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RECOMMENDATIONS FOR WORK SYSTEM ASSESSMENT OF SNI 9001: 2008 IMPLEMENTATION BASED ON MACRO ERGONOMICS AT PT SPU

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Abstract. The increasingly intense competition, the number of customer choice options and the more selective customers in choosing medical equipment products require PT SPU as one of the Indonesian National Medical Device (*Alkes*) industry engaged in the production process of medical devices and rehabilitation to always improve a better work system. To improve product quality PT SPU has implemented the SNI ISO 9001: 2008 Quality Management System which contains standard requirements used to measure the organization's ability to meet customer requirements and appropriate regulations. The purpose of this research is to identify and assess how much influence each component of the work system has on the satisfaction of customers, employees and leaders. The method used is Macro Ergonomics and data were collected through questionnaires and analyzed using regression analysis. The magnitude of the contribution of the work assessment process of SNI ISO 9001: 2008 implementation to the influence of significant macro ergonomic aspects on organizational conditions (52.45%), physical environment (37.37%), production processes (12.53%), infrastructure (9.69%), production process services (5.90%), and R&D activities (2.82%).(3) Proposed recommendations for improving organizational conditions by confirming the roles and responsibilities of each person so that there are no undisciplined employees between sections, improving communication. Physical work environment by rearranging the place and rejuvenating production process support tools that are not ergonomic and have been damaged, redesigning a conducive and comfortable work environment. Production process improvements including employees actively communicating with each other and development of standard operating procedures (SOPs) with legacy competencies through knowledge transfer. Improvements to Facilities and Infrastructure by adding air conditioning, such as blower/exhaust ventilators, and sufficient room ventilation. Improvements to R&D: by facilitating employee exchanges for R&D activities, training, technical guidance, and experience exchange; increasing access to cooperation with government and private organizations.

Keywords: Work system assesment, Macro Ergonomics, SNI 9001:2008, Medical device industry

1. INTRODUCTION

PT SPU Palembang, one of Indonesia's national medical device manufacturers, must continue to improve a better work system as a result of increasingly fierce competition and increasingly selective customers. One of the most important components in the progress of the organization is a good work system, which is the key to success in

increasing productivity and efficiency of the company and reduce the risk of work [1]-[3]. The work system consists of a series of different work systems that are combined to produce goods or services that generate value for the customer or profit for the company or organization [4][5].

It is essential that the worker, the work process, and the work environment fit together. This method is called the ergonomics approach. Ergonomics is the field that combines science, technology, and artistry to align tools, work methods, and surroundings with human strengths, capabilities, and restrictions. The goal is to develop workplaces and environments that are healthy, secure, pleasant, and productive [4][6][7]. Each component of the work system is increasingly complex due to advances in science and technology. Factors such as organization, technology, procedures and tasks, organization, physical, social, cultural, and behavioral environments, and regulation are some examples. Thus, micro ergonomics methods on the production floor are no longer relevant. In addition, researchers can assess such work systems by using a macro ergonomics approach, which is a top-down sociotechnical approach that aims to optimize the design of work systems and ensure that they function properly [8]-[11]. As a medical equipment manufacturing industry with many competitors, the main problem of PT SPU Palembang is whether the services provided are in accordance with customer expectations, because these customers are potential market consumers who will repeatedly purchase PT SPU medical equipment products repeatedly. Therefore, PT SPU Palembang should always provide good service by improving the performance of its employees for the satisfaction of its customers and make more potential consumers. This is what is called customer orientation. Organizations should have a good quality management system to improve the quality of their goods and services.

SNI ISO 9001:2008 is a globally recognized and internationally acclaimed quality management system standard. SNI ISO 9001:2008 has been adopted by BSN to become SNI for various business fields and improve the ability to compete. SNI ISO certification has many advantages, such as a better reputation, awareness of the importance of maintaining quality, procedures, and responsibilities become clearer and better documented, eliminate unnecessary work, audits become easier and easier to track, better service potential markets, increased customer and employee satisfaction, and continuous improvement. With the implementation of the SNI ISO 9001:2008 quality management system, services are better than ever. Every action is done systematically, recorded, and can be routinely analyzed. PT SPU will face many problems to fulfil their expectations and desires and increase customer satisfaction due to the demands, responsibilities, and elements of the work system itself [12]-[14]. Nonetheless, whether PT SPU has fulfilled the expectations and desires of customers by providing services in accordance with the service quality standards of SNI ISO 9001: 2008, and whether customer satisfaction has been met. Therefore, the influence of macro ergonomic elements on work system components on the level of customer satisfaction must be identified and evaluated. Organizational conditions, production processes, physical environment, business process services, research and development activities, adaptation facilities and infrastructure for the advancement of manufacturing technology and human resource development are macro ergonomic aspects of the work system in question. From the results of this assessment, the most important influence of macro ergonomic aspects on the work system will be identified and the work system components will be further analyzed.Unlike previous studies that focus on micro-level ergonomic interventions, this study adopts a macro ergonomics framework to assess organizational-level factors impacting ISO implementation. Although the SNI ISO 9001:2008 has been widely adopted in various industries, few studies have assessed its implementation through a macro ergonomics lens in the Indonesian medical device sector. Therefore, this study aims to identify which macro ergonomic components most influence work system effectiveness and stakeholder satisfaction at PT SPU.

2. METHODS

The object of the research is PT SPU Palembang customers who feel directly the results of the service on the implementation of work assessment based on macro ergonomics related to the implementation of SNI ISO 9001: 2008. There are 2 variables, namely the dependent variable is the level of customer satisfaction and the independent variable is the macro ergonomic elements of each component of the work system including organizational conditions, production processes, physical environment, business process services, R&D activities, as well as facilities and infrastructure adaptation for the advancement of manufacturing technology and human resource development [15]-[17].

The essential information is gathered from both primary and secondary sources, specifically: (1) primary data collected through firsthand observation and assessment of the research subject in the actual environment, which is: (a) preliminary observation by conducting direct observation of the real conditions in the work system related to customer satisfaction as the object of research and conducting interviews with PT SPU leaders, employees, and customers. (b) Macro ergonomic Organizational Questionnaire Survey (MOQS), a research questionnaire about the condition of the observed work system. The MOQS procedure includes; conceptualization,

namely determining the variables or components of the work system to be assessed, operationalization, namely determining the dimensions of the concept being assessed, and making a questionnaire consisting of: an open questionnaire to obtain indicators of macro ergonomic aspects to be studied, a preliminary closed questionnaire (tryout). The lattice that has been obtained is then compiled and developed into question items in a closed questionnaire, and a closed questionnaire (research). If the preliminary questionnaire data is declared valid and reliable, the questionnaire is suitable for use as an instrument for collecting actual research data, (2) secondary data, including: Data on the history, scope, structure, and management of the organization are included in the category of secondary data in this study, (3) data processing, analysis methods and discussion. The research flow chart is sequentially as follows; start-preliminary study & literature study-problem formulation and initial hypothesis-compiling & distributing open questionnaires-determining indicators and preparing grids-compiling & distributing closed questionnaires (tryout) SNI ISO 9001: 2008-tabulation of questionnaire data (tryout)-testing the validity and reliability of the instrument-results valid & reliable?, if not will be repeated back to the previous stage and if yes continue to the next stage-distribution of closed questionnaires-tabulation of questionnaire data-correlation and regression analysis-discussion analysis (proposed improvements based on macro ergonomics)-finished.

3. RESULTS AND DISCUSSION

Each indicator of the research variable was collected from the open-ended questionnaire. The question grid in the closed questionnaire can be determined by looking at the tabulation of the open questionnaire. The lattice was developed into question items with 5 answer options and an ordinal scale using a Likert scale of 1-5. These items are indicators of macro ergonomic elements of the work system that affect the level of employee satisfaction. The lattice of macro ergonomics aspects is presented in Table 1.

Table 1. Macro Ergonomics Aspect Grid

Variable	Indicators	Item Number
Organizational Conditions	Type of leadership	1,2
	Communication issues	3
	Rules and regulations	4,5
Production Process	Production process methods	7,8,12
	Extra production process activities	10, 11
	Workmanship of the production process	9
Production Services	Production service problems	14, 15, 16, 17, 18
Physical Environment	Conditions of physical environmental factors	20, 22
	Arrangement of production floor stations	21
Research Activities	Access to cooperation with outside parties	24, 25
Facilities and Infrastructure	Equipment condition	27, 28, 31, 33, 35
	Optimization of facilities and infrastructure	29, 30, 32, 34
Employee Satisfaction	Labor satisfaction level	6, 13, 19, 23, 26, 36

The alternative answers used are as follows:
SS (Strongly Agree): scored 5; S (Agree): scored 4; N (Neutral): scored 3; TS (Disagree): scored 2 STS (Strongly Disagree): scored 1.

The causal relationship of the research variables between macro ergonomics aspects of the conditions of the components of the work system at PT SPU Palembang to the level of satisfaction of customers, employees and leaders can be interpreted as follows: very strong relationship between (a) organizational conditions with processes at production floor stations, physical environment, (b) services with physical work environment, R&D activities, (c) physical environment with R&D, and (d) production processes with infrastructure facilities. The simultaneous contribution correlation shows the relationship or relationship between the conditions of all aspects of macro ergonomics on the components of the work system to customer satisfaction, employees and leaders of the correlation is very strong [2][4][5].

The influence of macro ergonomics aspects on the components of the work system on customer satisfaction, employees and leaders of PT SPU has a significant effect, namely; organizational conditions (52.45%), physical environment (37.37%), production processes (12.53%), infrastructure (9.69%), production process services (5.90%), and R&D activities (2.82%). (a) The organizational condition of the indicator is the form of interaction communication between leaders, employees and customers. Communication that is less harmonious and in line between the leadership, in this case the General Manager and the owner. General Manager and owner are sons-in-

law with in-laws not in line so that employees become confused about which one to follow and have an impact on the execution of the production process and service to customers [5][10]. (b) The physical work environment is an indicator that the layout of the production floor is not conducive, the room temperature still exceeds the threshold value by 35%, and exposure to dust and chemicals has not been eliminated with PPE that meets the requirements [9][11]. (c) Production process indicators are the lack of products returned by customers due to quality that has not been consistently maintained. (d) Infrastructure facilities indicators are still many tools and machinery that need to be upgraded to be more modern and more efficient. (e) Production process services are indicators that service access is slower and less friendly, does not provide a family atmosphere and is sometimes still based on individualism. And (f) R&D activities, the indicator is the absence of periodic training for employees to improve skills that follow the development of the production process and are more efficient [9][14].

Recommendations for improvement of organizational conditions are to improve communication harmonization, reinforce the role of the job description of each employee and leader, engage in thorough back-and-forth discussions focused on realizing the goals of the organization by setting aside personal pride. The second principle of quality management, which relates to leadership, emphasizes that leaders create and foster a cohesive direction and mission for the organization [12][16][17]. Consider the needs of all interested parties, including customers. Set challenging and socialized goals and targets and create and support values of togetherness, honesty and ethical task models at all levels of the organization. Physical environment with more ergonomic/comfortable production floor layouts and stations, improved air circulation. To meet the stipulations of ISO SNI 9001:2008 clause, it is essential to evaluate the workplace surroundings, which include physical elements, environmental conditions, and additional influences such as sound levels, temperature, moisture, illumination, and atmospheric conditions. Production process through a process orientation approach (principle 4), namely a desired result will be achieved efficiently, if the related activities and resources are managed as a process. Integration of sequential processes of people, materials, methods, machines, and equipment in an environment to produce value-added output for customers. Clause 6.1 of ISO SNI 9001:2008 on resource provision, where the organization must determine and provide the necessary resources [18]-[20].

The six recommendations related to the influence of the work system on customer satisfaction, employees and leaders of PT SPU, as mentioned earlier, exemplifies the application of quality management principles, specifically the concept of ongoing enhancement. The relentless pursuit of improving the organization's overall performance must be a constant objective of the entity. Ongoing enhancement entails methodical and cumulative actions that address the changing requirements and anticipations of customers, staff, and management, which will guarantee a vibrant development of the quality management framework, rooted in an ergonomic scientific methodology. Consistently implement the organization's approach through macro, micro, and total ergonomics for continuous performance improvement, provide and send employees for training/internships on continuous improvement methods and tools, implement continuous improvement on product, process and system objectives, and set goals and objectives as guidelines, and measure achievements for continuous improvement and reward and recognize improvements.

Theoretical Implications are this study contributes to the growing body of literature on macro ergonomics by demonstrating how a systems-based ergonomic approach can enhance the implementation of quality management standards such as SNI ISO 9001:2008. It reinforces the relevance of viewing work systems as sociotechnical structures in which organizational, physical, and process-level elements interact to affect employee and customer satisfaction [21]. The findings also validate the use of the Macro-ergonomic Organizational Questionnaire Survey (MOQS) as a diagnostic tool for evaluating ergonomic conditions in quality-focused manufacturing environments [22].

Practical implications; from a practical standpoint, the results provide actionable insights for managers and practitioners in the medical device industry, particularly those operating in developing economies. The identification of key ergonomic factors—especially organizational conditions and the physical work environment—offers a clear roadmap for targeted interventions. Companies can apply these findings to enhance internal communication, optimize workplace layout, and align standard operating procedures (SOPs) with ergonomic best practices. Moreover, the study supports integrating macro ergonomics with ISO-based quality improvement efforts to increase productivity, reduce errors, and improve employee well-being and customer satisfaction.

This study is limited to a single case study and self-reported data; future research could apply a comparative multi-site approach using mixed methods.

4. CONCLUSION

Based on the results of data processing and analysis that has been done, several things can be concluded, among others: (1) macro ergonomic aspects and indicators of customer, employee and leader satisfaction including organizational conditions, communication issues, applicable regulations, and leadership aspects. The physical

work environment is indicated by the condition of physical environmental factors and the layout of the workspace. The production process is indicated by the SOP method, additional activities outside the SOP, regeneration and competency transfer. Production process services are indicated by service problems at each work station. Infrastructure and facilities with indicators of equipment condition, optimization of facilities and infrastructure. R&D with metrics of access to cooperation with outside parties, training, technical guidance. (2) The influence of macro ergonomic aspects on the components of the work system on the satisfaction of customers, employees and leaders of PT SPU has a significant effect, on organizational conditions (52.45%), physical environment (37.37%), production processes (12.53%), infrastructure (9.69%), production process services (5.90%), and R&D activities (2.82%). (3) Proposed recommendations for improving Organizational Conditions are as follows: Affirm the roles and responsibilities of each person so that there is no undisciplined inter-section labor; improve communication. Recommendations for intensive two-way communication between company, factory, and section/department leaders and their employees. Reorganize the premises and rejuvenate the tools supporting the production process, especially for kits and equipment that are not ergonomic and have been damaged, to improve a conducive and comfortable working environment. Improvements to the production process included the workforce actively communicating with each other and the development of standard operating procedures (SOPs) with legacy competencies through knowledge transfer. Improvements to Facilities and Infrastructure are as follows: The presence of air conditioners, such as blower/exhaust ventilators, and sufficient ventilation, will make the workstation space less comfortable for the workforce. Recommendations for Improving Production Process Services: Labor is more friendly to customers and labor; Labor is more responsive to needs among labor and customers. Recommendations for R&D improvement: Facilitate labor exchange for research and development activities and experience exchange; increase access to cooperation with government and private organizations.

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