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Aerospace Heat Treating Standard Recognized By US FDA, Giving Nudge To MedAccred Supplier-Control Program





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► Shawn M. Schmitt

THE AGENCY'S CENTER FOR DEVICES AND Radiological Health has formally recognized pyrometry standard AMS 2750 for heat treating. Originally drafted by SAE International in 1980 for the aerospace industry, the standard is the foundation of heat treating audit criteria for the burgeoning medical device supply-chain oversight program MedAccred.

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A pyrometry standard originally developed for the aerospace industry has been formally recognized by US FDA's Center for Devices and Radiological Health.

Drafted by SAE International in 1980 – and revised four times since – AMS 2750 covers pyrometric requirements for thermal processing equipment used for heat treatment. Temperature sensors, instrumentation, thermal-processing equipment, system-accuracy tests and temperature uniformity surveys fall under the standard's umbrella.

FDA defers to recognized consensus standards when reviewing products during the pre-market phase. The agency believes conformance with recognized standards “can support a reasonable assurance of safety and/or effectiveness” in devices, it states in its 2007 guidance, “Recognition and Use of Consensus Standards.”

“Heat treating hasn't gotten the attention that it should from the standpoint of it being an important critical

[manufacturing] process that isn't always done properly, and can cause some real issues if not done correctly,” said Connie Conboy, director of strategy and business development at the Performance Review Institute.

AMS 2750 is the foundation of heat treating audit criteria for MedAccred, a medical device supply-chain oversight program directed by Conboy.

Developed a few years ago and managed by industry, MedAccred is a consensus-driven approach to supporting critical-process quality throughout the supply chain. It aims to ensure high-quality finished products and offer clearer supply-chain visibility. The goal is to give device firms greater confidence in the vendors they choose.

In addition to heat treating, MedAccred focuses on seven other critical process-specific activities: cable and wire harness, plastics extrusion, plastics injection molding, printed boards, printed circuit board assembly, sterilization, and welding.

PRI audits suppliers of special processes using collaboratively created audit criteria, and accreditation is granted and accepted by the program's subscribing members. The process-focused audits – which do not focus on quality systems – are performed by industry-approved and -trained subject-matter experts.

Vendors of heat treating services that “follow standards that are appropriate for that industry really conduct pyrometry properly, and that eliminates a lot of issues and defects that are showing up in the supply chain,” Conboy said.

AMS 2750 “is a deep dive into the pyrometry of a furnace. It ensures that your furnace has consistent



DEVICE GIANTS TURN TO MEDACCRED

Did you know that device heavy-hitters Stryker, Medtronic, Johnson & Johnson, GE Healthcare, Philips Healthcare and Becton Dickinson are strong supporters and users of MedAccred?

In fact, Stryker plans to award future business to special-process suppliers based on whether they're certified to MedAccred.

"Eventually, the direction is to be making business decisions based on MedAccred. Awarding business based on accreditation [to MedAccred] is the end goal," Scott Goolsbey, manager of supplier controls for Stryker's endoscopy division, told *Medtech Insight* in a July 5 feature story that you can check out [here](#).

heat across the entire furnace, and that you don't have pockets where some products get heated to a certain temperature, and then others don't quite get heated to

that same temperature because the temperature isn't consistent across the furnace," Conboy explained in an interview with *Medtech Insight*.

"It ensures that consistency, and ensures that the thermocouples are located where they need to be in the furnace to ensure that you're able to monitor it properly," among other pyrometry-specific activities, she added. "This is part of what MedAccred is all about: we do that deep, deep dive audit into the critical process."

Last updated in 2012, AMS 2750 was created for the aerospace industry. "It has been used as the standard in aerospace for years and has been mandated by the big airplane manufacturers," Conboy said. "This is something that's a standard within the [aerospace] industry that is critical to producing high-quality final products."

In fact, MedAccred's roots lie in aerospace. The program is modeled after Nadcap, a popular supplier quality initiative for the aerospace industry that is also administered by PRI.

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