

THE EFFECTIVENESS OF ISO 9001:2008 AT POLITEKNIK KESEHATAN MANADO*EFEKTIVITAS ISO 9001:2008 DI POLITEKNIK KESEHATAN MANADO*

by:

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Abstract : Products and services are the result of activities or processes that transform inputs into outputs and the quality of products and services is directly related to the quality of the process that produces them. The purpose of this study is to analyze how Politeknik Kesehatan Kemenkes Manado implements ISO 9001:2008 standard in order to meet the academic, professional and society's expectations. ISO is an international standard that gives requirements for an organization related to its quality management system which focuses on meeting customer expectation and delivering customer satisfaction. In order to get the data needed for this study, the study uses data collection tools such as observation, interview and literature analysis. From primary and secondary data. The results of this study show that the implementation of ISO 9001:2008 in Politeknik Kesehatan Kemenkes Manado is successful and meets the standards of ISO 9001:2008, Some supporting facilities and infrastructures as well as the educational service and process are qualified according to the standard.

Keywords : *ISO 9001:2008, Customer expectation*

Abstrak : Produk dan layanan adalah hasil dari kegiatan atau proses yang mengubah input menjadi output dan kualitas produk dan layanan terkait langsung dengan kualitas proses yang menghasilkannya. Tujuan dari penelitian ini adalah untuk menganalisa bagaimana Politeknik Kesehatan Kemenkes Manado mengimplementasi standar ISO 9001:2008 untuk memenuhi harapan akademik, profesional dan masyarakat. ISO adalah standar internasional yang memberikan persyaratan bagi sebuah organisasi terkait dengan sistem manajemen mutu yang berfokus pada pemenuhan harapan pelanggan dan memberikan kepuasan pelanggan. Untuk mendapatkan data yang dibutuhkan untuk penelitian ini, penelitian ini menggunakan alat pengumpulan data seperti observasi, wawancara dan analisis literatur dari data primer dan data sekunder. Hasil penelitian ini menunjukkan bahwa penerapan ISO 9001: 2008 di Politeknik Kesehatan Kemenkes Manado berhasil dan memenuhi standar ISO 9001: 2008. Beberapa sarana dan prasarana pendukung serta layanan pendidikan dan prosesnya memenuhi syarat sesuai standar.

Kata Kunci : *ISO 9001:2008, harapan pelanggan*

INTRODUCTION

Research Background

In today's global environment, organizations are constantly looking for the ways to expand and improve their business in terms of quality and quantity. Many companies invest great efforts into achieving appropriate organization and through it better quality of products and services. The changes in the competitive landscape at an ever quickening pace and the flow of the business process is the result of globalization. This has been proven the importance of standardization for business companies worldwide. However through TQM implementation such as ISO 9001 in all companies is a way to achieve it. The introduction of the ISO 9001 in a company does not always produce the desired results in practice, this is usually due to ineffective implementation

Quality is to produce products or present services that fulfill the requirements of the customer, standard technical specifications, and/or technical specification issued by the organization. This is one of the hundreds definitions of the word Quality (Michael, 2013). However, at all cases quality is the key word that all societies, organizations, individuals, are looking for and aiming to reach. ISO 9000 establishes a basic set of quality system requirements necessary to ensure that the process is capable of consistently producing products that meet the customer's expectations. Products and services are the result of activities or processes that transform inputs into outputs and the quality of products and services is directly related to the quality of the process that produces them. Therefore, product quality improvement necessitates process quality improvement. There are so many specifications related to ISO 9000.

ISO 9000 is a standout amongst the most broadly perceived in the world. ISO 9000 is a quality management standard that presents rules planned to expand business productivity and keep consumer loyalty. It has been implemented by more than one million organizations in 187 countries since its introduction in 1987. The objective of ISO 9000 is to install a quality management framework inside an organization, expanding profitability, diminishing superfluous expenses, and guaranteeing characteristics of procedures and products. ISO 9001:2008 is pertinent to organizations and associations from each division. The procedure arranged methodology makes the standard material to administration associations also. Its general rules consider the adaptability required for now's differing business world.

Since the 2000 version of the standard, ISO 9001 integrated the Total Quality Management principles into the standard and more focuses on the process and performance rather than documentation. In addition ISO 9001 is based on right quality management principles, namely customer focus, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making, and mutually beneficial supplier relationship.

In the International Workshop Agreement, the learner is the customer while the education service is the product. Politeknik Kesehatan Kemenkes Manado is a professional health education providers institution established based on the decision of the Minister of Health and Social Welfare number 298 / Menkes.Kesos / SK / IV / 2001 dated April 16, 2001. The merger of several Academy in the Ministry of Health Environment became Health of Polytechnic is wrong an effort to develop health personnel resources which must also be adjusted with changes in policies and sets of provisions for the implementation of education oh Health Manpower. In order to meet the consumer expectation, Politeknik Kesehatan Kemenkes Manado, should have the good quality of facilities and services.

The expected quality in an educational organization defined as the curriculum requirement, including the learning outcomes and specific performance indicators. The resource needs for the provision of the educational service should be identified by the organization. For the effective functioning of the quality management system, the organization should also ensure the resources availability and provide the resources to meet the learner requirements. In the term of human resources, the organization should ensure the human resources availability for the effective performance of the quality management system. To support the teaching-learning processes and the educational services, the organization should also identify all the infrastructures, facilities, environment and equipment needed. In order to prove that the organization meets the standard, it has the certification of ISO 9001:2008.

Along these lines, on account of that circumstance, the study will analyze The Effectiveness of ISO 9001:2008 At Politeknik Kesehatan Kemenkes Manado.

Research Objectives

Based on research problem, the objectives of this research is to find out a significant :
The formulated objectives of the research as follows:

1. To identify the factors that impact of ISO 9001:2008 at Politeknik Kesehatan Kemenkes Manado.

2. To analyze the implementation of ISO 9001:2008 at Politeknik Kesehatan Kemenkes Manado.

THEORITICAL FRAMEWORK

Production Operation Management

According to Michael (2013) operations management is the process, which combines and transforms various resources used in the production/operations subsystem of the organization into value added product/services in a controlled manner as per the policies of the organization. Therefore, it is that part of an organization, which is concerned with the transformation of a range of inputs into the required (products/services) having the requisite quality level. The set of interrelated management activities, which are involved in manufacturing certain products, is called as production management. If the same concept is extended to services management, then the corresponding set of management activities is called as operations management.

Total Quality Management

Total Quality Management (TQM) is an approach that seeks to improve quality and performance which will meet or exceed customer expectations. This can be achieved by integrating all quality-related functions and processes throughout the company. TQM looks at the overall quality measures used by a company including managing quality design and development, quality control and maintenance, quality improvement, and quality assurance. (Malik and Blumenfeld, 2012). TQM takes into account all quality measures taken at all levels and involving all company employees.

Quality Management

Quality management involves the formulation of strategies, setting goals and objectives, planning and implementing the plans; and using control systems for monitoring feedback and taking corrective actions Malik and Blumenfeld (2012).

International Organization for Standardization

The ISO 9001 standard gives a set of generic requirements for implementing a quality management system (QMS) independently on the organization's activities (Mohammed, 2006). It is already adopted as the Indonesian National Standards (SNI) and inaugurated by the head of Badan Standarisasi Nasional or National Body of Standardization Number: 127/KEP/BSN/12/2008 on December 31st, 2008. Listed below are the standard guidelines of ISO 9001:2008.

General Requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard (Mohammed, 2006). The organization shall determine the processes needed for the quality management system and their application throughout the organization, determine the sequence and interaction of these processes, determine criteria and methods needed to ensure that both the operation and control of these processes are effective, ensure the availability of resources and information necessary to support the operation and monitoring of these processes, monitor, measure where applicable, and analyze these processes, and implement actions necessary to achieve planned results and continual improvement of these processes (Miles and Huberman, 1994).

Management Responsibility

According to Oakland (2011), top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness.

Customer Satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. The educational

organization should identify all type of resources needed for the provision of the educational service and ensure their availability for the effective performance of the quality management system (Novsia, 2014).

Infrastructure

According to Oakland (2011), the organization should define responsibilities and authorities for carrying out bidding, purchase, receipt, storage, safeguarding, installation, usage, and maintenance activities. The educational organization should determine programs for planning, providing and maintaining the necessary infrastructure, and for analyzing the associated risks regarding people's security, safety, and hygiene. Infrastructure includes but is not limited to buildings, working spaces: classrooms, laboratories, workshops, libraries, green areas, online components and related services, such as health facilities, physical security, transport, bookstore, and cafeterias, among others.

Quality

According Michael (2013), defines that quality is conformance with the hope customer. Definitions of the above experts assessed that there are some elements of quality, a total picture of the product characteristics and suitability to the needs and expectations of customers. Definition of quality based on the results of the study are a total picture of the characteristics of the products / services in accordance with customer needs either expressed or not to improve the competitiveness of enterprises.

Quality Control

Quality control is a conventional way that businesses have to use for manage quality. Quality control is concerned with checking and reviewing work that has been done. This is mainly done by inspection of products and services (checking to make sure that what's being produced is meeting the required standard) take place during and at the end of the operations process.

Quality Assurance

Quality assurance is a prevention based system, which improves product and service quality with increased productivity by placing the emphasis on product, service and process design. Quality assurance emphasis on defect prevention, unlike quality control that focuses on defect detection once the item is produced.

Educational Management

Educational Management is a part of Quality Management. According to Oakland (2011), Educational management is the process of planning, organizing, directing and controlling the activities of an institution by utilizing human and material resources so as to effectively and efficiently accomplish functions of teaching, extension work and research.

Previous Research

Novsia (2014) they are discuss about the effectiveness of ISO 9001 implementation in food manufacturing companies: A proposed measurement instrument. This research aims to propose an instrument that can be used to measure the effectiveness of ISO 9001 implementation in food manufacturing companies. The research is important because there is lack of research on the development of measurement instrument of ISO 9001 implementation effectiveness. In order to develop the measurement instrument of ISO 9001 implementation effectiveness in food manufacturing companies, desk study was performed. The data sources of this desk study are ISO 9001 standard and its standard family, supporting documents that provided by ISO for implementing the standard. ISO 9001 literature and previous researches on the measurement instrument of ISO implementation effectiveness. The analysis was performed by two stages. First, they selected the dimensions of the measurement instrument of ISO 9001 implementation effectiveness in food manufacturing companies. Related to this matter, the criteria they used to select the dimension are the dimension should include lagging dimension and leading dimension. The proposed measurement instrument of ISO 9001 implementation effectiveness in food manufacturing companies has some strength points compare with other instruments available in current literature. First, the proposed instrument has lagging and leading dimensions. The presents of leading dimension make the companies could identify the specific area of improvement while the existence of lagging dimensions make the companies could identify the contribution of ISO 9001 implementation to the companies' success. To date, the measurement instrument of ISO 9001 implementation effectiveness available in current literature only focuses on lagging dimensions or leading dimensions. Second, the proposed measurement instrument was developed based on the synthesis of other researchers' ISO 9001 implementation

effectiveness measurement instrument. Hence, it is expected that our proposed measurement instrument has adequate content validity. Third, the proposed measurement instrument involves dimension representing eight quality management principles. This is useful for checking whether the method of the companies in implementing ISO 9001 is aligned with the eight quality management principles.

Conceptual Framework

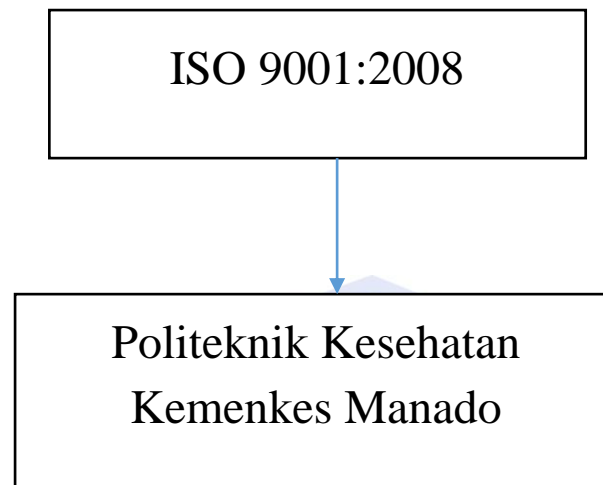


Figure 1. Conceptual framework

Source: Conceptual Theory (2018)

The researcher focuses on three indicators which are facilities, human resources and educational process as the objects of the research. In order to improve current status of institution and making it a better place for effective teaching-learning process, some implementable suggestions were made, when followed would help to provide suitable environment. The educational process itself depends on the facilities provided by the institution and the human resources.

Politeknik Kesehatan Kemenkes Manado is an institution in educational industry. In order to survive and operate well in the global competition, it needs to implement the quality management standards. There are some indicators needed to assess the implementation of quality educational management standards, include: access, customer service, leadership, physical environment, and facilities, educational process, students, administration staffs, public relation, organization's standards.

RESEARCH METHODOLOGY

Type of Research

The qualitative approach in this research aims to outline the data and explain the findings in the field of research and also to find out the real image of what is really happening in the field of research about the implementations of the ISO standards.

Place and Time of Research

This research is taking place in Politeknik Kesehatan Kemenkes Manado, Jl. R.W.Monginsidi, Kelurahan Malalayang Dua, Kecamatan Malalayang, Kota Manado, Sulawesi Utara. This research will be conducted on August 2017.

Population and Sample

Sample in qualitative research is not called as respondent instead as a sources, participant, informant, friend and teacher in research process. Sample in qualitative research also is not statistical sample but a theoretical and constructive sample because the purpose is to gain theory and the source data is the source of constructed phenomenon that was previously unclear before. Purposive sampling is used with some considerations. At first, the researcher collected information from websites, newspaper, or relatives about the

potential respondents that can give information regarding the effectiveness implementation of ISO 9001:2008 in Politeknik Kesehatan Kemenkes Manado.

Data Collection Method

Data collection method that used in this research are the primary data and secondary data, and the respondents in this research 10 respondents. The primary data used to answer the research questions and draw conclusions for the answers of the research questions. While secondary data is used to supplement information with this research.

Data Analysis Method

The process of data analysis in this research were done before entering the social situation while analysis process was done during collecting the data and after finishing the collection data in certain period of time. Doing analysis before entering the social situation used secondary data to decide the tentative limitation of the research. During interview and observation process, analyzing the answers that were given by the informant was done. If the answers or descriptions that were explained by the informant are still unclear, then will continue to ask and find the answer to find credible data.

Data Collection

Data collection is the process where this study find information or data from any kind of source such as books, internet website and gather deeper information from the informant.

Data Reduction

Miles and Huberman (1994) explained data reduction refers to the process of selecting, focusing, simplifying, abstracting, and transforming the "raw" data. Data reduction involves making decisions about which data chunks will provide your initial focus.

Data Display

Data display it helps qualitative researches to organize information and view it in a way that enables them to identify linkages and develop explanations that relate their findings to existing theories.

Drawing and Verifying Conclusion

Drawing conclusion involves deciding what the identified themes and patterns and how they help to answer the research question. Verification involves checking and re-checking the data ensure the initial conclusions are realistic, supportable and valid.

Coding

Coding is the analytic process through which the qualitative data that gathered by doing interview are reduced, rearranged, and integrated to form a theory. It helps in drawing meaningful conclusion about the data. The result from doing coding is called codes. To conduct qualitative analyses, researcher is must understand coding.

Categorization

In categorization, the codes that previously done in the coding process is organized, arranged, and classified. In the process or situations, the patterns and relationship between the data are started to be noticed.

Data Validity Method

There are several ways in maximizing data reliability and validity in qualitative research. Triangulation is one of the common ones. The idea behind triangulation is getting the same result from different methods or sources.

RESULT AND DISCUSSION

History of Company

Politeknik Kesehatan Kemenkes Manado is a professional health education providers institution established based on the decision of the Minister of Health and Social Welfare number 298 / Menkes.Kesos / SK / IV / 2001 dated April 16, 2001. The merger of several Academy in the Ministry of Health Environment became Health Polytechnic is wrong an effort to develop health personnel resources that must also be adjusted with changes in policies and sets of provisions for the implementation of education of Health Manpower.

At this time, Politeknik Kesehatan Kemenkes Manado has 4 Diploma IV Diploma Program, namely D-IV Environmental Health (Environmental Epidemiology & PAPLC), D-IV Nutrition (Interests of Clinical Nutrition & Community Nutrition), D-IV Midwifery (Interests Bidan Pendidik) and D-IV Nursing (Emergency Care) and has 6 Diploma III Study Programs, namely D-III Nursing, D-III Midwifery, D-III Nutrition, D-III Environmental Health, D-III Pharmacy and D-III Dental Health.

Result

The study conducted using qualitative method where it describes the existing problems in the institution and identifies the findings of the study so that the researcher can state the conclusion. The focus of this study is the implementation of ISO 9001:2008 standards in the institution, and the sub-focuses are in the terms of facilities, services and the effectiveness of the educational processes.

Implementation Of ISO

Politeknik Kesehatan Kemenkes Manado first applied the ISO in 2010 and now it's in the third re-certification. Politeknik Kesehatan Kemenkes Manado is one of the institution in the North Sulawesi region that implemented the ISO 9001:2008. In order to meets the learner's satisfaction. It was a big achievement for the institution to show its commitments for giving a good quality of product and service. How to introduce ISO 9001: 2008 quality management system to all employee by way of socialization by the campus. The socialization implemented against employees who do not understand about ISO 9001: 2008 quality management system. The Implementation of quality management system in this ISO 9001: 2008 covers the whole of the learning activities on campus. This cannot be separated from the focus of the ISO quality management system 9001: 2008 itself, which is customer focused. The customers in Politeknik Kesehatan Kemenkes Manado are students. The institution already certified by ISO as an institution which successfully meets the standards, The instruments have been prepared by Politeknik Kesehatan Kemenkes Manado to obtain the certificate of quality management system ISO 9001: 2008 is documents used as the foundation. The document is level I documents, level II documents, document III, and documents level IV. The first level document is a quality manual, the quality manual is guidelines in the pursuit of one goal. Quality guidelines contain vision, mission, and institution quality targets endorsed by the ministry of education. The second document is the Core Procedure. The purpose of this document main activity of functions or units that exist in Politeknik Kesehatan Kemenkes Manado which aims to meet the requirements demanded by customers or requirements other applicable.

In implementing the implementation of ISO 9001: 2008 quality management system, there are some obstacles that arise from various things. Inappropriately the constraints will be an obstacle in every implementation. Obstacles it will adversely affect the system. When constraints is allowed to drag on and not solve its solution. The obstacles facing Politeknik Kesehatan Manado in implementing ISO 9001: 2008 quality management system is human resource, taste carelessness and workload.

Table 1.Implementation of ISO

No	Standard	Terms	Actual
1	Human Resources	The employees should have basic competencies	Every employee has attended on the basic competence training

education, training, skills, and and has passed the training.

work experience.

Politeknik Kesehatan Manado

also has the established

procedures for each employee.

2 Facilities

The organization shall plan The organization has

and implement the production established, provided, and

and supply of services. maintained the necessary

infrastructure to achieve its

customer needs.

For example,

study room, library,

laboratory, etc.

Source: The Clausal for ISO 9001:2008 (2014)

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CONCLUSION AND RECOMMENDATION

Conclusion

1. In the terms of facilities provided by the institution, Politeknik Kesehatan Kemenkes Manado clearly meet the standard of ISO 9001:2008. It also means that this institution is meet the expectations of the academic, professional and society. Politeknik Kesehatan Kemenkes Manado keeps showing its efforts to continuously improve its quality by designing the quality objectives for the near future and keeping its quality assurance which was adopted from ISO 9001:2008 standard as its guidelines.
2. The educational process of this institution is maximal because they have a good human resources and the supporting of infrastructure is good too.

Recommendation

1. Based on the results and the conclusions of the study, the write has several recommendations for the institution as follows:
2. The institution should continuously improve its quality management system and educational process by providing the good quality of facilities and infrastructures and service. The institution should coordinate with the top management to measure, monitor and improve its educational resources based on the ISO 9001:2008 standard and based on the learner is feedback.
3. The institution considers the design and development of education for the benefits of learners.
4. The institution should review the requirements given by the standard and the expectation of the customers. When the learning requirements are changed, the organization should ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
5. The institution should establish good maintenance periodically for the facilities and infrastructures.
6. In the term of maintenance, the institution should work together with the customer to raise awareness of the sense-of-belonging and the sense-of-responsibility because all the facilities and infrastructures are belong to all the users which are the faculties, staffs and students.
7. Additional the control variables be sides firm characteristic to find out another specific factors that may be significantly associated with market reactions

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