Analysis and Evaluation of Various Risk, Hazards, and Safety Measures in Machine Guarding for Pharmaceutical Company

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Abstract— Moving machine parts have the potential to cause severe workplace injuries, such as crushed fingers or hands, amputations, burns, or blindness. Amputations, lacerations, and abrasions are costly and have the potential to increase workers' compensation premiums. (Amputation is one of the most severe and crippling types of injuries in the occupational workplace, often resulting in permanent disability.) The main purpose of this study is to monitor the overall risks and hazards around the machines in pharmaceutical company and then to reduce accidents to workers through the use of machine guards and other safe guards. Hazard Identification and Risk Assessment is one of the vast and best methods to be followed for such research, so in our work we will implement try to implement the method practically in the company and monitor the results.

Keywords: OSHA (Occupational Safety & Health Administration), Hazard Identification & Risk Assessment (HIRA), Practical applications, Pharmaceutical safety Guards

I. INTRODUCTION

While adjusting a conveyor belt, a millwright is drawn into the unguarded tail drive of a belt conveyor and suffers fatal crushing injuries. A young worker feeding sheet rubber into a guillotine shear loses both hands when the machine cycles unexpectedly. A lumber piler cleaning up around a lumber sorting table (green chain) is strangled when his loose clothing is caught on an exposed keyway at the end of a slowly rotating shaft [1].

The work done here in this thesis is for everyone who owns, operates, maintains, or sells machinery and equipment. Employers will find information to help them comply with the Occupational Health and Safety Regulation (OHSR) and with the Workers Compensation Act. It will also help them exercise due diligence in providing a safe work environment. Supervisors will find information to help them assess the risks to their workers from harmful contact with machinery and equipment. It will also help them evaluate safeguarding solutions that satisfy the competing needs of safety, production, and quality assurance. Workers will gain greater awareness of the hazards associated with equipment operation and maintenance and of the safeguarding protection they have a right to expect. Suppliers will understand what they must do to provide machinery and equipment that conform to the Workers Compensation Act and the OHSR. They will have a quick reference to different options for meeting this responsibility [2].

A. Relation between Guard, Safety Guard and Lockout

It is important to distinguish between safeguarding and lockout. Safeguarding is the first line of defense in ensuring the safety of workers operating powered machinery and equipment. Lockout protects workers when machinery or equipment is shut down for maintenance (including repairs and clearing jams). In all cases, training and supervision are essential to ensure worker safety around machinery. For information on Work Safe BC requirements for locking out equipment, please see the Work Safe BC booklet Lockout.

The terms "guarding" and "safeguarding" tend to be used interchangeably, but they have precise meanings in the language of machinery and equipment safety.

Fig. 1: Safeguard Outlooks in Industry [3]

Hazards associated with machines, power tools, and machine shops can include, but are not limited to:

1) Being struck by ejected parts of the machinery
2) Being struck by material ejected from the machinery
3) Contact or entanglement with the machinery
4) Contact or entanglement with any material in motion
5) Electrical hazards
6) Chemical hazards (from cutting fluids, lubricants, etc.)
7) Burns, cuts and other injuries from materials or substances used/exhausted by the machinery
8) Noise levels
9) Material Storage and handling (manual material handling, ergonomics)
10) Safe access to/from machines (access, egress)

II. LITERATURE REVIEW

Parker et.al [16] the purpose of this nationwide intervention was to improve machine safety in small metal fabrication businesses (3 to 150 employees). The failure to implement machine safety programs related to guarding and lockout/tag out (LOTO) are frequent causes of Occupational Safety and Health Administration (OSHA) citations and may result in serious traumatic injury.

Donald R. Vaillancourt et.al [17] a series of machine-guarding drawings were developed during the 1940s, which represent the relationship between gap size and safe distance. Since the development of these drawings, larger and more comprehensive anthropometric surveys have been conducted, but they have never been compared with the drawings. The purpose of this investigation was to determine whether these original recommendations presented in the

drawings are still consistent with data in the larger anthropometric surveys, especially relating to women and minorities, who are now much more prevalent in the American workplace.

Appil Ora et.al [18] As we are in twenty-first century, industries are growing at rapid rate and thus evolution of advanced and more complicated machinery takes place. Basically humans are the ones who need to operate such machinery although some of them are operated remotely, but many demand direct human interaction. Every machine has its own unique hazard such as crushing, shearing, entanglement, cutting and drawing-in which may result in mechanical injuries such as abrasion, laceration, avulsion, and others.

Edwin G. Foulke et.al [19] this guide can help you, the small business employer, identify and manage common amputation hazards associated with the operation and care of machines. The first two sections of the document, Recognizing Amputation Hazards and Controlling Amputation Hazards, look at sources of amputations and how to safeguard machinery and control employee exposure to hazardous energy (lockout/ tag out) during machine servicing and maintenance activities.

DCBS et.al [20] this guide focuses on point-of-operation hazards and safeguarding methods and offers a comprehensive look at equipment and machinery commonly found in various Oregon workplaces. It does not specify all machine guarding requirements or all types of machinery or equipment.

III. COMPANY DOMAIN

For decades, the Indian pharmaceutical industry has been driving better health outcomes for the economy. Cipla's commitment to high quality standards has made us the most trusted brand among patients and one of the top Indian pharma companies among healthcare professionals. India continues to be one of the most important and focused markets for Cipla. In FY 19-20, Cipla's overall domestic business contributed to 39% of the global revenues. Today, Cipla is the 3rd largest pharmaceutical company in India, with product portfolio spanning across various therapeutic areas including Respiratory, Anti-infective, Cardio-metabolic, Gastro and Urology. Our strong brand equity, product range and unique dosage forms help us stand out in the fiercely competitive Indian pharmaceutical industry environment [26].

Fig. 2: CIPLA [27]

Over last 2 years, Cipla has been focusing towards establishing its Engine 2.0 of growth based on the foundation of Innovation and Specialty medicine. The Company has committed significant capital towards acquiring and in-licensing assets which address unmet clinical needs of patients.

The focus has been to establish a franchise of specialty medicines in the areas of Respiratory, CNS and Critical Care with a focus to build Institutional Specialty business. The operations of a Specialty focused company differ significantly from the operations of a generic company and hence to establish a robust business model, Cipla Technologies LLC (CipTec) has been established with its headquarters in San Diego, California. This also gives the Company ability to participate and operate in the biotech and life sciences innovation hub in the US.

IV. PROBLEM AND REQUIREMENT

There are as many hazards created by moving machine parts as there are types of machines. Safeguards are essential for protecting operators from preventable injuries. Any machine part, function, or process that might cause injury must be safeguarded. When the operation of a machine or accidental contact with it could injure the operator or others in the vicinity, the hazards must be either controlled or eliminated. Examples of the types of equipment that could be used at Princeton University that require machine guarding include (but are not limited to): saws, lathes, milling machines, meat slicers, and grinders.

Dangerous moving parts in three basic areas require safeguarding

1) The point of operation: that point where work is performed on the material, such as cutting, shaping, boring, or forming of stock.
2) Power transmission apparatus: all components of the mechanical system that transmit energy to the part of the machine performing the work. These components include flywheels, pulleys, belts, connecting rods, couplings, cams, spindles, chains, cranks, and gears.
3) Other moving parts: all parts of the machine that moves while the machine is working. These may include reciprocating, rotating, and transverse moving parts, as well as feed mechanisms and auxiliary parts of the machine.

A. Types of Hazards

A wide variety of mechanical motions and actions may present hazards to workers operating or working around machinery. The three basic types of hazardous mechanical motions and actions are:

1) Hazardous Motions – including rotating machine parts, reciprocating motions (sliding parts or up/down motions), and transverse motions (materials moving in a continuous line);
2) Points of Operation – the areas where the machine cuts, shapes, bores, or bends the stock being fed through it;
3) Pinch Points and Shear Points – the area where a part of the body or clothing could be caught between a moving part and a stationary object. This would include power transmission apparatuses such as flywheels, pulleys,

belts, chains, couplings, spindles, cams, gears, connecting rods and other machine components that transmit energy.

There are also non-mechanical hazards that can injure machine operators or personnel working in the vicinity of machinery. These hazards include flying splinters, chips or debris; splashes, sparks or sprays that are created when the machine is operating. These hazards can be prevented through the use of machine guarding and wearing/use of required personal protective equipment (PPE).

B. Methods of Safeguarding in Pharmaceutical Industries

There are five (5) general types of machine safeguards that can be used to protect workers and personnel in the immediate vicinity of machinery. They are [35]:

1) Guards – these are physical barriers that prevent contact. They can be fixed, interlocked, adjustable, or self-adjusting.
2) Devices – these limit or prevent access to the hazardous area. These can be presence-sensing devices, pullback or restraint straps, safety trip controls, two-hand controls, or gates.
3) Automated Feeding and Ejection Mechanisms – These eliminate the operator's exposure to the point of operation while handling stock (materials).
4) Machine Location or Distance – this method removes the hazard from the operator's work area.
5) Miscellaneous Aids – these methods can be used to protect both operators and people in the immediate vicinity of operating machinery. Examples include shields to contain chips, sparks, sprays or other forms of flying debris; holding tools that an operator can use to handle materials going into the point of operation; and awareness barriers to warn people about hazards in the area.

V. PROCEDURE ADOPTED

A safeguard is a solution or a combination of solutions that eliminate or reduce the risk of exposure to hazardous moving parts or other harmful conditions. Safeguards range from fixed barrier guards (most effective) and safeguarding devices to safe work procedures and personal protective equipment. A comprehensive risk assessment will determine which safeguards are most effective.

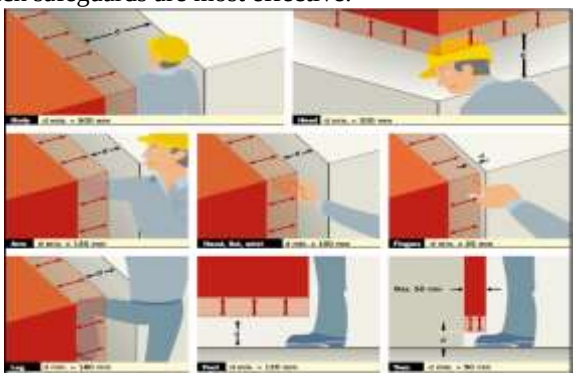

Fig. 3: Minimum Gap to avoided crushing strength [38]

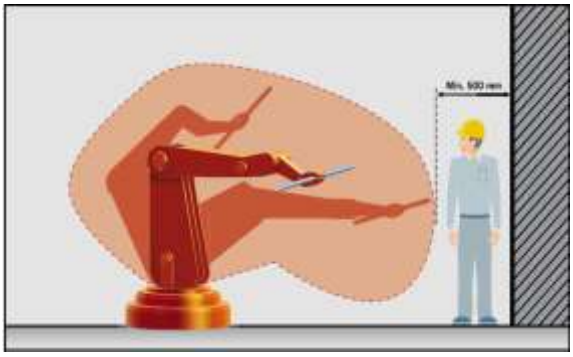

Fig. 4: minimum gaps between the Robot and Guard [38]

VI. CALCULATION AND RESULTS

OSHA can provide extensive help through a variety of programs, including technical assistance about effective safety and health programs, state plans, workplace consultations, voluntary protection programs, strategic partnerships, training and education, and more. An overall commitment to workplace safety and health can add value to your business, to your workplace, and to your life.

Effective management of employee safety and health protection is a decisive factor in reducing the extent and severity of work-related injuries and illnesses and their related costs. In fact, an effective safety and health program forms the basis of good employee protection and can save time and money and increase productivity and reduce employee injuries, illnesses, and related workers' compensation costs [47]. To assist employers and employees in developing effective safety and health programs, OSHA published recommended Safety and Health Program Management Guidelines.

These voluntary guidelines can be applied to all places of employment covered by OSHA. The guidelines identify four general elements critical to the development of a successful safety and health management system:

1) Management leadership and employee involvement,
2) Worksite analysis,
3) Hazard prevention and control, and
4) Safety and health training.

The guidelines recommend specific actions, under each of these general elements, to achieve an effective safety and health program.

A. Risk and Hazard analysis Model

A risk assessment must involve the operator, maintenance personnel, and the supervisor. You should also consult with the manufacturer, suppliers of safeguards, and safety professionals. Each party sees the machine from a different perspective, and will provide a valuable contribution.

Gathering the information necessary for a good risk assessment may require repeated observations, especially when determining what the worker does when normal production flow is interrupted. The length of time that a piece of equipment is in service without causing an injury has no bearing on whether or not it is safe.

Some significant factors that increase the probability of contact with unguarded hazardous machine moving parts include:

1) Lack of familiarity with the machine

2) Hand feeding a machine activated by a foot control
3) Reaching into a machine to clear jams and miss-feeds
4) Boredom and repetition
5) Frequent access to danger areas of the machine for setup and adjustments
6) Lack of operator training and experience
7) Machine cycle speed

The main purpose of a risk assessment is to decide which machine should be given priority, and which parts of the machine should be safeguarded first.

Company Name Cipla Limited	Date of Survey November 10, 2020	Survey Done by Mr. Raj Nagal (Supervisor) Mr. Ajay Bidare (Maintenance) Mr. Hitesh Barai (Operator)		
Machine Name Chemical mixing LINE	Machine Function mixing			
Identify and describe every hazardous machine motion or harmful condition to which the worker's body parts are exposed (e.g., rotating shafts, in-running nip points, shearing parts, reciprocating parts, punching action, impact hazards, flying debris, abrasive surfaces, electrical hazards, hot/toxic fluids, vapors, emissions, radiation). Be as descriptive and detailed as possible.	Describe the worst injury that would reasonably occur due to each hazard. Use the following descriptions as a guide: Fatal Major (normally irreversible: permanent spinal damage, loss of sight, amputation/crushing, respiratory damage) Serious (normally reversible: loss of consciousness, burns, fractures) Minor (bruising, cuts, light abrasions)	Estimated severity of injury: Minor = 1 Serious = 5 Major = 7 Fatal = 10	Estimated likelihood of injury: Unlikely = 1 Possible = 5 Probable = 7 Certain = 10	Estimated level of risk: Estimated severity ×× estimated likelihood
Initial in feed belt creates pinch Point near front roller.	Minor bruising of fingers	1	5	5
Crushing hazard between tray wrap film folder arms and machine frame	Amputation injury to fingers or severe crushing of hands	7	7	49
Out feed tray/film heat belt is very hot	Burns to hands	5	5	25
Web belt drive unit for out feed belt has no guard — infrequent access required	Bruising of fingertips	1	5	5

Table 1: Machine Risk Assessment Survey used in Pharmaceutical Industry

VII. CONCLUSION

At Cipla Limited, the threat of injuries or illnesses especially in chemicals to be properly controlled. According to one previous audit by Occupational Safety and Health Administration (OSHA), the agency confirmed that employees must be protected thorough the adequate implementation of machine guards helping to prevent the probability of workers' injuries.

Some departments at Cipla exhibited solid machine guard systems; however moderate improvements could be implemented on other departments. Workplace injuries can be prevented through proper machine guard systems implementation, as well as a correct application of safety programs such as Lockout-Tagout (LOTO).

OSHA recommended companies working with machinery daily to establish sound machine guard systems and a machine safety program to avoid or reduce workplace injuries. On the contrary, not guarding machines properly can lead to an unsafe workplace and an increase in employees' injuries.

Machine safeguards can be improved in a variety of ways. Employees felt more protected if a machine was adequately guarded, in contrast to a machine that lacked adequate machine guard systems. Suitable machine guards installed to protect the worker from the point of operation or danger zone have proven to be effective in guarding the employees properly and helped increase the overall employee's health and safety. Properly installing machine safeguards would prevent operators from reaching into moving parts and other hazardous areas.

Furthermore, some operators agreed that several of the fixed guards were irremovable and inflexible. Employers are obligated to provide the employee with highest level of safety consistently. Operators must work around the guards potentially creating new pinch points, and opportunities to sustain lacerations due to sharp edges. Replacing existing fixed machine guards with durable, yet, removable safeguards would allow the operator easier access to areas that need repair and would avoid the creation of new hazards.

Moreover, a couple of operators believed that installing or adding safeguards to machines where needed was necessary, but occasionally more emphasis should be

placed on proper machine maintenance and cleanliness of machines. The operators believed that the machines would operate smoother and could facilitate a more suitable or adequate machine guard operation, as a result. Likewise, an employee from a different department suggested the same recommendation: perform regular and systematic machine maintenance to avoid downtimes that last longer, and experience smoother machine operations both short and long term.

REFERENCES:

[1] United States Department of Labor, Occupational Safety and Health Administration (OSHA). Regulations: 29 CFR 1910.212. Machinery and Machine Guarding; General Requirements for All Machines.
[2] United States Department of Labor, Occupational Safety and Health Administration (OSHA). Regulations: 29 CFR 1910.147. The Control of Hazardous Energy (Lockout/Tagout).
[3] United States Department of Labor, Occupational Safety and Health Administration (OSHA). Regulations: 29 CFR 1910.219. Machinery and Machine Guarding; Mechanical Power-Transmission Apparatus
[4] United States Department of Labor, Occupational Safety and Health Administration (OSHA). Regulations: 29 CFR 1910.217. Machinery and Machine Guarding; Mechanical Power Presses
[5] Boyle D, Parker D, Larson C, Pessoa-Brandao L. Nature, incidence, and cause of work-related amputations in Minnesota. Am J Ind Med. 2000;37: 542–550
[6] Largo TW, Rosenman KD. Michigan work-related amputations, 2008. J Occup Environ Med. 2013;55:280–285.
[7] Bulzacchelli MT, Vernick JS, Sorock GS, Webster DW, Lees PS. Circumstances of fatal lockout/tagout-related injuries in manufacturing. Am J Ind Med. 2008;51:728–734.
[8] United States Department of Labor, Occupational Safety and Health Administration (OSHA). Fatality and Catastrophe Investigation Summaries.
[9] Anderson L. Comprehensive needs assessment for addressing lead contamination in Herculaneum, Missouri. Health Educ Behav. 2004;31:417–419.
[10] Gupta RN. Safety in the Pharma Industry. Pharmabiz.com, April 24, 2001:11-16.
[11] Subrahmanyam CVS. Pharmaceutical production and management. Delhi: Vallabh Prakashan; 2005.
[12] Berry MA, Dennis A. Rond J. Environmental Management in Pharmaceutical Industry: Integrating Corporate Responsibility and Business Strategy Environmental Quality Management, 2000: 21-35.
[13] Occupational Health Safety Assessment Series, British Standards OHSAS:BS: 18001:2007 – Safety Management system. 1-34.
[14] Gupta D. Towards Green Pharma, Express Pharma, June 20011,1-3.
[15] Parker DL, Yamin SC, Brosseau LM, et al. National machine guarding program: Part 2. Safety management in small metal fabrication enterprises. Am J Ind Med. 2015;58:1184–1193.
[16] Parker, David L. MD, MPH; Yamin, Samuel C. MPH; Xi, Min PhD, MS; Brosseau, Lisa M. ScD; Gordon, Robert MA; Most, Ivan G. ScD, Findings From the National Machine Guarding Program–A Small Business Intervention Machine Safety, Journal of Occupational and Environmental Medicine, Volume 56, Issue 9: 2016
[17] Donald R. Vaillancourt, Stover H. Snook, A review of machine-guarding recommendations, Applied Ergonomics, Volume 2, Issue 26: 1995
[18] Appil Ora, K. Dharani Kumar, Rishi Dewan, Recent development in machine safeguarding for protecting humans from complicated machines, Advance in fire process safety: 2018
[19] Edwin G. Foulke, Safeguarding Equipment and Protecting Employees from Amputations, OSHA: 2018
[20] DCBS, Machine safeguarding at the point of operation, A guide for finding solutions to machine hazards: 2017
[21] David L. Parker, Samuel C. Yamin, Lisa M. Brosseau, Min Xi, Robert Gordon, Ivan G. Most, and Rodney Stanley, National Machine Guarding Program: Part 1. Machine Safeguarding Practices in Small Metal Fabrication Businesses: AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 58:1174–1183 (2015)
[22] David L. Parker, Samuel C. Yamin, Lisa M. Brosseau, Min Xi, Robert Gordon, Ivan G. Most, and Rodney Stanley, National Machine Guarding Program: Part 2. Machine Safeguarding Practices in Small Metal Fabrication Businesses: AMERICAN JOURNAL OF INDUSTRIAL MEDICINE 58:1174–1183 (2015)
[23] Waqas Ahmed Khan, Talha Mustaq and Anmol Tabassum, OCCUPATIONAL HEALTH, SAFETY AND RISK ANALYSIS, International Journal of Science, Environment and Technology, Vol. 3, No 4, 2014, 1336 – 1346
[24] John R Etherton, Melvin L Myers, Machine Safety Research at NIOSH and the Future Directions, International Journal of Industrial Ergonomics · September 1990
[25] Krishnananda Kamath K, Dr. A.R. Shabaraya, Dr. E.V.S. Subramanyam, Role of Environment Health and Safety (EHS) in Pharmaceutical Industry, Srinivas College of Pharmacy, Valachil, Mangalore, Karanataka- 574143
[26] Occupational Safety and Health Administration. (OSHA, 2018a). Machine guarding: General requirements.
[27] Occupational Safety and Health Administration. (OSHA, 2018b). Machine guarding: Overview.
[28] Occupational Safety and Health Administration. (2007). Occupational safety and health standards: Safeguarding equipment and protecting employee from amputations (Standard No. OSHA 3170-02R 2007).
[29] National Safety Council. (2017). Work injury costs: Work injury costs and time lost.
[30] Martin, D. K., & Black, A., (2015). Preventing serious injuries & fatalities: Study reveals precursors & paradigms. Professional Safety, 60(9), 35-43.
[31] Picarda, M., Girardb, S.A., Simardb, M., Larocqueb, R., Lerouxa, T., &Turcottec, F. (2008).Association of work-related accidents with noise exposure in the workplace and noise induced hearing loss based on the experience of some 240,000 person-years of observation. Accident Analysis and Prevention, 40, 1644–1652.

[32] Sese´, A., Palmer, A.L., Cajal, B., Montano, J.J., Jime´nez, R., & Llorens, N. (2002). Occupational safety and health in Spain. Journal of Safety Research, 33, 511–525.
[33] Shannon, H.S., Robson, L.S., & Sale, J.M. (2001).Creating safer and healthier workplaces: role of organizational factors and job characteristics. American Journal of Industrial Medicine, 40, 319–334.
[34] Shikdar, A.A., & Sawaqed, N. M. (2003). Worker productivity, and occupational health and safety issues in selected industries. Computers & Industrial Engineering, 45(4), 563-572.
[35] Towlson, D. (2003). NEBOSH: International general certificate in occupational safety and health. RRC Bussiness training, London.
[36] Topuz, E., Talinli, I., & Aydin, E. (2011). Integration of environmental and human health risk assessment for industries using hazardous materials: A quantitative multi criteria approach for environmental decision makers. Environment International, 37, 393–403.
[37] Unsar, S., & Sut, N. (2009). General assessment of the occupational accidents that occurred in Turkey between the years 2000 and 2005. Safety Science, 47, 614–619.
[38] Walters, D. (2004). Workers representation and health and safety in small enterprises in Europe. Industrial Relations Journal, 35 (2), 169–186

