PROACTIVE AND REACTIVE INTERVENTIONS TO IMPROVE SAFE MAINTENANCE (AWARDED CASE IN THE EUROPEAN CAMPAIGN ON SAFE MAINTENANCE 2010/2011)

1. Case metadata

- ***Country/ies of origin:***

Malta

- ***Year of publication by agency:***

2011

- ***Sector:***

C21.20 - Manufacture of basic pharmaceutical products and pharmaceutical preparations (NACE II)

- ***Keywords:***

24401C Case studies,	24361C Good practice,	21401C Maintenance
39921C Manual handling,	21321C Equipment,	40321C Electrical hazards
19641D Risk assessment,	20641D Worker participation	
20201D Safety policies and procedures		
47321C Work accidents,	38201D Pharmaceuticals,	57521C Chemical plants

2. Organisations involved

Actavis Ltd, based in Bulebel Industrial Estate, is a manufacturing operation specialised in the development and production of generic pharmaceuticals. The company claims its success on its strong human resource element. Actavis employs ca. 600 employees, distributed throughout various manufacturing departments as well as supporting services such as quality, planning, purchasing, transportation, human resources, validation, development, engineering, finance, IT & environmental health & safety.

3. Description of the case

3.1. Introduction

Actavis Ltd. views maintenance as a very critical operation within the company's processes. A sound and effective maintenance programme is fundamental to the business operation to maintain equipment and plant running. At Actavis, an active preventive maintenance programme is in place covering all the major plant and production equipment. This preventive maintenance program is designed not only to ensure that all equipment continues to operate in an efficient manner, in the interest of production, but also serves to check that all safety features in the equipment are operational and working effectively, in the interest of safety. Over and above this, the company also

applies corrective maintenance to address those situations where a machine breakdown or fault may give rise to production or safety concerns.

The performance of maintenance jobs falls under the responsibility of a group of technical personnel based in Engineering and Production. As is customary for maintenance jobs, the hazards to which these employees are exposed are different to the hazards to which an employee operating a machine is exposed. In most cases, the hazards are greater and may pose a higher risk. It is for this reason that the Actavis approach towards risk assessments separates risk assessments for operating and maintaining equipment. As part of the ongoing risk assessment programme, Actavis has risk assessments of preventive maintenance jobs in order to ensure that the hazards to which maintenance personnel are exposed are adequately controlled and any required corrective actions to improve the safety of the job are taken.

Risk assessments for the maintenance jobs are carried out by the employees performing the maintenance directly once they have followed a training course on the risk assessment process. At Actavis, management and workers strongly believe that the best people to come up with solutions to render an operation safer are the employees performing that job directly. It is for this reason that employees are actively consulted throughout the risk assessment process such that a common and agreed solution can be found.

Some of these solutions are directly related to safe maintenance. The following examples will be presented in more detail:

- Interventions on a Capsule Filling Machine to improve safe operation - corrective maintenance
- Improvements arising from the risk assessment of the preventive maintenance of a coating machine
- Improvements arising from the risk assessment of the preventive maintenance of a house vacuum machine

3.2. Aims

- Improve the safe operation of a Capsule Filling Machine while operating in inching mode. Operation of the machine in inching mode disables the safety functions which are effective under normal production mode.
- Proactive maintenance through risk assessment on the preventive maintenance of a coating machine
- Proactive maintenance through risk assessment on the preventive maintenance of the house vacuum system

3.3. What was done, and how?

Task 1: Improving the safe operation of a Capsule Filling Machine while operating in inching mode. Operation of the machine in inching mode disables the safety functions which are effective under normal production mode.

The equipment in this case is a high performance capsule filling machine designed for the automatic filling of powders and pellets into capsules. This equipment forms part of the production process within Actavis Ltd.

During the routine assembly of the machine for production, an operator was operating the machine in inching mode to check the alignment of the tamping pin guide with the cover plate. Since the machine was being operated in inching mode, some safety functions, such as door contacts, are rendered non-functional. This allows the operator to access the internal area where there are moving parts in order to be able to check the set up of the machine.

During the assembly process, an accident occurred whereby the operator's left hand thumb was squeezed between the tamping pin guide and the cover plate.

Fig.1

Thumb was trapped between the cover plate and the tamping pin guide

Investigation into this accident highlighted the following problems in the machine features:

• Accessibility of the operator to moving parts when the machine is in inching mode (i.e. moving stepwise at a slow pace). The inching mode could be operated with only one hand allowing the person to use the other hand to intervene on the machine.

• The area where the person had his thumb trapped was not properly guarded.

The solution:

Following a thorough investigation into the root cause of this accident, the following solutions were implemented. These were direct interventions performed by our maintenance personnel in order to render the operation of the capsule filling machine in inching mode safer for both production and maintenance personnel.

• Installation of a guard to cover the areas where there are moving parts such as the tamping pin guide and cover plate.

Fig. 2 New guards were installed to cover the area where moving parts were accessible

Installation of a second inching button such that operation of the machine in inching mode can only be done using both hands at the panel. This effectively removed the risk that an operator uses one hand to inch the machine while checking the machine with the other.

Left: original button used to switch to inching mode		Right: second button introduced in panel requiring dual hand operation in inching mode

Fig.3 – Detail of improvements made

Following discussions with the Malta Standards Authority (MSA) regarding the legal responsibilities of the proposed changes, the case was reviewed with the manufacturer. Drawings of the proposed improvements to the machine were sent to the manufacturer. Although, as was pointed out by the MSA, the legal responsibilities for the proposed changes would remain with Actavis, the manufacturer feedback was positive and stated that “Actavis did a good job regarding the additional safety of the operators on the machine”. This feedback was again discussed with the MSA who advised that the manufacturer’s position on the case was acceptable.

Effectiveness of results:

This case demonstrates an example of corrective maintenance following an unfortunate incident. Once the solutions shown above were implemented, the effectiveness of the results could be demonstrated in the following ways, some measurable and others not.

- From a Production point of view, the implemented solutions did not slow down the production process in any manner
- No more accidents occurred when operating the machine in inching mode
- Operator morale improved as, despite the accident, with the implemented measures, operators feel safer when working on this machine
- Interventions made on the machine were such that risk of an accident was effectively minimized.

Case 2: Preventive Maintenance of the Coating Machine used within the Actavis Tableting area is a scheduled monthly operation. The preventive maintenance job involves both interventions on the coating machine within the production area as well as maintenance jobs on the external technical areas such as ductwork, exhaust systems, dust collectors etc. As part of the

ongoing Risk Assessment system, an assessment was performed to determine the risks associated with this preventive maintenance job and what corrective actions could be taken to address it.

From the assessment performed, the following were the main safety concerns arising during the performance of this maintenance job:

- Accessibility in the technical area – part of the activity involves the collection of pharmaceutical process waste from the dust collectors of the equipment. The area where this is done did not have proper access for the maintenance personnel
- Manual handling – handling of the pharmaceutical process waste was raised as a concern due to the weights involved
- Electrical hazards – when performing this preventive maintenance activity, there is the potential for exposure to an electrical hazard.

The above concerns were raised in the relevant risk assessment – RA/EN2008/013. This triggered an active discussion and review with the respective Manager in order to determine how these risks could be minimized. Once the corrective actions to be taken were agreed, these action points were entered into the EHS database for follow up to ensure that the action points could be effectively closed off.

The Solution:

The following corrective actions were implemented for the above mentioned risks:

- Improved accessibility to the external technical areas: Access to the external technical area was originally through a window, which, following the Risk Assessment, was converted into a door. Moreover, accessibility to perform the jobs required on the dust collector was improved through the provision of a working platform.

Fig.4 Access to external technical area was originally through a window which was converted to a door for easier and safer access

Fig.5 Installation of a working platform around the Dust Collector improved accessibility and rendered the preventive maintenance job safer

Manual Handling concern: As part of the monthly preventive maintenance activity, pharmaceutical process waste is removed from the dust collector to be prepared for proper disposal. This involves the collection of pharmaceutical dust in disposal bags and their transportation to a waste storage area. Considering the relative difficulty to access the area and the need to transport this waste over a relatively long distance to the storage area, manual handling concerns were raised in the risk assessment. The main difficulty was in the carrying of these process waste bags from near the dust collector up across the roof and then down to the waste storage area. In order to address this concern, a lifting device has been installed in the proximity of the dust collector such that the bags could be hoisted using this winch device. Moreover, Actavis Ltd. has rolled out a Manual handling training program for all employees, including maintenance technicians. This training program covers the correct techniques for the handling of loads and also includes exercises to help protect the back and minimize injury.

Fig.6 Hoist device located on roof area to assist technicians in transporting the pharmaceutical process waste bags

Electrical hazards: Any preventive maintenance activity commonly involves the intervention by a technician on equipment operated with electricity. This has its inherent hazards. One of the most critical risks identified during the risk assessment of most preventive maintenance jobs was the risk of an operator or another employee operating a machine while a preventive maintenance job was being done on the same equipment. In view of this, Actavis has placed a lot of effort into the introduction of safe systems of work for such situations. One key improvement in this respect is the implementation of an Engineering Lock off procedure. This lock off procedure (ES – 43) describes the system being used to safely isolate all sources of energy/ power to equipment to safeguard one's own health and safety and that of other persons. As a result of this procedure, Safe Isolation Instructions (SIIs) are being issued for all equipment, describing the locks and procedures to be used prior to starting any preventive/corrective maintenance work on a piece of equipment. This was also implemented for the maintenance of the coater machine where the isolator of the machine is locked off by the maintenance technician before preventive maintenance work is commenced.

Fig.7 Lock off device used to isolate equipment prior to a maintenance activity

Effectiveness of results:

The risk assessment for this preventive maintenance activity helped Actavis identify the risks inherent to the job and the corrective actions to be taken. Once the corrective actions were effectively implemented, the main result was that the preventive maintenance job could be done in a safer manner with a lower incidence of accidents and improved staff morale.

Case 3: One of the preventive maintenance activities conducted is on the 4 house vacuum systems which collect pharmaceutical dust from the production areas for eventual disposal as hazardous waste. These are located on System 1, System 6, System 7 and System K4. These systems have an energy source of 400V 3phase electricity and Compressed Air Supply of 5 Bar. Stored kinetic energy is from the rotation of the motor fan and compressed air in line between the isolating valve and the machine.
The preventive maintenance job includes:

- Visual checks for leakages on the outside of the unit and on filter housing and cartridges.
- Checking and replacing the plastic sack in the container or moving container.
- Checking for any excessive vibration and temperature, measuring filter drop and cleaning cycle.
- Replacement of filters
- Checking control cabinet and cleaning the chamber and carrying an insulation resistance test.

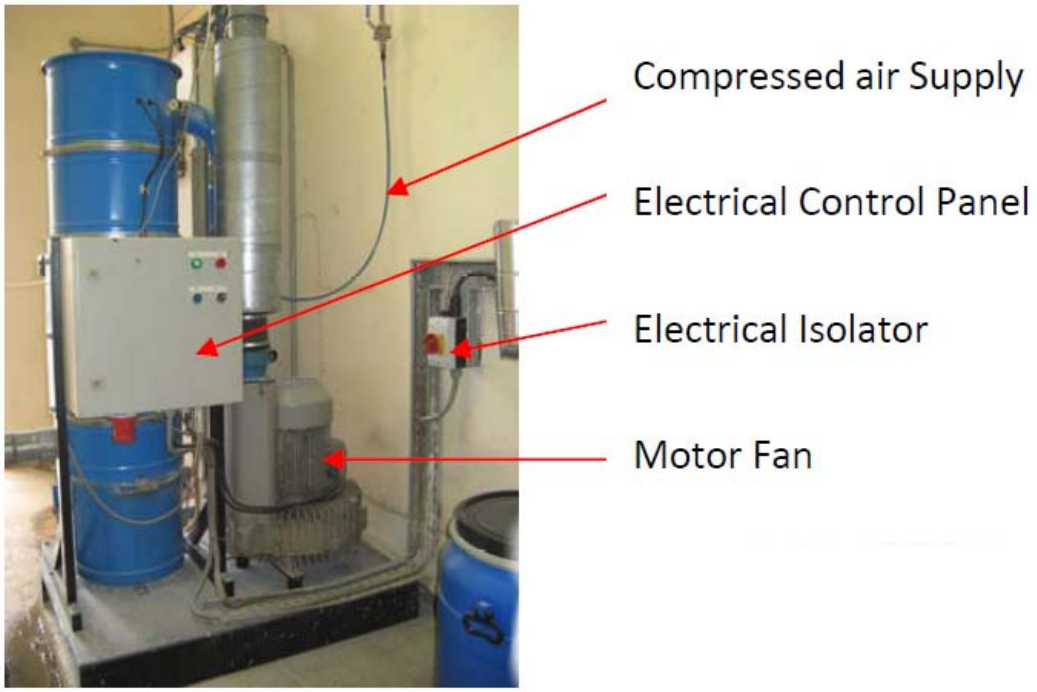

Fig.8 General view of a House Vacuum System

PROBLEM

Due to the nature of this system, the main hazards highlighted from a risk assessment of the preventive maintenance activity were the following:

- Presence of pharmaceutical dust which is created during operation of the house vacuum.
- Electrical and compressed air hazards.
- When handling and replacing large sacks situated on these systems, manual handling issues are present.
- During visual inspection of the cleaning cycle, noise levels are exceeding 80 dB(A).

SOLUTION

Several corrective actions were implemented. The main points to address the above concerns were the following:

- Safe isolation instructions to lock electrical and compressed air supplies. This is complemented with the TOLOT (ES-43) procedure system.
- Instructions were issued such that when replacing heavy sacks, the activity is always a two men job.
- Change in procedure such that the visual checking of the cleaning cycle is performed for only a few minutes to minimise impact of noise exposure. Moreover, during the replacement of the large sacks, the system being maintained is turned off, so that no noise or pharmaceutical powder is being pumped out.
- Training on TOLOT, manual handling and noise issues. The Tag Out Lock Out training provided the technicians involved with insight on the importance of isolating energies to avoid harm to technicians involved. Manual Handling Training provides technicians with an understanding of the correct handling techniques and the consequences of improper handling. Noise information sessions provided information on harm resulting from high noise levels if no corrective measures are implemented.

- • Enforce the use of proper PPE such as eye and ear protection.

Fig. 9 Electrical Isolator
Locked off and tagged

Fig.10 Manual Compressed Air Valve
Locked off and tagged

EFFECTIVENESS OF RESULTS
On finalising the maintenance scheduled, the technicians involved are ensuring that all panels and guards that were removed for maintenance are all re-fitted correctly and that all parts are tightened properly. System is ensuring that none of the co-workers are doing any other works on the equipment and that no tools are left inside the equipment. Engineer is informed that all works are done and the Lock Out Tag Out devices can be removed accordingly. All valves are left in their normal operation position. This provides for the system to be working correctly.
These improvements allowed for a safer preventive maintenance system by the technicians involved, eliminating or reducing hazards. No incidence of improper manual handling and other possible injuries have occurred or symptoms of sickness from exposure to dust have been reported. All the measures taken have provided a better work environment for the technicians involved.

3.4. What was achieved?

The implemented solutions for the different hazards/risks associated with the identified activities spanned the hierarchy of control measures generally associated with the Risk Assessment process. These included:

- Elimination of Hazard
- Engineering Controls
- New Equipment /re-design of area
- Training

The effectiveness of the results arising from the implemented solutions vary in nature and range from an actual removal of the hazard to effective improvements in process efficiency as operators are working in a better environment which is less conducive to accidents and ill health.

The performance of a SAFE maintenance job has become an important feature of our safety culture and employees are appreciative of the fact that due care is being taken to ensure that all jobs are done safely.

Interventions made on the equipment were such that risk of an accident was effectively minimized.

In 2011 Actavis stated: “In the case of the capsule filling machine, we have not had any more related accidents on this machine since the actions implemented have virtually eliminated the risk of a similar accident happening. There has also been correspondence with the equipment manufacturers about the modifications implemented to the machine and even though they stopped short of including the modifications in the design of the machine, the feedback obtained was positive and they commented that ‘Actavis did a good job regarding the additional safety of the operators on the machine’.”

3.5. Success factors

The most important success that has been achieved through these improvements is the fact that employees are fully aware that a maintenance job has to be done in a safe manner. This has led to a proactive approach as new jobs and new equipment are immediately reviewed to ensure that maintenance and operation can be done safely, triggering an all important safety culture change.

Employees’ morale improved as, with the implemented measures, they feel safer when working on these machines.

The national jury for the Good Practice Award in Germany commended the case, stating: “Good consultation with workers and their representatives. Modifications on equipment carried out in consultation with manufacturer and standards authority.”

3.6. Further information

Contact:

Ms Daniela Cauchi

Actavis Ltd

BLB16 Bulebel Industrial Estate Zejtun ZTN 3000

Telephone Number: 00356 2367 9102

Email Address: dcauchi@actavis.com.mt

3.7. Transferability

The solutions can be applied with fairly little effort also in similar companies.

4. References, resources: