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Controlling OSHA's Replacement In Kind

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Controlling OSHA's Replacement In Kind

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OSHA, the NRC and the FDA all use the terms "essentially identical","functional equivalence" and "replacement in kind" when talking about repairs to covered facility systems:

"**OSHA1910.119(l)**
Management of change.
1910.119(l)(1)
The employer shall establish and implement written procedures to manage changes (except for "replacements in kind") to process chemicals, technology, equipment, and procedures; and, changes to facilities that affect a covered process."

These phrases and processes were put in place to allow industry to complete repairs in some circumstances without the sometimes onerous paperwork involved in work in FDA, NRC and OSHA regulated facilities. These repairs generally were intended to include replacement of worn out components with similar components thus not affecting previous safety studies or requiring new safety studies. The presented material is applicable to parts of NRC, FDA and OSHA controlled facilities; where they apply depends on the system and facility production units.

The idea was to save time and money by allowing facilities to replace a burned out motor with an essentially identical motor in a fashion similar to changing a burned our light bulb. No big safety study was required and Management of Change processes were significantly simplified.

As frequently happens the process got out of control.

BACKGROUND

Before we look at the definition let's look at some effects of misinterpreting the phrases.

In the pharmaceutical industry each system has a History File which documents all activities about the equipment and has sufficient details to rebuild the system. So for a piece of equipment with a mounted electric motor there is sufficient detail about the motor to buy a replacement. If you review these files on motors you frequently find the following information about the motor in its History File:

Horsepower	Type (Open, etc.)	RPM	Model Number
Torque	Temperature Rise	Manufacturer	Frame
Insulation Type	Voltage	Full Load Amps	Serial Number

In the pharmaceutical industry replacement of this motor, unless done with the FDA's "replacement in kind", requires a revalidation of the system or at least the completion of a deviation report coupled with a variety of approval signatures. The revalidation involves significant testing, time and expense; the deviation report requires multiple signatures of plant management personnel. Until one or the other of these two items is signed off as complete production using this motor may not proceed.

This gives us a small view of the degree of complexity we can run into with what in a non-regulated industry would be simply a note in the maintenance files for the equipment.

MISTAKES IN UNDERSTANDING THE DEFINITION

A criticalerror which causes costs to go up and time to make the repair increase is misinterpreting the intent of any of these three phrases: "essentially identical", "functional equivalence"and "replacement in kind". Normally this misinterpretation ends up as "exactly the same." Perhaps this error comes from a fear of making an error but more than likely people believe the replacement must be identical because that makes sense to them.

EXAMPLE

Acme Chemicals has an Empire10Hp pump motor with the following characteristics: nominal speed 1800 rpm, classification TEFC (Totally Enclosed Fan Cooled), NEMA frame 215T, model abc1234 (not an actual model) and serial number S/N123456 (not an actual number), voltage 440/3/60.
So if their mechanic misinterprets the requirement of "essentially identical" to mean "exactly the same" he will spend time looking for an item exactly matching Column 3in the following table.

Characteristic	Original	Misinterpreted Replacement	Actual Required In Kind Replacement	Actual Process Required Replacement
1	2	3	4	5
Manufacturer	Empire	Empire		
Horsepower	10	10	10	
Nominal rpm	1800	1800	1800	1800
Classification	TEFC	TEFC	TEFC	
NEMA Frame	215T	215T	215T	
Model	abc1234	abc1234		
S/N	123456			
Voltage	440/3/60	440/3/60	440/3/60	

Notice under the Misinterpreted Replacement,Column 3,the mechanic correctly left out the serial number as a critical item to duplicate.

Under the Required In Kind Replacement, Column 4, I have left out three of the original characteristics: Manufacturer, Model Number and Serial Number. I can do this because the actual effect of the motor is to turn something in the process (in our example a pump) at 1800 rpm. The process will not be adversely affected if any of the left out motor characteristicsare changed from the original.

In the final column (#5) (Actual Process Required Replacement) only rpm (speed) is considered as important. This brings the pump back to a state of "functional equivalence."

In other words the pump was designed and sized operating at 1800 rpm and by turning it at that speed we're back to the original design.At this speed the pump produces the desired effect on the process by creating a fluid flow of a specific gallons per minute and pressure. How we achieve the 1800 rpm's is immaterial in most instances.

There are several methods of turning our pump at the correct rpm's as follows:

Electric motor
Air motor
Hydraulic motor
Direct coupled
Belt driven
Variable Frequency Drive

With sufficient verbiage the engineer could prove scientifically that using any of the above produced the desired effect, flow rate and pressure, on the process connected to the pump and thus satisfy "functional equivalence." Generally speaking unless there is overwhelming need some of these approaches would be questionable even if functional.

The important thing to remember here is that to satisfy the original design, flow and pressure, we only have to turn the pump at 1800 rpm's. It is not necessary to meet any other equipment characteristics such as power consumption or noise levels nor do we need to produce the same heat release from the motor or motor temperature rise since these generally do not have an effect on the process. This gives us satisfaction to the phrase "functional equivalence."

It is theoretically possible to meet the process requirements of flow and pressure by replacing the original pump with a pump with a slightly larger diameter impeller but turning at a lower speed.

Scientific proof of equivalence by the engineer is possible and should in addition to flow and pressure include shear effects on the fluid (if any) and any other significant physical effects that might change with impeller diameter or rpm's such as fluid temperature rise across the pump. The engineer needs to remember that his proof may have to satisfy some regulatory inspector.

Looking at the pump we see that there are several effects related to this equipment:

- Internal effects in the pump
  - Fluid pressure rise
  - Fluid kinetic energy level rise (flow)
  - Fluid temperature
  - Fluid shear
  - Fluid internal pressure (compressible flow)
- Downstream effects
  - Flow down the pipe and into other equipment
  - Pipe turbulence
  - Shear in the pipe

Determination of all of these effects may be required in the scientific proof.

DEFINITION

Perhaps the most appropriate phrase of the three above is "functional equivalence." The idea of the change is that the replacement component brings the effect of this portion of the system back to the original design.

APPLICATION

The engineer's charge is to determine what is critical and what is not important in selecting the replacement component. Sometimes to properly complete the paperwork the engineer must provide "scientific"proof that whatever change is made does not adversely affect the process. We'll look at the motor above one more time with this concept in mind.

	Characteristic	Original	Critical?	EXPLANATION
	1	2	3	
1	Manufacturer	Empire	NO	A GE motor of the same NEMA frame and Hp will mount exactly where the original Empire motor was
2	Horsepower	10	YES	This is only critical if the motor is

				operating at or near full load.
3	Nominal rpm	1800	YES	This is the key motor characteristic for most equipment and our pump flow and pressure capability were selected based on these rpm's
4	Classification	TEFC	NO	If there are no safety concerns an Open motor with the proper NEMA frame number will fit and work
5	NEMA Frame	215T	NO	Although some mounting modifications might be required a change in frame doesn't affect the process if the replacement motor is properly mounted and turns at the proper speed
6	Model	abc1234	NO	Manufacturers frequently change model numbers to cover minor internal changes which do not affect rpm or the process, for example better encapsulation resins
7	S/N	123456	NO	Normally every motor from one manufacturer has a unique S/N (serial number) so this cannot be duplicated anyway
8	Voltage	440/3/60	NO	Does not affect the process only requiring a transformer or other voltage change, some motors are dual voltage and may only require rewiring to use the new motor
9	Insulation Grade	"B"	NO	Effects local environment only because of a change of heat release
10	Temperature Rise	140°F	NO	Effects surface temperature of the motor and may introduce a safety hazard if it is too high
11	Full Load Amps	X	NO	Depends on voltage used
12	Torque	Y ft-#'s	NO	Controlled by Hp and rpm
13	Power Factor	Z	NO	Affects electrical cost to operate the motor but not the process

TEFC means Totally Enclosed Fan Cooled while Open means Open Drip Proof (ODP) and both refer to how the motor is self cooled.

APPLICATIONS

We'll look at various types of equipment and determine which characteristics should be classified as critical to accomplish an "in kind" replacement. Remember the goal here is to understand which equipment characteristics affect the process and only those characteristics which affect the process.

Equipment	Characteristic	Critical	Comments
Motor	rpm	YES	
	Hp	NO	Assuming the motor is of sufficient Hp
	Frame	NO	Some changes in frame size may require some mounting point changes
	Voltage	NO	May require rewiring
Centrifugal pump	RPM	YES	
	Impeller diameter	YES	
	Power coupling type	NO	Most coupling types will work if sufficient in size for the horsepower
	Casing drain plug	NO	Since this is just a plugged hole in the casing it has no effect on the process
Squirrel cage fan	RPM	YES	
	Impeller diameter	YES	
	Motor type (TEFC, etc.)	NO	As long as there are no safety problems any class motor will work
Liquid Filter	Filter pore size	YES	
	Housing pressure rating	NO	The rating of the housing doesn't affect the pore size of the filter media
	Mounting bracket	NO	No effect on filtering capability
Pressure Relief Valve	Orifice size	YES	
	Flanged or threaded connections	NO	Just a physical mounting arrangement with no effect on relief capacity
	Manufacturer	NO	As long as the orifice is properly sized using the manufacturer's data any valve can be sufficient
Flow control valve	Valve CV	YES	Indicates flow rate
	Flanged or threaded connections	NO	Just a physical mounting arrangement with no effect on relief

			capacity
	Manufacturer	NO	As long as the valve is properly sized using the manufacturer's data any properly sized valve is sufficient
Silicon "O" ring gasket	Ring diameter	YES	
	Cross sectional shape	YES	
	Manufacturer	NO	As long as the material and dimensions match the manufacturer is not critical
Replacement condenser tube	Diameters (ID / OD)	YES	
	Length	YES	
	Material of construction	YES	
	Manufacturer	NO	As long as the material and dimensions match the manufacturer is not critical
Replacement Vessel Agitator	Blade Diameter	YES	
	Number and angle of blades	YES	
	RPM	YES	
	Shaft length	YES	
	Motor / gear box type	NO	As long as output rpm's are correct, some gear boxes will have longer lives than others
	Shaft seal	NO	Choice is dependent on the material in the vessel
	Manufacturer	NO	As long as the material and dimensions match the manufacturer is not critical
Cooling Tower	Manufacturer	NO	As long as the tonnage is correct this is not important
	Tonnage	YES	
	Number of cells	NO	Assuming tonnage is correct

When the time comes to replace a piece of equipment whether or not the process is covered by a regulatory body the engineer should analyze the equipment based solely on its effects on the

process and from this analysis select the appropriate component based on cost, delivery and expected life span.

REFERENCES

"**OSHA1910.119(l)**Management of change.

CONCLUSION

Incorrectly interpreting the phrases “essentially identical”, “functional equivalence” and “replacement in kind” can cause the costs for repairs to increase as well as drag out the delivery time for the required components.

Properly thought out selection of parts to arrive at “functional equivalence” can save money and time. Preparation of scientific proof for the files is simple following an analysis of the work to be done.An understanding of the individual; characteristics of equipment which actually affect the process is valuable in future design and safety analyses.

Developing the habit of selecting equipment using the “effect on the process” analysis approach means the engineer generally selects new equipment or replacement components in the most economical manner.