

What the Medical Industry Can Learn from the Aerospace Industry

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Heat treatment standards are stricter in the aerospace industry than in the medical industry where lives are on the line. This doesn't make sense and something is being done about it.

Recently, I was asked to give a vacuum heat treating presentation to a group of design engineers at a large medical device company. The lead engineer asked if I would help educate his team on this subject primarily because they had just experienced a major failure caused by improper heat treatment. After learning more about the failure, it became evident that the medical device engineers in that room could learn a great deal from the aerospace industry, especially regarding knowledge of aerospace materials and secondary aerospace processes. It also became apparent that an industry-managed oversight program addressing the technical competency required in special processing was necessary in order for medical device companies to improve design and manufacturer of future medical devices.

With heat treating being performed at multiple secondary suppliers around the world, problems pop up anywhere. Medical device companies need to understand that simply citing a material specification and hardness measurement on a drawing does not guarantee the product will be free from defects. There are certain stringent parameters that a heat treater must follow in order to provide the end user with a quality product.

Nadcap™ (formerly National Aerospace and Defense Contractors Accreditation Program) is the organization in the aerospace industry that helps establish stringent industry, prime contractor, and regulatory standards and enforces compliance with those standards. Nadcap's mission is to improve supply chain quality and conformity within the aerospace industry. In today's world of global manufacturing, organizations increasingly find they must rely on effective supply chains or networks of specialized suppliers in order to compete. Supply chains and their management have grown and become increasingly complex over the years. With that growth come many internal challenges of which uniformity among suppliers in their conformance to technical quality standards is one of the most important.

In the aerospace heat treating industry, Nadcap helps regulate the following technical areas. It is this author's opinion that these areas should be just as thoroughly regulated in the medical industry as well.

Pyrometry: This has to do with how temperature measurements are taken and reported. There can be wide variations in temperature readings over time and between varying temperature reading instruments. Pyrometry standards help everyone know that 1250°F is really 1250°F. In the aerospace industry, pyrometry is governed specifically by AMS2750 Rev. E.

Temperature Uniformity Surveys: Many heat treat processes require uniform heating within a defined volume of a furnace. To ensure that temperatures are consistent in all areas of a furnace hot zone, temperature uniformity surveys must be conducted. Exactly how frequently and where thermocouples are located and how long a furnace must remain at temperature varies widely. Industry standards on how and when to run a temperature uniformity survey help eliminate variability and ensure a more consistent heat treated product. Nadcap standards and AMS2750 Rev. E protocol strictly prescribe how testing is to be done and reported in order to assess proper functioning and any limitations of a specific heat treat furnace.

Procedures: Nadcap requires each supplier to have detailed technical procedures regarding equipment capability, pyrometry, furnace operations and preventive maintenance, contract review, technical instructions to the shop floor, testing and reporting of results, as well as quality assurance for those

What the Medical Industry Can Learn from the Aerospace Industry (Cont'd)

situations where a non-conformance is found. These procedures help reduce unknowns and ensure consistent and acceptable heat treated product.

Training: Nadcap also details procedures, records and statements of limitations regarding all personnel involved in the processing or quality control of work passing through the supplier facility. Since many errors are human errors, these training procedures aim to reduce this category of error.

Internal Audits: Nadcap requires regular, periodic internal review and recording of results and corrective actions. This includes all areas covered by Nadcap such as competency, equipment, procedures, etc.

Purchasing: Control of critical supplies used by heat treaters are also carefully scrutinized. Heat treat suppliers must include technical information on purchase orders regarding industrial gas quality, heat treat hardware, capital equipment purchase, controls, thermocouples, and many other supplies critical to the heat treating process.

Flow Down of Requirements: When customers write purchase orders to control the purchase of heat treatment services, the flow down of all pertinent contract and technical requirements from the OEM must be complete and effective. The heat treat supplier must have the critical information necessary and the technical capability to understand all requirements and act on them accordingly.

The aerospace industry enjoys the good fortune of a fairly complete set of vetted and approved industry-managed documents. These documents help control the heat treatment of metals in a uniform and well-tested system. This system provides the backdrop for Nadcap auditing and determination of compliance to technical requirements.

When an aerospace engineer designs flight-critical parts, he is thinking ultimately of passenger safety. In an even more important way, the medical device engineer also designs for safety. Heat treated parts such as knee and hip joint, needles, surgical tools and other life-critical medical parts should be as safe to use and insert as aerospace parts are to fly. To assist the medical device industry and assure quality products compliant with the highest standards, it is critical that the medical industry adopt an industry-managed supply chain oversight program like Nadcap.

To that end, we are glad to hear of the establishment of MedAccred by the same organization that manages Nadcap, the Performance Review Institute, out of Pittsburgh, Penna. My company has been involved from the very early stages and any reputable heat treater desiring to process medical parts should sit up and take notice. We believe this type of certification is healthy for the industry and we wholeheartedly support the effort.

For medical device manufacturers, I suggest a more thorough understanding of heat treat standards and the MedAccred program. This type of standardization tends to be helpful to the manufacturer, vendors, and end users.