

Machine Safety on GRAM Cryos

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Abstract — *The purpose of this project was the improvement of two GRAM Cryo tumblers which are new equipment that required complete installation qualification (IQ) validations, prior to delivering them to the manufacturing and process areas. These tumblers needed machine safety improvements to comply with the observations indicated in an audit conducted in 2018. All the observations stated on the audit were analyzed and actions were determined to comply with each item pointed out. A validation plan (VP) was created prior to the technical improvements performed by the technical contractor. Wiring labeling, addition of safety relay, emergency stop, reset button, indicator lights and new sensor in compliance with Performance Level d (PLd) were installed in the equipment. IQ protocol was updated and executed with no issues.*

Key Terms — *Installation Qualification (IQ), Machine Safety Improvements, Performance Level d (PLd), Wiring Labeling*

INTRODUCTION

Johnson & Johnson (J&J) Vision in Añasco, Puerto Rico is a company specialized in the manufacturing of intraocular lenses. The site emphasizes the creation of cataract treatment devices. Some of the most recognizable products manufactured are TECNIS Eyhance IOL and TECNIS Synergy IOL.

On 2022 the manufacturing equipment was assessed for J&J machine safety conditions as part of the 2018 Worldwide Responsible Accredited Production (WRAP) audit assessments conducted on site. As a result of this audit, it was found that over 300 pieces of equipment were not meeting the machine safety standards established by the company. Therefore, machine safety observations identified in these WRAP assessments must be

closed as part of the global machine safety risk reduction of 90%.

The focus of this project was two GRAM Cryo tumblers which were new equipment that required complete installation qualification (IQ) validations, to deliver them to the manufacturing and process areas. These GRAM Cryo tumblers needed some machine safety upgrades to comply with the observations indicated in the audit.

Based on this, the following objectives were established:

- Reduce the level of risk to low classification.
- Complete 22 actions on GRAM Cryos during 2023.
- Minimize machine safety related incidents.

LITERATURE REVIEW

Machine safety was created to guarantee the health and safety of people exposed to the equipment by neutralizing, eliminating, or lowering all the risks involved in the operation, process or maintenance of the equipment. “The goal of machine safety is to guarantee the health and safety of people exposed to the installation, operation, adjustment and maintenance of machinery” [1]. This helps manufacturers receive certifications such as Conformance Europeene (CE) and Underwriter Laboratories (UL). “Helps manufacturers to self-certify their machine for the EU market” [2].

In machine safety, when creating a safety circuit, to achieve the redundancy stated in all the components involved it is necessary to achieve certain performance level (PL). Performance levels, as shown in Table 1, are values used to define the capacity of safety related parts on the control systems related with safety to create a safety function under predictable conditions. “The safety performance level is an important element for ensuring that a machine is safe to use and is

therefore key to its functional safety” [3]. On the other hand, the required performance level (PLr) purpose is to achieve the required risk reduction for each safety function. Therefore, there is a relationship between the performance level (PL) of safety related parts on a control system, supposed to be equal or higher than the required performance level (PLr).

ISO 13849-1 is a safety standard that provides guidance for the design and evaluation of control systems with a safety function integrated with the purpose of risk reduction. “ISO 13849-1 specifies a detailed iterative process for determining and validating the Performance Level (PL)” [3]. The calculation of the performance level is not particularly easy. A range of calculation tools are therefore available, which help engineers to evaluate the safety controls.

Table 1
Performance Level (PL) and Probability of Dangerous Failure per Hour (PDFH)

Performance Level	Probability of Dangerous Failure per Hour (PDFH)
a	$\geq 10^{-5}$ to $< 10^{-4}$
b	$\geq 3 \times 10^{-6}$ to $< 10^{-5}$
c	$\geq 10^{-6}$ to $< 3 \times 10^{-6}$
d	$\geq 10^{-7}$ to $< 10^{-6}$
e	$\geq 10^{-8}$ to $< 10^{-7}$

Wiring labeling importance is due to facilitating the troubleshooting and the safety of the technicians when performing a preventive maintenance. Since “many of the wiring is electrical, which means that it can be very dangerous if not handled correctly” [4]. Wires not labeled, may cause people working to accidentally cut or unplug the wrong ones, which can be very hazardous or result in a injury or death.

METHODOLOGY

All the observations stated on the audit WRAP assessments of the equipment were examined and analyzed with the technical contractor with the purpose of discussing and determining the improvements that will be done to comply with

each item pointed out. As part of this evaluation, all the components needed for implementing the safety improvements were bought. Also, meetings were held with the project’s supervisor and the machine safety electronic technician with the purpose of establishing a strategy to perform the improvements in the simplest way, preventing the incursion into a computer system validation (CSV) which would have taken more time.

A validation plan (VP) draft was submitted and validation review board (VRB) meeting was held with each department representative. Minutes with the changes needed were sent to the VRB participants and all the requested changes were done. Requested signings from all the participants of the VRB meeting, with the purpose of confirming the changes stated in the minutes were approved and signed by each department representative. Then, the technical contractor realized the wiring diagrams and started the wiring labeling process of the first GRAM Cryo. Heat treatment labels were selected since they are more durable and were easy to install on the equipment. As shown in Figure 1, all the wiring was label using the correct color code. Once the safety relay and sensor arrived, some tests were run to make sure how there were supposed to be wired so the safety circuit complied with the performance level indicated in the audit. Following with the installation of the safety relay, new cabinet sensor, emergency stop and indicator lights.

At the same time all the technical improvements were executed, Installation Qualification (IQ), A-IQR-0016 was updated and submitted to change control procedure. Along with the URS, RTM and VP final documents. Once approved, Installation Qualification (IQ) was executed on the first of two GRAM Cryos and at parallel to this IQ protocol execution the machine safety improvements were held to the second GRAM Cryo. After finishing the machine safety improvement on the second GRAM Cro the Installation Qualification (IQ) was executed with no deviations and issues. Finally, after both IQ’s were approved by the department representative

and change control analysts the equipment were released for production and manufacturing process.

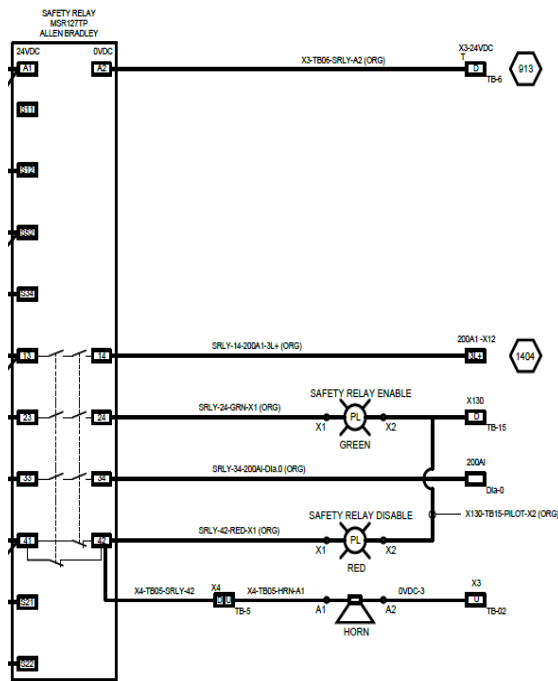


Figure 1
Safety Relay Wiring Configuration

CONCLUSIONS

The project was a success since the three objectives established at the beginning of the project were accomplished. The two GRAM Cryo tumblers which were new equipment and required complete IQ validations to deliver them to the manufacturing and process areas were finished on schedule. All 22 actions on the GRAM Cryo were claimed in the machine safety program and it is expected that, with this improvement, safety incidents will be reduced.

The major findings of this project were the identification of performance levels; the addition of wiring labeling, Emergency Stop and Reset Button; and the creation of electrical wiring diagrams will help in the reduction of safety incidents and when performing troubleshooting. This project will have to be replicated in the next stages on the remaining 20 GRAM Cryo tumblers that are still in need of machine safety improvements.

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