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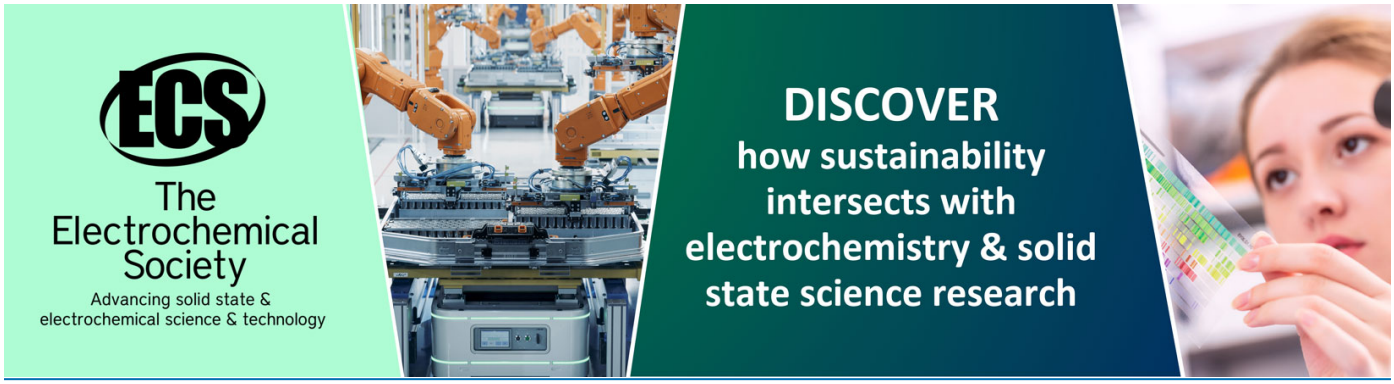

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From ISO 9001:2008 to ISO 9001:2015: Significant changes and their impacts to aspiring organizations

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Abstract. ISO 9001:2015 is the latest version of ISO Quality Management System standard that has been updated recently from ISO 9001:2008. It is necessary for all organizations that have implemented and been certified with ISO 9001:2008 to prepare the transition and upgrade their Quality Management System because the certification will expire by September 2018. This paper attempts to provide knowledge on the significant changes from ISO 9001:2008 to ISO 9001:2015, what new requirements are added, and how they would impact the organizations. An exploratory and applied research was chosen as the research approach and aimed to explore what transition designs are needed to anticipate the changes as well as their impacts. The research applied a methodology of Plan-Do-Check-Action (PDCA) cycle into four organizations and their results were compared and discussed to explain the transition designs. Some qualitative methods such as observation and interview were used to collect the data. By addressing the new requirements, three transition designs that should be prepared are: (i) identifying needs from interested parties, (ii) analyzing internal and external factors of the organizations to formulate relevant strategies and quality objectives, and (iii) registering risks associated to business processes as well as organizational strategies.

Keywords: Standardization, ISO 9001: 2015, Quality Management System

1. Introduction

ISO 9001 is an International Standard of Quality Management System (QMS). This Standard describes the requirements for organizations to help them promote continual improvements and achieve customer satisfaction. This Standard has been revised several times [1, 2]. The first version which was published in 1987 and known as ISO 9001:1987 was formulated based on the concept of quality assurance. It comprised three classifications i.e. ISO 9001:1987 as a model for organizations with the creation of new products, ISO 9002:1987 for those without the creation of new products, and ISO 9003:1987 as a model for final inspection and testing purposes. The Standard was later developed into the second version i.e. ISO 9001:1994 and was improved based on the concept of preventive action. The third version, ISO 9001:2000, was formulated based on the concept of quality management to help organizations improve their business process. The fourth version was ISO 9001:2008 which underwent minor changes (merely to improve and make a better version of the standards) from the previous version.

ISO 9001 Quality Management System Standard is now transforming itself into a new brand with major changes from the earlier 2008 version. This new version was published in 2015 and known as ISO 9001:2015. The changes include more clauses and use a new concept and approach. The comparison of the changes between the old and new versions was well explained by [3]. If ISO 9001:2008 emphasizes on continual improvement and customer satisfaction, ISO 9001:2015 puts more focus on risk-based thinking. Risk-based thinking, as the concept and approach added in the new version, requires organizations to identify and analyze potential risks that could arise both from inside and outside of the organizations. Thus, organizations can formulate strategies to prevent any impact of the risks and they can be expectantly more resilient and sustainable by accommodating the risks. Other changes in the new version are the consideration of the organizational stakeholders' needs, the importance of knowledge management and less emphasis on documentation [4, 5]. The new version of ISO 9001 has 10 clauses and a brief comparison of clauses between both versions is presented in Table 1.

Table 1. The comparison of clauses between two latest versions of ISO 9001.

ISO 9001:2008	ISO 9001:2015
Clause 1: Scope	Clause 1: Scope
Clause 2: Normative References	Clause 2: Normative References
Clause 3: Terms and Definitions	Clause 3: Terms and Definitions
Clause 4: Quality Management System	Clause 4: Organizational context.
Clause 5: Management Responsibility	Clause 5: Leadership
Clause 6: Resource Management	Clause 6: Planning
Clause 7: Product Realizations	Clause 7: Support
	Clause 8: Operation
Clause 8: Measurement, Analysis and Improvements	Clause 9: Performance Evaluation
	Clause 10: Improvement

Previous related studies have been consistently conducted in the last four years. The period between 2014 and 2016 showed that among 219 internal researches on the design and application of various ISO conducted by Industrial Engineering, University of Surabaya – Indonesia [6], five of them were case study researches on service and manufacturing companies producing a generic methodology using Plan-Do-Check-Action (PDCA) approach. A study to improve the effectiveness and efficiency of ISO implementation was done by integrating the lean concept [7, 8] and its result was known as Lean Quality Management System (LQMS). The study was then continued with the application of simplified LQMS on some micro and small enterprises through QMS certification program [9]. Roy & Ghose [10] revealed the stress sensation of the QMS certified companies and their urgencies to adjust their QMS. Cochran [3] explained theoretically the necessary preparations in term of the upgrading process; however, practical experiences on designing and applying new version of ISO 9001 is needed to see the compatibility. The increasing demands from the QMS certified organizations to prepare the transition by September 2018 (otherwise their certifications will expire) called for this research. Hence, this research aims to: (i) identify the gap between existing QMS and the requirement of ISO 9001:2015, (ii) formulate action plans for bridging the gap, and (iii) derive the suggested transition designs and their impacts on organizations to cover the significant changes of ISO 9001:2015.

2. PDCA approach for research methodology

This research was an applied-exploratory research; it tried to explore the practical application of ISO 9001:2015 in some QMS certified organizations. The mixed qualitative and quantitative methods, displayed in Table 2, such as structured interview, questionnaire and sampling, literature review, focus group discussion, statistical analysis were used during data collection and analysis [10]. Figure 1 describes briefly the framework of Plan-Do-Check-Action (PDCA) approach that was used.

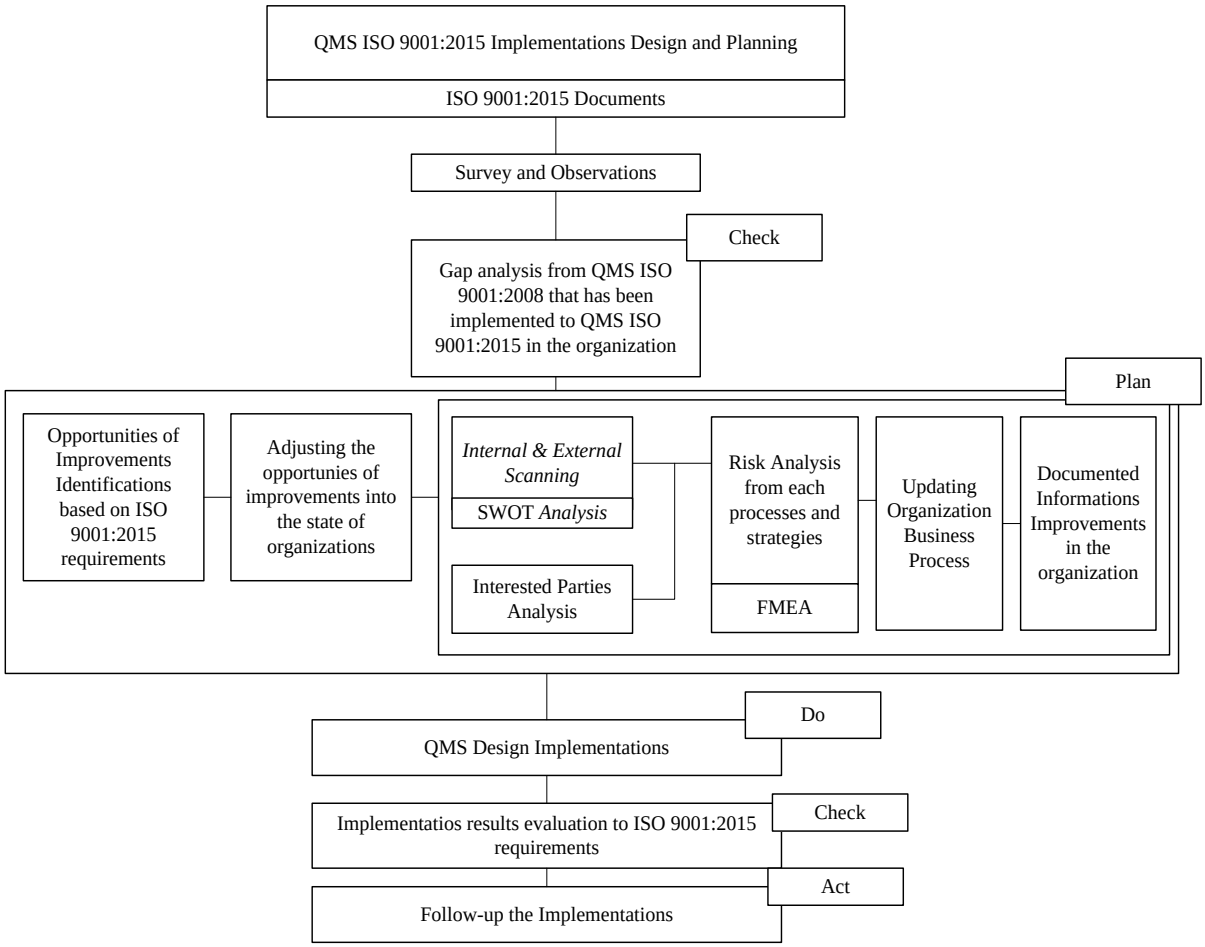

Figure 1. Research steps: PDCA cycle approach.

a. Gap identification and analysis (Check)

The main purpose of gap identification was to investigate how the current QMS complies with ISO 9001:2015 requirements. The gap identification was done through [6]: (i) a questionnaire comprising a list of questions derived from the requirements of the Standard, (ii) observation and survey, guided by the questionnaire, to collect the information on how the current QMS complies with the requirements. The gap identification, followed by its analysis, was aimed to present the percentage of conformity and nonconformity of current QMS towards the Standard. It also helped to identify opportunities for improvements in order to upgrade organizations' QMS.

b. Transition designs (Plan)

Based on the previous gap analysis, there would be several opportunities for improvement for transition designs, especially to take into consideration the changes in ISO 9001:2015. The transition designs covered the usage of concepts such as: (i) Strength Weakness Opportunity & Threat (SWOT) analysis to incorporate internal and external issues of organizations [11] in determining strategies and objectives, (ii) the stakeholders' analysis to identify the needs of interested parties of organizations [3], and (iii) the risk analysis [12]. Furthermore, this planning stage became the focal point of discussion in this publication.

c. Implementation of the transition designs (Do), Evaluation (Check) & Follow-up (Act).

The organizations need to implement the transition designs in order to validate them. After the organizations implement the transition designs, they are then able to evaluate the implementation to ensure the fulfilment of the Standard. Any feedback can be taken to revise the previous designs.

Table 2. The mixed qualitative & quantitative research methods.

No	Research Step	Research Methods
1	Selection of research objects	***Purposive sampling***. There were four organizations voluntarily involved in the research, the selection criteria were the needs for upgrading the QMS and having been certified ISO 9001:2008
2	Gap identification between current QMS and ISO 9001:2015 requirements	***Questionnaire, observation & structured interview***. Gap identification was done using lists of questions, with two categorical answers i.e. confirm or not, supporting by observation to current QMS and secondary data.
3	Gap analysis	***Descriptive statistics***. Tabulated data and numerical analysis.
4	Proposed action plan to close the gap	***Literature review***. Literature search about the new requirements added to ISO 9001:2015 and their practical implications.
5	SWOT analysis, strategies and objectives formulation	***Observation & interview.*** Using the specific concept to identify SWOT, involving the managerial level to validate the SWOT analysis and to formulate relevant strategies and objectives.
6	Stakeholders' analysis	***Focus group discussion.*** Involving the discussion among the stakeholders' parties.
7	Risk identification	***Observation & interview.*** Using the specific concept to identify risk, involving the operational level to registering the risks and determine the risk level.

3. Results and discussion

The framework of PDCA cycle as research methodology was applied into four organizations during 2016, with the characteristics of each organization described in Table 3. All organizations are located in East Java, one is in service industry (organization A) and the rest are manufacturers. Two of the organizations (C and D) are public-listed companies. All organizations have previously been certified by the earlier version of ISO 9001.

Table 3. Four organizations as research objects during 2016.

Research Objects	Location	Industry	Description
Organization A	Surabaya, East Java	Library Unit of Service in a private university	Certified ISO 9001 since 2009.
Organization B	Surabaya, East Java	Thread manufacturer	Certified ISO 9001 since 2003. Certified ISO 22001 since 2013.
Organization C	Sidoarjo, East Java	Glass manufacturer Public-listed company	Certified ISO 9001 since 1996. Certified ISO 14001 since 2005.
Organization D	Surabaya, East Java	Snack manufacturer Public-listed company	Certified ISO 9001 since 2003. Certified ISO 22001 since 2010.

Gap identification analysis is presented in Table 4. The gap analysis showed that the compliance of current QMS of Organization A and B were 71.8% and 79.5%, respectively, i.e. both organizations indicated similar conformity level. These percentages of compliance (%C) could be categorized as high because both organizations had implemented the earlier version of ISO 9001 in which most of the requirements were similar to those in ISO 9001:2015, especially in clauses 5 (Leadership), 7 (Support), 8 (Operations), 9 (Performance Evaluation) and 10 (Improvement). For the latter organizations (C and D), the conformity levels were higher because both organizations were public-listed companies thus had anticipated in advance to upgrade their current QMS especially by preparing the risk assessment. Based on the highest non-conformity percentage of these four organizations, it can

be seen that most of the non-compliance occurred on clauses 4 (Organizational Context) and 6 (Planning), presumably because these were newly added requirements in ISO 9001:2015.

Table 4. The compliance of current QMS with ISO 9001:2015 requirements.

Clause of ISO 9001:2015	Organization A		Organization B		Organization C		Organization D	
	%C	%NC	%C	%NC	%C	%NC	%C	%NC
4. Organizational Context	40.0	***60.0***	40.0	**60.0**	81.6	***18.4***	50.0	***50.0***
5. Leadership	83.3	16.7	71.4	28.6	97.9	2.13	83.3	16.7
6. Planning	20.0	***80.0***	60.0	***40.0***	85.7	***14.3***	66.7	***33.3***
7. Support	95.0	5.0	100.0	0.0	100.0	0.00	95.0	5.0
8. Operation	73.2	26.8	97.8	2.2	100.0	0.00	100.0	0.0
9. Performance Evaluation	100.0	0.0	100.0	0.0	97.2	2.78	100.0	0.0
10. Improvement	90.9	9.1	87.5	12.5	100.0	0.00	75.0	25.0
Total	**71.8**	**28.2**	**79.5**	**20.5**	**97.0**	**3.0**	**91.8**	**8.2**

Note: %C showed the percentage of compliance with the requirements of ISO9001:2015, %NC showed the percentage of non-compliance.

The impacts of the new version of the standard which could be taken as benefits for organizations were that the standard introduced risk-based thinking and helped the organizations address risks and opportunities in a systematic approach; it put more emphasis on leadership commitment especially on strategic planning. The changes in the new version can be divided into three groups:

a. ***Slight changes***. The existing QMS related to quality policy, resource management, management review, internal audit and corrective action has insignificantly changed and can remain the same as the previous one.
b. ***Moderate changes***. The existing QMS related to supply chain management, product or service provision, QMS scope, quality objectives and performance evaluation should be updated to comply with the standard.
c. ***Significant changes***. A list of new requirements, supported by the gap analysis above, should be incorporated into the current QMS from scratch. The description of the new requirements is described as follow [5]:
   - *Clause 4 Context of the Organization, Sub clause 4.1 Understanding the organization and its content*. The requirement states: "The organization shall determine external and internal issues that are relevant to its purpose and its strategic decision and that affect its ability to achieve the intended result(s) of its QMS." **Proposed action plan: transition design #1 (SWOT analysis)**,
   - *Clause 4 Context of the Organization, Sub clause 4.2 Understanding the needs and expectation of interested parties.* The requirement states: "The organization shall determine: (a) the interested parties that are relevant to the QMS, (b) the requirement of these interested parties that are relevant to the QMS. The organizational shall monitor and review information about these interested parties and their relevant requirements." **Proposed action plan: transition design #2 (stakeholder analysis),**
   - *Clause 6 Planning, Sub Clause 6.1 Actions to address risks and opportunities*. The requirement states: "When planning for the QMS, the organization shall consider the issues referred to in 4.1 and 4.2 and determine the risks and opportunities." **Proposed action plan: transition design #3 (risk analysis),** and
   - *Clause 7 Support, Sub Clause 7.1.6 Organizational Knowledge*. The requirement states: "The organization shall determine the knowledge necessary for the operation of its processes and

achieve conformity of products and services." Proposed action plan: management of information system, which is not discussed in this paper because the plan will be different and customized to each organization.

Throughout the literature review [3, 8] and brainstorming with experts and practitioners, there are three primary transition designs that should be prepared by organizations to upgrade their QMS from the earlier version to ISO 9001:2015: (1) the identification of internal and external factors of an organization (SWOT analysis), (2) the identification of interested parties of an organization (stakeholder analysis) and (3) the identification of risk (risk analysis). For further discussion, Organization A will be used as the case study to explain the examples of those three transition designs.

3.1. SWOT analysis

This analysis was aimed to identify the internal and external issues of an organization and the strategies were developed based on the SWOT analysis. A strategy should be followed by measurement indicators; therefore, the quality objectives of the current QMS need to be upgraded accordingly. Figure 2 explains how the SWOT analysis was done to determine the strategies and their quality objectives. Internal factors can be analyzed by using the value chain analysis to identify strengths and weaknesses through examining the organization's business processes. External factors can be analyzed by using Porter's Five Forces Model to identify organization's threats and opportunities. In Organization A, by combining its integrated information system (as the strengths) and the increasing usage of information technology (as the opportunities), a strategy as shown in Table 5 was formulated, i.e. to maximize the utilization of the Library by using the support of information technology. Its relevant quality objective was also formulated.

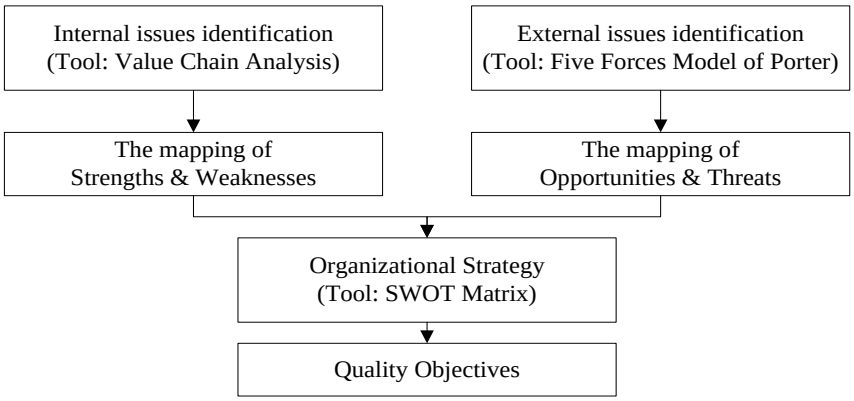

Figure 2. Transition design #1:
From SWOT analysis to organizational strategy and its quality objectives.

3.2. Stakeholder analysis

The objective of this analysis was to identify the interested parties of the organizations and their needs towards the organization. Thus, the organization can determine the business processes that can provide the realization of those needs. The term "interested parties" refers to the stakeholders and after their needs were determined, the organization could analyze whether the current processes were able to accommodate the needs. If not, the organization could create some new processes to fulfill the stakeholders' needs. In Organization A, the stakeholders of Library Unit of Service included the students, lecturers, owner, employees, government, suppliers, other related unit of services and the users from other universities. Table 6 shows an example on how the needs of students as one of the Library's stakeholders were captured in the QMS processes to accommodate the needs.

Table 5. A strategy and its quality objective were developed based-on the SWOT analysis.

SWOT (Organization A)	Strategy	Related Business Process	Quality Objectives	Target	Measurement Method
Strength: It has an integrated information system ***Opportunity:*** The increasing usage of IT	To maximize the utilization of library service by using IT	The provision of Information	The increased visitors of library user interface or online service (***digilib*** and ***elib***)	110%	Count the visitors of ***digilib*** and ***elib.*** The visitors of this period should be 110% for previous period.

Table 6. Transition design #2: From stakeholder's needs to related business processes.

Stakeholders	*Needs*		*Related QMS Processes*
Students	Library should provide good services which supported by good and complete facilities as well as clear procedures.	• Complete collection • Well-provided facilities • Good service quality	• The procurement process • The circulation service of literature material • The Recruitment process

3.3. Risk analysis

One of the major changes in ISO 9001:2015 is the concept of risk-based thinking, which requires the organization to determine the risk from its business processes or strategies. Risk needs to be addressed; it can cause high negative impact on organizational sustainability unless the organization can take control of it. Among the several methods for risk assessment, FMEA (Failure Mode and Effect Analysis) is the most common one that can be used by organizations for risk analysis [12, 13]. FMEA identifies failure potentials and determines the level of the risk by considering three scales of measurement, i.e. the severity (impact of the failure), occurrence (frequency of the failure) and detection (the inability of current control to detect the failure). The scales are weighted with the score of 1-10 or 1-5 (it is flexible as long as the organizations can define the meaning of the value). These three values are then multiplied to determine the RPN (risk priority number) where higher RPN indicates higher risk level. RPN is used to prioritize the risks; if the RPN reaches 25% of the total RPN then those risks should be anticipated [14].

There were two types of risks that were registered during the risk assessment, i.e. strategic and operational risks. Strategic risks were formulated by identifying any failure that could prevent the deployment of strategies. Operational risks were initially formulated by identifying any failure that is always faced by the process doer (internal source) or derived from the customer complaints (external source).The risk register can be updated subsequently during the period of internal audit to add the unidentified failure. Table 7 shows the examples of both strategic and operational risks in Organization A. The FMEA table above used the score of 1-5 for the value of Severity, Occurrence and Detection, with total maximum RPN of 5×5×5=125. Thus, a failure with RPN higher than 25% of the total maximum RPN (125×25% = 31.25) should be immediately anticipated; the recommended actions should be proposed and implemented accordingly.

4. Conclusion

Organizations are urged to prepare the transition of their Quality Management System (QMS) from ISO 9001:2008 to ISO 9001:2015 before the previous certification expires. For organizations that already implemented the earlier version, there were already high compliance levels of current QMS with the requirements of ISO 9001:2015(with the average of 75%), although they had not done anything yet in term of transition preparation. The organizations could prepare these three major transition designs. Firstly, the organizations can formulate their strategies and relevant quality objectives based on the SWOT analysis. Secondly, they can accommodate the stakeholders' needs by defining relevant QMS business processes. Finally, they also need to register the strategic and

operational risks which can be done by using FMEA. The paper showed how these transition designs could be prepared and the examples as the result of implementation in a service organization were also provided. By performing these three major transition designs, the organization is expected to be able to cover the gap and meet the new requirements in ISO 9001:2015.

Table 7. Risk register: Examples of strategic and operational risks.

Strategies or Business Process	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential Cause(s) of Failure	Occ	Current Process Controls	Det	RPN	Recommended Action(s)
Strategic Risk									
To maximize the utilization of library service	Overloaded web	Online catalogue was inaccessible	3	Crowded visitors	3	Historical record of web visitors	3	27	-
Operational Risk									
The Circulation Service of literature material	Books had not been returned by the borrowers	Books were listed in online catalogue but not available for rent	3	Limited quantity	5	Periodic checking	5	**75**	**Adding the activity to send reminder to users through email or smartphone notifications before and after the due date.**

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