



Equipment calibration

ARRELIC INSIGHTS

INTRODUCTION



Calibration is a comparison between measurements – one of known magnitude or correctness made or set with one device and another measurement made in as similar a way as possible with a second device.

In daily usage, consistent differentiation between the terms calibration and adjustment is frequently neglected.

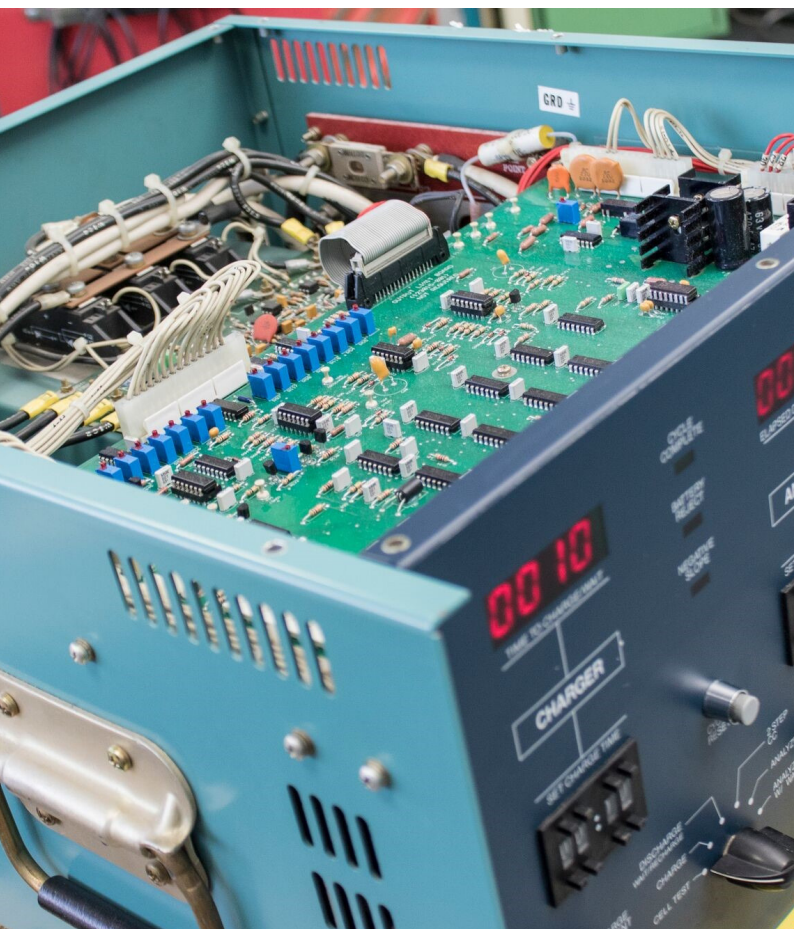
Calibration involves ascertaining and documenting deviation of the measured value from a retraceable, highly accurate test standard. The measured value obtained from a measuring instrument is thus compared with the known value of the test standard under specified reference conditions using reproducible measuring procedures. Calibration does not involve any manipulation of the measuring instrument, which remains entirely unchanged.

Validation

Validation, calibration maintenance, so the village to address this is, as you can see from an outline perspective. I want to begin with validation now, as we cover all these topics, specifically validation. Let me kind of offer an apology so to speak, which is to say that you've probably seen online and in-person webinars and seminars that deal exclusively with the validation process and these seminars and webinars can last up to multiple days.

you have a piece of equipment, it's out of calibration. What you do, then, we'll talk about so in a few minutes, speaking about calibration or May, which, which one do you use, and when do you use it, then we'll cover up with equipment maintenance.

When you talk about equipment, validation, it's used for automated equipment, you can't really we're talking about equipment, validation here and not design validation for equipment validation. That's used for a piece of automated equipment that you're going to try to verify you're going to try to make sure that this piece of equipment makes the product that works. There are three phases of this validation of this.





Establishment

- The first phase is installation qualification and we'll talk about each of these in a little bit of detail, operation, qualification and performance. Is it installed? Does it operate in to what extent, and can you repeatedly make product off of it? The question when it comes to installation qualification - it's really nothing more than is this piece of equipment, this sealing machine or packaging machine or sonic welder? Is this piece of equipment installed correctly and what you're going to have to do to determine this is you're going to have to ask yourself some questions, you're going to have to establish some parameters specifically, what are the design features of this piece of equipment? Then you have to look at installation conditions.

Well, this piece of equipment is more than likely going to be used in a controlled environment or even more so a cleanroom. If, in these cases, you need to make sure that this piece of equipment can be used in such a controlled environment or cleanroom, if you have, from an installation conditions, perspective a piece of equipment that gives that exhaust, you can't use that in your environment, your environmental Excuse me, conditions with regard to cleanroom render this piece of equipment unable to be used in that location.



OSHA (Occupational Safety and health administration)

The Occupational Safety and Health Administration (OSHA) is an agency of the United States Department of Labor. Congress established the agency under the Occupational Safety and Health Act, which President Richard M. Nixon signed into law on December 29, 1970. OSHA's mission is to "assure safe and healthy working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance"

.The agency is also charged with enforcing a variety of whistleblower statutes and regulations. OSHA is currently headed by Acting Assistant Secretary of Labor Loren Sweatt. OSHA's workplace safety inspections have been shown to reduce injury rates and injury costs without adverse effects to employment, sales, credit ratings, or firm survival.



Installation, Operational, performance qualification

- Let similarly you've got to know the highest possible temperature that will not result in a burnt seal, so you have to look at the process, control limits and what many firms do is they take? The advantage during the so queue to not just look at the absolute clips but to bring it in some percent to have action levels, so they can proactively determine well, I'm going to see these temperatures and I'm going to determine that that, even though my high, When I temperature limit is, let's say, 170 degrees, I'm going to set my action limit at 160 degrees. So I know that I've got to take action when it sink when it goes above 160 degrees because the when it hits 170 I'm out of my validation requirements, and then I have to preventively Pro excuse me. Reactively fix my piece of equipment.

The process for the OQ is obviously to know the pass/fail criteria for the product or process. Well talk a little more about the sealing machine, but on the low end, the pass/fail criteria for a sealed pouch. Is that it's not sealed. You get below a certain temperature, for example, and that pouch is not sealed. The high end of the capsule. Our criteria is that the pouch can't be burnt or have an otherwise less than perfect physical appearance, the cosmetic appearance

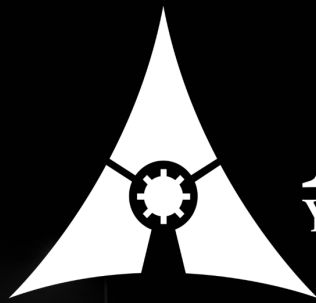


What Should be taken into considerations?

- You've got to make sure when you perform your OQ to take all of those process parameters into account because you're going to manipulate each of those to develop your cliffs, your high-end low cliffs. You want to manipulate each parameter, as I mentioned pressure temperature and dwell time with regard to a sealing machine that is, and all processors all parameters simultaneously.

Your goal during the OQ is to determine the nominal setting of each parameter, which is to say I have this particular pouch again using the sealing machine. I find I've given this webinar and actually in personal seminars quite a few times, and sometimes I speak about a little more complex pieces of equipment that have many more parameters for example, sonic welding





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