

## A Learning Approach to Equipment Setup

by Perry Parendo, president, Perry's Solutions

Companies desire capital equipment for several reasons: to create a competitive advantage by processing product faster; to use local manufacturing instead of experiencing increasing costs in China and other negative impacts; or to automate, utilizing leading-edge equipment to use lesser skilled workers and avoid skills gap. Regardless of the reason, companies are increasingly prioritizing the acquisition of new equipment in the manufacturing industry.

This new equipment acquisition trend comes with a big challenge. With a workforce that is smaller, busier and less experienced in setting up this new equipment, it is difficult to immediately obtain the return on investment (ROI) expected. What is being missed?

### Standard new equipment setup

“Informal” would be a good description of the typical approach for initializing equipment setup. It may include running a few scrap parts through the machine to check it out. We use these scrap parts mainly because we have those parts available for free. The test may include processing a raw material that is easily available or inexpensive. Maybe it is just checking a few of the settings to ensure nothing visibly bad happens. Each of these is a test of convenience.

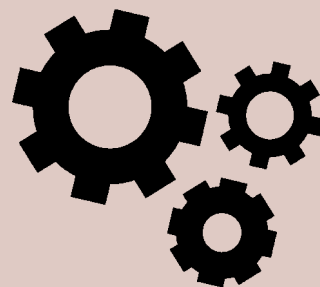
Without a thought-out plan, it is not possible to allocate time to the setup activity, making it easy for already limited resources to be pulled away to handle other emergencies. These emergencies often are caused by other equipment that was not evaluated appropriately upfront!

Eventually, the new equipment is pushed onto the production floor due to capacity needs, regardless of its readiness. Yet, when employees struggle to make it perform as needed, a crisis develops as they scramble to handle the new defective material created by the equipment that was supposed to solve some of those production problems. It is difficult to obtain additional raw materials to remake new batches of parts. Because of the pressure to perform, it is not a situation where we can reasonably expect to gain deeper understanding about the new equipment process. Instead, the organization is living in survival mode.

This standard focus is “checking it out” to confirm that it works right. Instead, we should take a learning approach. Can we better understand how the new equipment works first, with limited pressure?

### Typical New Equipment Setup

1. Buy machine.



2. Plug it in, and start to work.



3. Hope for the best.



### Preferred new equipment process

The process for evaluating and setting up a new piece of equipment should be the same approach used for any new design. Create a clear and detailed specification for the equipment first. It needs to be less about features and sensors, but instead about capabilities and functions. In fact, it should define the range of capabilities. Maybe you want the machine to run fast, but there could be times you need to slow it down. Is the equipment supplier expecting this varying capability?



Additionally, a test plan (subject to change as learning occurs) should exist up front to evaluate the key performance aspects. This can serve two major purposes. First, an estimate of time and materials to evaluate the new machine is possible. Second, it can clarify the requirements being requested. Is it acceptable for the vendor to perform this test? Do portions need to be repeated in-house to confirm that electrical and air quality difference do not impact process performance? Or to ensure training is adequate? Answering these questions can help the equipment definition and the equipment supplier. Considering conformance to the specification (Installation Qualification, for example, in the medical device industry) is a good starting point, but certainly does not mean the equipment is acceptable for use. Agreement on a plan at the time of purchase helps ensure the resources required will be available.

What else should the test plan include? Assume you are processing a range of raw material sizes. The sizes range from a 2x2 extrusion up to a 4x6 extrusion. In this case, both extremes should be confirmed. It also should include the raw material types that frequently are used or expected to be used. A rarely used material, which also can be processed on other equipment, may not need to be part of the test plan, but the high-volume materials need to be checked. If a range of pressures or flow rates are planned, then those should be evaluated with the parts associated with those process parameters.

How should we think about the test plan? When we are confirming understanding for simple, well-understood items, we can use simple comparative tests. However, when our focus needs to be on deeper learning, there is no better tool than using Design of Experiments (DOE). It is a structured approach to evaluate multiple input variables and understand impacts on multiple output specifications. Using this approach allows an optimal solution to be discovered and implemented.

Any new settings or sensors should be checked out in detail for functionality. Does it work as expected? Does it perform as needed? Is it helping the process, or is it excessive and cumbersome? Does another solution need to be created and implemented? The impact of different sizes or amounts of pellets in the hopper needs to be understood. Considering this range of functionality will complete the test plan scope to ensure we get what we need – not just what we asked for.

#### **Example 1: Bag sealer for final product**

Many components are packaged by a bag sealer. This can protect the component from contamination and can provide a given quantity of smaller components for inclusion with an assembly. This can be fairly standard and somewhat simple equipment. However, a company was experiencing rapid growth of a new product and needed new, fully automated sealing equipment quickly and confidently. As a medical device company, the expectations of acceptance for FDA approval are high. The company obtained its intended new sealing equipment prior to

purchase as a demonstration unit. If acceptable, then a purchase order would be generated and executed.

The project began in the traditional way with informal evaluation of standard materials at nominal settings. While it appeared to be working fine, the company wanted to ensure it could obtain an acceptable process capability right away. After working with the company to set up a DOE test, the company executed the test plan and gathered the requested data. Knowing the current process capability provided an expected and minimal level of performance, so we were able to determine the process capability would not be acceptable in certain regions of the required performance window. This would not be acceptable during production.

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This feedback was provided to the equipment vendor. While they voiced some initial questions, they finally acknowledged a software controls programming issue existed on the machine! It was unclear if this was a common issue or just on this specific piece of equipment. The equipment was reprogrammed and the DOE executed again. This time, the process capability was within the acceptable range, and the equipment purchase was completed.

The software issue was fixed by the vendor at no cost and in a very timely manner – partially because the vendor would not get paid until it was resolved. Production did not need to scream for the equipment! It was ready – and working properly – in plenty of time for the capacity increase and floor layout changes. It was a seamless transition into manufacturing and met the processing needs on day one.

#### **Example 2: Gasket injection molding**

An injection molded product was to be produced by a contract manufacturing organization. To achieve the cost and profit targets, the company desired to minimize flash on the product to eliminate secondary operations. Flash is the excessive material in the seams where the mold fits together. It was decided to use a DOE approach to evaluate molding parameters to achieve this goal.

During the execution of the test, no process window existed to fill the part, even though original settings were defined by mold flow analysis. Flash suddenly was a secondary priority

for this project. Another DOE was run to expand the process window being examined so the complete part could be filled. After no process solution was found again, another approach was needed. The team quickly generated a tooling change to allow the part to be fully formed in the cavity.

The followup DOE with the new tool produced acceptable results for the part dimensions and for flash. It was typical for these tool makers to avoid changes and extend process evaluation up to four months before they would consider expensive tool changes. In this case, the total evaluation and solution implementation was less than one month. This saved the company and the customer three months for delivery of the first quality parts!

Eventually, the customer admitted two other organizations had failed to deliver these same parts to them. Those orders were canceled, and our contract manufacturing company had the opportunity to deliver. By using the DOE approach, the company was able to not only provide parts for this order, but also gain trust and confidence from the customer for future orders. The company was recognized as a highly capable supplier.

#### Learning summary

Several benefits exist to this learning approach to new equipment setup. Vendor communications are much improved. Decisions across department and company boundaries can be made quickly (with multiple companies involved). Future unexpected work related to fixing a nonfunctioning machine will be avoided. These issues create overtime, schedule delays and low morale. These and many more advantages have been experienced when using the learning and DOE approach for equipment performance acceptance. It can save months and many headaches, while also achieving production objectives for ramp-up and scale-up of operations. The cost benefit for a typical project is \$400,000 to \$600,000, simply by using a learning approach. ■

*Perry's Solutions is a consulting company offering new product design, program management and training services, specializing in using Design of Experiments software to improve products and solve problems for medical device companies and other manufacturers. Perry Parendo, president, can be reached via phone at 651.230.3861 or through his website, [www.perryssolutions.com](http://www.perryssolutions.com).*



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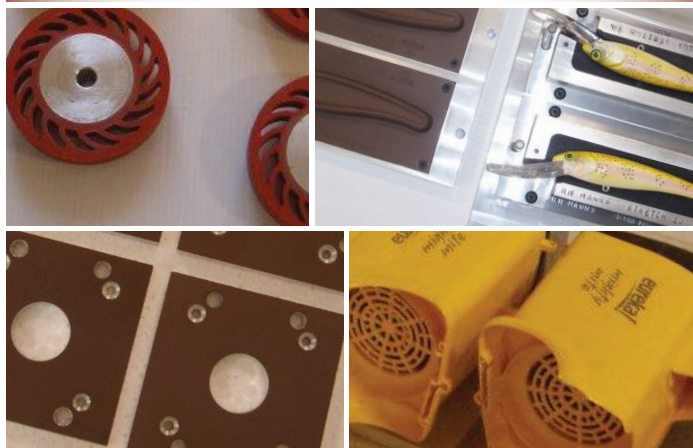
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