

Making Contact with Positive Material Identification

Quality procedures are put in place to document materials as they are received and as they move through the production process, but what happened to those raw materials before they arrived at the receiving dock? This was the problem facing St. Cloud, MN-based DCI Inc., a manufacturer of stainless steel and nickel alloy vessels and equipment.

Because most of the raw materials used in the manufacture of DCI's products eventually come in contact with products in the food/dairy/beverage, chemical, personal care, and pharmaceutical and biotechnology industries, incorrect alloy material could cause a myriad of compatibility issues with the products produced using its equipment.

In addition to compatibility issues, several other reasons can exist for material traceability including design, corrosion resistance, and compliance to codes and standards such as ASME Boiler and Pressure Vessel Code, 3A Sanitary Standard and ASME BioProcessing Equipment (BPE) Standard. Therefore, DCI found it imperative to provide material traceability to its customers.

The Traceability Problem

Each time raw material changes hands, the opportunity for error increases, result-



A final quality check of a vessel liner for use in the biopharmaceutical industry ensures that there will be no compatibility issues. *Source: Thermo Fisher Scientific*

ing in questionable traceability. Typical of most metal fabricators, by the time DCI receives the material from its suppliers, that material sometimes has been passed from the mill to service centers, from processing plants (e.g., pipe, tube and fittings) to subcontractors. DCI had procedures in place to receive marked material with certification; however, every step allows an opportunity for a traceability problem.

In an effort to verify and guarantee complete traceability of all materials, DCI committed to implementing a Positive Material Identification (PMI) program, which would validate all raw materials before the manufacture of its equipment began.

Moving Forward with XRF

DCI chose the handheld Thermo Scientific (BillERICA, MA) Niton X-ray Fluorescence (XRF) alloy analyzer to perform the analysis. With the Niton XRF instrument in hand, DCI developed and implemented an internal quality procedure for the PMI of raw materials and purchased components and parts. "We fol-

low ASTM E1476 and include calibrations checks with certified reference materials to verify that the material and documentation is correct before we begin production," says Brian Uhlenkamp, DCI's vice president of engineering.

"One of the important features of the Niton analyzer is its 21 CFR Part 11 compliance, which is a requirement for many of our customers," Uhlenkamp notes. "It is critical that we can assure our customers that the data we obtain is encrypted and locked against editing. The performance and capabilities of the Niton XRF unit in combination with DCI's quality procedures help guarantee reliable and accurate results."

When the Niton XL3t 800 Series was introduced in the spring of 2007, DCI willingly signed on as a beta site. Uhlenkamp's thinking was that if there was something better than the previous generation, DCI wanted to be a part of it.

"After working with the XL3, we found that it gives us faster and what we feel are even more accurate results," says Uhlenkamp. "This means quicker verifica-

Benefits

- DCI's quality procedures coupled with the capabilities of the Niton XRF analyzer help guarantee reliable quality products to its customers.
- Compliance with 21 CFR Part 11, an important requirement for many DCI customers, is ensured by the Niton analyzer's proprietary encrypted and locked data format.
- Incorrectly marked materials or wrong material certifications are detected before the production process begins.



In its PMI program, DCI tests materials at all phases of the manufacturing process using a Thermo Scientific Niton XL3t Series 800 XRF analyzer. *Source: Thermo Fisher Scientific*



DCI checks a heat transfer dimple jacket welded onto a vessel head as part of its ongoing QA process. *Source: Thermo Fisher Scientific*

tion times. With the gain in speed, we can accept materials faster and get them into production faster, so we can also increase our percentage of testing—with the same amount of labor.

“Additionally, we found that the unit’s smaller window size also gives us more accurate results for smaller areas, such as weld verification checks,” he says.

DCI also found the unit to be more user friendly, with improved ergonomics and a more comfortable, better-balanced feel, tilt screen display and color graphics.

Customer Confidence

Since DCI’s PMI implementation, the company has discovered numerous materials that have been mismarked and supplied to them with the wrong material certifications. Uhlenkamp relates, “One of the most interesting findings since we implemented the program was discovering 316 stainless steel in lieu of the marked and certified 6-Moly

Super Austenitic stainless steel we expected. This material was for a project where 316L stainless was being replaced because of corrosion issues realized after several years of service.”

Uhlenkamp continues, “In another instance a service center supplied us with skids of material marked with the same heat number, yet what we received was a mixed batch of 304 and 316L stainless steel skids.

“It’s hard to put an exact dollar value on

customer confidence,” says Uhlenkamp, “but I believe that the initial Niton unit paid for itself within the first two years of use. Using Niton analyzers, we are confident we have a higher quality product because we can verify it.”

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