Published online on the journal's web page: http://jurnal.usahid.ac.id/index.php/jamr eISSN: 2797-2917 Journal of Applied Management Research

Implementation of Occupational Safety and Health at PT Menarini Indria Laboratories Bekasi

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ARTICLE INFO

ABSTRACT

Received: 24 March 2024 Revised: 17 April 2024 Accepted: 10 May 2024

Keywords:

Employee Engagement, Work Life Quality, Organization Commitment, Turnover Intention

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E-mail addresses: <u>tatan.swk@gmail.com</u> (T. Sukwika). PT Menarini Indria Laboratories, a foreign pharmaceutical company in Indonesia, recognizes the importance of occupational safety as a critical step toward operational success. A significant focus on the Quality Control (QC) division and the Quality Control Laboratory, where drug quality testing is conducted, presents potential hazards to employees. Through the implementation of ISO 45001:2018 Standard, the company demonstrates its commitment to occupational safety and health. The results showed an excellent level of ISO 45001:2018 implementation with percentage values above 78 percent for each step of the PDCA cycle. Hazard Identification and Risk Assessment (HIRA) analysis helped identify potential hazards and risks in QC. Some areas, such as the use of heavy equipment, chemical spills, and laboratory operations, showed a level of risk that needed to be managed appropriately. The company has implemented appropriate controls, such as SOPs, ergonomics training, use of assistive devices, and Personal protective equipment (PPE). Proactive measures such as the Zero Accident Program and annual external audits are also implemented to achieve safety goals. Nonetheless, the company must continuously monitor and improve its safety management system to ensure a safe, efficient, and compliant working environment. By aligning ISO 45001:2018 implementation and risk mitigation strategies, PT Menarini Indria Laboratories can ensure continued operational success while providing optimal protection for its workforce.

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1. INTRODUCTION

The workforce is one of the capitals in the form of human resources, and its existence is essential for the company because it is the main asset that drives company operations. Professional, trusted, competent, and diligent human resources are the key to achieving goals. Thus, the company must manage and maintain its human resources well (Susanto et al., 2021; Baka et al., 2022; Apriyanti et al., 2023; Juarsa et al., 2023; Mudzakir et al., 2023; Sukwika & Zabhara, 2023). This belief is also held by PT Menarini Indria Laboratories, one of the foreign-owned pharmaceutical companies in Indonesia incorporated into the Menarini Group based in Italy. Established in 1886 in Naples, Italy, PT Menarini Indria Laboratories began in Indonesia in 2011 in the Delta Silicon Industrial Area at Cikarang, Bekasi Regency. Its products in health preparations, such as drinking liquids, semi-solids, and medical devices, pose a potential danger to workers. It requires the implementation of Occupational Safety and Health (OSH) in factories to reduce the chances of work accidents (Susanto et al., 2021; Apriyanti et al., 2023; Juarsa et al., 2023; Mudzakir et al., 2023; Lazuardi et al., 2022; Sukwika & Pranata et al., 2023).

The Quality Control Laboratory at PT Menarini Indria Laboratories also has the potential for accidents due to instrumentation requiring accuracy. This laboratory plays a role in testing the quality of medicinal preparation products, including taking and trying raw materials and containers, trying finished products, microbiological testing, and maintaining live product stocks. Increasing labor protection aims to ensure that every worker and other people in the workplace get protection for their safety, ensure that every source of production can be

used safely and efficiently, and ensure the production process runs smoothly without obstacles by Law No. 1 of 1970 concerning work safety (Sukwika & Kartikasari, 2021; Sulistyowati & Sukwika, 2022; Wildan et al., 2022).

This company has factors and potential hazards that can cause accidents or occupational diseases that can be fatal. Especially in parts that are directly related to the drug production process, such as near-miss, pinched, cut, electrocuted, hit by heavy objects, dropped, exposed to chemicals, or even death (Irianto et al., 2022; Lazuardi et al., 2022; Sukwika & Pranata, 2022; Yuvendra et al., 2022; Apriyanti et al., 2023; Mudzakir et al., 2023; Wary et al., 2023). The HSE division at PT Menarini is also preparing a work risk mitigation program, namely Zero Accident, where the company, through the HSE division, targets no accidents or illnesses due to work that occurs within a certain period, namely within the range of monthly routine work safety assessments, which HSE will usually submit to each related division.

Based on report data owned by the company, the recording of reports is still based on the company's workforce and OSH team. While reports related to the identification of potential accidents in companies using HIRA (Hazard Identification and Risk Assessment) can help provide accident identification information so far, therefore research using HIRA is considered essential to give an overview of the conditions of implementation of occupational safety and health at PT Menarini Indria Laboratories (Supriyadi et al, 2015; Atmariyani et al., 2022; Irianto et al., 2022; Lazuardi et al., 2022; Sukwika & Pranata et al., 2022; Sukwika & Harjanto, 2024). This study aims to determine the achievement of OSH implementation that has been implemented with the implementation of ISO 45001: 2018, find out the biggest causes of work accidents in the company and their mitigation, and find out the risk value of potential work hazards and possible occupational hazard categories at PT Menarini Indria Laboratories.

2. RESEARCH METHOD

This research uses qualitative descriptive types located at PT Menarini Indria Laboratories. Data collection uses three techniques: interviews, field observations, and data on potential hazard findings in the Quality Control section through questionnaires. Questionnaire data collection is a method of Saturated Sample Technique (Sugiyono, 2012; Sukwika, 2023a; 2023b). The population needed for data collection is all employees in the QC division who are in direct contact with the process of analyzing finished products, raw materials, and containers. The number of respondents included everyone involved in the analysis, which amounted to 15 people. The data obtained were analyzed using ISO 45001: 2018 and HIRA.

Data processing using HIRA is based on the following risk determination formula.

 $RISK = Consequence(E) \times Probability(P)$

Information : Consequence = Hazard severity (Effect) Probability = Likelihood of Occurrence (Probability)

The categories of health impacts in HIRA are presented in Table 1.

ificant	There are no injuries; material losses are minimal Requires P3K treatment, moderate material loss Requires modical treatment and require in temperant loss of
	•
roto	Dequires medical treatment and results in temperaty less of
late	Requires medical treatment and results in temporary loss of working days/loss of limb function, considerable material loss
/Mayor	Injuries that result in total disability/loss of body functions, non- running of the production process, significant material losses
<i>trophic</i> /Disaster	Causing death, harm Huge material
	/Mayor <i>trophic</i> /Disaster irce: Regulation of th

 Table 1. Risk Evaluation Against Health Impact Categories in HIRA

Table 2. Probability of Occurrence in HIRA

Category	Information						
A = Very Rare	Occurs once in five years						
B = Rarely	Occurs once in 1 – 2 years						
C = Possible	Occurs once in 1 – 2 years						
D = Often	Occurs several times a year						
E = Frequent occurrence	Occurs in a matter of weeks or months						

Source: Regulation of the Head of the National Disaster Management Agency Number 02 of 2012 concerning General Guidelines for Disaster Risk Assessment

		l able 3	S. RISK Mat							
MATRIX-		IMPACT								
MA	ATRIX	1	2	3	4 5					
	1	1	2	3	4	5				
ΪÌ	2	2	4	6	8	10				
BABI	3	3	6	9	12	15				
PROBAB	4	4	8	12	16	20				
	5	5	10	15	20	25				

Table 3. Risk Matrix in HIRA

Source: Regulation of the Head of the National Disaster Management Agency Number 02 of 2012 concerning General Guidelines for Disaster Risk Assessment

	Table	4. RISK LEVEI (HIRA)
ΡxD	RISK LEVEL	COLOR DESCRIPTION
1-3	Low	
4-6	Кеер	
8-12	Tall	

Table 4. Risk Level (HIRA)

Source: Regulation of the Head of the National Disaster Management Agency Number 02 of 2012 concerning General Guidelines for Disaster Risk Assessment

Information:

P = Probability

Extreme

D = Impact

15-25

The ISO 45001:2018 standard is based on a methodology known as the Plan-Do-Check-Act (PDCA)—a plan that sets goals and processes needed to achieve results according to the organization's OSH policy. Carry out the check process by monitoring and measuring process activities against policies, targets, laws and regulations, and other OSH requirements and reporting the results. The act is to take action to improve OSH's performance continuously (Karanikas et al., 2022; Šolc et al., 2022; Amirudin et al., 2024; Pratiwi et al., 2024).

3. RESULTS AND DISCUSSIONS

Application of ISO 45001: 2018. ISO 45001:2018 is an International Standard that specifies requirements for an Occupational Health and Safety Management System (OHSMS) containing an OHSMS guide. This standard enables organizations to proactively improve OHSMS performance in preventing injuries and ill health. OHS Management System implemented at PT Menarini Indria Laboratories refers to ISO 45001:2018, which has been in effect since September 2022 and is routinely carried out by external third-party audits yearly. The research data obtained through the interview and questionnaire stages is processed into a percentage graph, which is presented in the graph as follows.

Based on Figure 1, the final result is obtained in the form of a percentage value of each indicator, where the Plan indicator has a percentage value of 79.0 percent with the outstanding category, do has a percentage value of 79.6 percent with the outstanding category; Check has a percentage value of 78.7 percent with the

outstanding category. Act has a percentage value of 78.3 percent with an outstanding category. From these data, the implementation of OSH Management in PT is known. Menarini India Laboratories, which refers to ISO 45001: 2018, is doing well.

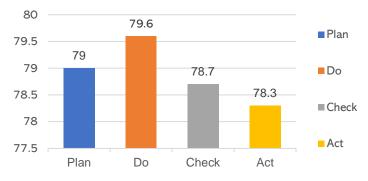


Figure 1. ISO 45001:2018 Recluse Percentage Result Graph

Risk Identification and Control of Occupational Safety and Health of Employees. Risk identification Hazard Identification Risk Assessment (HIRA) at PT. Menarini Indria Laboratories is conducted to determine jobs that pose a significant risk to the health and safety of employees and to know the hazards associated with specific equipment. Then, an analysis of hazard identification is carried out using field observation and discussion with workers who will occupy positions that are considered to have risks (Sukwika & Kartikasari, 2021; Atmariyani et al., 2022; Sulistyowati & Sukwika, 2022; Wildan et al., 2022; Irianto et al., 2022; Sukwika & Pranata et al., 2022). Based on research by Supriyadi et al. (2015), Lazuardi et al. (2022), Yuvendra et al. (2022), and Sukwika & Harjanto (2024) stated that the hazard identification process is a continuation of activity identification in the hazard identification process, the risk of each activity that has been identified will be explained. The data obtained are described in the table as follows.

Job/			Ris	sk evaluatio	n		R	isk Reductio	n
Project /Area	Activity Name	Danger	Impact	Like- lihood	Risk Level	Risk handling	Impact	Like- lihood	Risk Level
	Moving RM 120 Kg from warehouse to sampling room	Dropped goods, narrow and limited access space	3	1	3	Use material lifting aids from warehouse to sampling room, SOP Manual handling, Work ergonomics training, SOP Material sampling, PPE (gloves, safety shoes).	1	1	1
		RM spill and chemical splash	3	1	3	Emergency shower, SOP spill handling, display B3, Spill kit, APD Preparation.	1	2	2
		Removal of too heavy material is done manually	1	2	2	SOP manual handling, ergonomic measurement and socialization of how to work safely, PPE (Back support).	1	2	2
Sampling		RM spills that are hazardous to the environment or work area	2	2	4	The floor is impermeable to water, SOP for handling B3 waste, SOP in case of spillage, spill kits, and chemical hazard safety signs installation.	1	1	1
Room	lifting and moving raw materials	Tripping, crushing, pinching or bumping hand pallet/trolly	2	1	2	SOP for material loading, routine inspection of hand pallets, and PPE (Safety shoes, gloves, safety clothing).	2	1	2
		Manual handling due to job demands of >20Kg	1	2	2	Use of hand pallets, manual handling SOPs, ergonomic measurements and socialization of how to work safely, Back support.	1	1	1
		spillage of liquid or dense B3 material	2	2	4	The lifting equipment used is complete with containment, the floor is impermeable to water, SOP is for handling B3 waste, SOP is in case of spills, Spill Kit, Installation of chemical hazard safety signs.	1	1	1

Table 5. Risk Assessment Results (HIRA)

Job/			R	isk evaluatio				Risk Reductio	n
Project /Area	Activity Name	Danger	Impact	Like- lihood	Risk Level	Risk handling	Impact	Like- lihood	Risk Level
	pouring and weighing raw materials- weighing raw materials - weighing flamable materials (Chammomile Concentrate, Isopropyl alcohol, eucalyptol, HCI 32%	 Fire and explosion Tripping, crushing, pinching or pounding hand pallet/trolly B3 Exposure 	4	1	4	Dust collector, fire alarm, SOP for pouring and weighing materials according to material properties (flammable and non-flammable), chemical hazard safety signs, routine inspection of hand pallets, material weighing SOPs, MSDS review, use of fire extinguisher, PPE (gloves, masks, work clothes, safety shoes).	2	1	2
	and 37%, sage oil) pouring and weighing raw materials- weighing raw materials >50 Kg (manual), >50 Kg to	Exposure to or splashing of dust or chemical liquids, inhalation of vapors or dust of raw materials	2	1	2	Installation of scrubbers, Showers, and eye washes; Measuring and monitoring chemical exposure; adding chemical hazard safety signs; SOPS for pouring and weighing materials, MSDS Review, PPE 9 Gloves, masks, work clothes, safety shoes, safety goggles).	2	1	2
	275 Kg (trolley and shifting), 1400 Kg (Pallet)- weighing flamable materials	Manual handling due to job demands of >20Kg	1	2	2	SOP manual handling, ergonomic measurement and socialization of how to work safely, PPE (Back support).	1	2	2
	(Chammomile Concentrate, Isopropyl alcohol, eucalyptol, HCl 32% and 37%, sage oil)	spillage of liquid or dense B3 material, disposal of finishing waste (waste B3)	3	1	3	Use containment when pouring; the floor is impermeable to water; SOP for handling B3 waste; SOP in case of spillage; Provision of advanced cloth in the work area; and Installation of chemical hazard safety signs.	2	1	2
	Sampling Finish product Roche	Product dropped, broken Product spill Room temperature is not suitable for the working environment	3	1	3	Use containment when pouring; the floor is impermeable to water; SOP for handling B3 waste; SOP in case of spillage; Provision of advanced cloth in the work area; and Installation of chemical hazard safety signs.	2	1	2
	Bring the sample	The sample container broke due to a drop	2	1	2	Use of trolley, PPE (Gloves, safety shoes).	1	1	1
	that has been taken to the Lab	spilled sample	2	2	4	Waste is directly discharged to B3 waste disposal sites, B3 wastewater monitoring, B3 waste classification, and monitoring SOP.	1	1	1
	Operation of HPLC, GC, spectro, FTIR,	1. Electric shock 2. Gas line leak 3. Light exposure from computer and laptop screens 4. The presence of	3	1	3	Installation of gas detectors, SOPs, and MOPs Operation of HPLC, GC, Spectro, FTIR, Melting point, Installation of safety signs and identification labeling on each Gas, PPE (Gloves, masks, work clothes, safety shoes, safety goggles).	2	1	2
Lab Instrument	GC, spectro, FTR, Melting point instruments, working using computers and laptops, use of compress gas	high noise levels 1. Air pollution from mobile phase exhaust that has not been covered properly 2. Dispose of residual waste reagents 3. The rest of the finished product analysis	2	2	4	Waste is directly discharged to B3 waste disposal sites, gas leak monitoring, B3 wastewater monitoring, B3 waste classification and monitoring SOP, and B3 waste management SOP.	1	1	1
Production Room, PW room	Sampling Air	analysis 1. Box contains bottle for falling water sampling 2. Narrow sampling space for sp 6 3.exposure to hot sampling water (at the time after regeneration)	2	1	2	The use of sampling boxes that are equipped with handles to make it easier when carrying samples, water sampling SOP, people who take limited measurements, gloves, masks, work clothes, safety shoes, head coverings.	1	1	1
Chemistry	Chemical testing of	1. Exposed to heat2. Electric shock	2	1	2	Install a safety line to avoid heat exposure to workers, SOP for chemical testing of raw materials using heaters, MOP hot plates, PPE (gloves, work clothes, safety shoes, safety goggles).	2	1	2
Lab	raw materials using heaters (hot plate, waterbath, furnace, oven)	Reagent Splash View	3	1	3	Use of fume hood, Measurement and monitoring of chemical exposure, Periodic calibration of fume hood, SOP for material testing, MOP for hot plate use, Emergency shower, PPE (Gloves, masks, work clothes, safety shoes, safety goggles).	2	1	2

Job/				isk evaluatio		_		Risk Reduction Like- lihood	
Project /Area	Activity Name	Danger	Impact	Like- lihood	Risk Level	Risk handling	Impact		Risk Level
		Waste from burning, display of hot matter, air pollution by steam or ash burning waste	2	2	4	Installation of scrubbers and gas detectors, Use of fume hoods, fume hood calibration, and chemical leak monitoring.	1	1	1
	Chemical testing of	 Broken glassware Electric shock Untidy workplace Reagent bottle dropped while carrying reagent Using a Vibrating 	2	1	2	Provide material testing SOPs, Perform routine checks on work tools before use, Apply 5Rs in the workplace, Use containment when lifting or carrying chemicals, PPE (Gloves, work clothes, safety shoes).	2	1	2
	raw materials and finished products	Live display of chemicals	3	1	3	Fume hood, Monitoring of chemical display, SOP handling against chemical display, APD (Gloves,	2	1	2
		Chemical spills	3	1	3	mask, work shirt, safety shoes, safety goggles). The floor and walls are watertight; all water channels are connected to liquid waste channels; preparation and socialization of SOPs for handling spills or B3 spills, safety signs (labeling), and Provision of spill kits.	1	2	2
	Operation of HPLC, GC, spectro, FTIR, Melting point instruments, working using computers and laptops, use of compress gas	 Electric shock Gas line leak Light exposure from computer and laptop screens The presence of high noise levels 	3	1	3	Installation of gas detectors, SOPs, and MOPs Operation of HPLC, GC, Spectro, FTIR, Melting point, Installation of safety signs and identification labeling on each Gas, PPE (Gloves, masks, work clothes, safety shoes, safety goggles).	2	1	2
Lab Instrument		Exposure to analysis search gas, GC, exposure to chemicals (used in instruments)	3	1	3	Installation of gas detectors, Showers, and eye washes; Measuring and monitoring chemical exposure; SOP / MOP for instrument operation; MSDS Review, PPE (Gloves, masks, work clothes, safety shoes, safety gogqles).	2	1	2
		Air pollution from mobile phase exhaust Disposing of waste reagents The rest of the finished product analysis	2	2	4	Waste is directly discharged to B3 waste disposal sites, gas leak monitoring, B3 wastewater monitoring, B3 waste classification and monitoring SOPs, and B3 waste management SOP.	1	1	1
	1. Carry out the sample drying process using	1. Exposed to fire/ heat 2. Electric shock	1	2	2	Install safety signs for heat exposure and fire sources on tools (maker), PPE (gloves, masks, work clothes, safety shoes, goggles).	1	1	1
Chemistry Lab / fume hood	bunsen / meker (there is a fire source)2. Evaporating organic samples/reagents using waterbath3.	Exposure to vapors from regen or chemical reaction results during testing	2	2	4	Fumehood, Safety signs, chemical hazards in fume hoo, Monitoring chemical display, APD (mask).	1	1	1
	Perform sample analysis (titration)	Reagent spills, vapor reagents		1	1				
		Falling reagent bottle	2	1	2	Carrying containers with both hands, PPE (Lab Coats, Gloves, Safety Shoes)	1	1	1
Reagent Room	Removing, carrying, and returning reagents that will/have been used	exposed to chemicals	3	1	3	Exhaust in the reagent room, SOP for handling chemical exposure, PPE (Gloves, masks, Lab Coats, safety shoes, safety goggles).	1	1	1
		Spillage of environmentally harmful reagents into the work area	2	2	4	Waste is directly disposed of at the B3 waste disposal site, SOP for classification and monitoring of B3 waste.	1	1	1

Job/			-	isk evaluatio		-		n	
Project /Area	Activity Name	Danger	Impact	Like- lihood	Risk Level	Risk handling	Impact	Like- lihood	Risk Level
	Turn UV on and off UV on LAF and BSC	Exposure to UV radiation	2	1	2	MOP LAF, BSC, UV exposure monitoring, Safety signs of UV exposure hazards, Limited space and only carried out by certain people, PPE (gloves, masks, work clothes, safety shoes, head covers, goggles)	2	1	2
Ruang Micro Test	Conduct environment monitoring (paper	The fall of the carry box	1	1	1	SOP environment monitoring, Safety signs of goods dropped in the micro test room, PPE (gloves, safety shoes).	1	1	1
	cup and contact cup techniques) micro test room and air sampler techniques with air sampler tools	Lifting heavy loads (carry box and air sampler)	1	2	2	SOP manual handling and socialization of work ergonomics.	1	1	1
	Conducting media fertility tests using microbial tests on BSC	Exposed pathogenic microbes	1	2	2	Safety sign installation, Biosafety training in Lab, MOP biosafety cabinet, PPE (Gloves, masks, work clothes, safety shoes, goggles).	1	1	1
Ruang Micro Test	Regenerate	The fall of the carry box	1	1	1	SOP for microbial regeneration, PPE (Gloves, safety shoes).	1	1	1
	microbes (bacteria and molds / yeasts) on BSC	Exposed pathogenic microbes	2	1	2	Safety sign installation, Biosafety training in Lab, MOP biosafety cabinet, PPE (Gloves, masks, work clothes, safety shoes, goggles).	1	1	1
Microbiolo gy Preparatio n Room	Sterilization of Petri dishes into the oven	1. Falling petri cup (fraction of petri cup) 2.Hot display	2	1	2	Check actual condition regularly, Safety sign for oven use, MOP for oven use, PPE (Heat-resistant gloves, masks, work clothes, safety shoes, goggles).	1	1	1
	Making and cooking microbiological media for analytical preparation	 Overheating at the time of cooking the medium Exposed to hotplate at the time of heating the medium Scratched glass tools, if there are cracked glassware 	2	1	2	Safety line hot plate area and heat exposure sign on a hot plate, MOP hot plate use, PPE (gloves, masks, work clothes, safety shoes, goggles).	2	1	2
	Liquefying microbiological media with a hot plate heater for microbiological analysis	Overheating	2	1	2	Safety line hot plate area and heat exposure sign on a hot plate, MOP hot plate use, PPE (gloves, masks, work clothes, safety shoes, goggles).	2	1	2
	Cleaning the used media so that it is on	Falling petri cup (fraction of petri cup)	2	1	2	Prepare tools as a place when loading Petri dishes, SOPs for cleaning used micro test media that have been used and completed, and PPE (gloves, work clothes, safety shoes).	1	1	1
Microbiolo	the petri dish after finishing reading the incubation results	Exposed pathogenic microbes	2	1	2	SOP for cleaning used media after reading the results of incubation, PPE (gloves, masks, work clothes, safety shoes, head covers, googles).	2	1	2
gy Preparatio n Room	Making 70% alcohol by diluting	 Volatile materials (burning Erlenmeyer's fall was great for making alcohol 	2	1	2	SOP for making alcohol and labeling IPA, monitoring the use of alcohol that is safe and protected from heat (fire sources), and PPE (gloves, masks, work clothes, safety shoes, and goggles).	2	1	2
	Destroy waste finished products left over from microbiological analysis	Exposure to B3 waste from residual finished product samples	2	2	1	Provide SOPs for handling B3 waste and spill kits, Installation of safety signs (Labeling), and PPE (gloves, masks, work clothes, safety shoes, goggles).	2	1	2
Destructio n Room	Sterilization Using Autoclave Hirayama	 High pressure explosion Electric shock, Exposure to hot steam from an autoclave 	2	1	2	SOP for using autoclaves, periodic inspection of electric current cables, PPE (Gloves, Lab Coats, safety shoes, safety goggles).	1	1	1
		Exposed pathogenic microbes	2	1	2	Destruction of pathogenic microbes before disposal at the destruction site, PPE (Rubber gloves, masks, Lab Coats, safety shoes, head covers, goggles).	1	1	1

Job/			Risk evaluation				Risk Reduction		
Project /Area	Activity Name	Danger	Impact	Like- lihood	Risk Level	Risk handling	Impact	Like- lihood	Risk Level
	Washing used glassware for microbiological analysis (petri dishes, test tubes, etc.)	Exposure to bacteria from residual microbiological analysis	2	1	2	SOP for washing lab equipment and PPE (Gloves, masks, work clothes, safety shoes, and goggles).	1	1	1
Helium, Oxygen and Nitrogen Gas Cylinder Storage Room	1. Replacement of empty tubes with new ones2. Installation of gas regulators	 Drop, bump and pinch tube, weighing ± 80kg with a height of ±1.5 m There is a gas leak and there is an explosion due to high pressure of gas in the cylinder or the gas that comes out is exposed to heat so that a fire explosion occurs 	4	1	4	Gas detector, SOP operation, cylinder retrieval, Gas placed outdoors (open area) and routine gas leak tests, PPE (gloves, masks, work clothes, safety shoes), also available fire extinguisher in the area around the gas storage area.	2	1	2
	Heavy weight lifting	Aches, body aches	2	1	2	SOP manual handling and socialization of its application, provide tools for lifting gas and provide the availability of a back support belt.	2	1	2

Based on Table 5, that there are two levels of occupational risk, as follows: (1) Low-Risk Level (low), which is marked in green, indicates that the level of risk in the area is still relatively mild/low. However, control is still carried out to maintain employee health/job security during work. This risk with a green level is in every work area in the QC division; (2) Medium Risk Level, which is marked in yellow, indicates that the area's risk level is classified as moderate. This situation needs direct and routine handling as a form of prevention of work accidents. The risk with this yellow level is in the process area: sampling product quality testing in the physical chemistry test room, instrument lab, and microbiology. These data show that PT Menarini Indria Laboratories has a risk limit considered safe to work with, namely at medium risk level or level (2) because PT Menarini Indria Laboratories continues to routinely handle, control, and evaluate all existing work risks.

4. CONCLUSION

Based on the results of research and discussion, it can be concluded that the implementation of ISO 45001: 2018 in the QC laboratory area at PT Menarini Indria Laboratories has been carried out well marked by the value of Plan clause 77.7 percent, Do clause 79.6 percent, Check clause 78.7 percent, and Act clause 78.3 percent. In addition, the risk assessment process found a low-risk level (L) of 139 risks and a medium level of 11. The most significant cause of work accident risk is exposure to chemicals used both during the testing process and drug manufacturing materials, which occur due to the negligence of workers in the implementation without following applicable SOPs. This can be controlled by providing SOPs for each part of the work area, sanctions for violators of work SOPs, and using complete PPE when working.

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