ABSTRACT

Design of Standard Operating Procedure (SOP) Nonconformity and Corrective Action Based on Integrated Requirement ISO 9001:2015 and ISO 14001:2015 Clausul 10.2 with Risk Based Thinking Using Business Process Improvement Methode in CV. XYZ. Rahmah Fadhilah. Program of Study Industrial Engineering.

CV. XYZ is a company of manufacturing industry that produced spareparts. The vision of company is giving the best product with the high quality and safe to give customer satisfaction. So, the company want to implemented ISO (quality management system and environmental management system). The company was implemented ISO 9001:2008. In 2015 the organization of ISO have the new version, so the company should be review about the requirement.

One of the important process in the company is control nonconformity and corrective action process, because this process need standardization to avoid error when establish the corrective action. Requirement about this process is clausul 10.2 (nonconformity and corrective action) in ISO 9001:2015 and ISO 14001:2015. Based on the result of initial identification about gap between requirement and existing condition in company, there are several requirements that have not been fulfilled. Thus, in this study will be designed SOP control of nonconformities and corrective actions.

The integrated standar is must be completed before design the SOP, the function of integrated is to avoid duplication of document and more efficient when do standardization process, then idenfied the gap between the existing condition of the integration requirement. In ISO 2015 version, there some changes, one of which is the risk based thinking concept. Therefore, risk assessment and obtained 4 highest risk requiring risk control measures. The risk such as activity, will be input in SOP.

Drafting of the control process nonconformities and corrective measures considering the results of the analysis of the risk register, analysis of existing condition, analysis of gap the requirement. After the draft process is created, then the value added and streamlining analysis (method Business Process Improvement) for process improvement in the draft SOP. The result is design of Standard operating procedure for controlling nonconformity and corrective action based on requirement ISO 9001:2015 and ISO 14001:2015. Nonconformity control process and improvement action SOP that already made expected can be useful for company side as a solution to reduces error rate and mistake that can be done by person in charge, especially in an activity that take action against nonconformity and determine improvement action to the company.

Key Word : Standard Operating Procedure, Business Process Improvement