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Laser and Resistance Welding - Process Validation Fundamentals-2

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Process Validation Definition

"Process Validation" is the act of confirming by objective evidence that the product produced by the laser or resistance welding system meets its intended use. The terms "verification" and "validation" are often used interchangeably, but have very different meanings. "Verification" ensures that the product was made right. "Validation" ensures that the right product was made[1].

Why Validate?

There are four major reasons for validating the welding process:

One, the Food and Drug Administration (FDA) *requires* that all medical device manufacturing processes and equipment be validated as part a company's Quality System (QS). Many automotive component suppliers are facing the same quality mandate from their customers.

Two, for Six-Sigma manufacturers, there is *no* laser or resistance weld monitor or checker on the market today that can separate bad welds from good welds to a 100% confidence level. The only known means of determining weld quality without destroying 100% of the finished product is to validate the welding process.

Three, validation is a good marketing tool. Manufacturers capable of proving their weld quality level to their customers have a substantial advantage over their competition.

Four, the improvement to process yield through the reduction of product scrap far outweighs the cost of validating a welding process.

Welding Validation Components

Each manufacturer must establish a written validation protocol before starting the validation process. Validation protocols differ between industry sectors such as the medical device and automotive industries, but have the same basic components. Validation protocols also differ between manufacturers within the same industry sector. Figure-1 shows the five main components that comprise a medical device validation. Figure-2 contains the automotive equivalents for the same steps.

Figure 1 - Medical Device Validation Steps

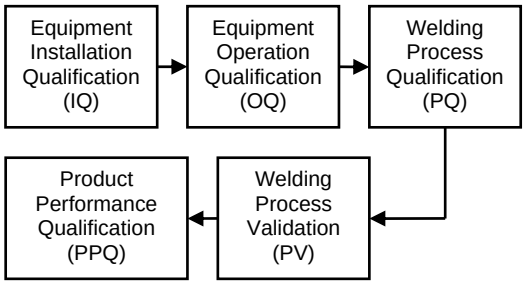

Figure 2 - Medical Device versus Automotive

Medical		Automotive	
Installation Qualification	IQ	Equip Set Up	-
Operation Qualification	OQ	Equip Dry Run	-
Process Qualification	PQ	DoE, Optimization Confirmation	MQ1.0 MQ1.5 MQ2.0
Process Validation	PV	Confirmation	R-R
Performance Qualification	PPQ	Environmental Tests	P-PAP

Installation Qualification (IQ)

IQ involves setting up the equipment and verifying equipment calibration. Perform calibration checks at the beginning and end of the validation process. Perform the IQ after moving or relocating equipment.

Make all calibration measurements using calibrated test equipment that is traceable to a known standard and has a resolution that is twice the smallest resolution of the measured parameter. Verify the measurements over the intended operating range.

Use a standard power load when measuring the resistance welding power supply output. Measure weld head static and dynamic forces using a load cell. If dynamic weld force data is gathered using a sampling technique, then the sampling rate must be twice as fast as the smallest power supply weld time increment. For example, a minimum weld time of 1-ms requires two weld force data samples during the 1-ms weld period. Thus the sampling rate is 2-KHz. Measure laser beam energy and power at the output focusing head using a laser power meter.

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Operating Qualification (OQ)
OQ establishes manufacturing procedures for equipment control, operation, and monitoring. Incorporate calibration, cleaning, and maintenance schedules, and planning for potential repairs. Determine the number of operators, write training procedures, and document the training. Identify important equipment elements that can affect the weld. Finally, verify that the entire welding system produces the programmed weld energy on a repeatable basis. IMPORTANT – Performing the OQ does NOT qualify or validate the welding process. Perform the OQ after moving or relocating equipment. In the automotive industry, the OQ may involve operating an automatic welding station without weld energy or parts for a 24-hour "dry run".

Process Qualification (PQ)
PQ involves establishing the weld quality metrics, performing Design-of-Experiments (DoE's), optimizing the welding parameters, and conducting a series of confirmation runs.

Weld Quality Metrics - One or more weld quality metrics, such as weld deformation, tensile, or peel strength usually comprise the weld quality specifications. Unfortunately, most of these weld quality metrics are arbitrarily predetermined with no relationship to how the final product is used. Using invalid weld metrics can cause field failures, low process capability (Cpk), and high production costs.

DoE – Conduct a Taguchi DoE to find out which welding parameters affect the weld quality metrics. The Taguchi DoE method quickly identifies the most important welding parameters with minimal parts.

Optimization - The Taguchi DoE model can't identify welding parameter interactions and may not produce the best optimized DoE results. Use a full-factorial DoE model to reveal welding parameters interactions and to optimize the weld quality metrics.

Confirmation Runs – Establish the capability of the welding system by making real parts at your automation vendor's facility before transferring the welding process to own manufacturing facility. Gather non-destructive weld monitor data over the entire confirmation run using a statistically significant sampling plan because resistance welding electrodes wear and oxidize and particles can cover the laser output lens over the defined lot run. These changes can negatively affect the weld quality metrics in terms of low Cpk and PPM capability.

Process Validation (PV)
PV establishes that the welding process consistently produces a part or product meeting its predetermined specification. **PV** involves correlating the non-destructive weld monitor measurements obtained during **PQ** with destructive weld quality metrics.

Weld Quality Correlation – Non-destructive resistance weld monitor metrics include weld current, voltage, force, and weld deformation. Laser metrics include measuring the radiation from the weld pool at different wavelengths. Measurements may be peak, average, or time integrated. Destructive weld quality metrics typically include tensile, peel, bending, and kinking. IMPORTANT – Prove a correlation between the non-destructive metrics and destructive metrics that is statistically significant before implementing process limits.

Product Performance Qualification (PPQ)
PPQ establishes with documented evidence that the finished product meets all requirements for functionality and safety. **PPQ** incorporates a series of environmental tests used to simulate the operating environment of the finished product. **PPQ** environmental tests include, but are not limited to: temperature, vibration, humidity, impact, and shipping. Assuming that no weld failures occur, the welding process used to make the product is considered to be validated. Should weld failures occur, the basic product design for weldability, the welding process, or the weld quality metrics are potentially faulty.

Conclusion
Validation is no longer limited to the realm of medical product manufacturing. Six-sigma oriented manufacturers are quickly discovering the economic benefits of establishing and maintaining validation over their resistance and laser welding processes.

References:
[1]FDA, CDRH, 21CFR-820.3(z)(1)

Acknowledgements:
Todd Hagerman, Senior Application Engineer, Miyachi Unitek Corp., Monrovia, CA