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Ogungbe, Oluwagbenga O. ***The Implementation of Hazardous Energy Control (Lockout/Tackout) Program at XYZ Inc., Plymouth, Minnesota***

Abstract

Unintentional activation and release of hazardous energy in the course of servicing or maintaining any piece of industrialized machine or equipment results in injuries and deaths of personnel on the one hand and damage to facilities on the other hand. The Occupational Safety and Health Administration (OSHA) introduced a regulation under Title 29 Code of Federal Regulation (CFR) Part 1910.147 for the control of hazardous energy which is popularly called Lockout/Tagout (LOTO) program in industry parlance. This study considered the factors, processes, procedures and policy frame works that were required to properly implement a standardized LOTO program in a manufacturing facility, using XYZ Medical Inc., as a case study.

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Chapter I: Introduction

On the 5th of September, 2012 at the Introducers' Department of XYZ Inc., in Plymouth, Minnesota, an employee sustained a crush injury to the second and third fingers of his left hand. The incident investigation conducted revealed that the injured employee was troubleshooting a Mold Press machine when the press came down with force and hurt his fingers. The root-cause analysis of the incident indicated that 'failure to bleed out a compressed air line' was responsible for the accident (XYZ, 2012). On account of this incident and a couple other related near-misses, the company decided to overhaul its control of hazardous energy program. The purpose of this was to identify components of its policy, program, processes or procedures that might not be optimal or be at par with industry best practices.

The control of hazardous energy program, popularly referred to as Lockout/Tagout (LOTO), is a citable regulation by the Occupational Safety and Health Administration (OSHA) under Title 29 Code of Federal Regulations (CFR) Part 1910.147 [OSHA 29 CFR 1990.147] which was introduced in 1989. The aim of the regulation was to prevent the unintentional start-up and release of hazardous energy from machines and equipment when they are being serviced or maintained. However, the failure to control an energy source and thereby prevent it from being unintentionally re-activated renders it hazardous and can result in severe bodily injury and death of employees as well as damage to facility property. OSHA estimates that about 6 million workers have job duties that require the performance of maintenance or servicing of equipment, out of which as many as 10% sustain serious injuries which are attributable to failure of the control of hazardous energy (OSHA, 1989). In the United States alone, OSHA estimates that well-implemented LOTO programs across board will prevent a total of 50,000 injuries and 120 fatalities on an annual basis (OSHA, 2002). It is a truism that accidents and recordable incidents

are most likely to occur in manufacturing industries that lack programs to control hazardous energy. However, in settings where the available LOTO programs are substandard, accidents are still recorded.

This research paper reflects the measures instituted to evaluate the LOTO program of company XYZ Inc., with a view to identifying existing gaps, and implementing measures that are geared towards standardizing the program to reflect industry best practices. XYZ Inc., in Plymouth, Minnesota is a member of a consortium of manufacturing companies that specializes in the production of quality medical devices. The company, which was small when founded in 1970, has grown much bigger over the years, and through on-going mergers and acquisitions, has grown in leaps and bounds to the current portfolio of capabilities it offers. XYZ, which has facilities in six states in the United States and three countries internationally in Mexico, France and Switzerland, designs and manufactures medical devices which have applications in three broad categories namely orthopedics, vascular access, and cardiac rhythm management and neuromodulation.

The facility of XYZ in Plymouth, Minnesota manufactures vascular access devices such as implantable grade batteries (IGB) components like batteries, capacitors, device headers, feed-through, simulation leads and device enclosures, amongst others, which are used in the management of cardiac rhythm and neuromodulation (XYZ, 2013). At this facility, a lot of heavy equipment and machinery, with high-capacity energy sources that are potential hazards when left uncontrolled, are utilized in the production process. The need to prevent possible injuries and deaths of personnel as well as damage to equipment and the facility structures, coupled with compliance with OSHA regulations, necessitates efforts to overhaul the LOTO program at this facility.

Statement of the Problem

What are the processes, procedures and policy frameworks that must be taken into consideration in order to ensure that programs implemented for the control of hazardous energy in manufacturing industries do not fail?

Purpose of the Study

The purpose of this study was to determine the factors that must be accounted for so as to ensure that programs implemented to control hazardous energy in manufacturing industries do not fail.

Study Questions

The following research questions were addressed by this study:

i. What are the factors that determine whether programs designed to control hazardous energy are adequate and effective?

ii. What are the factors that contribute to the failure of control of hazardous energy in industrial settings without comprehensive LOTO programs?

iii. What are the contributory factors to the failure of control of hazardous energy in industrial settings with LOTO programs?

iv. What strategies need to be put in place to ensure adequate implementation of standard LOTO programs in manufacturing industries?

v. What are the means by which the effectiveness of standard LOTO programs be measured?

vi. What are the ways of auditing LOTO programs to ensure they are adequate and that employees are compliant?

Significance of the Study

Since OSHA introduced the control of hazardous energy program, the rate of avoidable incidents that result in injuries and fatalities has not reduced significantly. A significant number of manufacturing industries are yet to implement LOTO programs while the few that did, have substandard programs. As a result, this study addressed the following:

i. Critically appraised the methodologies for proper implementation of standard LOTO programs for manufacturing industries so as to avoid accidents.

ii. Conducted critical gap analysis aimed at determining how the current LOTO program at XYZ compares with industry best practices.

iii. Laid out the benefits of standard LOTO programs to manufacturing industries.

iv. Developed a system of auditing LOTO programs in order to determine adequacy and measure the effectiveness of standard LOTO programs.

v. Emphasized the need for further formal studies on the effectiveness of standard LOTO programs on the safety structures of manufacturing industries.

Limitations of the Study

The scope of this study was limited by the following factors:

i. Inability to access the LOTO programs of other manufacturing facilities in order to determine local trend as compared to industry best practices.

ii. Limited pool of actual LOTO-related incidents which made a robust review difficult.

iii. Difficulty in accessing records of LOTO-related incidents in industrial settings due to concerns about regulatory agencies taking them up.

iv. Under-reporting of LOTO-related incidents, especially in manufacturing industries where the incentive programs for safety are premised on recordable events.

Methodology

This study critically appraised the processes that were employed in the design and implementation of programs utilized for the control of hazardous energy in manufacturing companies. Hence, qualitative research methodology, specifically applying the grounded theory approach, was used in this study. Information was gathered on the machines and equipment on which lockout/tagout procedures were performed. Sources of the information and materials used in this study include checklists, field notes, reflexive journals, surveys, and analysis of documents, materials and publications on lockout / tagout.

Definitions of Terms

Below is a list of some of the terms that were used in this research paper.

Affected employee. An employee who is required to operate, use, or be in the area where a machine or equipment could be locked or tagged out for service or maintenance.

Authorized employee. An employee who locks or tags out a machine or equipment to do service or maintenance.

Employer. An employer is any person, firm, corporation, partnership, business trust, legal representative, or other business entity which engages in any business, industry, profession, or activity and employs one or more employees or who contracts with one or more persons.

Energized. Connected to an energy source or containing residual or stored energy.

Energy-isolating device. A mechanical device that physically prevents energy from being transmitted or released. This includes, but is not limited to:

– Manually operated electrical circuit breakers

– Disconnect switches

– Line valves

– Blocks

– Similar devices used to block or isolate energy.

Energy source. Any source of electrical, mechanical, hydraulic, pneumatic, chemical, thermal or other energy, including gravity.

Lockout. Placing a lockout device on an energy-isolating control point by using an established procedure to make sure the machine or equipment cannot be operated until the lockout device is removed.

Lockout device. A device that uses a positive means, such as a key or combination lock, to hold an energy-isolating device in the “safe” or “off” position. This includes blank flanges and bolted slip blinds.

Normal production operations. Using a machine or equipment for its intended production function.

Primary authorized employee. An authorized employee who has overall responsibility for meeting the requirements of the lockout/tagout procedures.

Service and maintenance. Activities such as constructing, installing, setting-up, adjusting, inspecting, modifying, maintaining, and servicing machines or equipment. It also includes lubricating, cleaning, unjamming, and making tool changes.

Setting-up. Work done to prepare a machine or equipment for normal production operations.

Tagout. Placing a tagout device on an energy-isolating device using an established procedure to indicate that the energy-isolating device and the machine or equipment being controlled may not be operated until the tagout device is removed.

Tagout device. A prominent warning device, such as a tag and a means of attachment. It can be securely fastened to an energy-isolating device to indicate that the energy-isolating device and the machine or equipment being controlled may not be operated until the tagout device is removed

Chapter II: Literature Review

The Problem

Two Lockout/Tagout (LOTO)-related fatalities were investigated in 2003 by the California Fatality Assessment and Control Evaluation (FACE) program of the California Department of Health (CDH). In the first instance, a 37-year old escalator mechanic was crushed to death when a co-worker mistakenly dropped the escalator's electrical circuit box because the box had not been locked prior to the repair work. In a related incident, a 52-year old welder was also crushed to death by a hydraulic door when he was attempting to remove a jammed piece of metal from the door but the door had not been blocked nor had the pressurized hydraulic line been relieved prior to starting the repair (CDH, 2003). In another incident, the Occupational Safety and Health Administration (OSHA) fined West Fertilizer Co., a fertilizer plant in Texas, to the tune of $118,300.00 for the massive explosion that occurred in the plant in April, 2013 which resulted in 15 fatalities and over 100 injuries. The plant was cited for over 24 workplace violations, and the investigation conducted highlighted 'inadequate relief valves' as one of the root causes of the incident (SHRM, 2013).

Historical Perspective

Efforts to control hazardous energy, through a process by which a piece of equipment or machine is prevented from being inadvertently energized while it is being repaired or maintained, began to be under serious considerations over half a century years ago. However, intensified efforts to design an appropriate, industry-wide program for the control of hazardous energy, also known in industry parlance as Lockout/Tagout (LOTO), began in the mid-twentieth century. Several documents published by the Occupational Safety and Health Administration (OSHA) to address other occupational health and safety concerns also partially made reference

to the control of hazardous energy. Some examples of these documents, which were published in their corresponding OSHA regulations, include marine terminals (1917 Subpart C), long-shoring (1918 Subpart G), construction (1926 Subparts K and Q), electrical (1910 Subpart S), and electric power generation, transmission and distribution (1910 Subpart R and 1926 Subpart V) (OSHA, 2010).

The National Safety Council (NSC), a not-for-profit organization that was chartered by the United States Congress and currently has over 55,000 public and private organizations and individuals whose businesses and concerns are related to occupational health and safety, drafted a document, "Guidelines for a Lockout Program", in November 1971. This document was used as a reference guide by the Accredited Standards Committee Z244 of the American National Standards Institute (ANSI) in March, 1973 at its first organizational meeting in New York to develop a standard on lockout/tagout (ANSI/ASSE, 2003). Due to a combination of several factors which ranged from administrative to procedural problems, the LOTO standard was prevented from being released. However, after over a decade of persistence, the American National Standard for Personal Protection – Lockout/Tagout of Energy Sources – Minimum Safety Requirements Z244.1 was published in March 1982. Using the ANSI guideline on LOTO, Z244.1, as reference, OSHA was able to develop "The Control of Hazardous Energy Sources (Lockout/Tagout)" guideline with code 29CFR 1910.147, in April 1988 and promulgated its final rule in September 1989 (ANSI/ASSE, 2008).

The Need for a Program to Control Hazardous Energy

The rapid growth in and copious applications of advancements in technology in the industrial sector have had the unintended consequences of predisposing personnel who maintain and service heavy, industrialized equipment to certain hazards. Some of these hazards are those

related to the unintentional start-up and/or release of hazardous energy when equipment and machines are being maintained, serviced or repaired. The magnitude and extent of these hazards that are ‘lockout-related’ have been studied by many government agencies and the organized labor. Such agencies include the Bureau of Labor Statistics (BLS) of the United States Department of Labor (DOL), OSHA’s Office of Data Analysis (ODA), the National Institute of Occupational Safety and Health (NIOSH), OSHA’s Office of Experimental Programs (OEP), and OSHA’s Office of Mechanical Engineering Safety Standards (OMESS).

In its Work Injury Report Study (WIRS) which was conducted between August and November 1980, findings from the BLS study indicated that LOTO-related accidents (LRA) were observed across all sectors of industry. The LRA rate was highest in the manufacturing sector while sectors of the industry that had fewer employees were observed to have more LRAs. In virtually all cases of LRA reviewed in the study, the following were common themes observed: (i) a significant proportion of the injured employees did not receive LOTO trainings, (ii) most injured employees worked in establishments that had substandard LOTO programs while (iii) other employees worked in facilities that had very serious issues of lack of compliance with LOTO programs (BLS, 1998).

The OSHA Office of Data Analysis (ODA) conducted a study between 1974 and 1980 entitled ‘Selected Occupational Fatalities Related to Lockout/Tagout Problem”, as found in the Reports of OSHA Fatality/Catastrophe Investigations”. Findings from the study indicated that all the LOTO-related incidents were caused by failure to properly de-energize energy control points prior to performing maintenance, repairs or servicing of machines or equipment (OSHA, 2002). A related study entitled "Occupational Fatalities Related to Fixed Machinery”, as found in the Reports of OSHA Fatality/Catastrophe Investigations, which was conducted between 1974 and

1996 by the same OSHA's Office of Data Analysis, evaluated the impact of LOTO programs. The study was unique as it covered periods prior to and after OSHA introduced regulation to control hazardous energy. Findings from the study indicated a slight decrease in the average annual crude, LOTO-related, death rate in manufacturing industries. Another study that was published in the *Injury Prevention* journal to evaluate the effect of OSHA's LOTO program corroborated the findings of the OSHA studies. However, the study went a step further to state conclusively that the non-significant change in LOTO-related fatality rate in the OSHA study was attributable to low compliance of employers and their employees to adequate LOTO standard (Bulzacchelli M et al, 2007). These findings highlighted the importance of compliance to standards and the fact that accidents could still occur in the presence of standard programs when compliance was an issue.

In September 1983, the National Institute of Occupational Safety (NIOSH) published the result of a study it conducted, entitled "Guidelines for Controlling Hazardous Energy during Maintenance and Servicing". The study analyzed over 300 LOTO-related accidents to determine the countermeasures that could have been instituted to prevent those accidents. The result of the NIOSH study concluded that the accidents analyzed were preventable if the following measures were instituted: (i) effective energy control techniques were available, (ii) employees were well trained to use the techniques, and (iii) management provided the motivation to ensure the use of the techniques (NIOSH, 1983). In a similar vein, two offices within OSHA, the Office of Experimental Programs (OEP) and the Office of Mechanical Engineering Safety Standards (OMESS) jointly conducted studies related to LOTO. The study by OEP analyzed LOTO-related OSHA Form 36 (Preliminary Fatality/Catastrophe Event Report) which usually determined the need for OSHA's investigations of reported fatal/catastrophic incidents. The second study by

OMESS identified, categorized and recorded LOTO-related ‘general duty clause’ citations. The studies concluded that approximately 8.1% of fatalities and 10% of catastrophic incidents respectively would have been prevented had standardized programs to control hazardous energy been implemented (OSHA, 1992).

The concern about the need to control hazardous energy in industrial settings also had inputs from the organized labor which was represented by the United Automobile Aerospace and Agricultural Implement Workers of America (UAW). The organization presented the findings of a study it conducted on LOTO-related fatalities at a hearing organized by OSHA in the course of developing LOTO regulations. UAW compiled data of fatalities which the body referred to as “lockout fatalities’ that had claimed the lives of no fewer than 74 of its members, a figure that represented ~7% of all occupational fatalities, between the years 1973 and 1988. The data submitted by the UAW further corroborated OSHA’s convictions that control of hazardous energy was more than a simple failure to lockout a piece of equipment or that of ‘lockout versus tagout’. The UAW data highlighted the following as contributory factors to LOTO-related accidents and ultimately fatalities:

i. Inadequate training

ii. Inadequate procedures

iii. Un-enforced, adequate procedures

iv. Inferiority of tagout when used in place of lockout procedures.

To summarize its final submission to the rulemaking record of OSHA, UAW made a strong case for OSHA to:

a. Provide for standard energy control procedures

b. Design adequate training for the procedures provided.

And, in its post-hearing comment, UAW reiterated the urgent need for the introduction of a program to control hazardous energy. The organization actually believed the data reported in its submission to OSHA was under-estimated due to various reasons, including but not limited to, under-reporting and improper categorization of lockout accidents and fatalities (OSHA, 1992).

The Current Status of LOTO Program

Failure to lock and block out machinery before servicing it is a major cause of injury in the United States. A study on Lockout/Tagout by the Center for Agricultural Research Publications indicated that 80% of workers surveyed failed to turn off equipment before performing work (Bennett, D et al, 2002). The annual rates of accidents and fatalities attributable to LOTO are still unacceptable despite over 35 years of concerted efforts by government agencies, employers, organized unions and trade associations. A joint effort in 2008 by ASSE and ANSI reviewed the standard on LOTO and produced a document, ANSI/ASSE Z244.1 (ANSI/ASSE, 2008). The document suggested the following as one of the reasons why LOTO programs fail:

a. Failure to address all forms of energy and not electrical energy only.
b. Failure to also train operational personnel in LOTO (and not only maintenance personnel).
c. Grossly overlooking secondary and residual energy sources like pneumatic, hydraulic, gravitational, thermal and other pressurized energy sources.
d. Failure to adequately control hazardous energy sources of complex processes and equipment.
e. Substandard LOTO programs characterized by:

i. Lack of commitments by employers to provide resources and infrastructures needed for adequate LOTO programs.
ii. Failure to develop adequate lockout procedures
iii. Lack of adequate training of employees
iv. Inability of employers to continuously improve their LOTO programs.

In an article published in the *Industrial Safety and Hygiene News* (ISHN) in May, 2000, a review of the problems that OSHA inspectors observed about the LOTO rule was analyzed (ISHN, 2000). The article identified the following as factors that account for why LOTO programs fail:

a. Weak supervision of LOTO programs and procedures
b. Ineffective training.
c. Overlooking hazardous energy.
d. Attempts to find shortcuts to the LOTO regulation and/or written procedures.
e. Lack of or inadequate enforcement policy.
f. Complacency especially on the part of so-called experienced personnel.
g. Non-inclusion of hands-on demonstrations as part of LOTO training.
h. Omission (overlooking) of secondary and residual energy sources.
i. Lack of effective communication, especially during shift change

Implementing a LOTO Program

Applications of the concepts of a robust safety management system is required to establish either a new Lockout/Tagout program or addressing gaps that exist in substandard ones will require the application of the concepts of robust safety management systems. This requires the implementation of inter-related and inter-connected activities and processes that are aimed at

achieving a standardized operational safety management system. Figure 1 below by DuPont provides a schematic diagram of the activities and processes that make up an effective safety management system (DuPont, 2013).

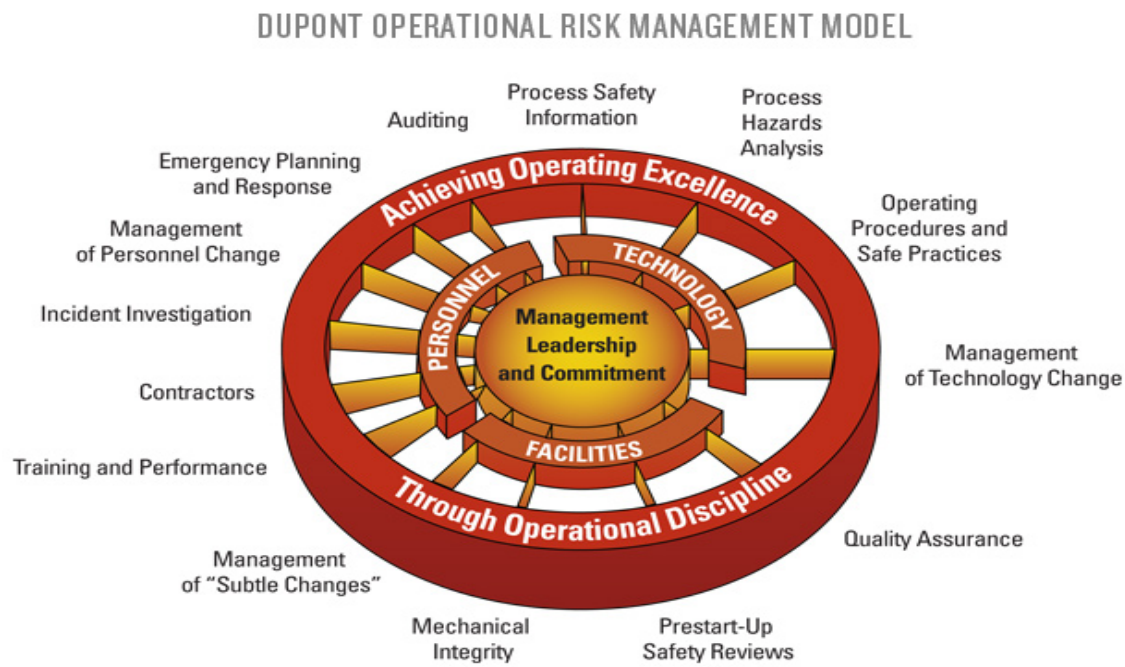

Figure 1. DuPont Operational Risk Management Model

Prior to implementing a safety program however, it is very critical to conduct adequate analysis of hazard and risk assessment on every piece of equipment or machine as well as an overall safety audit of the facility in question. Such a panoramic overview, according to the loss causation model developed by the International Loss Control Institute (ILCI), would highlight the factors that are likely to cause losses, or accidents, at every stage of the activities and processes highlighted in a risk management system (SIA, 2012). As indicated in Figure 2 below, the 'root causes' of losses, per the ILCI Loss Causation Model, are 'lack of management

controls', of which non-compliance to, absence of and inadequate standards are the three key components..

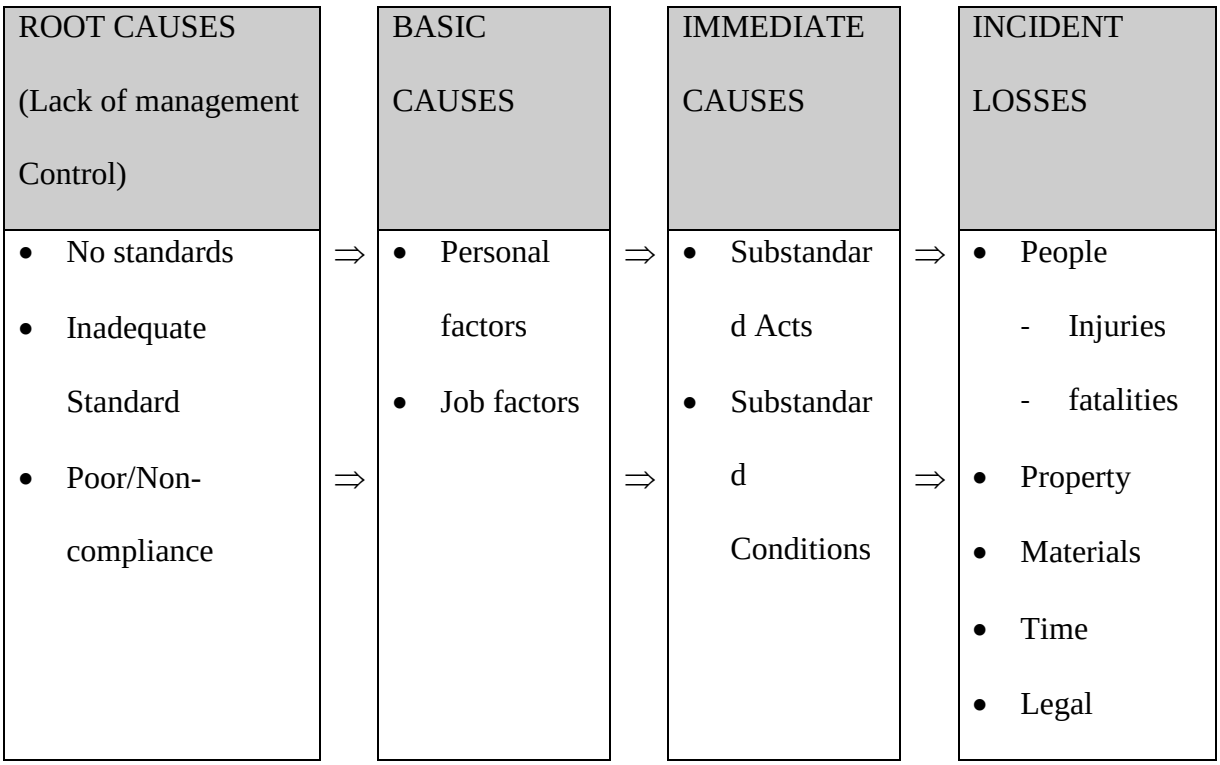

Figure 2. ILCI Loss Causation Model

The conclusions of some of the studies described above suggested the need for a lockout/tagout safety policy that would satisfy the following criteria: (i) the policy must be endorsed by the top management team, (ii) it must be adequate and standardized, and (iii) both management and personnel must comply with the policy. This becomes critical for the LOTO policy to conform to OSHA's regulation 29 CFR 1910.147 for the control of hazardous energy.

Chapter III: Methodology

The methods and procedures used in the study are explained in this chapter under the sub-headings that are described below.

Methods

The study design was quantitative research method with specific application of the grounded theory approach (GTA). Information was gathered on the machines and equipment on which lockout/tagout procedures were performed. Per the GTA, sources of information that were used in this study include checklists, field notes, reflexive journals, surveys, and analysis of documents, materials and publications on lockout / tagout. The goal was to critically appraise the current LOTO program at XYZ Medical Inc., identify gaps that exist, and implement activities and procedures that reflected industry best practices.

Based on the documents and materials collated, a series of activities and processes that were pivotal to designing a standard LOTO program were reviewed. Some of these include:

i. Writing a standard LOTO policy for XYZ Medical Inc.

ii. Selection of some equipment for the pilot LOTO program

iii. Design of training manuals and scheduling trainings for:

   a. Personnel in the production and maintenance departments.

   b. Managers and supervisors.

   c. hands-on demonstration trainings for technical personnel

iv. Performing hazard analysis on equipment selected for the pilot LOTO program.

v. Designing LOTO procedures for selected equipment.

vi. Performing annual and other scheduled audits of LOTO program

Writing a Standard LOTO Policy

As described in the ILCI Model of loss causation, sub-standard policies form part of the root causes of losses. It therefore behooves that any policy on Lockout/Tagout is updated to standard. This was achieved by reviewing the core requirements of OSHA's regulation 29 CFR 1910.147 which mandates and regulates the control of hazardous energy. A checklist was designed to guide and ensure that the LOTO policy to be drafted has key components, some of which are, but not limited to: (i) definition of terms, (ii) determination of authorized personnel and their responsibilities, (iii) in-class and hands-on trainings for authorized personnel and their supervisors, (iv) detailed hazard analysis for each piece of equipment, (v) inclusion of sections that addressed special situations, (vi) pre-empted and addressed factors that account for failure of LOTO programs, and (vi) provided for continuous improvement and regular safety audit (Appendix 3.1)

Selection of Equipment for the Pilot LOTO Program

The set of equipment that was selected for this study was that itemized for the pilot LOTO program at XYZ Medical Inc. The process of enrolling the equipment into the study was by stratified random selection method through which 40 out of 200 pieces of equipment in seven departments in the plant were selected for the study. The selection process took into cognizance the following two considerations, amongst others: (i) the department in which the equipment were utilized and (ii) the stage of the production process in which the equipment were used (Appendix 3.2).

Design of Training Manuals for Authorized Personnel

The training of personnel and the supervisors or managers who will enforce compliance is an integral part of implementing a standard policy. In designing training manuals for the LOTO program, the following factors were put into consideration (Appendix 3.3):

i. The training manuals were customized for the specific pieces of equipment that were available at the facility, in addition to other general concepts.

ii. Hands-on demonstrations were included as integral components of the training, especially for personnel in the production and maintenance units.

iii. Separate trainings were conducted for supervisors and managers in order to highlight the business importance of the policy by highlighting the following:

   a. The basic regulatory requirements of LOTO

   b. The roles of managers in ensuring a closed communication loop system

   c. The need to encourage and, when applicable, enforce employees' compliance to the LOTO policy.

   d. An understanding of the importance of the LOTO program how it contributes to the bottom line of the company.

iv. Records of all personnel who participated in the trainings were taken for proper documentation purpose (Appendix 3.4)

v. A checklist was developed for the hands-on part of the training in order to ensure that personnel display acceptable practical skills in performing LOTO procedures (Appendix 3.5).

Also, in view of the unique differences in the educational, cultural and professional backgrounds of the personnel at an egalitarian facility like XYZ Medical Inc., the training manuals were designed to address these factors.

Hazard Analysis and Risk Assessment

A key component of a standard LOTO program, which is oftentimes omitted, is performing comprehensive analysis of the hazards as well as assessment of risks posed by every energy source in any piece of equipment. For this study, a detailed hazard assessment of the selected equipment was performed to determine the amount of energy sources that each piece of equipment has, the inherent hazards of each energy source, the magnitude of the risks posed by each hazard and the procedures required to adequately de-energize and lock out the equipment. As detailed in Appendices 3.6 and 3.7, the risk assessment process involved the identification of the sources and types of energy, the characterization of hazards, assessment and quantification of the severity of risks, and the determination of acceptable level of risk to 'As Low As Reasonably Practicable" (ALARP).

Writing LOTO Procedures

Sequel to the risk assessment process was the risk reduction exercise which involved performing a set of procedures, i.e. Lockout/Tagout procedures, which were aimed at adequately controlling hazardous energy by mitigating the identified risks. Prior to the LOTO process however, safe shut-down procedures of equipment and machines were performed (Appendix 3.8).

Auditing LOTO Program

In order to ensure that the LOTO policy is current and up-to-date, an annual audit of the program was designed to inspect, among other things, that: (i) each LOTO procedure is still

relevant to the specific equipment it was designed for, (ii) appropriate LOTO devices are available for the control of specific energy sources, (iii) the list of personnel authorized to perform LOTO procedures is reviewed to be current, and (iv) LOTO-related accidents in the previous year have been reviewed and appropriate corrective measures instituted to avert recurrence (Appendix 3.9)

The outcomes of the series of activities outlined and described above are highlighted and discussed in the next chapter.

Chapter IV: Results

Quantitative research methodology, using the grounded theory approach, was used in this study to design a template for the implementation of a program for the control of hazardous energy in a manufacturing industry. Checklists were utilized for the collection of data, information, documents and materials used in this study.

Appraisal of the Current LOTO program of XYX Medical Inc.

A critical appraisal of the current LOTO program of XYZ Medical Inc. was performed which identified the following gaps:

v. Inadequate training
    a. Failure to train all authorized, and not only maintenance, personnel in LOTO
    b. Training programs that were devoid of hands-on demonstrations
vi. Inadequate procedures
vii. Inferiority of tagout when used in place of lockout procedures.
viii. Failure to address all forms of energy and not electrical energy only.
    a. Grossly overlooking secondary and residual energy sources like pneumatic, hydraulic, gravitational, thermal and other pressurized energy sources.
    b. Failure to adequately control hazardous energy sources of complex equipment
    c. Overlooking hazardous energy due to lack of comprehensive hazard analysis.
ix. Lack of effective communication, especially during shift change.

In the course of implementing a standardized LOTO program for XYZ Medical Inc., the above gaps were taken into cognizance.

Written Standard LOTO Policy

Using the checklist for designing a LOTO program as indicated in Appendix 3.1, a standard policy was drafted for the control of hazardous energy for XYZ Medical Inc. The key components of the policy, detailed in Appendix 4.1, include the following:

a. **Overview of the LOTO policy.** This ensured that the policy was in conformity with OSHA regulations and in line with the company's safety climate.

b. **Definition of terms**. This aspect addressed all the technical and conceptual terminologies that were used in the policy in order to ensure clarity and prevent ambiguity.

c. **Authorized personnel and affected persons.** This segment of the policy addressed the individuals in the organization who qualified as authorized personnel as well as those who could be considered as affected persons.

d. **Hazard analysis**. This section addressed the components of comprehensive hazard analysis and risk assessment.

e**. Special situations**. This section addressed three special situations that were very crucial to the successful implementation and every-day applications of the LOTO policy. These special situations include:

i. Handing over of LOTO procedures during an end or change-of-shift.

ii. Removal of LOTO devices by personnel other than those who installed them are inadvertently absent from the scene or when the lock keys are missing or broken (Appendix 4.1.2).

iii. When LOTO procedures are to be performed by contractors.

f. **Policy Audits.** This section detailed the need for regular auditing of the policy, changes that were tracked over a year period and the justifications for any changes made to the policy.

Equipment Selected into the Pilot LOTO Study

Out of 200 heavy industrialized equipment and machines that are used in production at XYZ Medical Inc., a total of 40, representing 20% of all heavy industrialized equipment, were enrolled from seven departments into the LOTO project through stratified random selection method (Appendix 4.2). Table 1 below shows the breakdown of the equipment enrolled into the LOTO project.

Table 1

List of Equipment Selected for the LOTO Program

Departments	Number of Equipment
Clean Room C	8
Catheter Dept I	5
Catheter Dept II	6
Leads Dept	7
Intro Dept	5
Micro Dept II	6
Micro Dept II	3
Total	40

Training Manuals Designed for Authorized Personnel

As detailed in Appendix 4.3, the key points of a training program for Lockout / Tagout (LOTO) were highlighted to include employer's responsibilities in providing LOTO training for employees, writing standard LOTO procedures for equipment, supply of adequate LOTO devices and ensuring that the work environment is conducive. Other important points highlighted in section include the responsibilities of authorized employees, their understanding of the

procedures for controlling hazardous energy, and the need for annual refresher trainings and audit of the program. For proper record keeping and documentation purposes, a list of personnel who participated in-class training sessions was maintained, as indicated in Appendix 4.4. On the other hand, Appendices 4.5.1 to 4.5.9 has the details of authorized personnel who completed the hands-on demonstration training with particular emphasis of the actual performance of critical steps in performing LOTO procedures.

Hazard Analysis and Risk Assessment

In order to reduce the risks to the ALARP level for the purpose of performing Lockout/Tagout procedures, robust hazard analysis and risk assessments of all the equipment and machines were performed. A hazard analysis and risk assessment checklist was completed for AB-200 Top Mold Press, as detailed in Appendix 4.6. Details of all the energy sources that the equipment has, locations of the energy control points, methods of controlling the energy sources, the energy control devices that are used, and the appropriate personal protective equipment (PPE) that are required are indicated in the checklist. Special comments or recommendations as well as the names of the different personnel who completed, reviewed and approved the document were also indicated in the checklist.

Written LOTO Procedures

The LOTO procedures designed for each piece of equipment were specific to and tailored after the hazard analyses and risk assessments performed on the respective machine and equipment. Details of a lockout procedure on a piece of equipment are indicated in Appendix 4.8

Audited LOTO Program

Per the policy of XYZ Medical Inc. the LOTO program will be audited on annual basis. As indicated in Appendix 4.9, the audit is designed to reflect the following:

i. Each LOTO procedure is still relevant to the specific equipment it was designed for

ii. Appropriate LOTO devices are available for the control of specific energy sources

iii. The list of personnel authorized to perform LOTO procedures is reviewed to be current, and

iv. LOTO-related accidents in the previous year have been reviewed and appropriate corrective measures instituted to avert recurrence.

Chapter V: Discussion

Discussion

Unintentional release of hazardous energy in the course of maintaining, repairing or servicing heavy industrialized equipment and machines is a major cause of injuries and deaths of personnel and damage to equipment and facilities in industrial settings. In 1989, OSHA introduced a regulation for the control of hazardous energy which is popularly known in industry parlance as Lockout/Tagout (LOTO). In the course of this study, the LOTO program of XYZ Medical Inc. was evaluated with a view to identifying existing gaps, and implementing such measures as policy frame works, processes, and procedures that were aimed at standardizing the program to reflect industry best practices.

This study was undertaken by utilizing the grounded theory approach of qualitative research methodology in which data, information, documents, and materials were collected using checklists. The checklists were utilized in appraising the current LOTO program of XYZ Medical Inc., designing and writing a standardized LOTO policy, designing an effective training manual for personnel, conducting hazard analysis and risk assessment on machines and equipment, designing robust LOTO procedures for every piece of equipment and for the annual auditing of the entire LOTO program.

A detailed analysis of the completed checklists revealed some major findings, some of which include:

i. An appraisal of the current LOTO program showed that there were gaps in the program.

ii. The training was designed to include hands-on demonstrations which ensured that personnel has a practical application of the concepts of LOTO were addressed during in-class training sessions.

iii. The comprehensive hazard analysis and risk assessment that were performed on every piece of equipment ensured that no hazardous energy sources was omitted

iv. LOTO procedures designed for every piece of equipment were tailored after hazard and risk assessment results so as to ensure that no hazardous energy source was omitted.

v. The purpose of the annual audit was to ensure, among other things, that the LOTO policy is current and updated.

Conclusions

To ensure that a properly implemented program to control hazardous energy in a manufacturing company does not fail due to existence of gaps, a standardized policy frame works must be drafted, comprehensive processes put in place while the LOTO procedures must be adequate. Processes such as a review of the current program coupled with comprehensive risk and hazard assessment were instrumental to identifying existing gaps and in determining factors that cause LOTO programs to fail. Conversely, processes such as adequate LOTO training programs for personnel and designing comprehensive LOTO procedures were helpful in closing the gaps identified and in the design of a robust LOTO policy.

Recommendations

The following recommendations can be made with respect to this study:

a. Concerted efforts must be made by all stakeholders to ensure that LOTO policies and procedures are standardized.

b. Comprehensive hazard analysis and risk assessment must be performed on every equipment or machine prior to designing their LOTO procedures. The hazard analysis must be thorough and must not omit secondary and residual energy sources.
c. LOTO training programs must be designed in such a way that they are customized for a particular facility and also include hands-on demonstrations.
d. The use of tagout, in lieu of lockout devices, to perform LOTO procedures must be discouraged and never used.
e. Authorized personnel must be discouraged from using short-cuts or skipping vital steps when performing LOTO procedures.
f. Adequate supervision of LOTO programs and procedures, and enforcement of LOTO policies by designated personnel.
g. Effective communication is required in the course of performing all LOTO-related procedures and activities.

There are several potential opportunities for further studies in the design and implementation of programs to control hazardous energy. In a world that is driven by information technology and having highlighted the important roles that checklists played in this study, the design of electronic LOTO checklists (e-checklists) will be good tools for safety and maintenance personnel. Taking a step further, mobile applications may be designed for the e-checklists so as to limit the burden of going about with laptops which are much bigger than cell phones.

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Appendix 3.1: Checklist for Designing a LOTO Program

Section A Overview of the LOTO policy

i. Is the LOTO policy in line and compliant with OSHA regulation (29 CFR 1910.147) on the control of hazardous energy?

ii. Did the top management of the organization sign up on the policy?

iii. Is the policy up-to-date and does it reflect current trends in LOTO?

iv. Is the policy integrated into the safety management system of the organization?

Section B Definition of terms

i. Are technical terms used in the policy well defined to prevent ambiguity?

ii. Are concepts in the policy, especially those pertaining to special situations and events, well explained?

iii. Is there clarity in the description of “who-should-do-what?”

Section C Authorized Personnel vs. Affected Persons

i. Is there a clear distinction between who an authorized personnel and an affected persons is, per the LOTO policy?

ii. Are the responsibilities of authorized personnel well detailed?

iii. Does the policy reflect what the expectations of other affected persons are, prior to the start of a LOTO procedure?

Section D Hazard Analysis

i. Was a comprehensive hazard analysis performed on every piece of equipment?

ii. Were the risks posed by every identified hazard adequately assessed?

iii. Did the LOTO procedure designed for every equipment adequately address the identified hazards and risks?

iv. Did the LOTO policy adequately address measures to control residual and secondary energy sources?

Section E Special Situations

i. Did the policy address the conduct of LOTO procedures by third-party contractors?

ii. Did the policy address processes to be taken in the event of LOTO or BROKEN lock keys?

iii. Did the policy address the sequel of events that must take place in an end or change-of-shift situation?

Section F Policy Audit

i. How often is the LOTO policy audited?

ii. When was the last time this policy was audited?

iii. Between the last audit and now, have there been any changes/updates to the policy?

a. If yes to F(iii) above, what are those changes? List them below.

Appendix 3.2: List of Equipment Selected for the LOTO Program

Departments	Number of Equipment
Clean Room C	
Catheter Dept I	
Catheter Dept II	
Leads Dept	
Intro Dept	
Micro Dept II	
Micro Dept II	
Total	

Appendix 3.4: LOTO Training Records

XYX Medical Inc	**Training Record**	
Document Number:	Rev:	Description:
Trainer Signature:	Date:	Trainer may indicate entire list of trainees are effectively trained by signing to the left. Trainer must also sign and date by the check box if a trainer is being designated. **A designated trainer must be authorized by an Engineer, Supervisor, or Lead.**
Trainer Associate Number:		

Trainee Name	Trainee Signature	Trainee Initials	Trainee Associate Number	Date Trained	Authorization for Designated Trainee: (Trainer Sign & Date) Check box if TRAINER is authorizing Trainee to be a designated trainer for this revision
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐
					☐

Roster ID: _____ Initials: _____ Date Entered: _____

Appendix 3.5: Checklist for LOTO Hands-On Demonstrations

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**		
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Hands-On LOTO Observation Training Form

Associates Name		**Date**	
Associates Signature		**Associate ID Number**	
Equipment Name and Number		**Department**	

Observation of LOTO	Yes	No
1. Did the person review the Lockout/Tagout placard?		
2. Did the person obtain all required locks, lockout devices and tags needed?		
3. Did the person notify affected employees in the area?		
4. Did the person shut down the equipment by normal means?		
5. Did the person identify, isolate and deactivate all energy sources?		
6. Did the person apply required lockout devices, locks and tags?		
7. Did the person dissipate, drain, or safely release any stored or residual energy?		
8. Did the person verify isolation of zero energy?		

Observation of release of LOTO	Yes	No
1. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?		
2. Did the person notify affected employees in the area of impending equipment start up?		
3. Did the person remove locks, lockout devices and tags?		
4. Did the person return the system to fully functional?		
5. Did the person notify affected employees that equipment is operational?		
Associate passed Hands-On Observation Training		

Comments:

Trainers Name		**Trainers ID number**	
Trainers Signature		**Trainers Title**	

Appendix 3.6: Hazard Analysis & Risk Assessment for LOTO

Energy Source Determination

DATE: _____

CONDUCTED BY: _____

In order to determine all energy sources for each piece of equipment, all questions must be answered. Both actual and potential sources of energy need to be considered when responding to the questions. If the question does not apply, write N/A in the blank. Circle "yes" or "no" or fill in the blank.

Location: _____ Work Center: _____

Line: _____ Equipment No.: _____

Equipment Name: _____ Serial No.: _____

Lockout/Tagout Procedure # Assigned: _____

1. Does this equipment have any of the following?

a. Electric power (including battery)? YES/NO

if yes, Motor Control Center (MCC) or power panel and breaker number _____

Does it have a lockout device? YES/NO

Battery location: _____

b. Mechanical power? YES/NO

Mark each type of energy source that applies:

1. Engine driven? YES/NO

If yes, switch or key location: _____

Is lockout device installed? YES/NO

If no, method of preventing operation: _____

2. Spring loaded? YES/NO

If yes, is there a method of preventing spring activation? YES/NO

If no, how can spring tension be safely released or secured? _____

3. Counter weight(s)? YES/NO

If yes, does it have a method of preventing movement? YES/NO

If yes, can it be locked? YES/NO

If no, how can it be secured? _____

4. Flywheel? YES/NO

If yes, does it have a method of preventing movement? YES/NO

If no, how can it be secured? _____

c. Hydraulic power? YES/NO

If yes, where is the location of main control/shut off valve? _____

Can control/shut off valve be locked in "off" position? YES/NO

If no, where is the location of closest manual shutoff valve? _____

Does manual shutoff valve have lockout device? YES/NO

If no, what is needed to lock valve closed? _____

Is there a bleed or drain valve to reduce pressure to zero? YES/NO

If no, what will be required to bleed of pressure? _____

d. Pneumatic energy? YES/NO

If yes, where is the location of main control/shut off valve? _____

Can control/shut off valve be locked in "off" position? YES/NO

If no, where is the location of closest manual shutoff valve? _____

Does manual shutoff valve have lockout device? YES/NO

If no, what is needed to lock valve closed? _____

Is there a bleed or drain valve to reduce pressure to zero? YES/NO

If no, what will be required to bleed off pressure? _____

e. Chemical system? YES/NO

If yes, where is the location of main control/shutoff valve? _____

Can control/shutoff valve be locked in off/closed position? YES/NO

If no, where is the location of closest manual shutoff valve? _____

Does manual shutoff valve have lockout device? YES/NO

If no, what is needed to lock valve closed? _____

Is there a bleed or drain valve to safety reduce system pressure and drain system of chemicals? YES/NO

If no, how can system be drained and neutralized? _____

What personal protective clothing or equipment is needed for this equipment? _____

f. Thermal energy? YES/NO

If yes, where is the location of main control/shutoff valve? _____

Can control/shutoff valve be locked in "off" or closed position? YES/NO

If no, where is the location of closest manual shutoff valve. _____

Does manual shutoff valve have lockout device? YES/NO

g. Gravitational Energy? YES/NO

If yes, where is the location of main control/shutoff device? _____

Is there a device to restrain or control the gravitational energy? YES/NO

If no, what will be required to control or restrain the gravitational energy? _____

Can the device used to restrain or control the gravitational energy be locked in a position that will prevent the gravitational energy from being released? YES/NO

h. Other Sources of Energy?

Are there any other actual or potential energy sources? YES/NO

If yes, where is the location of main control/shutoff valve? _____

Can control/shutoff valve be locked in an off or closed position? YES/NO

Is there a way to drain or bleed of pressure? YES/NO

If no, how can energy be controlled or neutralized? _____

Is personal protective clothing or equipment needed to protect employees from the energy source? YES/NO

If yes, what equipment is needed? _____

If no, what is needed to lock valve closed? _____

Is there a bleed or drain valve to safely reduce system pressure and temperature and drain system? YES/NO

If yes, what is the location of the valve? _____

If no, how can system pressure and temperature be reduced and drained? _____

What personal protective clothing or equipment is needed for this equipment? _____

Special precautions not noted in the preceding (i.e., fire hazards, chemical reactions, required cool down periods, etc.): _____

Recommendations or Comments: _____

Completed by: _____ Date:_____

Reviewed by: _____ Date:_____

Approved by: _____ Date:_____

Appendix 3.8: Design of Lockout/Tagout (LOTO) Procedures

Specific Lockout Procedure

Equipment, Machinery, Or Process: _____

Lockout Procedure No.: L/O-___-__

Date: _____

Approved/Implemented by:_____

Specific Lockout Procedure

NOTE: Required for all equipment, machinery and/or processes that fails to meet the exceptions noted in 29 CFR 1910.147(c)(4)(i).

1. The purpose of these specific procedures is to protect our personnel from injury and death.

NOTE: Failure to comply with these procedures will result in disciplinary action and may result in employee discharge.

2. TYPE(S) AND MAGNITUDE(S) OF ENERGY AND HAZARDS:

3. NAME(S)/JOB TITLE(S) OF EMPLOYEES AUTHORIZED TO LOCKOUT/TAGOUT:

4. NAME(S)/JOB TITLE(S) OF AFFECTED EMPLOYEES AND HOW TO NOTIFY:

5. TYPE(S) AND LOCATION OF ENERGY ISOLATING MEANS:

6. TYPE(S) OF STORED ENERGY - METHODS TO DISSIPATE OR RESTRAIN:

List of All Lockout Procedures

PROCEDURE NO.. EQUIPMENT, MACHINERY OR PROCESS

_____

_____

_____

_____

Appendix 3.9: Annual LOTO Audit

Date(s) of Evaluation _____

Evaluation was made by _____ .

A. General policy has been reviewed: YES/NO

B. Is the LOTO policy current and up-to-date? YES/NO

C. General comments on LOTO policy:

D. Are appropriate LOTO devices available in appreciable quantities? YES/NO

   If NO, comment below:

E. List below the specific LOTO procedures that have been reviewed:

F. The following specific procedures were modified:

G. The following specific procedures were added (list below):

H. List all LOTO-related accidents and injuries below.

I. What were the corrective measures taken to address the cases stated above?

J. Is the list of personnel authorized to perform LOTO procedures current? YES/NO

   If NO, indicate below:

Appendix 3.10: LOTO Annual Certification Post-Audit

Lock-Out/Tag-Out Annual Certification Form

Dept. / Shop Inspected: _____ Date: _____

Is this an equipment/ machine specific LOTO procedure or general LOTO procedure? SPECIFIC/GENERAL

Specific Equipment/ Machine Name (Serial #):

_____

Location (Building & Room :) _____

ANNUAL INSPECTION ITEMS	Acceptable? Yes	No	NA
1. Has initial lock-out/tag-out training been documented for the affected & authorized employees in this Dept./ Shop? (Check w/ OESO Training Coordinator & attach training records.)			
2. Has initial lock-out/tag-out training on the equipment. / Machine specific LOTO procedure been documented by the Dept. / Shop? (Shop must show records with names & dates of attendance.)			
3. Has there been a change in job assignments, machines, equipment or processes that present a new hazard, or has there been a change in the LOTO procedure?			
4. If YES to #3, has there been re-training of employees to make them aware of the change?			
5. Does the authorized/affected employee know his/her responsibilities under the Lockout program? (Required to be asked of <u>each</u> authorized & affected employee by the inspector.) **— To report to his/her supervisor any unsafe conditions concerning the control of hazardous energy sources.** **— To follow safe work procedures while performing work on or near equipment with hazardous energy sources.** **— To ask his/her supervisor for assistance or clarification of work procedures as necessary.** **— To accurately label and prominently attach lock-out/tag-out devices when required.** **— To utilize his/her own padlock and key when applying and removing lockout devices.** **— To remove ONLY his/her OWN lock-out/tag-out devices at the completion of the task.** **Does the authorized employee know his/her responsibilities under the Tag-Out program and the limitations of tags?** **— <u>Locks and tags are required</u> wherever equipment/ machines are "capable of being locked out."**			

— **Tags must provide equivalent protection to that obtained by using a lockout program.** — **Tags are warning devices affixed to energy isolation devices and do NOT provide the physical restraint on those devices provided by a lock.** — **Tag must NOT be removed except by the authorized employee responsible for it and never bypassed, ignored or otherwise defeated. This includes contractor's danger tags.** — **Tags must be legible and understandable by all employees in order to be effective.** — **Tags must be made of durable materials, AND** — **Securely attached to energy isolating devices at the same location a lockout device would have been attached.** — **Tags provide a false sense of security, and their meaning needs to be understood as part of the LOTO program.**			
6. Does the authorized employee have his/her own lock? (Each employee must have his/her own lockout device in a group lockout.)			
7. Is the lock individually keyed? (Can someone else's key open the lock?)			
8. Are the tags being used durable, legible, understandable to all affected & authorized employees, and securely attached? (Are non-English speaking employees present in the workplace?)			
9. Were lock-out/tag-out procedures performed correctly? (Following written policy in the Safety Manual or Equipment/ Machine Specific procedure.)			
10. Were lock-out/tag-out removal procedures performed correctly? (Following the written policy in the Safety Manual or Equipment/ Machine Specific procedure.)			
11. Were affected employees notified (before and after)? What is the method of notification of affected employees for application and removal of lock-out/tag-out devices? _____			
12. If this is a periodic inspection of a <u>GENERAL</u> LOTO procedure, Are there any machines/ pieces of equipment for which this Dept./ Shop is responsible that require a <u>SPECIFIC</u> LOTO procedure? (See rules for accepting a machine/ piece of equipment from having a specific LOTO procedure.)			
13. If this is a periodic inspection of a <u>SPECIFIC</u> LOTO procedure, Does this piece of equipment have its own <u>*written*</u> lock-out/tag-out procedure? (Attach copy.)			
a) Does the <u>*written*</u> procedure have procedural steps from shutting down, isolating, blocking and securing machines or equipment to control hazardous energy?			
b) Does the <u>*written*</u> procedure include procedural steps for the placement, removal, and transfer of lockout devices or tag-out devices and the responsibility for them?			
c) Does the <u>*written*</u> procedure include specific requirements for testing a machine or equipment to determine and verify the effectiveness of lockout devices, tag-out devices, and other energy control measures?			

<u>Deviations or inadequacies observed:</u>

Certified by _____ Date _____

Appendix 4.1.1: Sample of a Standardized LOTO program

Hazardous Energy Control (Lockout/Tagout) Program

Section A. Overview

This lockout/tagout program has been developed to ensure the safety of any employee servicing, maintaining or repairing any piece of equipment, and for other employees who may be within the danger zone within which the equipment is being worked on. The Lockout/Tagout (LOTO) program is in compliance with the regulation title 29CFR 1910.147 of the Occupational Safety and Health Administration (OSHA). This program is approved by the top management of XYZ Medical Inc's and is certified to be in line with its hazardous energy control standard which has been integrated into the overall safety management system of the organization. A copy of this policy can be referenced as needed for clarification of the terms used in this program, general equipment and program requirements, and for training purposes. The most current revision of this standard may be accessed on the website of XYX Medical Inc.

Section B Definition of Terms

The terms used in this policy are contained in Appendix 4.1.2, which is an addendum to this appendix.

Section C Authorized Personnel

Per this policy, an authorized personnel is an employee whose job function and responsibilities requires him to perform lockout/tagout procedures on a piece of equipment. The said employee would have satisfactorily completed both the in-class and hands-on LOTO trainings and must have the required skills to perform the appropriate

maintenance or repair work on a particular piece of equipment. On the other hand, an affected person is an employee who has any part of the body within the vicinity of a danger zone. A danger zone is defined as any part of the work place where a hazardous energy, when inadvertently discharged, can extend to.

By these definitions, an authorized personnel will always also be an affected person whereas other affected persons may be other employees who are by-standers or nearby workers.

Section D Hazard Analysis & LOTO Procedures

Prior to performing a LOTO procedure on any piece of equipment, a comprehensive hazard analysis and risk assessment would have to be conducted first. The outcomes of the analyses would determine the procedures that are required for performing effective control of hazardous energy on that piece of equipment.

The equipment necessary to comply with the procedures described in this program must meet the requirements described in XYZ's Hazardous Energy Control Standard. This equipment will be provided to XYZ employees servicing affected equipment. The color coded **RED** locks, tags, and other devices that are issued and assigned to comply with this program may not be used for any other purpose.

If equipment or procedures other than those associated with this program will be used, (e.g., if an outside contractor will be using their own lockout/tagout equipment or procedures while servicing equipment) these procedures must be communicated to appropriate foreman/supervisors, who in turn, must ensure that all affected personnel are adequately informed.

Failure to comply with all parts of this program or to follow established procedures will result in disciplinary action, up to and including termination.

Required lockout/tagout procedures will vary in complexity depending on the equipment or systems involved. Foremen/supervisors are responsible for ensuring their personnel are adequately trained and equipped to comply with the lockout/tagout requirements before they are authorized to perform related procedures. A list of authorized employees may be found in the section of this program labeled Authorized Employees. XYZ's Hazardous Energy Control Standard does not apply, and the use of lockout-tagout procedures is not required, to work on cord and plug connected electric equipment for which exposure to the hazards of unexpected 'energization' or start up of the equipment may be controlled by the unplugging of the equipment from the energy source and the plug is under the exclusive control of the employee performing the servicing or maintenance.

Lockout-tagout procedures contained in this program are basically classified as follows:

1) *Simple Lockout/Tagout Procedure*

When authorized employees will be working on machinery or equipment which has only ONE hazardous energy source that can be readily identified or isolated, a simple lockout tagout procedure may be used providing ***all*** of the following conditions apply:

- there is no potential for stored or residual energy or re-accumulation of stored energy after shutdown which could endanger employees
- the isolation and locking out of the energy source will completely de-energize and deactivate the machine or equipment

- the machine or equipment is isolated from the hazardous energy source and locked out during servicing or maintenance
- a single lockout device will achieve and is used to maintain a locked-out condition while servicing/maintenance activities are being performed
- the lockout device is under the exclusive control of the authorized employee performing the servicing or maintenance
- the servicing or maintenance does not create hazards for other employees
- there have been no accidents involving the unexpected activation or re-energization of the machine or equipment during servicing or maintenance while using this procedure
- a particular sequence does not have to be followed to safely shut down or start up the machine or equipment being locked out
- the employee has not been instructed to follow more restrictive procedures and there are no signs or labels posted indicating the need to follow more restrictive measures

If an employee has not been trained in the lockout/tagout procedures that are required, they must notify their supervisor before servicing the machine / equipment.

2) *Complex Lockout/Tagout Procedure*

Whenever ***any*** of the conditions that are required for a simple lockout-tagout procedure to be used as previously described ***do not*** apply, more complex lockout-tagout procedures are required. Machines and equipment that have been identified as requiring

complex lockout-tagout procedures are listed in the section of this program labeled COMPLEX LOCKOUT/TAGOUT MACHINE EQUIPMENT LIST.

Authorized employees must be provided with an approved written procedure for machinery or equipment requiring complex lockout\tagout procedures ***prior to*** performing related service or maintenance activities. An approved template for drafting complex lockout-tagout procedures may be found in the section of this program labeled WRITTEN PROCEDURE TEMPLATE. Written procedures that have already been developed and approved for machines and equipment requiring complex lockout tagout procedures may be found in the section labeled WRITTEN PROCEDURES.

Approved checklists or an equally effective means of verifying that all hazardous energy sources have been isolated and all lockout-tagout devices have been applied must be used whenever complex lockout-tagout procedures are used. Checklists that have already been developed for the machines and equipment requiring complex lockout-tagout procedures may be found in the section of this program labeled LOCKOUT/TAGOUT CHECKLISTS (EQUIPMENT SPECIFIC). A blank, generic checklist template that can be modified and used for this purpose may be found in the section labeled LOCKOUT/TAGOUT CHECKLISTS.

In addition to written procedures, approved, single-line drawings, or an equally effective means of readily locating hazardous energy source isolation points must also be made available to authorized employees as a reference source. Line drawings and similar reference sources may be found in the section of this program labeled LINE DRAWINGS.

If an employee has not been trained in the lockout/tagout procedures that are required, they must notify their supervisor before servicing the equipment. Regardless of the type of procedure used, **NEVER USE OR DEPEND UPON ANOTHER PERSON'S LOCK**. When equipment or machinery is locked out and there is a change of personnel who could be exposed to the hazard(s) involved (e.g., due to a shift change), arriving personnel must apply their own locks *before* the employee who is leaving can remove theirs.

Tagout Procedures

In this policy for the control of hazardous energy at XYZ Medical Inc., tagout devices shall never used and shall be deemed as inappropriate means of controlling hazardous energy!

Section E Special Situations

a. **Group or multiple lockouts** – In the case of group lockouts, all the personnel performing LOTO shall apply and remove their own locks, and just as it is in all cases, each lock will have only one key because duplication keys are not allowed!
b. **Lockout procedures by contractors** – Contractors that have been vetted to have LOTO programs that conform to OSHA's regulation and GB's policy may perform LOTO procedures for any equipment at GB. However, in all cases, the contractors shall supply their own locks so as to prevent any avenue for confusions, mistrusts or litigations.
c. **Missing or broken keys** – These two scenarios are the only exceptions to the 'rule' that personnel performing LOTO shall remove their own locks. However,

the safety, facility or maintenance manager, or any other designated supervisor, must be in charge of removing the key. The process requires that form *XYZPLY LOTO-001* on the intranet be completed to reflect the incident (Appendix 1) by following the following steps:

i. An authorized supervisor must ensure that the person who applied the lock and/or tag is not available in the workplace.

ii. All persons in the work area that could be affected by the removal of the lock and/or tags must be warned.

iii. A visual check of the affected equipment and work area must be made prior to the removal of the lock and tag to ensure all persons have been safely positioned or removed and are clear of related circuits, parts and equipment.

iv. The supervisor who authorizes the removal of a lock and/or tag by someone other than the person that applied it must ensure that the person who originally applied the lock and/or tag is informed as soon as possible that the removal has taken place.

v. The supervisor who authorizes the removal of a lock and/or tag must document by checklist or equally effective means the steps taken when locks and/or tags are removed by someone other than the person who originally applied them.

d. **End of shift situation** – Due to a lack of, misconstrued or improper communication during situations when LOTO procedures need to extend

beyond a shift, accidents occur quite frequently. Hence, the hand-over process must be coordinated in such a way to ensure that no energy source is left unlocked or unsecured for any time period when shift changeover is taking place.

e. **Temporary return of equipment to service** – Whenever a piece of equipment is locked out during repair work and there is a need to temporarily return it to service, for instance when a part of it is to be tested, all the energy sources must be returned to service and not just the part desired. If however, further repair is still required, the equipment will be locked out completely, all over again!

Section F Policy Audit

The Lockout/Tagout policy of XYZ Medical Inc. shall be audited on an annual basis and each yearly audit shall reflect changes and updates that have been made to the policy over the last time it was reviewed.

Signed

Safety manager

Safety Director

Executive Director, XYZ Medical Inc.

Date Revised: (12/01/13)

Appendix 4.1.2: Definitions of Terms

Below is a list of terms that are used in this study and their definitions:

i. **Affected employee**: An employee who's required to operate, use, or be in the area where a machine or equipment could be locked or tagged out for service or maintenance.

ii. **Authorized employee:** An employee who locks or tags out a machine or equipment to do service or maintenance.

iii. **Can be locked out:** An energy-isolating device that can be locked in the "off" or "safe" position.

iv. **Employer:** An employer is any person, firm, corporation, partnership, business trust, legal representative, or other business entity which engages in any business, industry, profession, or activity in this state and employs one or more employees or who contracts with one or more persons.

v. **Energized:** Connected to an energy source or containing residual or stored energy.

vi. **Energy-isolating device:** A mechanical device that physically prevents transmitting or releasing energy. This includes, but is not limited to:

– Manually operated electrical circuit breakers

– Disconnect switches

– Line valves

– Blocks

– Similar devices used to block or isolate energy.

Push buttons, selector switches and other control circuit type devices are not energy isolating devices.

vii. **Energy source:** Any source of electrical, mechanical, hydraulic, pneumatic, chemical, thermal or other energy, including gravity

viii. **Hot tap:** A procedure which involves welding on pressurized pipelines, vessels, or tanks to install connections or accessories. It's commonly used to replace or add sections of pipeline used in air, gas, water, steam, and petrochemical distribution systems without interrupting service

ix. **Lockout:** Placing a lockout device on an energy-isolating device using an established procedure to make sure the machine or equipment can't be operated until the lockout device is R removed.

x. **Lockout device:** A device that uses a positive means, such as a key or combination lock, to hold an energy-isolating device in the "safe" or "off" position. This includes blank flanges and bolted slip blinds.

xi. **Normal production operations:** Using a machine or equipment for its intended production function

xii. **Primary authorized employee:** An authorized employee who has overall responsibility for meeting the requirements of the lockout/tagout procedures

xiii. **Service and maintenance:** Activities such as constructing, installing, setting-up, adjusting, inspecting, modifying, maintaining, and servicing machines or equipment. It also includes lubricating, cleaning, unjamming, and making tool changes.

ix. **Setting-up:** Work done to prepare a machine or equipment for normal production operations.

xiv. **Tagout:** Placing a tagout device on an energy-isolating device using an established procedure to indicate that the energy-isolating device and the machine or equipment being controlled may not be operated until the tagout device is removed.

ix. **Tagout device:** A prominent warning device, such as a tag and a means of attachment. It can be securely fastened to an energy-isolating device to indicate that the energy-isolating device and the machine or equipment being controlled may not be operated until the tagout device is removed

Appendix 4.2: List of Equipment Selected for the LOTO Program

Departments	Number of Equipment
Clean Room C	8
Catheter Dept I	5
Catheter Dept II	6
Leads Dept	7
Intro Dept	5
Micro Dept II	6
Micro Dept II	3
Total	40

Appendix 4.3: Key Point for Lockout/tagout (LOTO) Training Program

GENERAL RULES

* Procedures developed, documented and utilized for control of potentially hazardous energy.

* Employer has provided locks, tags, chains, wedges, key blocks adapter pins, self locking fasteners, or other hardware to isolating, securing or blocking machines or equipment.

* Lockout/Tagout devices singularly identified.

* Lockout/Tagout devices are used only for controlling energy.

* Lockout/Tagout devices are not used for other purposes.

* Durable lockout/tagout devices must be capable of withstanding the environment to which they are exposed for the maximum period of time that exposure is expected.

* Standardized lockout/tagout devices must be standardized with each facility in at least color, shape, or size.

* For tagout devices, also standardized print and format.

* Must be legible and understandable.

* Identifiable lockout/tagout devices must indicate the identify of the employee applying the devices.

* When major modifications are made to machinery electrical systems or when new machinery is installed, the energy source must be designed to accept a lockout device.

* Inspection conducted at least annually.

* Performed by authorized employee other than those utilized energy control procedure under inspection.

* Designed to correct any deviations or inadequacies observed.

* Include review of each authorized employee's responsibilities under the procedure(s). If tagout used, than include review of limitations of tags.

Appendix 4.4: Records of LOTO Trainings for Authorized Personnel

XYX Medical Inc	**Training Record**	
Document Number: 4.4000	Rev: A	Description: LOTO Training Records
Trainer Signature: [redacted]	Date: 12/01/2013	Trainer may indicate entire list of trainees are effectively trained by signing to the left. Trainer must also sign and date by the check box if a trainer is being designated. **A designated trainer must be authorized by an Engineer, Supervisor, or Lead.**
Trainer Associate Number: 106306		

Trainee Name	Trainee Signature	Trainee Initials	Trainee Associate Number	Date Trained	Authorization for Designated Trainee: (Trainer Sign & Date) Check box if TRAINER is authorizing Trainee to be a designated trainer for this revision
[redacted]	[redacted]	A.B.	100300	12/01/13	☐
[redacted]	[redacted]	K.L.	1003001	12/01/13	☐
[redacted]	[redacted]	H.H	1003002	12/01/13	☐
[redacted]	[redacted]	Y.D	1003003	12/01/13	☐
[redacted]	[redacted]	D.H.	1003004	12/01/13	☐
[redacted]	[redacted]	Y.K.	1003005	12/01/13	☐
[redacted]	[redacted]	L.A.	1003006	12/01/13	☐
[redacted]	[redacted]	B.S.	1003007	12/01/13	☐
[redacted]	[redacted]	L.J.	1003008	12/01/13	☐
[redacted]	[redacted]	C.D	1003009	12/01/13	☐
[redacted]	[redacted]	B.D.	1003010	12/01/13	☐

Roster ID: 4.4.1 Initials: O.O. Date Entered: 12/01/13

Appendix 4.5.1: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100300
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Micro I**

Observation of LOTO	Yes	No
9. Did the person review the Lockout/Tagout placard?	**X**	
10. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
11. Did the person notify affected employees in the area?	**X**	
12. Did the person shut down the equipment by normal means?	**X**	
13. Did the person identify, isolate and deactivate all energy sources?	**X**	
14. Did the person apply required lockout devices, locks and tags?	**X**	
15. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
16. Did the person verify isolation of zero energy?	**X**	
Observation of release of LOTO	Yes	No
6. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
7. Did the person notify affected employees in the area of impending equipment start up?	**X**	
8. Did the person remove locks, lockout devices and tags?	**X**	
9. Did the person return the system to fully functional?	**X**	
10. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.2: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100301
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Micro II**

Observation of LOTO	Yes	No
17. Did the person review the Lockout/Tagout placard?	**X**	
18. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
19. Did the person notify affected employees in the area?	**X**	
20. Did the person shut down the equipment by normal means?	**X**	
21. Did the person identify, isolate and deactivate all energy sources?	**X**	
22. Did the person apply required lockout devices, locks and tags?	**X**	
23. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
24. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
11. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
12. Did the person notify affected employees in the area of impending equipment start up?	**X**	
13. Did the person remove locks, lockout devices and tags?	**X**	
14. Did the person return the system to fully functional?	**X**	
15. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.3: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100302
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Leads**

Observation of LOTO	Yes	No
25. Did the person review the Lockout/Tagout placard?	**X**	
26. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
27. Did the person notify affected employees in the area?	**X**	
28. Did the person shut down the equipment by normal means?	**X**	
29. Did the person identify, isolate and deactivate all energy sources?	**X**	
30. Did the person apply required lockout devices, locks and tags?	**X**	
31. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
32. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
16. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
17. Did the person notify affected employees in the area of impending equipment start up?	**X**	
18. Did the person remove locks, lockout devices and tags?	**X**	
19. Did the person return the system to fully functional?	**X**	
20. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.4: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100303
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Catheters I**

Observation of LOTO	Yes	No
33. Did the person review the Lockout/Tagout placard?	**X**	
34. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
35. Did the person notify affected employees in the area?	**X**	
36. Did the person shut down the equipment by normal means?	**X**	
37. Did the person identify, isolate and deactivate all energy sources?	**X**	
38. Did the person apply required lockout devices, locks and tags?	**X**	
39. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
40. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
21. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
22. Did the person notify affected employees in the area of impending equipment start up?	**X**	
23. Did the person remove locks, lockout devices and tags?	**X**	
24. Did the person return the system to fully functional?	**X**	
25. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.5: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100304
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Catheters II**

Observation of LOTO	Yes	No
41. Did the person review the Lockout/Tagout placard?	**X**	
42. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
43. Did the person notify affected employees in the area?	**X**	
44. Did the person shut down the equipment by normal means?	**X**	
45. Did the person identify, isolate and deactivate all energy sources?	**X**	
46. Did the person apply required lockout devices, locks and tags?	**X**	
47. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
48. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
26. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
27. Did the person notify affected employees in the area of impending equipment start up?	**X**	
28. Did the person remove locks, lockout devices and tags?	**X**	
29. Did the person return the system to fully functional?	**X**	
30. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.6: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100305
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Intro**

Observation of LOTO	Yes	No
49. Did the person review the Lockout/Tagout placard?	**X**	
50. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
51. Did the person notify affected employees in the area?	**X**	
52. Did the person shut down the equipment by normal means?	**X**	
53. Did the person identify, isolate and deactivate all energy sources?	**X**	
54. Did the person apply required lockout devices, locks and tags?	**X**	
55. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
56. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
31. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
32. Did the person notify affected employees in the area of impending equipment start up?	**X**	
33. Did the person remove locks, lockout devices and tags?	**X**	
34. Did the person return the system to fully functional?	**X**	
35. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.7: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100306
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Clean Room C**

Observation of LOTO	Yes	No
57. Did the person review the Lockout/Tagout placard?	**X**	
58. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
59. Did the person notify affected employees in the area?	**X**	
60. Did the person shut down the equipment by normal means?	**X**	
61. Did the person identify, isolate and deactivate all energy sources?	**X**	
62. Did the person apply required lockout devices, locks and tags?	**X**	
63. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
64. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
36. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
37. Did the person notify affected employees in the area of impending equipment start up?	**X**	
38. Did the person remove locks, lockout devices and tags?	**X**	
39. Did the person return the system to fully functional?	**X**	
40. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.8: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100307
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Micro I**

Observation of LOTO	Yes	No
65. Did the person review the Lockout/Tagout placard?	**X**	
66. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
67. Did the person notify affected employees in the area?	**X**	
68. Did the person shut down the equipment by normal means?	**X**	
69. Did the person identify, isolate and deactivate all energy sources?	**X**	
70. Did the person apply required lockout devices, locks and tags?	**X**	
71. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
72. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
41. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
42. Did the person notify affected employees in the area of impending equipment start up?	**X**	
43. Did the person remove locks, lockout devices and tags?	**X**	
44. Did the person return the system to fully functional?	**X**	
45. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.5.9: Checklist for LOTO Hands-on Demonstration

XYZ Medical Inc	**Hands-On LOTO Observation Training Form**

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Hands-On LOTO Observation Training Form

Associates Name	[redacted]	**Date**	12-01-13
Associates Signature	[redacted]	**Associate ID Number**	100308
Equipment Name and Number	AB-200 Top Press Mold S/S: 02-6029	**Department**	**Catheters II**

Observation of LOTO	Yes	No
73. Did the person review the Lockout/Tagout placard?	**X**	
74. Did the person obtain all required locks, lockout devices and tags needed?	**X**	
75. Did the person notify affected employees in the area?	**X**	
76. Did the person shut down the equipment by normal means?	**X**	
77. Did the person identify, isolate and deactivate all energy sources?	**X**	
78. Did the person apply required lockout devices, locks and tags?	**X**	
79. Did the person dissipate, drain, or safely release any stored or residual energy?	**X**	
80. Did the person verify isolation of zero energy?	**X**	

Observation of release of LOTO	Yes	No
46. Did the person upon completion of work, inspect area for potential hazards. Ensure safety of equip/area (guards replaced)?	**X**	
47. Did the person notify affected employees in the area of impending equipment start up?	**X**	
48. Did the person remove locks, lockout devices and tags?	**X**	
49. Did the person return the system to fully functional?	**X**	
50. Did the person notify affected employees that equipment is operational?	**X**	
Associate passed Hands-On Observation Training	**X**	

Comments: Both in-class and hands-on LOTO trainings were successfully completed

Trainers Name	[redacted]	**Trainers ID umber 106306**	
Trainers Signature	[redacted]	**Trainers Title** EHS manager	

Appendix 4.6: Hazard Analysis & Risk Assessment for LOTO

Energy Source Determination for **AB-200 Top Mold Press**

DATE: **11-10-2013**

CONDUCTED BY: [redacted]

In order to determine all energy sources for each piece of equipment, all questions must be answered. Both actual and potential sources of energy need to be considered when responding to the questions. If the question does not apply, write N/A in the blank. Highlight "yes" or "no" or fill in the blank.

Location: **XYZ Medical Inc.** Work Center: **Leads Department**

Equipment No.: **S/N: 02-6025**

Equipment Name: **AB-200 Top Mold Press**

Lockout/Tagout Procedure # assigned: **XYZ/LOTO/001**

1. Does this equipment have:

a. Electric power (including battery)? YES / NO

If yes, Motor Control Center (MCC) or power panel and breaker number : **T/ID/001**

Does it have a lockout device? YES / NO

b. Mechanical power? YES / NO

Mark each type of energy source that applies:

1. Engine driven? YES / NO

If yes, switch or key location: _Switch

Is lockout device installed? YES / NO

If no, method of preventing operation: **Spare Mold Block is used to block the moving parts after electrical energy source is de-activated**

2. Spring loaded? YES / NO

If yes, is there a method of preventing spring activation? YES/NO

If no, how can spring tension be safely released or secured? _____

3. Counter weight(s)? YES / NO

If yes, does it have a method of preventing movement? YES/NO

If yes, can it be locked? YES/NO

If no, how can it be secured? _____

4. Flywheel? YES / NO

If yes, does it have a method of preventing movement? YES/NO

If no, how can it be secured?

c. Hydraulic power? YES / NO

If yes, where is the location of main control/shut off valve? _____

Can control/shut off valve be locked in "off" position? YES/NO

If no, where is the location of closest manual shutoff valve? _____

Does manual shutoff valve have lockout device? YES/NO

If no, what is needed to lock valve closed? _____

Is there a bleed or drain valve to reduce pressure to zero? YES/NO

If no, what will be required to bleed of pressure? _____

d. Pneumatic energy? YES / NO

If yes, where is the location of main control/shut off valve? **At a central supply connector near the ceiling**

Can control/shut off valve be locked in "off" position? YES / NO

If no, where is the location of closest manual shutoff valve? _____

Does manual shutoff valve have lockout device? YES / NO

If no, what is needed to lock valve closed? **Valve Lockout device**

Is there a bleed or drain valve to reduce pressure to zero? YES / NO

If no, what will be required to bleed off pressure? **The residual pressure is bled off when the pneumatic line is unhooked prior to application of pneumatic lock**.

e. Chemical system? YES / NO

If yes, where is the location of main control/shutoff valve? _____

Can control/shutoff valve be locked in off/closed position? YES / NO

If no, where is the location of closest manual shutoff valve?_____

Does manual shutoff valve have lockout device? YES / NO

If no, what is needed to lock valve closed? _**Pneumatic lockout device**

Is there a bleed or drain valve to safety reduce system pressure and drain system of chemicals? YES / NO

If no, how can system be drained and neutralized? **The residual pressure is bled off when the pneumatic line is unhooked prior to application of pneumatic lock**

What personal protective clothing or equipment is needed for this equipment? **Safety glasses, gown, head cover, gloves,**

f. Thermal energy? YES / NO

If yes, where is the location of main control/shutoff valve? **At the point of operation**

Can control/shutoff valve be locked in "off" or closed position? YES / NO

If no, where is the location of closest manual shutoff valve? _____

Does manual shutoff valve have lockout device? YES / NO

g. Gravitational Energy? YES / NO

If yes, where is the location of main control/shutoff device? _____

Is there a device to restrain or control the gravitational energy? YES/NO / NA

If no, what will be required to control or restrain the gravitational energy? _____

Can the device used to restrain or control the gravitational energy be locked in a position that will prevent the gravitational energy from being released? YES/NO / NA

h. Other Sources of Energy?

Are there any other actual or potential energy sources? YES / NO

If yes, where is the location of main control/shutoff valve? _____

i. Can control/shutoff valve be locked in an off or closed position? YES/NO

Is there a way to drain or bleed of pressure? YES/NO

If no, how can energy be controlled or neutralized? _____

Is personal protective clothing or equipment needed to protect employees from the energy source? YES / NO

If yes, what equipment is needed? **Safety glasses, gowns, gloves, heads covers**

If no, what is needed to lock valve closed? _____

Is there a bleed or drain valve to safely reduce system pressure and temperature and drain system? YES / NO

If yes, what is the location of the valve? **At the control point of the equipment**

If no, how can system pressure and temperature be reduced and drained?

What personal protective clothing or equipment is needed for this equipment? **Gowns**

Special precautions not noted in the preceding (i.e., fire hazards, chemical reactions, required cool down periods, etc.): **None**

Recommendations or Comments**: Ensure that all the energy sources are verified to have been de-activated and locked out prior to commencing any maintenance/repair procedure. And, prior to returning the equipment to service, verify that all control points are in the neutral position**.

Completed by: [redacted] Date: **11-10-13**

Reviewed by: [redacted] Date: **11-11-13**

Approved by: [redacted] Date: **11-20-13**

Appendix 4.8: Design of Lockout/Tagout (LOTO) Procedures

Specific Lockout Procedure

Equipment: **AB-200 Top Press Mold**

Lockout Procedure No.: **XYZ -LOTO - 001**

Date: December 1st, 2013

Approved by: [redacted]

Implemented: [redacted]

Specific Lockout Procedure

NOTE: Required for all equipment, machinery and/or processes that fails to meet the exceptions noted in 29 CFR 1910.147(c)(4)(i).

1. The purpose of these specific procedures is to protect our personnel from injury and death.

NOTE: Failure to comply with these procedures will result in disciplinary action and may result in employee discharge.

2. TYPE(S) AND MAGNITUDE(S) OF ENERGY AND HAZARDS:

- **a. Electrical / 230V**
- **b. Pneumatic / 120 psi**
- **c. Mechanical / 80 rpm**
- **d. Gravitational / 500 lbs**
- **e. Thermal / 500^{0}F**
- **f. Hydraulic / 120 psi**

3. NAME(S)/JOB TITLE(S) OF EMPLOYEES AUTHORIZED TO LOCKOUT/TAGOUT:

- **i. Ade, Bash / Maintenance Supervisor**
- **ii. Kurt, Loo / Maintenance Technician**

iii. **Hart, Hun / Production Engineer**

iv. **Yee, Dav / Senior EHS Technician**

v. **Dee, Hi / Plant Manager**

4. NAME(S)/JOB TITLE(S) OF AFFECTED EMPLOYEES AND HOW TO NOTIFY:

Prior to starting the Lockout procedure, all employees who are within the vicinity of the equipment to be locked out must be informed to steer clear of the perimeter of hazard (i.e. danger zone)

5. TYPE(S) AND LOCATION OF ENERGY ISOLATING MEANS:

a. **Electrical – 230V**

i. **Shut-down process: The switch is turned to the 'off' position.**

ii. **Lockout procedure: The electric cord is unplugged and cylindrical lock applied and tagged**

iii. **Verification process: Verification is done by attempting to re-energize the equipment by turning the switch to the 'on' position.**

b. **Mechanical – 80 rpm**

i. **Shut-down process – The mechanical energy is shut down by de-energizing the electrical energy source.**

ii. **Lockout procedure- The rolling part of the drill is 'locked out' when the electrical energy source is de-energized.**

iii. **Verification process: LOTO procedure verified by attempting to re-energize the electrical energy source.**

c. **Pneumatic – 120 psi**

i. **Shut down process – The hose of the pneumatic line is unhooked from the connector behind the unit.**

ii. **Lockout procedure – let out residual air and apply pneumatic lock**

iii. **Verification process – By ensuring that the gauge on the equipment reads zero.**

d. **Gravitational - 500 lbs**

i. **Shutdown process – The gravitation energy is shut down when the electrical source is de-energized**

ii. **Lockout procedure: With electrical energy source de-energized, apply block.**

iii. **Verification process – Ensure than the drill press cannot be activated when attempts are made to re-energize the electrical energy source.**

e. **Hydraulic – 120 psi**

i. **Shutdown – The valve handle of pressurized glycol is turned to the off position, using a three-way ball valve, while the residual pressure is released**

ii. **Lockout procedure – The valve is locked out with a valve handle lockout device.**

iii. **Verification – Ensure that the gauge on the equipment reads zero!**

f. **Thermal – 500^0F**

i. **Shut-down process – De-energizing the electrical energy source also shuts down the heat**

ii. Lockout procedure – The heat dissipates when the electrical energy is shut down.

iii. Verification – Wait for 30 minutes for heat to dissipate and ensure that the temperature gauge reads 50^0F or less.

6. RETURN EQUIPMENT TO SERVICE

After the maintenance or repair process, return the equipment to service by following these steps:

a. Replace all guards and covers

b. Remove tools and all non-essential equipment

c. Verify that all personnel and affected persons are clear and in a safe place

d. Verify that all controls and switches are in the 'off' or neutral position

e. Remove all locks and tags as appropriate

f. Re-energize equipment and follow safe start-up procedures

g. Notify affected persons that energy has been restored to equipment

h. Ensure that the equipment is functioning properly and safely

Posted on 01-Dec-13

Review by 30-Nov-14

Appendix 4.9: Annual Audit of LOTO Program

Date of Evaluation: **December 2nd, 2013**

Evaluation was made by: [redacted]**v / EHS Manager**

K. General policy has been reviewed**: YES** / NO

L. Is the LOTO policy current and up-to-date? **YES** / NO

M. General comments on LOTO policy:

The policy is standardized and adequate. It is current and in conformity with OSHA regulations as well as the corporate safety goals of the organization.

N. Are appropriate LOTO devices available in appreciable quantities? **YES** / NO

If NO, comment below:

O. List below the specific LOTO procedures that have been reviewed:

i. The scope of LOTO training broadened to include hands-on

ii. Hazard analysis and risk assessment on all equipment

iii. New LOTO procedures address all energy sources, as opposed to a few

iv. Energy control procedures were designed for residual energy sources

P. The following specific procedures were modified:

i. Control for pneumatic energy sources, including release of residual energy

ii. Control for hydraulic energy sources, including release of residual energy

iii. Phasing out of the use of Tagout devices

Q. The following specific procedures were added (list below): NA

R. List all LOTO-related accidents and injuries below.

i. A near-miss accident in the Leads department

ii. An incident that resulted in injuries to the middle and third fingers of the left hand of an employee.

S. What were the corrective measures taken to address the cases stated above?

i. Training exercise was conducted for affected employees

ii. Thorough accident investigation s were conducted to determine root causes

iii. Unsafe acts and conditions were corrected.

T. Is the list of personnel authorized to perform LOTO procedures current? **YES** / NO

If NO, indicate below:

Signed

Craig, Dav

EHS Manager