LOADINGS FOR THE MODIFIED PATH MODEL

(T-VALUES AND P-VALUES)

Outer Loadings

	Original Sample	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AA_EFF <- MONITORING	0.924	0.927	0.015	61.664	0.000
AA_MP <- MONITORING	0.740	0.741	0.080	9.259	0.000
AA_MT <- MONITORING	0.764	0.771	0.049	15.598	0.000
AA_TQTY <- MONITORING	0.923	0.925	0.015	60.843	0.000
AC_AM <- MONITORING	-0.323	-0.321	0.088	3.657	0.000
AC_Acm <- STRATEGIC RISK	0.259	0.212	0.250	1.036	0.301
AC_AnM <- MONITORING	0.845	0.834	0.053	16.028	0.000
AC_Gnot <- STRATEGIC RISK	0.603	0.446	0.308	1.954	0.051
AD_TRaE <- AUDIT REPORT	0.387	0.459	0.334	1.157	0.248
AD_TRaP <- AUDIT REPORT	0.989	0.848	0.303	3.261	0.001
AE_Ayr <- AUDITOR KNOWLEGDE	0.804	0.748	0.198	4.068	0.000
AE_E <- AUDITOR KNOWLEGDE	0.572	0.499	0.233	2.460	0.014
AE_ReEn <- AUDITOR KNOWLEGDE	0.633	0.546	0.213	2.970	0.003
AS_DOC <- AUDIT EFFECTIVENESS	0.258	0.232	0.338	0.762	0.446
AS_EVAL <- STRATEGIC RISK	0.508	0.385	0.407	1.249	0.212
AS_ST <- AUDIT PLANNING	0.884	0.790	0.206	4.296	0.000
A_CA <- CORRECTIVE ACTION	0.936	0.928	0.026	36.151	0.000
DR_D <- AUDIT PLANNING	0.127	0.108	0.293	0.434	0.665
DR_F <- AUDIT PLANNING	-0.259	-0.188	0.161	1.606	0.109
DR_PrAu <- AUDIT PLANNING	-0.426	-0.354	0.348	1.227	0.220
DR_T <- AUDIT PLANNING	0.508	0.421	0.350	1.448	0.148
EAS_EA <- OPERATIONAL RISK	0.608	0.120	0.601	1.011	0.313
EDS_FDA <- AUDIT EFFECTIVENESS	0.376	0.298	0.389	0.968	0.334
EG_NEWp <- STRATEGIC RISK	0.374	0.344	0.305	1.225	0.221
EG_POL <- STRATEGIC RISK	-0.362	-0.324	0.252	1.438	0.151
EG_REG <- STRATEGIC RISK	-0.530	-0.489	0.267	1.986	0.048
EG_STD <- STRATEGIC RISK	0.452	0.381	0.282	1.603	0.110
IAS_AP <- OPERATIONAL RISK	-0.752	-0.173	0.717	1.048	0.295
IAS_ENC <- OPERATIONAL RISK	0.909	0.191	0.816	1.114	0.266
IAS_IA <- OPERATIONAL RISK	0.318	0.110	0.438	0.726	0.468
IAS_Sinv <- OPERATIONAL RISK	0.934	0.195	0.841	1.110	0.267
IR_AuRes <- AUDIT PLANNING	-0.450	-0.366	0.362	1.245	0.214
NC_AP_Nc <- OPERATIONAL RISK	-0.482	-0.050	0.491	0.981	0.327
NC_E_FIND <- OPERATIONAL RISK	0.600	0.119	0.595	1.008	0.314
NC_IA <- STRATEGIC RISK	0.627	0.567	0.283	2.215	0.027
NC_IA_Nc <- OPERATIONAL RISK	-0.098	0.043	0.247	0.396	0.693
NFP_INV <- AUDIT EFFECTIVENESS	0.917	0.842	0.205	4.468	0.000
QOG_BU_NC <- BUSINESS RISK	-0.893	0.218	0.652	1.369	0.172
QOG_LTP <- BUSINESS RISK	-0.819	0.277	0.512	1.600	0.110
QOG_SP <- BUSINESS RISK	-0.228	0.185	0.635	0.358	0.720
RW_Pa <- CORRECTIVE ACTION	0.375	0.345	0.268	1.398	0.163
TC_AQ <- AUDIT PLANNING	0.874	0.790	0.207	4.231	0.000
TC_TAP <- AUDIT PLANNING	-0.193	-0.145	0.229	0.844	0.399
TC_TCA <- CORRECTIVE ACTION	0.858	0.849	0.072	11.851	0.000
TC_TPL <- AUDIT PLANNING	0.423	0.381	0.339	1.248	0.212
TP_TpP <- AUDIT EFFORT	0.524	0.521	0.234	2.242	0.025
TR_TC <- AUDIT EFFORT	0.944	0.824	0.363	2.602	0.010
TR_TdPOP <- AUDIT EFFORT	0.839	0.697	0.319	2.634	0.009
TR_TdRES <- AUDIT EFFORT	0.958	0.828	0.337	2.840	0.005
T_Ce <- AUDITOR KNOWLEGDE	0.593	0.477	0.470	1.262	0.207
T_Tr <- AUDITOR KNOWLEGDE	0.576	0.462	0.471	1.221	0.223

APPENDIX S

BOOTSTRAPPING: INDIRECT EFFECTS FOR THE MODIFIED PATH MODEL (T-VALUES AND P-VALUES)

Mean, STDEV, T-Values, P-Values

	Original Sample	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AUDIT EFFORT -> AUDIT EFFECTIVEN	-0.075	-0.025	0.142	0.530	0.596
AUDIT EFFORT -> AUDIT REPORT					
AUDIT EFFORT -> CORRECTIVE ACTIO	0.179	0.192	0.177	1.015	0.311
AUDIT EFFORT -> MONITORING	0.142	0.155	0.144	0.990	0.323
AUDIT PLANNING -> AUDIT EFFECTIVE	0.020	0.018	0.064	0.317	0.752
AUDIT PLANNING -> AUDIT EFFORT			0.000		
AUDIT PLANNING -> AUDIT REPORT	0.110	0.101	0.122	0.902	0.367
AUDIT PLANNING -> CORRECTIVE AC	0.035	0.049	0.066	0.536	0.592
AUDIT PLANNING -> MONITORING	0.028	0.040	0.055	0.512	0.609
AUDIT REPORT -> AUDIT EFFECTIVEN	0.185	0.154	0.186	0.994	0.321
AUDIT REPORT -> CORRECTIVE ACTI		0.000	0.000		
AUDIT REPORT -> MONITORING	0.256	0.215	0.220	1.164	0.245
AUDITOR KNOWLEGDE -> AUDIT EFFI	0.006	0.034	0.108	0.060	0.952
AUDITOR KNOWLEGDE -> AUDIT EFF	0.170	0.127	0.174	0.977	0.329
AUDITOR KNOWLEGDE -> AUDIT PLA					
AUDITOR KNOWLEGDE -> AUDIT REP	0.095	0.076	0.090	1.048	0.295
AUDITOR KNOWLEGDE -> CORRECTI	0.031	0.036	0.048	0.640	0.522
AUDITOR KNOWLEGDE -> MONITORIN	0.024	0.030	0.039	0.614	0.540
BUSINESS RISK -> AUDIT EFFECTIVEN	0.000	0.001	0.019	0.001	0.999
BUSINESS RISK -> AUDIT EFFORT	0.000	0.004	0.043	0.008	0.994
BUSINESS RISK -> AUDIT PLANNING		0.000	0.000		
BUSINESS RISK -> AUDIT REPORT	0.000	0.002	0.027	0.007	0.994
BUSINESS RISK -> CORRECTIVE ACTI	0.000	0.001	0.015	0.004	0.997
BUSINESS RISK -> MONITORING	0.000	0.001	0.013	0.004	0.997
CORRECTIVE ACTION -> AUDIT EFFEC	0.573	0.481	0.295	1.945	0.052
CORRECTIVE ACTION -> MONITORING		0.000	0.000		
MONITORING -> AUDIT EFFECTIVENES		0.000	0.000		
OPERATIONAL RISK -> AUDIT EFFECT	-0.001	-0.002	0.036	0.015	0.988
OPERATIONAL RISK -> AUDIT EFFORT	-0.015	0.002	0.083	0.176	0.860
OPERATIONAL RISK -> AUDIT PLANNI		0.000	0.000		
OPERATIONAL RISK -> AUDIT REPORT	-0.008	0.000	0.037	0.222	0.824
OPERATIONAL RISK -> CORRECTIVE A	-0.003	0.000	0.019	0.139	0.889
OPERATIONAL RISK -> MONITORING	-0.002	0.000	0.016	0.132	0.895
STRATEGIC RISK -> AUDIT EFFECTIVE	0.054	0.101	0.156	0.345	0.730
STRATEGIC RISK -> AUDIT EFFORT					
STRATEGIC RISK -> AUDIT REPORT	0.293	0.231	0.183	1.599	0.110
STRATEGIC RISK -> CORRECTIVE AC	0.095	0.104	0.097	0.973	0.331
STRATEGIC RISK -> MONITORING	0.075	0.083	0.078	0.962	0.336

APPENDIX T

FINAL MODELS: INDICATORS NAME AND DESCRIPTION

Item #	Indicator Name	Indicator Description
1	DR_PrAu	DETECTION RISK YEARS OF PREVIOUS AUDIT
2	DR_T	DETECTION RISK TOOLS
3	DR_F	DETECTION RISK FORUM
5	DR_D	DETECTION RISKQTY OF DEFECTS
8	IR_AuRes	INHERENT RISK - AUDITS USED FOR PLAN
13	TC_AQ	TIME CONTRAINTS AUDIT YEARLY
14	TC_TPL	TIME CONTRAINTS FOR PLAN PREPARATION
15	TC_TAP	TIME CONTRAINTS PLAN APPROVAL
17	AS_ST	AUDIT SAMPLING - SAMPLING TECHNIQUES
18	T_Tr	AUDIT TRAINING - TRAINING QTY
19	T_Ce	AUDIT TRAINING - CERTIFICATION QTY
22	AE_E	AUDITOR'S EXPERIENCE IN AUDIT
23	AE_ReEn	AUDITOR'S EXPERIENCE IN A REGULATED ENVIRONMENT
24	AE_Ayr	AUDITORS EXPERIENCE - AUDIT COMPLETED IN A YEAR
25	EDS_FDA	EXTERNAL DATA SOURCE - FDA OBS LAST YEAR
40	AC_Gnot	AC-GOAL NOT MET
41	AC_Acm	AC-AUDIT MET AC
42	EG_STD	EXTERNAL GOVERNANCE - STANDARDS CHANGE
43	EG_REG	EXTERNAL GOVERNANCE - REGULATIONS CHANGE
44	EG_POL	EXTERNAL GOVERNANCE - CORPORATE POLICIES CHANGES
45	EG_NEWp	EXTERNAL GOVERNANCE - NEW PROD INTRODUCTION
46	AS_EVAL	AUDIT STRATEGY - QTY OF DOCUMENTS TO ASSESS
48	AS_DOC	AUDIT SOURCE - EXTERNAL FINDINGS DOCUMENTS RECEIVE IN LAST YEAR
49	NFP_INV	NOT FOLLOWING PROCEDURE - INVESTIGATION DUE TO NOT FOLLOWING PROCEDURE
54	NC_IA	NC-INTERNAL AUDIT FINDING
55	AD_TRaP	AUDIT DELAY-TIME TO RERPORT AFTER PLAN
56	AD_TRaE	AUDIT DELAY-TIME TO REPORT AFTER EXECUTION
60	A_CA	ACTIONS - CORRECTIVE ACTIONS IN A YEAR
63	RW_Pa	RW_AUDIT PERFORMED IN A YEAR
66	TC_TCA	TIME CONSTRAINTS - TIME FOR CORRECTIVE ACTION
67	AA_TQTY	ASSESSMENT ACTIVITY - QTY OF EFFECTIVENESS TASK
68	AA_EFF	ASSESSMENT ACTIVITY- EFFECTIVENESS OF EFFECTIVENESS TASK
69	AA_MT	ASSESSMENT ACTIVITY - FREQUENCY OF MONITORING TASKS
70	AA_MP	ASSESSMENT ACTIVITY - MONITORING PERIOD
73	AC_AnM	ACCEPTANCE CRITERIA - AREAS NOT MET
74	AC_AM	ACCEPTANCE CRITERIA - AREAS MET AC
75	TP_TpP	TIME TO PREPARE THE PLAN
81	TR_TC	TIME TO REPORT - TIME TO COMMUNICATE
82	TR_TdRES	TIME TO REPORT - TIME TO DISCUSS RESULTS WITH MGT
83	TR_TdPOP	TIME TO REPORT - TIME TO DISCUSS WITH POPULATION

APPENDIX U

NORMALITY TEST FOR MODIFIED MODEL USING IBM SPSS STATISTICS SOFTWARE (51 VARIABLES)

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EXAMINE VARIABLES=DR_PrAu DR_T DR_F DR_D IR_AuRes TC_AQ
TC_TPL TC_TAP AS_ST T_Tr T_Ce AE_E AE_ReEn AE_Ayr
EDS_FDA AC_Gnot AC_Acm EG_STD EG_REG EG_POL EG_NEWp
AS_EVAL AS_DOC NFP_INV NC_IA AD_TRaP AD_TRaE A_CA RW_Pa
TC_TCA AA_TQTY AA_EFF AA_MT AA_MP AC_AnM AC_AM TP_TpP
TR_TC TR_TdRES TR_TdPOP
  /PLOT BOXPLOT STEMLEAF HISTOGRAM NPPLOT
  /COMPARE GROUPS
  /STATISTICS DESCRIPTIVES
  /CINTERVAL 95
  /MISSING LISTWISE
  /NOTOTAL.
```

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
DR_PrAu	.397	50	.000	.645	50	.000
DR_T	.491	50	.000	.373	50	.000
DR_F	.524	50	.000	.152	50	.000
DR_D	.180	50	.000	.836	50	.000
IR_AuRes	.288	50	.000	.838	50	.000
TC_AQ	.175	50	.001	.930	50	.006
TC_TPL	.166	50	.001	.903	50	.001
TC_TAP	.310	50	.000	.495	50	.000
AS_ST	.180	50	.000	.927	50	.004
T_Tr	.376	50	.000	.631	50	.000
T_Ce	.364	50	.000	.600	50	.000
AE_E	.365	50	.000	.794	50	.000
AE_ReEn	.257	50	.000	.828	50	.000
AE_Ayr	.175	50	.001	.930	50	.006
EDS_FDA	.435	50	.000	.616	50	.000
AC_Gnot	.471	50	.000	.482	50	.000
AC_Acm	.181	50	.000	.835	50	.000
EG_STD	.390	50	.000	.689	50	.000

EG_REG	.290	50	.000	.708	50	.000
EG_POL	.228	50	.000	.819	50	.000
EG_NEWp	.499	50	.000	.467	50	.000
AS_EVAL	.125	50	.050	.896	50	.000
AS_DOC	.120	50	.068	.960	50	.085
NFP_INV	.267	50	.000	.673	50	.000
NC_IA	.218	50	.000	.812	50	.000
AD_TRaP	.271	50	.000	.641	50	.000
AD_TRaE	.166	50	.001	.890	50	.000
A_CA	.203	50	.000	.840	50	.000
RW_Pa	.499	50	.000	.467	50	.000
TC_TCA	.163	50	.002	.843	50	.000
AA_TQTY	.279	50	.000	.632	50	.000
AA_EFF	.278	50	.000	.635	50	.000
AA_MT	.349	50	.000	.636	50	.000
AA_MP	.294	50	.000	.772	50	.000
AC_AnM	.156	50	.004	.873	50	.000
AC_AM	.529	50	.000	.344	50	.000

TP_TpP	.164	50	.002	.916	50	.002
TR_TC	.507	50	.000	.316	50	.000
TR_TdRES	.540	50	.000	.201	50	.000
TR_TdPOP	.494	50	.000	.280	50	.000

APPENDIX V

PLS-SEM: COLLINEARITY STATISTICS (VIF)

Inner VIF Values

	AUDIT EFFECTIVENESS	AUDIT EFFORT	AUDIT PLANNING	AUDIT REPORT	CORRECTIVE ACTION	MONITORING
AUDIT EFFECTIVENESS						
AUDIT EFFORT	2.111			1.000		
AUDIT PLANNING	1.185	1.131				
AUDIT REPORT	1.517				1.000	
AUDITOR KNOWLEGDE			1.450			
BUSINESS RISK			1.058			
CORRECTIVE ACTION	2.968					1.000
MONITORING	2.878					
OPERATIONAL RISK			1.519			
STRATEGIC RISK		1.131				

APPENDIX W

BLINDFOLDING AND PREDICTIVE RELEVANCE Q2 (EFFECTS) FOR MODIFIED PATH MODEL

Construct Crossvalidated Redundancy

	SSO	SSE	Q^2 (=1-SSE/SSO)	Q^2 results
AUDIT EFFECTIVENESS	150.000	135.141	0.099	model predicted relevance for this particular construct
AUDIT EFFORT	200.000	185.917	0.070	model predicted relevance for this particular construct
AUDIT REPORT	100.000	104.905	-0.049	model did not predict relevance for this particular construct
CORRECTIVE ACTION	150.000	148.122	0.013	model predicted relevance for this particular construct
MONITORING	300.000	189.372	0.369	model predicted relevance for this particular construct
STRATEGIC RISK	400.000	400.000	N/A	Exogenous latent variable

q^2 Effect Results

Ommit latent variable	Latent variable	Q^2 included	Q^2 excluded	1 - Q^2	q^2	q^2 effect results
AUDIT EFFECTIVENESS	AUDIT EFFORT	0.070	0.046	0.930	0.026	small
	AUDIT REPORT	-0.049	-0.059	1.049	0.009	no effect
	CORRECTIVE ACTION	0.013	0.012	0.987	0.001	no effect
	MONITORING	0.369	0.361	0.631	0.012	no effect

Ommit latent variable	Latent variable	Q^2 included	Q^2 excluded	1 - Q^2	q^2	q^2 effect results
AUDIT EFFORT	AUDIT EFFECTIVENESS	0.099	0.126	0.901	-0.030	no effect
	AUDIT REPORT	-0.049				
	CORRECTIVE ACTION	0.013	0.001	0.987	0.012	no effect
	MONITORING	0.369	0.368	0.631	0.001	no effect

Endogenous latent variable	Exogenous latent variable	Q^2 included	Q^2 excluded	1 - Q^2	q^2	q^2 effect results
AUDIT REPORT	AUDIT EFFECTIVENESS	0.099	0.078	0.901	0.023	small
	AUDIT EFFORT	0.070	0.092	0.930	-0.023	no effect
	CORRECTIVE ACTION	0.013				
	MONITORING	0.369	0.377	0.631	-0.013	no effect

Ommit latent variable	Latent variable	Q^2 included	Q^2 excluded	1 - Q^2	q^2	q^2 effect results
CORRECTIVE ACTION	AUDIT EFFECTIVENESS	0.099	0.127	0.901	-0.031	no effect
	AUDIT EFFORT	0.070	0.071	0.930	-0.001	small
	AUDIT REPORT	-0.049	-0.047	1.049	-0.002	no effect
	MONITORING	0.369				

Ommit latent variable	Latent variable	Q^2 included	Q^2 excluded	1 - Q^2	q^2	q^2 effect results
MONITORING	AUDIT EFFECTIVENESS	0.099	0.069	0.901	0.033	small
	AUDIT EFFORT	0.070	0.065	0.930	0.006	no effect
	AUDIT REPORT	-0.049	-0.041	1.049	-0.008	no effect
	CORRECTIVE ACTION	0.013	0.014	0.987	-0.001	no effect

APPENDIX X

PLS-SEM: QUALITY CRITERIA RESULTS FOR THE FINAL PATH MODELS

Construct Reliability and Validity

	Cronbach's Alpha	rho_A	Composite Reliability	Average Variance Extracted (AVE)
AUDIT EFFECTIVENESS	0.147	0.151	0.554	0.349
AUDIT EFFORT	0.839	0.896	0.898	0.697
AUDIT REPORT	0.397	1.254	0.693	0.569
CORRECTIVE ACTION	0.611	0.828	0.786	0.582
MONITORING	0.768	0.923	0.865	0.609
STRATEGIC RISK	0.180	0.476	0.373	0.228

Construct Reliability and Validity

	Cronbach's Alpha	rho_A	Composite Reliability	Average Variance Extracted (AVE)
AUDIT PLANNING	0.232	0.828	0.290	0.273
AUDITOR KNOWLEGDE	0.673	0.812	0.771	0.409

APPENDIX Y

CONVERGENT VALIDITY FOR THE FINAL PATH MODELS

	AUDIT EFFECTIVENESS	AUDIT EFFORT	AUDIT REPORT	CORRECTIVE ACTION	MONITORING	STRATEGIC RISK
AA_EFF					0.923	
AA_MP					0.741	
AA_MT					0.765	
AA_TQTY					0.922	
AC_AM					-0.325	
AC_Acm						0.260
AC_AnM					0.845	
AC_Gnot						0.595
AD_TRaE			0.409			
AD_TRaP			0.985			
AS_DOC	0.277					
AS_EVAL						0.517
A_CA				0.936		
EDS_FDA	0.367					
EG_NEWp						0.368
EG_POL						-0.366
EG_REG						-0.529
EG_STD						0.446
NC_IA						0.624
NFP_INV	0.915					
RW_Pa				0.339		
TC_TCA				0.870		
TP_TpP		0.512				
TR_TC		0.941				
TR_TdPOP		0.853				
TR_TdRES		0.955				

	AUDIT PLANNING	AUDITOR KNOWLEGDE
AE_Ayr		0.820
AE_E		0.601
AE_ReEn		0.658
AS_ST	0.923	
DR_D	0.204	
DR_F	-0.253	
DR_PrAu	-0.377	
DR_T	0.477	
IR_AuRes	-0.384	
TC_AQ	0.915	
TC_TAP	-0.193	
TC_TPL	0.322	
T_Ce		0.547
T_Tr		0.529

APPENDIX Z

BOOTSTRAPPING: PATH COEFFICIENTS FOR THE FINAL PATH MODELS

(T-VALUES AND P-VALUES)

Mean, STDEV, T-Values, P-Values

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AUDIT EFFORT -> AUDIT REPORT	0.559	0.447	0.311	1.798	0.073
AUDIT REPORT -> AUDIT EFFECTIVENESS	-0.248	-0.245	0.120	2.067	0.039
CORRECTIVE ACTION -> MONITORING	0.795	0.799	0.055	14.333	0.000
MONITORING -> AUDIT EFFECTIVENESS	0.799	0.801	0.085	9.380	0.000
STRATEGIC RISK -> AUDIT EFFORT	0.594	0.652	0.171	3.475	0.001

Mean, STDEV, T-Values, P-Values

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AUDITOR KNOWLEGDE -> AUDIT PLANNING	0.846	0.830	0.245	3.459	0.001

APPENDIX AA

BOOTSTRAPPING: OUTER LOADINGS FOR THE FINAL PATH MODELS (T-VALUES AND P-VALUES)

Outer Loadings

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AA_EFF <- MONITORING	0.923	0.926	0.014	65.659	0.000
AA_MP <- MONITORING	0.741	0.742	0.084	8.780	0.000
AA_MT <- MONITORING	0.765	0.775	0.052	14.599	0.000
AA_TQTY <- MONITORING	0.922	0.925	0.014	65.632	0.000
AC_AM <- MONITORING	-0.325	-0.327	0.097	3.351	0.001
AC_Acm <- STRATEGIC RISK	0.260	0.206	0.253	1.027	0.305
AC_AnM <- MONITORING	0.845	0.832	0.057	14.736	0.000
AC_Gnot <- STRATEGIC RISK	0.595	0.440	0.303	1.965	0.050
AD_TRaE <- AUDIT REPORT	0.409	0.509	0.293	1.395	0.164
AD_TRaP <- AUDIT REPORT	0.985	0.868	0.248	3.968	0.000
AS_DOC <- AUDIT EFFECTIVENESS	0.277	0.278	0.276	1.002	0.317
AS_EVAL <- STRATEGIC RISK	0.517	0.390	0.422	1.228	0.220
A_CA <- CORRECTIVE ACTION	0.936	0.933	0.019	49.882	0.000
EDS_FDA <- AUDIT EFFECTIVENESS	0.367	0.296	0.332	1.104	0.270
EG_NEWp <- STRATEGIC RISK	0.368	0.339	0.316	1.167	0.244
EG_POL <- STRATEGIC RISK	-0.366	-0.325	0.254	1.441	0.150
EG_REG <- STRATEGIC RISK	-0.529	-0.485	0.279	1.899	0.058
EG_STD <- STRATEGIC RISK	0.446	0.370	0.276	1.617	0.107
NC_IA <- STRATEGIC RISK	0.624	0.557	0.301	2.076	0.038
NFP_INV <- AUDIT EFFECTIVENESS	0.915	0.889	0.073	12.551	0.000
RW_Pa <- CORRECTIVE ACTION	0.339	0.312	0.257	1.317	0.188
TC_TCA <- CORRECTIVE ACTION	0.870	0.862	0.064	13.690	0.000
TP_TpP <- AUDIT EFFORT	0.512	0.496	0.236	2.171	0.030
TR_TC <- AUDIT EFFORT	0.941	0.844	0.308	3.055	0.002
TR_TdPOP <- AUDIT EFFORT	0.853	0.704	0.341	2.500	0.013
TR_TdRES <- AUDIT EFFORT	0.955	0.832	0.328	2.915	0.004

Outer Loadings

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AE_Ayr <- AUDITOR KNOWLEGDE	0.820	0.794	0.165	4.972	0.000
AE_E <- AUDITOR KNOWLEGDE	0.601	0.561	0.233	2.580	0.010
AE_ReEn <- AUDITOR KNOWLEGDE	0.658	0.587	0.211	3.119	0.002
AS_ST <- AUDIT PLANNING	0.923	0.882	0.173	5.346	0.000
DR_D <- AUDIT PLANNING	0.204	0.207	0.255	0.798	0.425
DR_F <- AUDIT PLANNING	-0.253	-0.169	0.152	1.660	0.098
DR_PrAu <- AUDIT PLANNING	-0.377	-0.309	0.292	1.291	0.197
DR_T <- AUDIT PLANNING	0.477	0.386	0.327	1.457	0.146
IR_AuRes <- AUDIT PLANNING	-0.384	-0.298	0.299	1.286	0.199
TC_AQ <- AUDIT PLANNING	0.915	0.883	0.173	5.280	0.000
TC_TAP <- AUDIT PLANNING	-0.193	-0.135	0.224	0.861	0.390
TC_TPL <- AUDIT PLANNING	0.322	0.272	0.270	1.191	0.234
T_Ce <- AUDITOR KNOWLEGDE	0.547	0.422	0.445	1.227	0.220
T_Tr <- AUDITOR KNOWLEGDE	0.529	0.405	0.447	1.183	0.237

APPENDIX BB

BOOTSTRAPPING: INDIRECT EFFECTS FOR THE MODIFIED PATH MODEL (T-VALUES AND P-VALUES)

Mean, STDEV, T-Values, P-Values

	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics (|O/STDEV|)	P Values
AUDIT EFFORT -> AUDIT EFFECTIVEN	-0.139	-0.129	0.117	1.186	0.236
AUDIT EFFORT -> AUDIT REPORT					
AUDIT REPORT -> AUDIT EFFECTIVEN					
CORRECTIVE ACTION -> AUDIT EFFE	0.636	0.642	0.089	7.174	0.000
CORRECTIVE ACTION -> MONITORINC					
MONITORING -> AUDIT EFFECTIVENE					
STRATEGIC RISK -> AUDIT EFFECTIVI	-0.082	-0.086	0.086	0.958	0.338
STRATEGIC RISK -> AUDIT EFFORT					
STRATEGIC RISK -> AUDIT REPORT	0.332	0.287	0.225	1.475	0.141

Note. There are not indirect effects between Auditor Knowledge and Audit Planning, only direct.