Impact of upgrading iso 9001:2008 to ISO 9001:2015 on internal rejects in automotive company

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Abstract. In Automotive Industry, precision is very important due to safety reason. Result of need for precision in automotive product, it can make Company making high internal reject. Improvement of reduce internal reject is a must if Company want to improve their Productivity. For that, Automotive Industry need to implement ISO 9001:2015 that consist of new clause that Company in the beginning or in development stage, should making an analysis for Risk and Opportunity in every Process. The purpose of this paper is to see the effects of ISO 9001:2015 on internal reject conditions in the Company. After implementing ISO 9001:2015, Company from Automotive Industry can improve to reduce Internal Reject 0.45% from 0.75% to 0.30%.

1. Introduction
ISO 9001 Quality Management System is the most widely implemented standard in various types of companies, both goods and services, around the world. In 2016, there were 67.28% of companies with ISO 9001 and 68.02% certificates in 2015 compared to other ISO standards [1].

Table 1. Amount of Certificate ISO standard year 2015 and 2016 in the world

| Standard         | 2015      | Percentage | 2016      | Percentage |
|------------------|-----------|------------|-----------|------------|
| ISO 9001         | 1,034,180 | 68.02%     | 1,106,356 | 67.28%     |
| ISO 14001        | 319,496   | 21.01%     | 346,189   | 21.05%     |
| ISO 50001        | 11,985    | 0.79%      | 20,216    | 1.23%      |
| ISO 27001        | 27,536    | 1.81%      | 33,290    | 2.02%      |
| ISO 22000        | 32,061    | 2.11%      | 32,139    | 1.95%      |
| ISO/TS 16949     | 62,944    | 4.14%      | 67,358    | 4.10%      |
| ISO 13485        | 26,255    | 1.73%      | 29,585    | 1.80%      |
| ISO 22301        | 3,133     | 0.21%      | 3,853     | 0.23%      |
| ISO 20000-1      | 2,778     | 0.18%      | 4,537     | 0.28%      |
| ISO 28000        | -         | 0.00%      | 356       | 0.02%      |
| ISO 39001        | -         | 0.00%      | 478       | 0.03%      |

ISO 9001 is a standard that sets requirements for the Quality Management System and helps businesses and organizations become more efficient and increase customer satisfaction. In September 2015, the International Organization for Standardization launched the ISO 9001 Quality Management System with the 2015 version which is an upgrade from the previous version of the 2008 version.
The purpose of Quality Management Systems (QMS) is the quality continuous improvement not only in products/services, but also in all the processes in the firms, allowing customers satisfaction and encouraging the efforts and responsibility of everyone in the organization [2].

Standardization is a mechanism that favors exchange and international trade in today’s global economy, removing the obstacles that arise from each country practices [3].

ISO 2015 version or the general one written with ISO 9001:2015 must have been implemented by the company implementing ISO 9001:2008 no later than 3 years since the release, which is September 2018. If the new company will take ISO 9001 certification, must use ISO 9001 version 2015.

The previous study has indicated that the companies that implement ISO 9000 more consistently have a tendency to improve their financial performance in the series of five years, compared to companies that are less consistent in the implementation [4].

New released of ISO 9001 version 2015 will have major benefits for Quality Management System with less emphasis on documentation and new/reinforced approaches such as the consideration of organizational context and (relevant) stakeholders, Risk Base Thinking and Knowledge Management and should be a step toward TQM [5].

2. Method and materials

There are 5 stages of the development of the concept of quality:

1) The first stage is known as an era without quality. This period began before the 18th century where the products made were not considered quality. Things like this might happen because at that time there was no competition (monopoly) in the modern era at this time, this practice could still be found.

2) The second stage is inspection era. This era began to take place around the 1800s, where the sorting of the final product was carried out by inspectors before being released to the customer. The responsibility for product quality is left entirely to the inspection department (Quality Control). The Quality Control position is finally targeted if there are defective products that pass to the customer. On the other hand, quality costs become higher because the product should have been prevented from entering the next process before being inspected by the inspection officer.

3) The third stage, known as the Statistical Quality Control era. This era began in 1930 by Walter Shewart of Bell Telephone Laboratory. The inspection department is equipped with statistical tools and methods to detect irregularities that occur in the products produced by the production department. The production department uses the data to make improvements to the system and process.

4) The fourth stage, is Quality Assurance era. This era began to develop in the 1950s. The concept of quality extends the production stage (downstream) to the design stage (upstream) and coordinates with the service department (Maintenance, Warehouse, etc.). Management began to be involved in determining suppliers. The concept of quality costs began to be recognized, that preventive activities will reduce expenses rather than efforts to repair the defects that have already occurred. Wrong design for example will result in production or installation errors. Therefore very accurate design to reduce costs. An example of this era is the use of the 1994 version of ISO 9000.

5) The fifth stage, known as Strategic Quality Management / Total Quality Management. In this era the involvement of top management is very large in making quality as capital to put the company ready to compete with competitors. This system is defined as a strategic and integrative management system that involves all managers and employees and uses qualitative and quantitative methods to continuously improve organizational processes in order to meet and exceed customer expectations. An example of this era is the use of the ISO 9001 Quality Management System 2000, 2008 and 2015 versions.
ISO 9001 builds on seven quality management principles, which is [6]:

1. Customer Focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence-based decision making
7. Relationship management

Implementing a quality management system refers to ISO will help company [6]:

- Assess the overall context of organization to define who is affected by organization work and what they expect from organization. This will enable organization to clearly state their objectives and identify new business opportunities.
- Put customers first, making sure organization consistently meet their needs and enhance their satisfaction. It can make organization will have repeat order from customer, new customer and increasing business.
- Work in a more efficient way as all processes will be aligned and understood by everyone in the business or organization. It can improve productivity and efficiency, and reduce internal cost.
- Meet the necessary statutory and regulatory requirements.
- To have new customer, because some customer require ISO 9001 implementation before doing business with them.
- Identify and address the risks associated with organization.

Previous study, have linked the success in the implementation of Quality Management System ISO 9001 to the organization motivations (most significant result when the motivation are internal rather than external) and to the way the standard is interpreted and implemented [7]. Another studies shows, implementing Quality Management (QM) effectively influences firm performance positively [8], [9].

Refer to general literature on ISO 9001, the key success factors for this standard are essentially related to international factors, such as the motivation for certification, commitment of managers, involvement of employees, internal communication, resources for quality management, and follow-up of the standard [10], [11].

The main purpose of ISO 9001 is to give confidence in the organization’s ability in order to provide consistently conforming products to the requirements of its customers [12].

The major different between ISO 9001:2015 and previous one, ISO 9001:2008 is ISO 9001:2015 follows the same overall structure as other ISO management system standards (known as the high-Level Structure), making easier for anyone using multiple management systems. Major difference of ISO 9001:2015 compare to ISO 9001:2008 is it focus on risk-based thinking. While this has always been part of the standard, the new version gives it increase prominence [13].

The new version of the standard brings the uses a number of benefits, for example, ISO 9001:2015 [13]:

- Put greater emphasis on the leadership engagement
- Helps address organizational risk and opportunities
- Uses simplified language and a common structure and terms, which are particularly helpful to organizations using multiple management system, such as those for the environment, health & safety, or business continuity
- Addresses supply chain management more effectively
- Is more user-friendly for service and knowledge-based organizations

In automotive company, when they implementing ISO 9001 version 2008, amount of internal reject in 2 years, 2016 and 2017, is 0,75%. That amount is need to reduce if company want to increase their productivity that related to quality of the products. If the internal reject become high, it can make the...
productivity become reduce. It also in opposite way, when the internal rejects become reduce, it can make the productivity become high.

Table 2. Internal reject in year 2016 and 2017 with ISO 9001 version 2008

| Year | Month | Internal Reject | Year | Month | Internal Reject |
|------|-------|-----------------|------|-------|-----------------|
| 2016 | Jan   | 0,71%           | 2017 | Jan   | 0,57%           |
|      | Feb   | 1,44%           |      | Feb   | 0,44%           |
|      | Mar   | 1,23%           |      | Mar   | 0,34%           |
|      | Apr   | 1,27%           |      | Apr   | 0,64%           |
|      | May   | 1,21%           |      | May   | 0,39%           |
|      | Jun   | 0,69%           |      | Jun   | 0,37%           |
|      | Jul   | 0,62%           |      | Jul   | 0,54%           |
|      | Aug   | 1,11%           |      | Aug   | 0,43%           |
|      | Sep   | 1,03%           |      | Sep   | 0,42%           |
|      | Oct   | 0,95%           |      | Oct   | 0,41%           |
|      | Nov   | 0,90%           |      | Nov   | 0,41%           |
|      | Dec   | 1,28%           |      | Dec   | 0,61%           |
|      | Overall average of internal rejects | 0,75% |

3. Results and discussion

ISO 9001 version 2015 (the newest version of the standard) is consist of a number of different sections, each focusing on the prerequisites associated in different aspects of a Quality Management System (QMS) [6], [14], [15]:

- Clause 1 – Scope
- Clause 2 – Normative Reference
- Clause 3 – Terms and Definitions
- Clause 4 – Context of the organization
- Clause 5 – Leadership
- Clause 6 – Planning
- Clause 7 – Support
- Clause 8 – Operation
- Clause 9 – Performance evaluation
- Clause 10 – Improvement

ISO 9001:2015 also improve on PDCA (Plan Do Check Action) approach [14], [15]:

![PDCA Approach in ISO 9001:2015 clause](image)

Figure 1. PDCA Approach in ISO 9001:2015 clause

Major improvement this company when implementing ISO 9001:2015 is activity to deal with risks and opportunities, with steps as below:
1. Understand the situation when planning a QMS (Quality Management System)
   • Organization and its linkages (clause 4.1)
   • Requirements, needs and expectations of customer needs and other related parties (clause 4.2)
2. Consider Risks and Opportunities that need to be addressed for (clause 6.1.1)
   • Give assurance that the QMS can achieve the desired results
   • Increase the expected impact
   • Prevent or reduce unexpected impacts
   • Achieve improvement
3. Establish actions against risks and opportunities (clause 6.1.2.a)
   Actions taken are proportional to the potential impact on the suitability of products and services
4. The actions taken are integrated and applied into process at QMS (clause 6.1.2.b)
5. Effectiveness evaluation (clause 6.1.2.b)

After implementing ISO 9001:2015 in year 2018, result of internal rejects in Table 3 as below:

| Year | Month | Internal Reject |
|------|-------|-----------------|
| 2018 | Jan   | 0.32%           |
|      | Feb   | 0.31%           |
|      | Mar   | 0.31%           |
|      | Apr   | 0.32%           |
|      | May   | 0.30%           |
|      | Jun   | 0.30%           |
|      | Jul   | 0.29%           |
|      | Aug   | 0.28%           |
|      | Sep   | 0.28%           |
|      | Oct   | 0.30%           |

Overall average of internal rejects 0.30%

4. Conclusion
From result of internal reject in 2018 when implementing ISO 9001:2015 with average 0.30% from production, it can reduce from previous year 2016 and 2017 when the company implementing previous version (ISO 9001:2008) with average 0.75%. The internal reject reduction of 0.45% is obtained by carrying out actions to overcome the risks and opportunities contained in the latest version of ISO 9001 that is ISO 9001: 2015. With improvements of reducing the internal reject, it is expected to increase the productivity of the automotive company.

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