New Material and Personal Lifting for Material Management Building

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Abstract — A new elevator will be installed in the materials handling building of Lilly del Caribe. For it, a facility commissioning will be carried out, since where the stairs of the building are, it will be installed there. It will validate a protocol that has to comply with the regulations and specifications established by the industry and has 14 activities that must be completed. The existing elevator is only for material handling and can only exert a force capacity of 4,000 pounds. With the installation of the new freight elevator, the material can be handled and disposed of by the operator. Therefore, this elevator will improve the utilization and efficiency of such material handling. The new elevator can exert a force capacity of 10,000 pounds and being a new piece of equipment, it meets a 95% reliability. To execute the validation, DMAIC was used.

Key Terms — DMAIC, facility commissioning, regulations, validate.

RESEARCH DESCRIPTION

Acquire and install a new elevator for the material handling building. This new elevator must be able to transport material and personnel at the same time between the three floors of the building. On the first floor, the new elevator has access from both sides. Elevator access to the second floor will be through the Warehouse. On the third floor, access to the elevator will be through a preparation area that will be created by segregating the Mechanics Room. For this reason, a protocol will be created, which is a document where what will be validated will be specified. This is known as "Facility Commissioning" [1]. This project will be carried out in a regulated Industry, and it must comply with the established regulations, in addition

to the inspection by an OSHA (Occupational Safety and Health Agency) inspector that the elevator meets the specifications for its operation. A qualification is an action of testing documenting that properly installed utility and accessory systems are functional and establishes confidence that utility and ancillary systems are capable of consistently operating within established limits and tolerances. Qualification is part of the validation, but the individual qualification steps alone do not constitute a validation of the process. A written plan is included that identifies the system or process to be qualified or validated, indicating how the qualification or validation will be carried out, what parameters, expected results, and methods will be used to test the system or process. Documented evidence will demonstrate that the system or utility meets its intended design and performance. This evidence is worked into a document that we call in the industry a protocol. this document must follow Finally, good documentation practices.

PROBLEM STATEMENT

Currently, the existing material elevator is used to move material between floors in the material handling building. This equipment can only be operated from the first floor, requiring an operator to access the second and third floors via a building ladder to complete tasks in the area. Also, the computer has had multiple instances, in the near past, where it had stopped working while it was running; therefore, resulting in the implementation of a Business Continuity Plan (BCP) with administrative control measures as an alternative to continue activities in the building.

RESEARCH OBJECTIVES

- Identify what type of elevator will be implemented in the area, so that it meets the client's demands.
- Improve the efficiency of elevator operation.
- Obtain the related Equipment documentation and specifications such as Manuals (installation, operation, and maintenance), and Equipment Data Sheets (As-Built) (as applicable).

LITERATURE REVIEW

During the quarter from August to October 2022, a final project will be carried out where we will validate improvements to facilities in the material handling building of The Company Lilly del Caribe. It is in C. Marginal, Trujillo Bajo, Carolina 00987, Puerto Rico. It is an industry that provides opportunities at an international level. It is dedicated to the manufacture and distribution of medical products. Insulin is manufactured in Puerto Rico. The purpose of the project is the implementation of a Business Continuity Plan (BCP) with administrative control measures as an alternative to continuing activities in the building. Our goal is to carry out a Facility Commissioning protocol, where it will be evaluated that these facilities comply with the manufacturer's specifications and with the regulations established in this industry.

The administrative controls of the industry are to improve performance and feedback in the different processes that the same has. These controls are designed to be "Effective, adaptable, continuous and aligned with the established objectives" according to Binteli Consultores [2]. To make different effective improvements in the material handling area, it will be determined what type of elevator meets the needs of the operators in that area. This is our main objective.

To carry out the installation of the new elevator, the protocol must comply with various documentation (see Table 1).

Table 1 Protocol Activities

Activities	Reviewed (Yes/No)	Completed (Yes/No)	Pending Items
Mechanical Completion	No	No	2002000
EHS Commissioning release	No	No	
Any design modifications, prior FC test protocol execution	No	No	
Drawings Walk-down Verification	No	No	
Standard Operating Procedure Verification	No	No	
Engineering Documentation Verification	No	No	
Certificates and Reports Verification	No	No	
Features Verification	No	No	
Safety Devices Verification	No	No	
Doors Verification	No	No	
Doors Access Verification	No	No	
Automatic Doors Operating Verification	No	No	
DAIS Verification	No	No	
General Facility Verification	No	No	
Percentage completed		0/14	

These activities must be executed in the protocol. To start executing the same, construction must deliver the Mechanical Completion. This is a document that activities have been completed on your part, that the area is safe from fatality, and facility validation can begin. As soon as we get that document, we start executing the protocol. Each activity must comply with the specifications of the manufacturer and the area. If they do not comply and/or remain pending, discrepancies are generated that are documents explaining the situation and what was done to solve it. These are attached at the end of the protocol. After the Mechanical Completion, comes the EHS (Environmental, Health and Safety) release. Document where a representative from the Environmental Health and Safety area walks to determine that the Mechanical Completion meets industry standards regarding area safety.

It should be noted that to develop this project we must have A written plan is included that identifies the system or process to be qualified or validated, indicating how the qualification or validation will be carried out, what parameters, expected results, and methods will be used to test the system or process. For this reason, to meet the established dates, we will be working as follows (see Figure 1).



Figure 1 Communication/Escalation

Finally, despite the installation of a new freight elevator, this will help to improve the efficiency of the operators' work in the material handling building.

METHODOLOGY

During the project, the DMAIC methodology will be used, it has a five-phase method, Define, Measure, Analyze, Improve, and Control, according to its acronym in English. DMAIC is a simple yet powerful tool focusing on process improvement, helps explore possible solutions, and implements process controls.



Figure 2 Cycle DMAIC

In the first Define phase, the problem and the objectives will be described. The regulations established by OSHA will measure the second measure phase. The third analysis phase will be analyzing and executing the sections of the protocol based on this commissioning facility governed by Lilly del Caribe. The fourth phase improves, the improvement of efficiency in this installation and the increased capacity to carry out the tasks in the material handling building. The last control phase, as will be controlled through preventive

maintenance for the said installed elevator. In the part of the results, we will find these more detailed phases.

RESULTS AND DISCUSSION

Define

Problem Description:

Currently, the existing material elevator is used to move material between floors in the material handling building. This equipment can only be operated from the first floor, requiring an operator to access the second and third floors via a building ladder to complete tasks in the area. Also, the computer has had multiple instances, in the near past, where it had stopped working while it was running; therefore, resulting in the implementation of a Business Continuity Plan (BCP) with administrative control measures as an alternative to continue activities in the building.

Objectives:

- Identify what type of elevator will be implemented in the area, so that it meets the client's demands.
- 2. Improve the efficiency of elevator operation.
- Obtain the related Equipment documentation and specifications such as Manuals (installation, operation, and maintenance), and Equipment Data Sheets (As-Built) (as applicable).

Measure

Currently, there are stairs in the material handling building. We want to modify this facility and install a new elevator. We want this new elevator to comply with the stipulated OSHA regulations since it is a cargo elevator and will be used for material handling with personnel from the area. This installation must comply with our Schedule, which is approximately 6 months.

In the inspection sheet made by the OSHA Certifying Engineer, the elevator must be duly inspected and must comply with the established requirements (Refer to Figure 3):

- Safety Code for Elevators and Escalators ANSI/ASME A17.1-2000.
- ANSI/ASME AI 7.2-2001 Elevator and Escalator Inspection Code.
- American with Disabilities Act Accessibility Guidelines for Buildings and Facilities ADAGG.

However, in addition to complying with those regulations, they must comply with OSHA regulation 18, Regulations for Elevators and Related Equipment. This regulation "establishes policies and procedures to require employers that elevators and related equipment be manufactured, installed, operated, inspected and repaired, guaranteeing worker safety." For more information on what employers must comply with by the regulation, visit the page of OSHA of Puerto Rico [3].



Figure 3
Elevator Inspection Certification

In Figure 3, we can observe the inspection certificate of the installed elevator and that it meets the requirements established by OSHA.

Analyze

Before doing the installation, we must know that the facilities must comply with the design specifications of the Caribbean. When the installation is carried out, the "Facility Commissioning" protocol will be executed to meet customer expectations. The parts of the protocol in ascending order are the following:

- Mechanical completion: document where it establishes that the area has already been completed, does not present any risk, and can be validated.
- EHS Release: Document specifies that the area meets the security standards and regulations governed by Lilly del Caribe.
- Drawings Walk-down Verification: project plans, where you walk in the area verifying and validating which are correct. If the walking area is not like the plane, it is made into a redline. The plane is marked where it is on the way, and it is signed by validations and the owner of the area.
- Standard Operational Procedure
 Verification: Where it is verified that in effect
 the owner of the area included in the SOP the
 new area and the functions of the same. The
 date on which this procedure was updated is
 also included.
- Engineering Documentation Verification: In this part of the protocol is where the documentation of said installation is included, specifically submittals.
- Certificates and Reports Verification: Where the elevator certificate (Figure 3), electrical inspections, and security are included.
- Feature Verification: If the elevator floors contain the bumper finishes and lighting finishes, and the results found when they go to the area are executed.
- Safety devices verification: If the additional installed components, such as fire alarms, paging systems, and emergency lights, are duly identified (Figure 4).
- Door verification: Where the material, model dimensions, and type of installed doors that give the elevator and that are as specified in the plane are verified.
- Door Access Verification: The different access to the doors is verified, either by the

Pushbutton Press Emergency or the Access/Exit Interlock.

- Automatic Doors Verification: They are verified if the doors to the elevator, which apply the push button (green), card reader, and door sensor verification works (Figure 5).
- **Dais Verification:** For this protocol, it is not necessary since there are no emergency doors.
- General Facility Verification: It is that all parts of the protocol were completely completed.

After completing all these parts of the protocol, it is reviewed so that there are no GMP errors. Then, a report is made that specifies that the executions, quality control, and owner of the area review the protocol and sign the report.

Table 2 indicates the percentage of the completed activities of the protocol. As the protocol can be observed, it is completed correctly and there were no discrepancies that affect this ease in the material management building.

Table 2
Protocol Activities Completed

Protocol Activities Completed			
Activities	Reviewed (Yes/No)	Completed (Yes/No)	
Mechanical Completion	Yes	Yes	
EHS Commissioning release	Yes	Yes	
Any design modifications, prior FC test protocol execution	Yes	Yes	
Drawings Walk-down Verification	Yes	Yes	
Standard Operating Procedure Verification	Yes	Yes	
Engineering Documentation Verification	Yes	Yes	
Certificates and Reports Verification	Yes	Yes	
Features Verification	Yes	Yes	
Safety Devices Verification	Yes	Yes	
Doors Verification	Yes	Yes	
Doors Access Verification	Yes	Yes	
Automatic Doors Operating Verification	Yes	Yes	
DAIS Verification	N/A	N/A	
General Facility Verification	Yes	Yes	
Percentage completed		100%	

1. 1	The results comply and meet expec	ted results and Lilly di	el Canbe, Inc. sp	ecifications.	Page of
Description	Specification	Actual Results (Yes / No / N/A)	Procedure (FV/DV)	Acceptable? (Yes/No)	Performed By/Date
Emergency Exits	Properly Identified and Installed?				
Emergency Lights	Properly Identified and Installed?				
	Properly Operation?				
Fire System Alarms, Indicator, and Sensors	Properly Identified and Installed?				
	Properly Operation?				
Other Alarms	Properly Identified and Installed?				
	Properly Operation?				
Paging System	Properly Identified and Installed?				
	Properly Operation?				
Fire Extinguisher	Properly Identified and Installed?				
Pest Control (Glue Board)	Properly Identified and Installed?				
Note 1: Make a copy as Note 2: FV- Field Verifi Acceptance Criteria	cation and DV - Document Verification Met? (Yes/No):			Initials/Date:	

Figure 4
Safety Device Verification

Figure 4 is an example of what was being executed when they installed the load elevator in the material management building. Several visits to the Field were made to verify if these specifications meet the standards and specifications of Lilly del Caribe.

Step	Test Procedure	Expected Results	Actual Results	Acceptable? (Yes/No)	Performed By/Date		
	Door Opera	tion with Push Button Verification	(if applicable)				
1	Verify that the control box power button is on.	The control box is powered.					
2	Verify that curtain is close. Press the "open button".	The door curtain will open.					
3	Allow a time delay before the door closes.	The door will close.					
	Door Operation with Card Reader Verification (if applicable)						
1	Sweep access card, indoor card reader.	The door will open.					
2	Allow a time delay before the door closes.	After the time delay, the door will close.					
3	Sweep access card, indoor card reader.	The door will open.					
		Door Sensor Verification					
1	Block the thru-beam between the emitter and photo-eye before the time delay is a challenge.	The door is open until the blockade is removed.					
2	Remove blocking device & allow for a time delay.	The door closes after the time delay.					

Figure 5
Automatic Doors Operating Verification

In this section of the protocol, it was executed only for the doors that apply, as specified in Figure 5. Also in this execution, from the access to the elevator doors, it must comply with the standards of Lilly del Caribe.

Improve

To meet the improvements in the material management building, the protocol could be installed and executed in accordance with the established standards. For this reason, that helps improve the efficiency in the part of what to make of the operator and in the part of the Business continuity plan. Here we have the administrative controls of the area to be more efficient when the material management process.

It should be noted that our problem was solved given that the existing elevator could only exercise a load capacity of 4,000 pounds. This elevator only

met 80% reliability in the process since it fulfilled its useful life. Install a new elevator in the area, it can exert a capacity force of 10,000 pounds. Therefore, there is more space to handle more material in a matter of time, speed, and money in the management of material in the building. Being a new team, it meets a 95% reliability for improvements in that process. Finally, when making this installation of greater capacity and reliability we have an additional 15% available time for our process.

Control

This process of controlling our equipment with new ease can be controlled through preventive maintenance. The preventive maintenance of this equipment must be carried out each quarter. Whenever preventive maintenance is on the team, it must have a Lock-Out Tag-Out card.

Unexpected energies released by machinery or equipment can be dangerous for any worker, they can cause serious injuries or death. Energy sources can be electric, pneumatic, thermal, mechanical, hydraulic, potential, chemical, or any other type of energy source. The OSHA standard for hazardous energy control (lock/labeling) (29 CFR 1910.147) establishes that adequate blockage/labeling practices and procedures must be executed (lotus) to protect workers from dangerous energy release [4] (Figure 6).

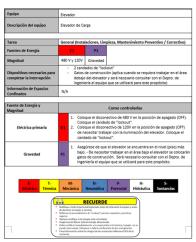


Figure 6 LOTO

Figure 6 shows the card that is placed when the elevator is given preventive maintenance. This card, known as LOTO, is the one used to carry out maintenance.

CONCLUSION

It was identified which type of elevator was going to be installed in the Materials Handling building, which was a freight elevator with an increased capacity of 10,000 pounds. As mentioned in our methodology, the issue was resolved as the previous lift could only exert a 4,000-pound capacity force and no person could be mounted. The old elevator only met 80% reliability in the process part, it met its useful life. By installing and validating a new lift in the area, it can exert a force capacity of 10,000 pounds. For this reason, there is more space to handle a larger amount of material in a matter of time, speed, and money in handling material in the building. Being new equipment, it meets reliability of 95% for improvements in said process. Therefore, by making such a higher capacity and more reliable installation, we have an additional 15% of the time available for our process. In the validation of said installation, different types of tables and required documentation were included and executed. Finally, this validation complied with the standards, regulations, and specifications governed by Lilly del Caribe.

REFERENCES

- Lilly. "Eli Lilly and Company." Lilly.com [Online] Available: https://www.lilly.com/ (Accessed Mar. 29, 2022)
- [2] Binteli Consultores. "El control administrativo como gestora del cambio y crecimiento de la empresa." Binteli.mx. [Online] Available: https://binteli.mx/elcontrol-administrativo-como-gestora-del-cambio-ycrecimiento-de-la-empresa2/#:~:text=El%20control% 20administrativo%20es%20parte,se%20estableci%C3%B3 %20en%20la%20planeaci%C3%B3n. (Accessed on Apr. 11, 2022).

- [3] PR Department of Labor. PROSHA.gov [Online] Available: https://trabajo.pr.gov/prosha/det_content.asp? cn_id=30#:~:text=Todo%20patrono%20que%20vaya%20a%20instalar%20u%20operar,pago%20correspondiente%2 C%20establecidos%20en%20el%20Reglamento%2018.%2 02. (Accessed May 9, 2022).
- [4] Occupational Safety and Health Administration. "The control of hazardous energy (lockout/tagout) 1910.147" Osha.gov. [Online] Available: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9804&p_table=S TANDARDS (Accessed May 9, 2022).