DESIGN OF STANDARD OPERATING PROCEDURE (SOP) OF DESIGN AND DEVELOPMENT OF PRODUCT ACCORDING TO ISO 9001:2015 CLAUSE 8.3 BASED ON RISK BASED THINKING BY BUSINESS PROCESS IMPROVEMENT METHOD AT CV. XYZ

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ABSTRACT

CV. XYZ is a manufacturing company that produces spare parts for motor vehicles. As an organization of supplier spare parts, CV. XYZ important to determining quality of the product and develop product design.To improve the quality of products, CV. XYZ needs to renew the latest standard ISO 9001: 2015. In this standard application of risk-based thinking is done to anticipate the risks that may occur. This paper proposes draft Standard Operating Procedure of Design and Development of Product by clause 8.3 of ISO 9001: 2015. This procedure improved by Business Process Improvement method to obtain simplification of business processes.
Key words: *ISO 9001:2015, Business Process Improvement, Standard Operating Procedure*

1. INTRODUCTION

CV. XYZ is one of the suppliers of spare parts for motor vehicles and play an important role in determining the quality of the product and perform product design development. Process design and development of products already owned by CV. XYZ where the company focuses on the manufacture of mold of products. Although it has implemented QMS (Quality Management System) ISO 9001: 2008, but now the company has not implemented the ISO 9001: 2008 to its full potential due to documenting the design process and product development is still done poorly.

To improve the quality of products, CV. XYZ needs to update its standards to ISO 9001: 2015. In this standard application of risk-based thinking is done to anticipate the risks that may occur. Risk register is documented information that validates an organization has done the risk-based thinking (Bob Deysher, 2015).

This research focuses on the design of the Standard Operating Procedure (SOP) for the design and development of products by clause 8.3 of ISO 9001: 2015. From the results of this design is expected to CV. XYZ has SOPs that can be used as a standard way that made by the company in carrying out its work and guidance in implementing quality management system.

2. THEORETICAL BACKGROUND

2.1. ISO 9001:2015

ISO 9001: 2015 is an international standard for quality management systems. ISO 9001: 2015 is a result of the review and a change from the previous ISO 9001 which is standard requirement that is used to access the organization's ability to meet customer and regulatory requirements as appropriate. ISO 9001: 2015 has the structural changes that the High Level Structure (HLS) developed into 10 clauses to maintain harmony with all of the standard management of existing systems, as well as the necessary application of risk-based thinking is that the organization must identify the risks in order to avoid undesirable results in the running process business.

Clause in ISO 9001:2015 structure are :

a) Clause 4 - Context of the organization
b) Clause 5 - Leadership
c) Clause 6 - Planning
d) Clause 7 - Support
e) Clause 8 - Operation

f) Clause 9 - Performance Evaluation
g) Clause 10 - Improvement

In ISO 9001:2015, PDCA cycle can be applied to all processes and quality management system as a whole that clause 4 to clause 7 is phase plan, clause 8 is phase do, clause 9 is phase check, and clause 10 is phase action. This figure show how clause 4 to clause 10 can related in the PDCA cycle.

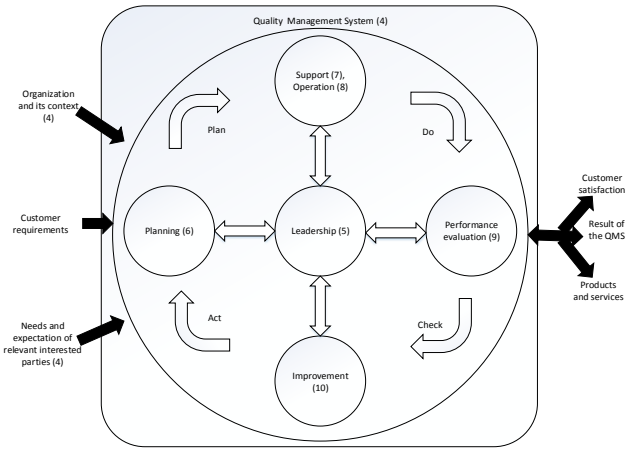

Figure 1. PDCA Cycle

2.2. Risk Assessment

The risk assessment is one of the risk management process that have 4 stages. First stage is risk identification, which lists the risks that may affect the achievement of organizational goals. Second stage is risk analysis, which analyzes the sources, opportunities, and the impact of risk occurrence.

Table 1. Probability Matrix

Criteria	Probability	Description	Freq/year
Very Low (VL)	0.10	Hardly possible	1-5x
Low (L)	0.30	Less likely occurred	6-10x
Medium (M)	0.50	May occur may not. fifty-fifty chances	11-20x
High (H)	0.70	Likely to occur	21-50x
Very High (VH)	0.90	Almost certainly occur	more than 50x

(Source: Leo J. Susilo, 2010)

Table 2. Impact

Impact	Description	Rating
Disaster (D)	All targets cannot be reached	I
High (H)	Important goals cannot be achieved	II
Medium (H)	Affect the achievement of some targets	III
Low (L)	Minor damage which can easily repaired	IV
Very Low (VL)	Little impact against targets that can be ignored	V

(Source: Leo J. Susilo, 2010)

Third stage is risk evaluation, which was to determine which risks require treatment.

Table 3. Risk Rating

Probability	Impact				
	VL	L	M	H	D
VH	M	H	H	VH	VH
H	M	M	H	H	VH
M	L	M	H	H	H
L	L	L	M	M	H
VL	L	L	M	M	H

(Source : Leo J. Susilo, 2010)

Last stage is treatment of risk, namely selecting the options that can reduce or eliminate the impact and likelihood of risk.

2.3. Risk Register

Risk register is simply a documented record of the identified risks, their significance or rating, and how they are managed or treated (Bob Deysher, 2015).

2.4. Standard Operating Procedure (SOP)

SOP is a guide to ensure the operational activities of the organization or company running smoothly (Arini, 2014).
The benefits of such SOP such a explain in detail the activities of the process being undertaken, standardize all activities undertaken by the parties concerned, and improving the consistency of a job.

2.5. Business Process Improvement

Business Process Improvement (BPI) is a systematic methodology developed to help

an organization make significant advances in the way its business processes operate (Harrington, 1991).

3. RESEARCH METHOD

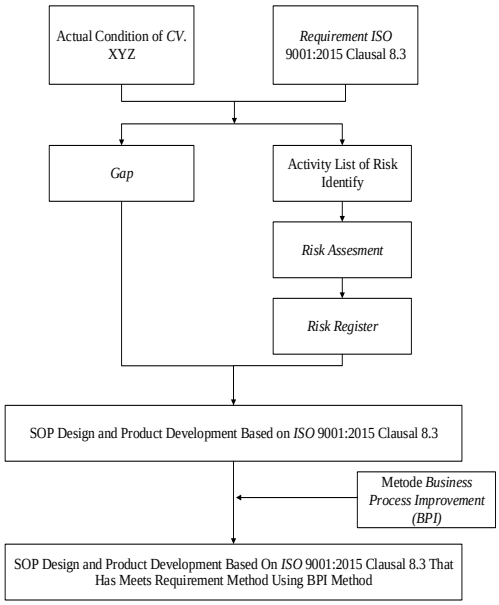

Figure 2. Conceptual Model

The initial stage is to fit the actual conditions CV. XYZ with the requirements of ISO 9001: 2015 clause 8.3 and will bring up the gap and the list of activities for the identification of risks. Then, from the list of activities are carried out consideration of the risks that may occur from any activity undertaken, known as a risk assessment process that includes the step are :

a. Risk identification
   Risk identification is obtained from potensial risk and list of activities from comparison between actual condition and requirements clause 8.3 ISO 9001:2015.

Table 4. Risk Identification

Risk	Code
Shortages of raw materials	R-01
Nonconformity mold products with customer's wishes	R-02
Output not fullfiled the requirements of input design and user desired	R-03
Nonconformity of output to input design	R-04
Failure of product	R-05
Failure of mold product	R-06
Unable to make improvement	R-07
Data is lost or not available when needed	R-08
Do not have a copy of the data as information for companies	R-09
The design process can not proceed to the next stage	R-10
Repeating the sample until approved customers	R-11

b. Risk analysis
   This step is after risk identification in which the author doing interview to determine how much impact and probability for each failure in each process of design and development in the organization. Then, doi the risk rating to determine the level of risk that will be selected for evaluation.
c. Risk evaluation
   From the risk analysis, then determination of risks which require priority treatment and how priority treatment of such risks.

Table 5. Risk Evaluation

Probability	Impact				
	VL	L	M	H	D
VH					
H					
M		R-03 R-09	R-02 R-06 R-08		
L		R-04 R-05 R-07	R-11		
VL	R-01 R-10				

d. Risk treatment
   This step is preparation of plan how the selected risk treatment will be applied. In this step can be using fishbone diagram to help to determine treatment of these risks by determination about the cause of risks previously.

From the results of the risk assessment process, and then will be done the manufacturing risk register where the risk register and the identification gap will be input in the design manufacture SOP. In designing this SOP will produce SOP, then this SOP will be improve using Business Process Improvement (BPI), which the BPI method is

done in 2 stages of analysis to business process improvement. First, the value added analysis phase is an analysis of every activity in the business process to determine its contribution to meeting end-customer expectations (Harrington, 1991). This phase proposes to classify each activity of the process into three types, among others, Real Value Added (RVA), Business Value Added (BVA), and Non-Value Added (NVA). Second, streamlining stage suggests the trimming of waste and excess, attention to every minute detail that might lead to improved performance and quality (Harrington, 1991).

Table 6. Value-Added and Streamlining

Activity	Classification	Streamlining
Conduct meetings design input determinatio n	RVA	Automation and/or mechanization, Standardization
Conduct a review of engineering drawings	BVA	Standardization, Automation and/or mechanization, Upgrading
Preparation of production	RVA	Automation and/or mechanization
Check availability of material	BVA	Automation and/or mechanization
Review the product design output	BVA	Simple Language, Standardization, Automation and/or mechanization, Upgrading
Informing the results of design and development	BVA	Upgrading

In this research will be used tools streamlining that in accordance with business process that is. Simple language to making our documents easy to comprehend by all who use them. Standardization to selecting a single way of doing an activity and having all employees do the activity that way all the time. Upgrading to making effective use of capital equipment and the working environment to improve overall performance. Automation and/or mechanization to applying computers.

The results of this study are SOP Design and Product Development Based on ISO 9001: 2015 Clause 8.3 That Has Meets Requirement Method Using BPI.

4. RESULT AND DISCUSSION

4.1. Risk Register

Table 7. Risk Register

No	R	P	IS	RR	RT
1	Nonconformity products with customer's wishes	M	M	H	Risk transfer
2	Failure of mold product	M	M	H	Risk Mitigation
3	Data is lost or not available when needed	M	M	H	Risk Mitigation

Note :
R : Risk
P : Probability
IS : Impact Scale
RR : Risk Rating
RT : Risk Treatment

First risk is about nonconformity products with customer’s wishes. Type of that risk treatment is risk transfer which is distribute risk with other parties (customers). This risk treatment is listed in procedure in activity of giving product sample to customer. Second risk is about failure of mold product. Type of that risk treatment is risk mitigation which is action to reduce unwanted effect. This risk treatment is listed in procedure in process of making mold products, where the machine operator must have the training and requirements ever experienced operate CNC machines. Third risk is about data is lost or not available when needed. Type of that risk treatment is risk mitigation which is action to reduce unwanted effect. This risk treatment is listed in procedure in activity design control in which the organization should make a copy of the document as well as making the storage media.

4.2. Design SOP of Design and Development of Product

The design of SOP has considered, among others: First, SOP has considered of requirement. Design SOP is done to meet requirements of ISO 9001: 2015 clause 8.3, and to address the gap between the actual conditions of companies with requirements. Second, SOP has considered of risk register. In addition to the results of gaps identification, risk register also be input in the design of SOP. Then the treatment's result of the risks inherent in the risk register are listed in the SOP on the activity product samples giving, control design, and manufacture of molds product. Third, SOP has considered of streamlining in BPI method. The design of this SOP is the result of improved with BPI method by streamlining tools i.e. language simplification for reducing form complexity, automation and/or mechanization to reduce the use of paper, standardization to standardize forms and processes, and upgrading to improve job performance. Fourth, SOP has considered of company needs. The design of this SOP is expected to assist the company in establishing, implementing, and maintaining the design and development process. Fifth, SOP has considered of effectiveness. The design of SOP is already involves other related procedures i.e. results for the output material procurement process design and production processes for product realization.

5. CONCLUSION

Risk registers contain information such as the risks of treatment elected to do. In this study, the risks that is elected are, nonconformity products with customer's wishes, failure of mold product, and data is lost or not available when needed.

This research result is the SOP design of Product Design and Development that covers all stages of design starts from design input, control design, and output design.

To improve business process with streamlining using automation and/or mechanization, can be reconsidered because the organization need more cost for implementation the application.

In applying the ISO 9001:2015, the organization need to involve the entire employee so that business processes can be controlled.

6. REFERENCES

(a) Deysher, B. (2015). *A "Risk Based Thinking" Model for ISO 9001:2015.*

(b) Harrington, D. H. (1991). *Business Process Improvement.* New York: Mc-Graw Hill.

(c) Hopkin, P. (2010). *Fundamentals of Risk Management.* United States: Kogan Page.

(d) Leo J. Susilo, V. R. (2010). *Manajemen Risiko Berbasis ISO 31000.* Jakarta: Penerbit PPM.

(e) Arini, T. (2014). *Mudah Menyusun SOP.* Jakarta: Penebar Plus.

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APPENDIX A

Design and Product Development Procedure (1)

Process Flow	Process Description	Record
Start		
1. Director, PDND, dan and PRD manager Conduct meetings determination of product design and development input	1.a. Director of design input determination to conduct meetings and joint product development PDND and Manager of PRD. Input design specification form, function, and form of products 1.b. Design products based on receipt of customer orders 1.c. The results of this meeting will be documented in the Form Designer and Product Development, then submitted to PDND to be made the product design.	1. Design & Product Development Form
2. PDND Creating a product design engineering drawings	2. PDF create engineering drawings of product designs that will be made based on the design and development input, using Solidworks software.	2.a. Engineering Drawing of Design Product 2.b. Design and Product Development Form
3. Head of PDND Conduct a review of the engineering drawings	3.a. Head of PDND reviewing engineering drawings whether in accordance with design input. 3.b. If there are changes in technical drawing will be recorded to the Form Design and Product Development and then returned to the second process. 3.c. If the engineering drawings have been completed then will be done verification and validation to ensure that the input meet the requirements and the use is desired.	3.a. Engineering Drawing of Design Product 3.b. Design and Product Development Form
4. Director Perform verification and validation of input products	4.a. If the product input does not match then back to process 1. 4.b. If the input of products have been appropriate, the Director approved the form and then handed over to assistant manager of PRD, assistant manager of machining, and head of PDND.	4. Design and Product Development Form
5. Assistant Manager of PRD, Assistant Manager of *Machining* Preparation of production	5.a. Asman PRD and Asman Machining make preparations for the planned production of material needs, machinery, mold of products, and production operators. 5.b. Needs are recorded in Form Production Preparation. 5.c. Form submitted to the Human Resources Manager to be verified and validated	5. Production Preparation Form
6. Manager of PRD Perform verification and validation Form Preparation Production	6.a. Manager of PRD verify and validate Form Production Preparation. 6.b. Form made copies, and handed over to the PRD and Asman machining, PMTC, and warehouse's PIC	6. Production Preparation Form
A		

Design and Product Development Procedure (2)

Process Flow	Process Description	Record
A		
7. PIC of *Warehouse* Checking the availability of material	7.a. PIC of Warehouse check availability of material required by Production Preparation Form. 7.b. If the material is still available, then the process continues to manufacture mold design products. 7.c. If the material is not available, then apply for the purchase of materials.	7. Purchase Material Submission Form
8. PMTC Check the readiness of machines required	8.a. PIC of maintenance required to check the readiness of the machine. 8.b. PIC of maintenance perform checklist in Testing Machine Form.	8. Machine Checking Form
9. PDND Make a mold design of products	9.a. PDND make mold design products i.e. top dibble plate and bottom dibble plate using Solidworks software 9.b. The results of the design that have been made then submitted to the programmer.	9. Engineering Drawing of Products Mold
10. *Programmer* Creating a CNC program in accordance with the product to be made	10.a. The programmer checking the engineering drawing of product's mold. 10.b. If the mold engineering drawings according to the requirements then product has continued to manufacture CNC program. 10.c. If the mold of engineering drawings has not according to the requirements then the product has returned to the process 8. 10.d. The results of the program and then submitted to the CNC operators to resume production process of products mold	
11. Operator of CNC Producing mold of product	11.a. CNC operator do the production process of products mold using CNC machines and guided by the document Work Instruction of The Use of CNC Machine. 11.b. CNC operators must fulfilling the requirements, such as: 1. Attended training 2. Experienced operate CNC 11.c. The printed product delivered to the assembly operator to be assembled.	
12. Assembly Operator Assemble mold of products	12. Assembly operator assembles products mold into finished products mold by combining the top dibble plate, the bottom dibble plate, spring, and ejector using open and wrench.	
B		

Design and Product Development Procedure (3)

Process Flow	Process Description	Record
B		
13. QC Operator Review and verify product mold	13.a. QC operator reviews and verifies finished products mold. 13.b. If printed product conforms to the requirements then proceed to production operators. 13.c If printed product does not meet the requirements then it's back to the process 10.	13. Inspection and Product Measurement Form
14. Production Operator Experimenting production output of product design	14.a. Production operators experiment the production output of the product design. 14.b. Production process of product design output based on Work Instruction Use of Injection Machine.	
15. Head of PDND Review the product design output	15.a. Head of PDND conduct a review of output to input predetermined design. 15.b. Results of the review output recorded in Design and Product Development Form 15.c If it does not pass the review step then back to the process 1. 15.d. If it passes the review stage then submitted to the Director for verification and validation.	15. Design and Product Development Form
16. Director Perform verification and validation of the Output Design	16.a Director verifies and validaties the output of Design and Development. 16.b The report that has been verified and validated then made copies, and then submitted to PDND. The original form stored in the archive at the design and development of document control.	16. Design and Product Development Form
17. PDND Informing the results of design and development	17. PDND inform product design and development results to PIC of Marketing	17. Handover Sheets of Product Design and Development Result
18. PIC of Marketing Providing product samples results of design and development to customers	18.a. PIC of Marketing provides sample design and development of products to customers. 18.b. Organizations must establish policies for each customer to supervise the product samples before mass production.	18. Official Report of Product Samples
Finish		