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Heat Treating: An Artistic Balance Part 2

Identification and Control
POSITIVE ABOUT MATERIAL IDENTIFICATION

by Keith Summers and Jim Stertz

Imagine supplying a new lot of parts to a medical device manufacturer: All of the documentation is in order and things could not have gone any better. Every toleranced dimension is right on the money. Surface finishes are perfect and all of the microscope-based attributes inspection matched perfectly with the customer's desired characteristics.

The parts arrive to your customer, full payment is received, and follow-on orders are coming into the shop. The lot of parts has been assembled into the device and several have been implanted already, when the call comes in: The customer informs you of a testing failure, and it has been traced to a material failure. The "X" titanium specified for the part was not used; instead this part was made of "Y."

An immediate recall and test on all non-implanted devices show both "X" and "Y" parts in the lot. Somehow a bar of "Y" got mixed into the stock for the order. And no one noticed because the visual and machining characteristics of the two materials are very similar. Unfortunately, the same cannot be said for performance characteristics. A "worst case scenario" for the patient, doctor, hospital, device manufacturer, and FDA descends upon the contact manufacturer—the responsibility of a defective device being implanted in multiple patients.

Separation of electrical solder.

Verifying the Material

Even *imagining* things like this can cause manufacturing managers to wake up in a cold sweat in the middle of the night. How can scenarios like this be prevented? The material handling process from the mill to the material distributor to the contact manufacturer to the device OEM and finally to the customer, depends on a system of identification and control—verifying the material is correct to its specifications through testing. And then controlling access and handling, to ensure it is not intermixed with other products.

Both the mill and the material distributor almost always will have access to testing abilities to re-verify material ID as needed. Either as part of a standard "test and control" procedure or to check and resolve any questions along the way. A common solution for this testing is an X-Ray Fluorescence test.

Material Identification System

The use of a hand held "positive material identification" system usually leads to a couple of questions, one being: How does it work and is it safe? The briefest and simplest summary of how it works is to think of X-rays as a form of invisible light. When an elemental material (remember all those materials on that periodic table in Science class?) is exposed to invisible X-ray light, it responds by emitting a unique energy signal.

An X-Ray Fluorescence test exposes a material sample to the invisible light and all of the elements that make up the tested material respond with their own unique signal that the tester captures and analyzes. This enables the tester to tell us very accurately about the content and percentages of each element that make up the sample being tested.

The illustration above shows the results of this analysis for a sample of electrical solder. The analysis identifies the type of material through comparing the tested sample to an internal library of material types, the quality of the match (of the sample) to its

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specifications, and the actual material content of the sample being tested.

Safety factors come most significantly from the dangers of anything invisible. If you look at the sun you quickly will avert your eyes because of the pain due to continued exposure. If you felt no pain, you possibly could continue to look at the sun, until your eyes were damaged. Because X-rays are an invisible light, however, we must be aware of any exposure to it, because a conditioned response will not be coming from our senses immediately. The energy used in material identification systems is similar to a dental X-ray and a few simple safety rules must be followed, and a certification of the devices energy emissions must be maintained.

The "test and control" system of material identification often gets truncated to just "control" when the material gets to the contract manufacturer. Without a means for testing, incoming lots are received, placed in inventory, moved to the manufacturing cell, processed, and packaged with no testing, and only trust in the material control system. This often leads to a rack or racks of partial stock, lacking clear identification.

Implementing Procedures

One local manufacturer who has implemented a proactive "identification and control" system is Lowell Incorporated. Jim Stertz, Lowell's director of quality, implemented an internal material identification system, where all material lots are sample inspected to be certain they meet the PO specifications on the order. The material identification results are used to create an internal material labeling system that moves with the stock, from the dock, to the storage rack. Prior to the material moving onto the manufacturing cell, each bar is tested for positive material identification with the results being easily transferred from the device to the network as part of the Device History Record. Stertz said the system was implemented several years ago and adds only a small amount of time for the material control person to complete the test, using a hand held X-Ray Fluorescence system that is kept near the receiving door.

Implementing "identification and control" procedures like these are relatively simple to develop and deploy. Testing systems are reasonably priced, easy to use and, with minimal training and planning, everyone can ensure that material identification "worst case scenarios" are prevented. PM

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