



Rules of the Game

From hazardous materials to technology transfer, government regulations around the globe challenge manufacturers.

- 21 CFR
- RoHS
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If you want to succeed in high tech, you need the best technology, right? But that alone isn't enough. It is an exquisite irony that often the most challenging part of being in a high tech business isn't the technology — it's the regulatory environment in which companies must operate.

In the pharmaceutical industry, for example, U.S. drug manufacturers must comply with 21 CFR, a Food and Drug Administration regulation that requires complete, unchangeable traceability of all processes. If they put in a machine vision system for marking or inspection, that system needs to be traceable as well. That requires hardware validation and the development and execution of a software validation master plan, according to David Wyatt, president of Midwest Integration (Mishawaka, Ind.). "It can cost as much to validate as it does to produce the product and install it," he said. "It can double the price, depending on the master plan of the pharmaceutical company."

GET THE LEAD OUT

On the first of July, the European Union will institute a directive on the restriction of certain hazardous substances in electrical and electronic equipment (RoHS). No new products can be sold that contain more than the specified low levels of six banned substances, including lead. For the electronics industry, which uses tin lead solder, the implications are profound. The replacement solders not only cost more but have higher melting points, meaning that reflow processes, for example, need to be hotter. RoHS is changing industry operations — and their cost basis. And it most likely represents only the tip of the banned substances iceberg.

"There are two different levels of compliance that we're seeing," said Eric Karov, senior research analyst at AMR Research (Boston). "One is a 'year one' compliance — do whatever we have to do to get compliant. It probably is not the best long term solution but let's at least get a

baseline level." The "year two" and beyond approach is to prepare for both RoHS as it currently stands and future regulations, which ultimately means visibility across the entire supply chain. "But doing that is really difficult and a lot of people are tripping over it," said Karov. "So that's why they're defaulting back to 'Let's just do what we can to get compliant for this specific regulation.'"

That short term approach will likely be costly in the long run. California has enacted a RoHS type law that goes into effect in January 2007, and both China and Korea are developing legislation. "As additional laws are enacted in other countries, there's going to be more work," said Stefanie Breyer, RoHS Program Manager at National Instruments (Austin, Texas). "I think companies are seeing that there's definitely an ongoing impact." In addition to RoHS, the EU has passed a directive on waste electrical and electronic equipment (WEEE) that requires manufacturers to

he noted. "That's the biggest issue for small suppliers in the world — the small suppliers can't afford to do it."

OVER THE BORDER

Of course, international sales bring up another regulatory issue — constraints on technology transfer. Most countries have some sort of regulations governing sale of technology outside of their borders. In the United States, for example, the International Traffic and Arms Regulations (ITAR) requires licensing to export technology, whether as products or as information. Other products are governed by the U.S. Department of Commerce (DoC), creating a multilayered and challenging compliance environment.

Compliance typically starts with a full account of device performance and capabilities, as well as an end user document from the customer stating the intended use and guaranteeing that the device will remain in their control. The process can be time-

company is headquartered in Ireland, cites an example of trying to buy third-generation intensifier tubes from the two sources available to him. "One is based here in the United States and the other is based in Japan. The Japanese company can sell that tube to us as a U.K. company without any export control; they can't sell to a United States company without compliance to some sort of an export regulation." Advantage: non-U.S. competitor. It cuts both ways, though, said Calling. "Conversely, there's a U.S. manufacturer of those tubes that can sell to U.S. manufacturers but was unable to sell to us. Before the company in Japan had a competing technology, we were locked out of a business segment because we could not process that particular tube because of a government regulation."

The licensing process can be time-consuming. At Andor U.S., the tasks eats up 50 percent of the work hours for the individual assigned to compliance. Edmund Optics (Barrington, N.J.) employs two full-time compliance officers, said president and COO John Stack. Because Edmund supplies military contractors, it is subject to ITAR. "There is no getting around (import/export regulations)," said Stack. "That is the biggest mistake people make." Another common error is implementing the regulations as a generic process. "The staff generally does not realize the ramifications from the process alone. "Once you've determined these rules apply to you, senior management needs to get involved, given the penalties for failure," he said. Which can, of course, include jail time for those same managers.

There is a silver lining, though, Stack said, citing the benefits to be had from bringing a company into compliance. "What I have found is that although the up-front cost of implementation was not cheap, over the long haul here it has actually gotten us more business." Prime contractors, who are vulnerable if their contracted suppliers are debarred, are more likely to go with companies who have demonstrated compliance procedures in place. "I also believe that we've got better control, our whole operation is leaner," he said. "It's just like ISO — you can get as much or as little out of it as you choose." **AI**

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take responsibility for the ultimate recycling and disposal of their products.

The potential costs can be sobering. Karov estimates that companies are spending between 2 percent and 4 percent of topline revenue on RoHS and WEEE compliance. "That's a big number," he said. "When you start to add in all of the other regulations, if they all represent a percent of revenue, all of a sudden your entire profit margin is eliminated." Karov said they've seen companies spend upward of 20 percent and below 1 percent on compliance. The difference basically comes down to philosophy — approach compliance from a year one perspective and the cost is always high. "If you do it right the first time, it might be more expensive but ultimately you'll end up ahead,"

consuming and detailed, especially when executed on a transaction by transaction basis. It is absolutely crucial to execute this licensing process properly, though — the penalties include not only fines but jail time. In some cases, businesses can even be shut down for violations.

All of which makes companies willing to invest time and money in getting it right. "My advice is to be as honest as possible because the penalties could be catastrophic," said Chris Calling, president of Andor USA (South Windsor, Conn.). "Put in everything you can, even overstate the performance so you know you're falling within the guidelines you put out there."

Export regulations can effectively alter the competitive landscape. Calling, whose