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Occupational Safety And Health Risk Analysis Using the Hiradc Method: Hepa Filter Integrity Test Case Study

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ABSTRACT

Occupational Safety and Health (OSH) fosters a safe, comfortable work environment and maintains company productivity. Despite OSH implementation, the potential for accidents due to worker activities remains, specifically at PT. X, the HEPA Filter Integrity Test activity, presents a possibility of work accidents. This article aims to address the implementation of an OSH program within the context of this activity. The study utilized the HIRADC (Hazard Identification, Risk Assessment, and Determining Control) method. This involved identifying problems, assessing risks, and determining appropriate risk controls related to the HEPA Filter Integrity Test activities in the production and Air Handling Unit (AHU) areas. Research findings from the two activity areas indicate varying risk levels. The process of moving integrity activities in the production area and opening the access door of the HEPA Filter in the AHU area was identified as having the least possible risk. Conversely, the scanning process of the HEPA Filter in the production area was found to pose the greatest risk. Regularly implementing the HIRADC method enables companies to enhance OSH, reduce injury incidents, and cultivate a safer working environment for all employees.

Keywords*: K3, Hazard Identification, Risk Assesment, Determining Control, Integrity Test HEPA Filter, HIRADC*

Introduction

Occupational safety and health (OSH) are fundamental aspects of modern industries and organizations, crucial for ensuring employees remain healthy, safe, and productive while performing their duties. [12]. A comprehensive OSH approach involves preventing accidents, injuries, and incidents in the workplace, alongside strategies to maintain employees' physical and mental well-being. [12]. Effective OSH management is vital for creating initiatives and programs that enhance worker safety and health conditions. [1]. As stated by the Manpower Minister of the Republic of Indonesia [2]. Work accidents, defined as unintentional or unforeseen events leading to harm or casualties, often stem from human factors and unsafe environments. [3]. These risks encompass a wide range of potential issues, including physical injuries like bruises, sprains, and fractures, as well as broader concerns such as fire, electric shock, and impacts on vision, hearing, and overall physical and mental health, all of which are critical for optimal worker performance. [4].

Maintaining a highly controlled environment in the pharmaceutical sector is paramount, and indoor air quality plays a significant role. [5]. High-efficiency particulate air (HEPA) filters effectively improve indoor air quality by removing pollutants. [6]. These filters, made of glass microfibers or other fibrous media, are essential biological air safety systems that prevent contamination from outside air. [7]. At PT. The validation department of X, a pharmaceutical company, conducts HEPA Filter Integrity Tests. However, a notable gap exists: no formal documentation of potential hazard analysis and risk assessment using the HIRADC method for this specific activity exists. This absence highlights a critical need for occupational safety research to identify factors that can cause accidents or injuries, enabling the company to implement effective preventive measures. [8]. When occupational safety is a top priority, not only is the health and welfare of workers maintained, but the productivity and efficiency of the company will also increase, so occupational safety is a strategic step that benefits all parties. [9]. The primary objective of this study is to analyze potential hazards and assess risks using the HIRADC method within the HEPA Filter Integrity Test activity. By doing so, appropriate risk controls can be determined and implemented, ultimately minimizing occupational safety and health risks. Prioritizing occupational safety safeguards worker welfare and enhances company productivity and efficiency, making it a strategic step beneficial to all stakeholders. [10].

An occupational health and safety management system aligns OSH initiatives with organizational strategic objectives, facilitating continuous improvement and resolution of OSH-related activities [11]. The planning aspect of such a system includes hazard identification, risk assessment, determination of control measures (HIRADC), compliance with legal requirements, and the availability of OHSE programs [12]. The HIRADC process is a comprehensive stage that provides essential information regarding potential hazards, the probability of associated risks, and applicable control measures [12].

While existing literature often examines individual OSH factors, concurrently analyzing multiple factors and their effects on employee safety satisfaction and performance is less common, yet crucial for a thorough understanding of workplace safety intricacies [13]. Therefore, it is imperative to clarify OSH management approaches and identify distinguishing factors for each [1]. Compliance with OSH legislation provides legal guidance for resource allocation towards health and safety initiatives, necessitating company expenditures to ensure adherence [14]. Despite these efforts, Indonesia, like many nations, is still striving to achieve a "Zero Accident" objective [15]. The effectiveness of Occupational Health and Safety Management Systems (OHSMSs) in mitigating workplace accidents remains a significant concern for authorities and corporations [16]. The methodology employed for effecting improvements is the 5W and 1H framework, which encompasses six fundamental types of questions used for information gathering [17]. Journalists widely employ this method to acquire comprehensive and precise information [18].

Research Methods

This study employed a qualitative approach to deeply explore occupational safety and health risks in the PT HEPA Filter Integrity Test activity. X (September-October 2023, validation department, 11 employee respondents). This methodology was chosen to uncover nuanced, context-specific insights into work processes and underlying causes of accidents that quantitative methods might miss. Direct observation provided firsthand insights to ensure validity, while semi-structured interviews gathered detailed perspectives. Data validity was further strengthened through triangulation, cross-referencing interview data with observations and company documents. Interview respondents were carefully selected based on experience, OSH knowledge, and communication skills to ensure credible information. The initial phase involved a field study (direct observation, interviews) and literature studies to understand existing problems. Subsequently, hazards were identified collaboratively with employees, followed by consequences and risk assessment analysis.

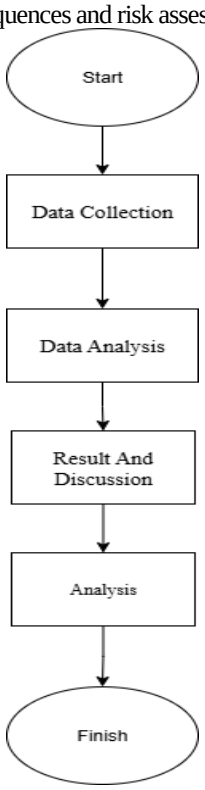

Figure 1. Flowchart Of Research Stages

The initial phase of the study involved a comprehensive field study to ascertain the existing problems related to the HEPA Filter Integrity Test activity. This included direct observation in the field to gain firsthand insights into the work processes and environment, complemented by in-depth interviews with employees in the validation department. Concurrently, literature studies were performed, reviewing relevant journals and books to establish a theoretical foundation and contextual understanding of OSH principles and HEPA filter operations. Following this foundational work, the next critical step was to identify hazards collaboratively with validation department employees. This collaborative process aimed to uncover potential impacts from the HEPA Filter Integrity Test activity and to understand the consequences if work accident hazards were not effectively mitigated. Subsequently, these identified hazards and their potential repercussions were thoroughly analyzed, leading to a comprehensive risk assessment.

Data Collection

In the data collection process, we use interview techniques with all employees who carry out the HEPA Filter Integrity Test activity with references to the OSH risk assessment in the OSH department of PT X. Interviews in the HIRADC method are the most important components in the process of making HIRADC documents. We have several instruments for the data collection, including:

1. Observation Sheet

The observation sheet is used when making observations in the work area. The internal watchlist of this study is based on the criteria for identifying hazards in the work area. This observation sheet is used to record observations in the workplace, namely, to analyze the potential risk of work accidents in the Hepa Filter Integrity Test activity in the validation department.

2. Interview Sheet

The interview sheet is a sheet from the results of the meeting between the interviewer and the resource person to exchange information through questions and answers, so that it can produce results in this topic. Through interviews, we have found more in-depth information about the conditions and types of work accidents experienced when this Hepa Filter Integrity Test activity was carried out. The object used in this interview is an employee of the validation department who carries out the Hepa Filter Integrity Test activity with a minimum of 1 year of experience. With a list of respondent criteria that refer to risk assessment in the OSH department of PT X, as follows:

1. Minimum 1 year of experience in the field.
2. Able to speak clearly and effectively.
3. Have basic knowledge of OSH.
4. Have participated IN OSH training.
5. Able to answer questions completely and accurately.
6. Have or witnessed a work accident.
   Able to answer questions completely and accurately

Data Analysis

The data analysis method under discussion entails systematically deconstructing data into discrete categories and concepts. This approach enables researchers to discern patterns and themes that naturally arise from the data, rather than imposing predetermined classifications. Such a process is particularly effective in exploratory research, which aims to cultivate a profound understanding of the subject matter. [19]. This methodology guarantees that the selected theme undergoes a thorough analysis, particularly during the subsequent phase in which primary data is collected through interviews for the case study analysis. [20]. In this study, the techniques used in data analysis are as follows:

1. Data Selection
   After all the data has been collected, the author determines whether the collected data can be processed. However, separating which data can be used and which cannot.
2. Data tabulation
   From the data tabulation activity, the author takes three steps, namely the activity of creating or providing the necessary table rows according to needs, entering each alternative answer from each item from the observation results, and the third step is the activity of calculating the frequency of alternative answers from each item and alternative answers.
3. Calculating alternative answers

To obtain research conclusions, the author establishes the HIRADC (Hazard Identification, Risk Assessment, and Determining Control) method with stages starting from risk identification by determining the source of danger from the activities reviewed, which are then assessed based on the existing risks and grouped based on their classification, so that targeted control can be carried out [21]. This study used systematic steps in compiling HIRADC up to determining control based on the hierarchy of hazard control in clause 4.3.3 OHSAS 18011:2007, namely elimination, substitution, engineering control, administrative, and personal protective equipment (PPE) [21]. The frequency of risky work, while the probability matrix scale can be seen in the following Table 1:

Table 1 Probability scale

Level	Criteria	Explanation
1	Rare	May occur only in special conditions
2	Unlikely	It may occur in some specific conditions, but it is unlikely
3	Possible	May occur in some specific conditions
4	Likely	It may occur in almost all conditions
5	Almost certainly	It can occur in almost all conditions

Source: Australian – New Zealand Standard Risk Assessment Matrix, 2004

The Severity Scale shows the severity value of the risk of a hazard that may occur. The severity matrix scale can be seen in the following Table 2 :

Table 2. Severity scale

Level	Criteria	Explanation
1	Insignificant	No material loss
2	Minor	Minor injuries require P2OSH treatment
3	Moderate	Requires medical treatment
4	Major	Injuries result in disability or loss of normal body function
5	Extreme	Causes a very large material disaster

Source: Australian – New Zealand Standard Risk Assessment Matrix, 2004

A risk assessment matrix is a tool used to identify, evaluate, and prioritize risks in a project or organization by mapping the likelihood of a risk occurring against its impact. This matrix is usually arranged in a table format, where the horizontal axis represents the level of likelihood of a risk occurring (e.g., low, medium, high) and the vertical axis represents the level of impact or consequence (minor, moderate, critical). The risk assessment matrix can be seen in Table 3 below:

Table 3. Risk assessment matrix

		Severity				
	Matriks	Insignificant	Minor	Moderate	Major	Extreme
Pobability	Almost Certainly	Moderate Risk	High Risk	High Risk	Critical Risk	Critical Risk
	Likely	Moderate Risk	Moderate Risk	High Risk	High Risk	Critical Risk
	Possible	Low Risk	Moderate Risk	High Risk	High Risk	High Risk
	Unlikely	Low Risk	Low Risk	Moderate Risk	Moderate Risk	High Risk
	Rare	Low Risk	Low Risk	Moderate Risk	Moderate Risk	High Risk

Source: Australian – New Zealand Standard Risk Assessment Matrix, 2004

In controlling hazard risks, there are several levels of control as shown in Figure 1 below:

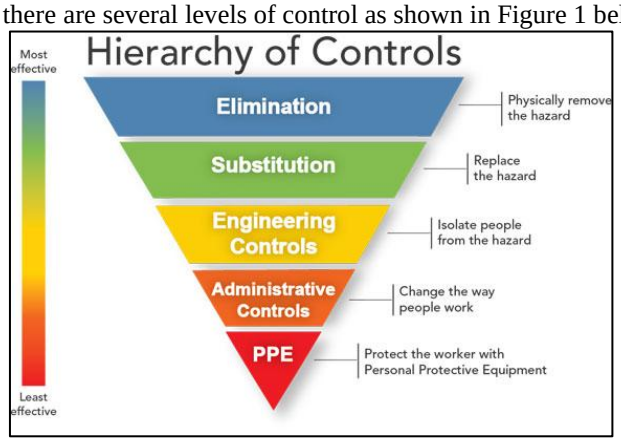

Figure 2. Hazard risk control

Source: Australian – New Zealand Standard Risk Assessment Matrix, 2004

When determining the hazard risk control to be established or considering changes to the hazard risk control that exists at the time the control is implemented, the determination of control must be considered based on the hierarchy that can be seen in the following Table 4:

Table 4. Hazard risk control table

Hierarchy Levels	Explanation
Elimination	Removing the source of danger
Substitution	Replacing the source of danger
Engineering Control	Isolating people from danger
Administrative Controls	Changing the way people work to avoid danger
PPE	Wearing personal protective equipment attached to the body

Source: Australian – New Zealand Standard Risk Assessment Matrix, 2004

Results And Discussion

The analysis of occupational safety and health risk management at PT X will be carried out in stages by the HIRADC method. The first stage is to conduct a risk assessment of the Integrity Test activity in the production room, which can be seen in the following Table 5:

Table 5. Risk assessment of integrity test activities in the production room

Activity	Hazard Source	Consequences	Severity	Possibility	Risk Level
Preparing the Integrity Tester	Tools	Bruised body parts are hit by falling equipment	Minor	Possible	Moderate Risk
Connecting the compressor to the Aerosol Generator tool	Hoses	The hose comes off the Aerosol Generator and causes abrasions on the skin	Minor	Possible	Moderate Risk
Opening the Corporate HEPA filter 	Corporate HEPA Filter, Personnel fall.	A corporate fall can cause injury to the person who is hit if personnel fall because the chair shifts, causing sprained body parts.	Moderate	Unlikely	Moderate Risk
HEPA Filter scanning process 	Personnel Fall	If personnel fall because the chair shifts, causing sprained body parts	Moderate	Possible	Hard Risk
The process of moving activities to the next HEPA Filter	Hoses	Personnel get caught by the hose on the production floor, causing personnel to fall.	Insignificant	Possible	Low Risk

The initial phase involved a thorough risk assessment of the Integrity Test activities conducted in the production room. The risk level for each activity was determined by combining the likelihood of an incident occurring with the severity of its possible consequences, a core principle of risk assessment as described in the HIRADC methodology. [21]. The risk assessment matrix (Table 3), a standard tool for evaluating and ranking risks by comparing probability against impact, was used to categorize risks as Low, Moderate, High, or Critical.

The second stage is to conduct a risk assessment of the Integrity Test activity in the AHU (Air Handling Unit) area, which can be seen in the following Table 6:

Table 6. Risk assessment of integrity activities in the ahu (air handling unit) area

Activities	Hazard Sources	Consequences	Severity	Likely	Risk Level
Preparing the Integrity Test tool	Tools, Rough Objects in the Air Handling	Bruised body parts hit by falling equipment, Body parts abraded by rough objects	Minor	Possible	Moderate Risk

Activities	Hazard Sources	Consequences	Severity	Likely	Risk Level
	Unit (AHU) area				
Connecting the hose from the compressor to the Aerosol Generator tool	Hoses	The hose comes off the Aerosol Generator and causes abrasions on the skin	Minor	Rare	Moderate Risk
Opening the HEPA Filter access door in the AHU	HEPA Filter Doors	The door opens when the wind from the AHU causes personnel to be thrown	Minor	Moderate	Low Risk
HEPA Filter scanning process	AHU	The hands and head of the operator hit a sharp area in the AHU, which causes personnel to be injured.	Unlikely	Likely	Moderate Risk

The third stage is sorting categories according to the risk control table for Integrity Test activities in the production room, which can be seen in the following Table 6:

Table 7. Risk control table for integrity test activities in the production room

Activities	Hazard Source	Consequences	Risk Control				
			Elimi-nation	Subtitution	Engineering Control	Administrative Control	PPE
Preparing the Integrity Tester	Tool	Bruised body parts are hit by falling equipment	-	-	-	Provide training to personnel related to the preparation of activities - Integrity Test.	-
Connecting the compressor to the Aerosol Generator	Hose	The hose comes off the Aerosol Generator and causes abrasions on the skin	-	-	-	Provide training to personnel related to the preparation of activities.	-
Opening the Corporate HEPA filter	Corporate HEPA Filter, Personnel fall	A corporate fall can cause injury to the person who is hit. If personnel fall because the chair shifts, it can cause sprained body parts.	-	Providing ladder facilities for HEPA Filter Integrity Test activities-	-	Providing training to personnel related to the preparation of Integrity Test activities and providing ladder facilities for HEPA Filter Integrity Test activities	-
HEPA Filter scanning process	Personnel Fall	If personnel fall because the chair shifts, causing sprained body parts	-	Providing ladder facilities for HEPA Filter Integrity	-	Providing ladder facilities for HEPA Filter Integrity Test activities	-

Activities	**Hazard Source**	**Consequences**	**Risk Control**				
			Elimi-nation	**Subtitution**	**Engineering Control**	**Administrative Control**	**PPE**
				Test activities-			
The process of moving activities to the next HEPA Filter	Hose	Personnel get caught by the hose on the production floor, causing a fall	-	-	-	Provide training to personnel regarding preparation for activities.	-

In Table 7, there are two types of risk control, namely substitution and administrative control. Substitution risk control by providing ladder facilities for this activity, and administrative control by giving training to related employees [23].

The fourth stage is to sort the categories according to the risk control table for Integrity Test activities in the AHU (Air Handling Unit) area, which can be seen in the following Table 8:

Table 8. Risk control table for integrity test activities in the ahu (air handling unit) area

Activities Preparing the Integrity Test tool	Hazard Sources	Consequences	Risk Control				
			Elimi-nation	Subtit ution	Engineering Control	Administrative Control	PPE
Connecting the hose from the compressor to the Aerosol Generator tool	Tools, Rough Objects in the Air Handling Unit (AHU) area	Bruised body parts hit by falling equipment, Body parts abraded by rough objects	-	-	-	Provide training to personnel related to the preparation for Integrity Test activities.	Providi ng long shirt facilitie s for personn el
Opening the HEPA Filter access door in the AHU	Hoses	The hose came loose from the Aerosol Generator and caused abrasions on the skin.	-	-	-	Provide training to personnel related to preparation.	-
HEPA Filter scanning process	HEPA Filter Doors	The door opened when the wind from the AHU caused the personnel to be thrown.	-	-	-	Provide training to personnel related to preparation.	-
Activities	AHU	The hands and head of the operator hit a sharp area in the AHU, which caused the personnel to be injured.	-	-	-	Provide ladder facilities for HEPA Filter Integrity Test activities.	Providi ng long shirt facilitie s for personn el

Table 8 shows two types of risk control: administrative control and personal protective equipment. Risk Control: Administrative control by providing training to relevant employees, and for administrative control, by providing long-sleeved shirts for personnel [23].

Based on the data obtained, work accidents are dominated by types of ergonomic accidents, including poor work methods, equipment, or ways of using tools, monotonous or repetitive activities, such as trips, abrasions on the skin, bruises, and sprained body parts due to high worker mobility. Several recommendations emerged, such

as training and education, providing good workwear facilities to workers when carrying out activities, and using work tools correctly and adequately. The recommendations are placed as risk mitigation, resulting in the expected risk reduction, and accidents will be eliminated. Meanwhile, some researchers state that one way to reduce the risk of occupational accidents is through active management actions related to how they act to be responsible for OSH, representing governance. Management must implement various safety programs to improve their safety climate beyond simple safety-related education and training. [24], management commitment [25], and develop a team to oversee ergonomics management [26].

Conclusion

Utilizing the HIRADC method, this study identified nine risks associated with PT. X's HEPA Filter Integrity Test activities—five located in the production area and four in the AHU area. The risk assessment categorized these findings into two low-risk, six medium-risk, and one high-risk activity. The HEPA filter scanning process in the production area was notably classified as high-risk, highlighting the need for immediate intervention to prevent potential incidents.

The risk control planning followed the hierarchy of controls. Substitution replaced inadequate aids, such as chairs, with proper stairs or ladders to mitigate fall hazards during HEPA filter scanning. Administrative controls included customized training programs and pre-activity briefings to promote safe work behavior. Regarding Personal Protective Equipment (PPE), the provision of safety helmets and long-sleeved shirts was emphasized. To enhance occupational safety and health (OSH) outcomes, PT. X is advised to prioritize immediate controls for high-risk tasks, continually pursue higher-level interventions like elimination or engineering controls, and cultivate a proactive safety culture through continuous training, ergonomic evaluations, and strong leadership commitment.

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