

# Standard Questions

*A manufacturing engineer with a medical device company has questions on the best specification for her company's shot peening process, how to prepare drawing prints for a shot peening job shop, and how to verify the shot peening process.*

**AN EDITORIAL CONSULTANT** with SAE Aerospace Material Specifications (AMS) recently forwarded me an email from a Senior Manufacturing Engineer (let's call her SME). Even though she works for a medical device manufacturer, SME's questions and concerns are relevant to other companies, especially those that outsource shot peening and/or have recently received the responsibility for the shot peening program in their company. Here is SME's email:

*SME: We have a part that's currently in production that calls out shot peening per AMS-S-13165. This part came from a mergers and acquisition project that the previous company created. I researched the standard and found on the SAE website that the latest version of AMS-S-13165A has been cancelled. So is this standard still applicable? Which version is applicable? Or is there another more relevant standard that we should use?*

*We are a medical device maker. The shot peening process is outsourced. Our shot peening vendor tells us that we need to call out their process number, which does not give the details of the process parameters. What is a typical shot peening call out/drawing spec?*

*We will also need to verify the output of the shot peening. The Almen strip provides a good indication as to the process and setup. To help verify the effect of the process on the part, we will need another verification method. Is X-Ray diffraction the typical applicable test? Is there a limitation to the size of the part? Our typical part is .200" in diameter and between 6" to 12" long.*

*Thank you in advance for your response!*

I advised SME that most organizations migrate to AMS 2430 from AMS-S-13165 (canceled) while some continue to use the canceled spec (not common, but some do). I then forwarded the email to Scott Hatfield, a Senior Manufacturing Engineer with Medtronic. Scott is an expert in shot peening validation for medical device manufacturers.

*Scott Hatfield: Sounds like you are in a common situation that plagues many companies in the post-merger environment. I will add some additional details to the good*

*advice Jack has already provided to hopefully help you navigate your way through this transition.*

*First, as Jack instructed, historically most organizations will migrate to AMS 2430 from AMS-S-13165. This migration can be achieved in many different ways, depending on your validation and design change policies. This could be as simple as a memo to file or design change rationale or as complex as performing fatigue testing, comparing the new data to baseline data as part of a full-blown re-validation. If your choice is to stay with the cancelled AMS-S-13165, it is always recommended to use the latest revision or the revision that was active at the time of cancellation unless a specific revision is stated on the part print.*

*You had asked if there is a more applicable standard for what you are peening. I suggest that you consider using SAE J3020 (Medical Device Shot Peening). This is a new shot peening specification that I sponsored as an active, long-term member of the medical device industry. I noticed a void in this area of our industry and I created it to address the needs of the medical device industry and the requirements of the FDA. Without knowing exactly what you are peening, (implant or non-implant) and to what level of compliance you are currently targeting, it is hard to give you a definitive answer to what is best for your needs. However, I feel confident that if you are peening medical devices, SAE J3020 will supply the guidance and requirements to meet your needs and the requirements of the FDA more completely than what can be achieved by either AMS-S-13165 or AMS 2430.*

*As for your vendor telling you that you need to call out their process number on your prints: I would advise you to never put a vendor's call out on your prints. This will only create a cornering of the market for your vendor, making them the only source that can peen your parts without a design change and a re-validation. This would put them in control of your product sourcing due to the FDA regulation on changing processors and procedures. I would suggest requiring them to meet the peening specification that you choose to list on your prints. If their internal process number conforms to that requirement, it can be added as*

## SHOT PEENING SPECIFICATIONS *Continued*

a purchase order note along with listing the specification that you noted on your print. This will assure that both specifications are delivered. If your vendor insists on their number being listed on the print and you don't want to be tied down to a single vendor, I would suggest finding an alternative vendor. There are many out there that are willing to peen to international standards and will execute to meet your requirements and supply you with all of the process information that you request.

You wrote, "What is a typical Shot Peening Call Out/ Drawing Spec?" Typically, the shot peening specification is listed as shot peening per (AMS-xxxx), followed by the required media specification (AMS-xxxx), a definition of the area requiring shot peening, the masked area, and the optional area followed by a coverage requirement per SAE J2277.

As for verifying the output of the shot peening: X-Ray Diffraction is a viable test and can be performed on small and large areas alike. However, you must know what depth of residual compressive stress is required to meet design intent. This is typically unknown and undocumented, making it a test that is not as widely used to verify the peening process as you may think.

Typically fatigue testing is the more commonly used option to verify the peening process in the medical device industry. This testing is performed already as part of the FDA submission process of new medical device implants with a defined requirement of cycle and load requirements. If the peening process passes the fatigue test, the peening operation is delivering the required results to meet design requirements. The Almen strip tests, besides being used to create a saturation curve, are used to determine shot peening intensity. Almen strip tests are used to establish the equipment's capability to repeat the required energy in the shot stream to produce a constant and repeatable improvement in fatigue life. It is a vital element in the validation of the peening process. It is also a vital part of the continued process monitoring to assure quality in the peening process.

I hope this helps you better navigate through this transition and if you would like additional information, please feel free to contract me with your questions.

We received a very nice "thank you" from SME and I look forward to meeting her someday; maybe at the next Shot Peening workshop in California. ●



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