DESIGN OF NONCONFORMITY AND CORRECTIVE ACTION STANDARD OPERATING PROCEDURE BASED ON INTEGRATED REQUIREMENTS FROM ISO 9001 AND ISO 14001

Rahmah Fadhilah[1] , Sri Widaningrum [2], Heriyono Lalu[3]

Industrial Engineering Department, Telkom University of Engineering
Jl. Telekomunikasi No. 1 Bandung Indonesia
[1]rahmahfadhilah@student.telkomuniversity.ac.id, [2]swidaningrum@telkomuniversity.ac.id ,
[3]heriyonolalu@telkomuniversity.ac.id

ABSTRACT

This study aims to write a standard operating procedure (SOP) of a company. The SOP covers the needs to control non-conformities and corrective actions, hence it needs to fulfill the requirements of ISO 9001:2015 and ISO 14001:2015 clause 10.2. The study compared the existing conditions against the requirements in ISO Standard of 2015, followed by risks consideration and related risks assessment. This lead to a business process design proposal. Using the Business Process Improvement method on the proposal the study gave a list of activities that needs to be done, and a design of required SOP.

Key words: Standard Operating Procedure, Integration Requirement of ISO 2015, Business Process Improvement

1. INTRODUCTION

In 2015 there is a changing standard from ISO 9001:2008 and ISO 14001:2004, become ISO 9001:2015 and ISO 14001:2015. In this research, carried out an integration of both standard, so there is no document duplication and the standardization implementation more efficient. ISO 2015 standard has a high level structure, so it facilitate the organization to integrate, it is because the whole existing definition is on same management standard.

One of improvement of previous ISO is the application of risk based thinking concept to know the risk that occur in the company. The concept application is supported by risk register document, which obtained from risk assessment result of each process (Deysher, 2015). In the organization there are several nonconformities, which needs a process to control the nonconformities occurs that need an improvement or corrective action, to prevent nonconformities occurs again. Requirement that need to fulfilled in controlling nonconformities and corrective action are can be found on clause 10.2 ISO 9001:2015 and clause 10.2 ISO 14001:2015.

CV. XYZ is one of company on manufacturing industry field that produce sparepart such as dies, mould, jig and fixture, precession part and plastic product. The company has a standard of ISO 9001:2008 and ISO 14001:2004, but since there is change of 9001:2015 standard (quality management system) and ISO 14001:2015 (Environmental management system), requires companies to conduct a review of compliance with the requirements of ISO 2015. So, this research design a SOP (standard operational procedure) as documented information to help implementation standard process related to the control nonconformity and corrective action in CV. XYZ (Badan Standardisasi Nasional, 2015)

2. THEORETICAL BACKGROUND

2.1 Quality Management System and Environment Management System

Quality management system is one of coordinated activity that has an objective to directing and controlling the organization that related to the quality. (DR. Ir. H.M. Budi Djatmiko & Heri Jumaedi, 2011).

Environmental management system ISO 14001 is an international standard. This system could make the organization to develop and applicate a policy and objectives that related to the environmental management system (Gasperz, 2012).

2.2 Integrated Management System (IMS)

Integrated management system is integrating several management system in organization. On quality management system ISO 9001 and environmental management system 14001 are using an approaching process and applying the continuous improvement methodology PDCA (Plan-Do-Check-Action) (Gasperz, 2012). Because of that, both system are compatible of one each other.

2.3 Risk Based Thinking

Risk based thinking is one of element in approaching process, an input to management review, and also one element of continuous improvement which focused on preventing action (Deysher, 2015).

2.4 Nonconformities and Corrective Action

Based on ISO 9001:2015 clause 3.19 are explaining that nonconformities is something that occurs because of unfulfilled requirement. The nonconformities is one of problem that able to make a failure to achieve an objective of the company, then it makes the each of nonconformities needs to know the cause. Based ISO 9001:2015 clause 3.21 are explained about corrective actions to eliminate the cause of conformities and to prevent the recurrence of the same nonconformities.

2.5 *Business Process Improvement (BPI)*

Business Process Improvement gives a system that helps in streamlining process of business processes, by giving an assurance that the internal and external consumer of organization will gaining a better output than before (Harrington, 1991).

3. RESEARCH METHOD

3.1 Design of Standard Operating Procedure

A process of this research starts with integrating from ISO 9001:2015 clause 10.2 and ISO 14001:2015 clause 10.2 requirement about nonconformity control and corrective actions. Then it will result of integration of both requirement. The result of requirement integration and existing company condition will become the input of activity list when identifying the risk. Other than that, a comparation of existing condition and result of requirement integration become a gap (process of activity that has not been fulfilled)

Then do a risk assessment from the activity list that includes: risk identification, risk analysis, and risk evaluation, The next step is controlling activity toward the risk that include to the high level category, then do the drafting of the control process nonconformities and corrective actions description based on needs analysis of the risk register, organization conditions, and requirements. After obtaining the process description, do a value added analysis and streamlining analysis from that process to simply the process that has been designed.

Then, after adjusted for improvement, then the design of improvement SOP are obtained to control the nonconformities and corrective action. The conceptual model can be seen on Figure 1.

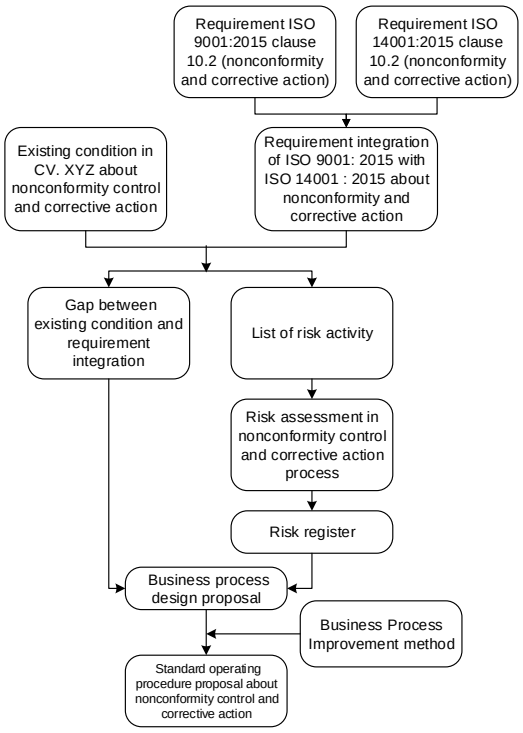


Figure 1 Conceptual Model

4. RESULT AND DISCUSSION

4.1 Integrated Result Requirement

The integration is done by comparing both requirement, which are ISO 9001:2015 clause 10.2 and ISO 14001:2015 clause 10.2, then do an analysis of both requirement, there are a gap of ISO 9001:2015 and 14001:2015, which is on ISO 9001:2015 there is a requirement to updating the risk, but on ISO 14001:2015 there is no such requirement, then these requirement should exist in the integration requirement. Here are the result of the integration of nonconformities and corrective action requirements:

10.2.1 When a nonconformity occurs, the organization shall:

a. React to the nonconformity, and as applicable: :
   1. takes action to control and correct it
   2. deal with consequences for quality and environment
b. Evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by :
   1. Reviewing the nonconformity of quality and environment.
   2. Determining the causes of nonconformity related to the quality of environment, and
   3. Determining if similiar nonconformities exist, or coulsd potentially occur
c. Implement any action needed related to the nonconformities of quality or environment
d. review the effectiveness of any corrective action taken about quality or environment., and
e. Updating the risks and opportunities that has been set up in the planning, if necessary.
f. Make changes to the quality management system and environment management system, if necessary

Corrective action shall appropriate o the effects of nonconformities encountered.

10.2.2 Organization shall retain documented information as the evidence of:

a. the nature of the nonconformities any subquent actions taken, and
b. the result of any corrective actions.

4.2 Gap Identification of existing condition with integrated requirement.

After integration has been done, then compare with the organization existing condition, so the organization could fulfil the requirement that has not been done. Here are the result of gap identifications: The company has not been updating the risks and opportunities; Organization does not having a document that proving the existence of the result of corrective action.

4.3 *Risk assessment*

Risk assessment starts using an activity list that obtained from risks that may occurs on activity from existing condition or requirement. The steps of risk assesments are:

1. Risk Identification: Identifying a risk that may occurs from activities of requirements.

2. Risk analysis: Do risk analysis, by determining a possibility level and impact scale of each risk. Here are the possibility and the impact scale that applied:

Tablel 1 Scale risk possibility/likelihood

scale	Criterion	Description	Frequence/year
1	Very Small	Almost did not occur (Hardly possible)	1-5 times
2	Small	Less likely occurred	6-10 times
3	Medium	Fifty-Fifty	11-20 times
4	High	Likely to occur	21-50 times
5	Very High	Almost certainly occur	More than 50 times

Source: (Susilo, Leo J; Kaho, Victor Riwu ISO 31000, 2010)

On the Table 1 it can be seen that scale that used is 1-5 scale, which are very small criterion, small, medium, big, very big the risk occur.

Table 2 Consecuence Scale
source : (Susilo, Leo J; Kaho, Victor Riwu ISO 31000, 2010)

Scale	Criterion	Description
1	Very Small	Small impact towards the target that can be ignored
2	Small	Small impact towards the target that can be ignored
3	Medium	Affect the achievement of some targets
4	High	The targets are important to be not achieved
5	Disaster	Whole targets are not achieved

Tabel 3 Risk register

Risk Number	Risk Identification	Risk analysis		Risk evaluation
	Risk	Consequence scale	Likelihood	Risk level
1	2	5	6	7
1	The amount of waste that is delegated to outsiders undocumented	2	5	High

Tabel 3 Risk register (continued)

Risk Number	Risk Identification	Risk analysis		Risk evaluation
	Risk	Consequence scale	Likelihood	Risk level
1	2	5	6	7
2	There are reports incomplete information	3	3	High
3	Reproduction process in repair	5	1	High
4	The risk tends to reoccur since the risk no preventive action	3	4	High

Risk Control Action:

1. Create a document or form related to the handling of waste (types of waste , the amount of waste that is transferred to an other parties , the party responsible for the waste, and the waste receiver)
2. Controlling the nonconformity document, with verification the document by management representative
3. Intensive inspection before delivery product
4. update the risk by making risk register as a validation that the company has been considering the risk

4.4 Process Description of Nonconformities and Corrective Action

Here are the description of nonconformities and corrective action based on needs analysis result from existing condition, risk register and requirements:

1. Plan a nonconformities controlling activity and corrective actions
2. Identification of nonconformities
3. Accepting the reports
4. Follow-up reports
5. Implementation of corrective action.
6. Implementing an evaluation
7. Reviewing and verification

4.5 Value Added and Streamlining Analysis

Implementation of value added and streamlining analysis. Value added analysis clarifying activity into Real Value Added (RVA), Business Value Added (BVA), and Non Value Added (NVA) category. While Streamlining is a simplifying process with 12 tools on streamlining. The result of value added and streamlining analysis, are:

1. Plan a nonconformities controlling activity and corrective actions (BVA), Streamlining = automation and /or (applicating tools and computer on work, risk register improvement that been made into excel software, to facilitate the facility risks and prevent the lost document of risk register.

2. Identifying Nonconformities (RVA), Streamlining = Standardization, improvement based on that streamlining is make a standardization of nonconformities report, so it can be use by the whole unit of the organization.

On the activity below, it does not need another simplification: Accepting the report (BVA), follow up reports (RVA), Implementation of corrective action (RVA), implementing an evaluation (BVA), reviewing and verification (BVA).

5. CONCLUSION

Based on research result that are obtained, so the conclusion of this research are:

1. The result of integrated requirement from nonconformities and corrective action based on ISO 9001:2015 and ISO 14001:2015 clause 10.2.
2. This research also determining the risks through risk assessment from the list of activity risks that appropriate with requirement and existing condition that resulting a risk register.
3. Process draft that has been made are based on analysis of data processing, the process is done by value added and streamlining process, and there are improvement in 2 activity using streamlining tools which are automation and standardization.
4. Business Process that has been improved by Business process improvement will resulting SOP of controlling nonconformities and corrective action based on ISO 9001:2015 and ISO 14001:2015 clause 10.2 with considering the risks. The SOP design of this research has fulfilled the requirement of ISO 9001:2015 and ISO 14001:2015 and appropriate to the needs of CV. XYZ, and also considering the risks control in the process of nonconformities and corrective action on CV. XYZ.

6. REFERENCES

(a) Badan Standardisasi Nasional. (2015). SNI ISO 14001:2015. *Sistem Manajemen Lingkungan - Persyaratan dan panduan penggunaan*.

(b) Deysher, B. (2015). ISO. *A "Risk Based Thinking" Model for ISO 9001:2015*, 8.

(c) DR. Ir. H.M. Budi Djatmiko, M., & Heri Jumaedi, S. (2011). *Manajemen Mutu ISO 9001.* Bandung: ST (Badan Standardisasi Nasional, 2015)EMBI-Bandung Business School.

(d) Gasperz, V. (2012). *Three-in-One ISO 9001, ISO 14001, OHSAS 18001 Sistem Manajemen Kualitas, K3, Lingkungan (SMk4L) dan Peningkatan Kinerja Terus-menerus Contoh Aplikasi pada Bisnis dan Industri.* Bogor: Vinchristo Publication.

(e) Harrington, H. J. (1991). *Business Process Improvement.* United States: MC. Grawhill.

(f) ISO 9001. (2015). International Standard. *Quality Management Systems-requirements*.

(g) Susilo, Leo J; Kaho, Victor Riwu ISO 31000. (2010). *Manajemen Risiko Berbasis ISO 31000.* Jakarta Pusat: PPM.

AUTHOR BIOGRAPHIES

Rahmah Fadhilah is a student at Industrial Engineering Department, Telkom University, Indonesia. Her research area is quality management. She is a member of quality system engineering profesionalism. Her email address is rahmahfadhilah@student.telkomuniversity.ac.id

Sri Widaningrum is a lecturer at Industrial Engineering Department, Telkom University,Indonesia. She obtained BSc in Industrial Engineering, Universitas Pasundan, Indonesia, and Master in Indutrial Engineering, ITB, Indonesia. Her research area is quality management. Her email address is swidaningrum@telkomuniversity.ac.id

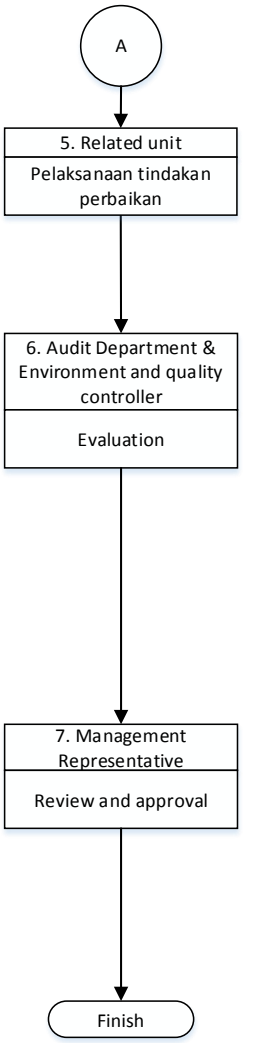
Heriyono Lalu is a lecturer at Industrial Engineering Department, Telkom University, Indonesia. Her research area is agent based modelling and simulation system analysis and design system thingking. Her email address is heriyonolalu@telkomuniversity.ac.id

APPENDIX A

NONCONFORMITY CONTROL AND CORRECTIVE ACTION PROCESS

Activity	Activity Description	Documented Information
Start		
1. Related Unit Planning nonconformity control and corrective action activity	1.a. Related unit planning nonconformity control and corrective action activity 1.b. Create or risk updating	1. *Risk register*
2. Related Unit Nonconformity identification	2.a. Related unit identify nonconformity within the unit 2.b. Related unit record the nonconformity in nonconformity and corrective report form (unit name, on behalf of, nonconformity type, cause, corrective suggestion) or audit report (if done while audit performed) 2.c. Related unit hand over the report to audit department	2.a. Nonconformity and corrective report form 2.b. Audit report
3. Audit Department Receiving report	3.a. Audit department receiving report 3.b. Audit department make sure the report form completely filled (unit name, on behalf of, nonconformity type, cause, corrective suggestion) 3.c. Audit department write the number in the report form 3.d. Audit department hand over the report to the right person	3.a. Nonconformity and corrective report form 3.b. Audit report
4. Receiver Processing the report	4.a. Receiver receive the report from audit department 4.b. Receiver analyze nonconformity cause 4.c. Receiver define the same conformity which had or potentially happened 4.d. Receiver consider the risk register in determining corrective action 4.e. Receiver write corrective action implementation plan in nonconformity and corrective report form (corrective action that will be done, implemetation date and time, person in charge) 4.e. Audit department inform corrective action implemetation plan that needed to do by related unit	4.a. Nonconformity and corrective report form 4.b. Audit report 4.c. Risk register
A		

NONCONFORMITY CONTROL AND CORRECTIVE ACTION PROCESS

Activity	Activity Description	Documented Information
	5.a. Related unit do corrective action 5.b. Audit depatment supervise and direct the corrective implementation 5.c. Audit Audit department write the result of corrective action in audit report form 6.a. Audit Department & Environment and quality controller evaluate the corrective result that had been done 6.b. Audit Department & Environment and quality controller update the result of evaluation (risk) in reisk register 6.c. If the corrective action is appropriate, so audit department edit the report status (close) and hand over the report to management representative 6.d. If the corrective action is not appropriate, so audit department return the report to the receiver for further step (back to activity 4) 7.a. Management representative review the result of corrective evaluation from the report 7.b. If it is approved, management representative sign the report 7.c. If it is not approved, so management representative did not sign and write recommendation action in note (back to activity 4)	5.a. Nonconformity and corrective report form 5.b. Audit report 6.a. Nonconformity and corrective report form 6.b. Audit report 6.c Risk register 7.a. Nonconformity and corrective report form 7.b. Audit report