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# Controlling Product Realization through ISO 9001:2008 (Case Study in R&D Unit PT. XYZ Indonesia)

Hutami, R. F.\* and Yusrina

Faculty of Economics and Business, Telkom University, Bandung 40257, Indonesia

#### **ABSTRACT**

PT XYZ, although the largest telecommunication services provider in Indonesia still focusses on improving their performance and existence, not only through excellent quality, but also by controlling their workflow process in making product realisations or innovations. This research aims to evaluate several processes of product realisation. Using descriptive analysis, data gathering is divided into two phases: the quantitative and qualitative phase. the research shows that PT XYZ, through its R&D Unit, has carried out every process in product realisation in accordance with ISO 9001:2008. However, the findings show that continuous improvement and innovation in several areas are still needed. Better documentation at every stage in design and development is needed to enable better control and evaluation of the product realisation process.

Keywords: Quality management sytem, ISO 9001:2008, innovation, product realisation

#### INTRODUCTION

The importance of maintaining quality, whether in products or services, is not something new. Literature and research findings show us how quality can result in profit for businesses. Research that discusses how a company can maintain the quality of its products and services is always welcome. This is because quality is still considered the key strategic

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E-mail addresses: riekahutami@telkomuniversity.ac.id, rieka.hutami@gmail.com (Hutami R.F.)

\* Corresponding author

factor in improving business performance and achieving business success, not only for a large company, but also for small companies, whether domestic or worldwide (Thai Hoang et al., 2006). The ability to deliver high-quality products consistently is considered to be one of the fundamental

and substantial competencies for a company to survive global competition (Kim et al., 2011; Willar et al., 2015).

ISO 9000:2008 is an international standard for managing quality. Implementing this standard can be considered the first step in building a quality-orientated environment to produce high-quality services and products. Adopting ISO 9001:2008 can be seen as management commitment from a company to control and improve its quality of product, process, people and environment continuously. ISO 9001:2008 can be implemented not only in manufacturing but also service industries (Thai Hoang et al., 2006). The right attitude and clear communication from the people at the top to those involved in the field is essential in ensuring smooth and proper workflow (Kessler & Alok, 2010).

Many companies realise that there are many benefits in implementing ISO 9001:2008. The benefits are 1) a company's customer base can be widened from domestic to worldwide coverage; 2) there will be improved effectiveness and reliability of a company's work processes; 3) there will be improved quality of products and services; and 4) there will be improved organisational performance and competitiveness. These benefits can be optimised if a company fully understands its motivation in adopting ISO and knows how to align its strategies with its organisational goals.

Up to December 2013 there were 1,129,446 certifications published in 187 countries. The number is 3% higher than that of the previous year with an addition

of 32,459 certifications. In Indonesia, the number of certification has increased from the previous year to 7,890 certifications in 2013, and this number is still growing (Boiral, 2011) (International Organisation for Standardisation, 2013). These data are summarised in Table 1.

Table 1
The Number of ISO 9001:2008 Companies in Indonesia

Year	Amount
2011	3999
2012	5392
2013	7890

Source: International Organisation for Standardisation (2013)

PT XYZ, as the largest telecommunication network and service provider in Indonesia, implemented ISO 9001:2008 not only to beat competition but also to gain a position in the worldwide marketplace. By implementing ISO 9001:2008, they have been able to control the quality of their products. However, PT XYZ realise that quality is not the only one indicator to ensure their existence in the industry. Some organisations have shifted their strategy from quality to innovation (Thai Hoang et al., 2006) because they realise that quality is no longer brings an edge to business (Prajogo & Amrik, 2004). Therefore, PT XYZ transformed their organisation and focussed their new strategy on being more innovative. Their new goal has resulted in their being listed among The World's Most Innovative Companies. This goal is set to

motivate the company to make innovative products. The unit responsible for creating innovative products for PT. XYZ is its Research and Development (R&D) Unit. From studying this unit, we may learn how PT XYZ controls the process of product realisation. Our research is an empirical study focussed on how PT XYZ controls the process of creating innovative products using ISO 9001:2008 clause 7. Clause 7 provides guidance for product realisation.

#### LITERATURE REVIEW

#### **Quality Management System (QMS)**

Quality Management System (QMS) is a set of processes to control procedures and standards in delivering goods or services to the market that are documented (Gasperz, 2012). The objective of a quality management system is to provide an infrastructure for managing product/process quality (Blessner et al., 2013). Another objective of implementing QMS is to meet a company's specified quality requirements or prescribed quality (Nakeeb et al., 1998). Whatever the objective a company chooses is important for improving performance of quality in an organisation (Kung et al., 2014).

The need for a quality management system was also confirmed by Feigenbaum (1992), who pointed out that a company must have a system that is clear and well-structured in order to identify, create documents, coordinate and maintain all the major activities necessary to ensure that quality actions run well inside the company.

Without a systematic guide, the company will find it difficult to carry out activities designed to fulfil the desires of customers.

### International Organisation for Standardisation (ISO) 9001:2008 as Part of Quality Management System

ISO 9000:2008 is a certification standard to develop a quality management system. It has several criteria related to quality that can be used by any organisation in any field of expertise. The standards provide guidance and tools for companies and organisations that want to ensure that their products and services consistently meet customers' requirements, and that quality is consistently improving. This standard is based on a number of quality management principles, including strong customer focus, motivation and implication of top management, employee involvement, process approach, quality management system approach and continued improvement (Gasperz, 2012; International Organisation for Standardisation, 2013). It is one of the quality management systems that can lead an organisation in achieving excellence. It is not a tool to replace Total Quality Management (TQM) but adopting it can be complementary to TQM (Willar et al., 2015). There are several benefits to implementing ISO 9001:2008 such as access to international markets, ease in communicating with foreign suppliers, improvement to the quality and uniformity of work and ultimately, improvement to productivity. In general, ISO 9001:2008 consists of eight topics or clauses that discuss: 1) the scope of ISO; 2) normative references; 3) terms and definitions; and 4) Quality Management System with subclauses highlighting general requirements, documentation requirements, management responsibility, resources management, product realisation, measurement, analysis and improvement.

## Product Realisation (ISO 9001:2008: Clause 7)

The term product realisation has a close relationship with innovation. It is a new way of doing something, which may refer to the need for incremental or radical changes (Azis & Hiroshi, 2010). Organisations that compete through innovation can gain greater advantage through the use of the incremental approach to product development and improvement, rather than by searching for big breakthroughs (Flynn, 1994). In ISO 9001:2008 (2015), a regulation about product realisation is described briefly in clause 7 as follows.

#### Planning of product realisation (Clause

7.1). This clause explains that the organisation should plan the processes needed for product realisation, including quality objectives and product requirement, documents and processes to provide resources, standard measurement for verification, validation, monitoring and inspection related to the criteria for product acceptance and evidence that must be documented to show that the realisation processes and resulting products meet the requirements. Planning of product

realisation should suit any methods used by the organisation.

#### Customer-related processes (Clause

7.2). In general, this clause describes three major topics: determination of product requirement, review of requirement and customer communication. When determining product requirement, specific points that describe the desired product criteria including delivery and post delivery must be taken into account. Post-delivery activities include maintenance service and supplementary services. A second indicator describes the importance of an organisation in conducting a review of the product requirement before the product is given to the customer. When reviewing products, certain criteria must be adhered to such as submission of tenders, acceptance of contracts or orders and acceptance of changes to contracts or orders. The third subclause describes customer communication, including how to determine and implement an effective way of communicating with customers about product information, contracts, feedback and complaints from customers. The desired product review process should be documented, this can help any personnel interested to know in detail about processes and product development.

#### Design and Development (Clause 7.3).

This clause describes requirements in the process of designing and developing products. It includes several sub-clauses that regulate in detail the stages of the design process and product development from

planning, input, output, review, verification, validation and control of changes. The goals are to produce products according to customer requirements. The first sub-clause explains design and development planning details; at these stages, managing interfaces between different groups is very important. Good communication and responsibility need to be managed in an efficient and productive way. The second refers to design and development input relating to product requirement; design and development details must be determined and records connected to them must be maintained and reviewed. The third sub-clause specifies that the generated design and development output must correspond with the input required for design and development. In addition, at this stage the characteristics of safe products and how to use them properly must be determined. The fourth sub-clause outlines that design and development review has two goals i.e. to evaluate whether the products are manufactured according to requested specifications and to identify problems early in order to take preventative action. The fifth sub-clause stipulates that design and development must be reviewed. The sixth sub-clause is concerned with design and development verification while the seventh considers design and development validation and the eighth, control design and development changes.

**Purchasing (Clause 7.4).** In order to satisfy customers with quality products, organisations must ensure that the raw materials are of good quality and conform

to specified purchase requirements. ISO 9001:2008 has several requirements related to the purchasing process. This process is described in detail in clause 7.4 and includes the purchasing process, purchasing information and verification of purchase products. The purchasing process outlines criteria for selecting and assessing suppliers. Purchasing information describes the product to be purchased and includes specified purchase requirements. Then, verification of the purchased product is obtained.

Production and service provision (Clause 7.5). The requirement regarding production process and service provision is described in detail in this clause. This clause regulates some activities including control of production and service provision, validation of processes for production and service provision, identification and traceability, customer property and preservation. In controlling products and services, an organisation should plan its activities, for which it needs information such as characteristics of the product, work instruction, suitable equipment, availability and use of monitoring and measuring equipment, the implementation of monitoring and measurement, implementation of product release, delivery and post-delivery activities. When the output cannot be verified by subsequent monitoring or measurement, the organisation must validate production and service provision processes. After these, identification and traceability are required so the organisation

can identify the product status with respect to monitoring and measurement requirements throughout product realisation. The organisation also must be concerned about the customer's property while it is under the organisation's control or is being used by the organisation. Customer property includes intellectual property and personal data. This activity leads to the next clause, which is preservation of product, including identification, handling, packaging, storing and protection. Preservation also applies to the constituent parts of a product.

Control of monitoring and measuring equipment (Clause 7.6). The organisation should determine the measuring tools, methods and equipment that are used to monitor and measure conformity of products to the organisation's criteria. It is also importrant to supervise the process of measuring and monitoring. All activities from determination gauges, implementation and evaluation up to problem solving must be recorded. This sub-clause regulates all these processes in detail.

This study, using six sub-clauses stated in ISO 9001:2008 are related to Clause 7 about product realisation as a variable, described briefly above. In the next section, we describe the processes of controlling product development or realisation in PT XYZ using ISO 9001:2008 Clause 7.

#### **METHODOLOGY**

This was a descriptive study to explain and describe the characteristics or perceptions of a population or phenomenon (Zikmund, 2000). This study also can be included as empirical study. This study used two approaches in gathering data or information. The first approach was the quantitative method using questionnaires. The questionnaire was made to obtain information on the realisation of products by measuring perceptions from the customer. Out of the 108 customers who participated in this research, 59.30% (64 respondents) were from the company's internal customer base while 40.7% (44 respondents) were from its external customer base. The internal respondents were diverse and came from other units such as the General Affairs Unit, Digital Lifestlye Ecosystem Unit, Product & Infrastructure Assurance Unit, Infrastructure & Development Unit and the Mobile Ecosystem Unit. Data from the questionnaires were analysed using descriptive statistics, in which the respondents' perception of product realisation was interpreted using criteria scores. The scores are documented in Table 2.

Table 2
Score Interpretation

Score	Criteria	
0%-20%	Very poor	
21%-40%	Poor	
41%-60%	Barely acceptable	
61%-80%	Good	
81%-100%	Very Good	

The second approach was the qualitative approach. This approach aimed to confirm, clarify and understand more deeply the process of product realisation, which was conducted by interview. Using the snowball sampling technique, the researchers gathered 19 informants from a total population of 27 employees in the R&D Unit. These interviews were chosen because the respondents understood very well the process of product realisation in the R&D Unit.

#### RESULTS AND DISCUSSION

The definition of product realisation used in ISO 9001:2008 matched the definition of product realization as understood by the company's R&D Unit. Product development activities of the R&D Unit also contained innovative activities, whether radical or incremental.

Table 3
Respondent Perception about Product Realisation

The analysis of information gathered from the questionnaires revealed that the process of product realisation followed by the R&D Unit was very good. This was based on the cumulative percentage score from all the questions under this variable; the total percentage was 81.62%. The results of the questionnaire data processing were also grouped by sub-variables to observe the level of implementation of each sub-variable in product realisation. The results, the percentage score from each sub-variable, are shown in Table 3 below. Table 3 shows that the sub-variable design and development obtained the lowest score among all the sub-variables. The following discussion provides deeper insight into this based on the responses collected from the questionnaires and interviews.

Sub-variable of Product Realisation	Average score per item (%)	Criteria
Planning of product realisation	81.78%	Very good
Customer-related processes	80.89%	Good
Design and development	80.56%	Good
Purchasing	82.52%	Very good
Production and service Provision	83.70%	Very good
Control of monitoring and measuring equipment	81.30%	Very good

### Planning of Product Realisation in R&D Unit

The process for making new products in the R&D Unit of PT XYZ is well planned. Representing this sub-variable, we asked some questions about quality objectives and product requirements, processes to provide resources, the standard measurement for verification and validation, quality criteria for product acceptance and evidence that must be documented to show the process of planning product realisation. All these activities were done well by the R&D Unit in correspondence with guidelines from ISO 9001:2008. One question received the lowest score, although the score was in the good category. The question had to do with specifications or quality criteria for

products, and the score accumulated was 77.78%. This information was relevant as the R&D Unit of PT XYZ did not have a specific criterion of service quality as they defined quality in general terms. The lack of criterion for specific products made it difficult to interpret the quality criteria for several areas such as non-products and service products. PT XYZ's policy for service products was set to minimum standards. The procedures that describe a specific criterion of service was formulated by the R&D Unit itself based on present acticities.

### **Customer-Related Processes in the R&D Unit**

Questions were also asked about customerrelated processes such as identification of customer requirements, including post-sales activities, effective ways of communicating and sharing information with customers and also handling of customer complaints. All these activities were done well by the R&D Unit, except for handling of customer complaints, which had the lowest score, 77.04 %. This was because the R&D Unit did not deal directly with the end customers, but with internal and external customers. The internal customers of PT XYZ came from its own units, while its external customer were all vendors. Complaints from both internal or external customers were relayed to the User Relation Unit (UREL) to handle. This unit was responsible for maintaining customers, handling customer complaints and gaining information about customer preferences. UREL has a specific

set of guidelines for servicing customers. All information about customer preferences or other unit requirements is gathered by UREL and then delivered to the R&D Unit. Although the R&D Unit does not make customised products, this feedback from customers is used to evaluate the quality criteria of services provided to customers. Information from the interview showed that the R&D Unit was more concerned about developing product innovation activities rather than creating custom products to fulfil specific customer requirements. However, when a new product was created, the specifications of the new product were taken from the input of other units or UREL that often intersected with customers directly.

### Design and Development in the R&D Unit

Eight questions were given to the respondents related to design and development. These questions included questions on the standard for designing new products, standard for developing new products, process of evaluation, validation and documentation both for design and development. The R&D Unit managed design and development activities very well. This is shown by the high score achieved for this activity, 80.56%. All design and development activities are carried out in accordance with the procedures with constant reference to the quality standards set by the company. Every stage of the design process and product development involves planning, input, process, output and review. However, there are still deficiencies. The two questions

that received the lowest scores were on documentation activities related to the design process of new products and the documentation process of developing new products. The score for documenting the design of new products was 77.4%, while the score for documenting the development of new products was 78.52%. Although both were in the good category, the interviews showed that of all the questions relating to this variable, improvement was felt to be needed by the respondents in the R&D Unit's quality of documentation. Another expectation from the respondents was for the design and development of new products not to be done routinely. Each stage, the respondents felt, ought to be carried out separately and documentation stored separately as well.

#### Purchasing Activity in the R&D Unit

Purchasing activities managed by the R&D Unit were done well based on respondent perception. The percentage score for this activity was very good, with a score of 82.52 %. The purchase of goods or services performed by the R&D Unit was based on need and categorised by type of product, namely general goods, specific goods, general services and specific services. The R&D Unit had a DRP (List of Procurement *Plan*) that contained information about the list of goods and services of both general and specific items. When making a purchase, the principles held by the R&D Unit was to be transparent, open and seek no monopoly. In addition to these principles, there were several rules regarding the purchases,

namely: 1) Making a purchase of general products such as a computer or laptop and general services such as the provision and installation of software should not be done through partners and must be taken through a bidding process, 2) Others rules about the purchase of specific goods such as measuring tools and specific services such as consultation can be made through the direct appointment process in accordance with the needs of the R&D Unit. The purchase of goods and services must be included in the budget and will be evaluated and documented each quarter.

### Production and Service Provision in the R&D Unit

The question related to the variable, production and service provision, focussed on controlling the provision of products or services, on-time delivery, accuracy of products or services and also controlling customer property. The R&D Unit were committed to delivering services to customers on time. Most of the time, delays happened when the customer did not fulfil the administration or payment requirements completely. Incompatibility related to delivery is documented, including the reasons for the discrepanct. The R&D Unit of PT XYZ also has provisions to maintain customer property based on the strictest requirements. Overall, production and service provision activities were done well, and the percentage score for this activity was in the very good category, achieving a score of 83.70%. The R&D Unit also continued to make improvements to service

and provision activities based on feedback collected through a customer satisfaction survey.

### Control of Monitoring and Measuring Equipment Used by the R&D Unit

The responses to the questionnaire showed that the R&D Unit was consistent in delivering their services to their customers and always monitored and measured any inconsistencies. Inconsistencies were always documented by the R&D Unit. The percentage score for this activity was very good, having received a total score of 81.30%. Although this was in the good category, one indicator received the lowest score. The indicator was the use of the application to perform the measurement and improvement services. From the interview, it was learnt that the R&D Unit had some applications to control, but the use of the application was not optimal. Some applications owned by the R&D Unit that are used to ensure compliance with the services provided are the Online Test Report (OTR) application, the Smile Application for procurement, and the Transformer Application for project management. However, some informants believed that there was still a shortage of such applications. For example, the Transformer application was less attractive to employees because the employees were not familiar with it. Also, according to the informants, there were no applications for evaluating the overall product. All information about shortcomings when delivering services is

always communicated to the R&D Unit to be followed up with and documented.

### CONCLUSIONS AND RECOMMENDATIONS

#### Conclusion

The following are the conclusions of this study.

- Implementation of quality management system clauses of ISO 9001:2008 for product realisation was done but the system needd improvement in some areas.
- 2. The overall score for product realisation was very good, amounting to 81.62%.
- 3. Percentage scores for the sub-variable, design and development, received the lowest score at 80.65%, while the highest score was obtained by the sub-variable, production and service provision (83.70%). Other variables received these scores: 81.78% for planning of product realisation, 80.89% for customer-related processes, 82.52% for purchasing and 81.30% for monitoring and measuring controls.

Although all the variables were in the good category, our research showed that some areas needed improvement. This was especially true for product. In the planning for product realisation, the specifications for quality were described in general. It is a challenge for the R&D Unit, which has the responsibility of designing the service. In terms of customer processes, the handling of customer complaints was the lowest scoring indicator.

#### RECOMMENDATIONS

The following are the recommendations of this study.

- 1. PT XYZ must assign one person or one unit to control and maintain documentation.
- The company show be more concerned about documenting every stage of its design and development process as documentation is necessary for control and evaluation of the product realisation process.
- 3. It would be good for the company to design a system such as a digital repository that would provide easy access to information on all aspects of production and quality to all in need of it.
- 4. PT XYZ should develop a specific set of criteria for quality for both services and products, and this must come from top down i.e. from top management to the R&D Unit to reflect the commitment of top management to quality. This will maintain the company's good performance.

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