wiley

NEWSLETTER

FDA Laser Regulation Underlines Importance of "Voluntary" Standards

November 2013

Many readers may be surprised to learn that since 1976, the U.S. Food and Drug Administration (FDA) has regulated lasers in virtually every context of their use. Compliance with FDA regulations and, sometimes, specific authorization is required for laser light shows at theme parks and rock concerts, DVD players and laser printers, laser pointers, children's toys, industrial manufacturing, and various medical devices.

As with other agencies, FDA struggles to keep up with technological innovation but—in response to White House directives—seeks to enforce rules that are consistent with standards developed through voluntary standards organizations, such as the International Electrotechnical Commission (IEC). A current debate over a recently proposed FDA rule shows the importance to companies in ensuring that those standards are up-to-date and balanced, and that government agencies are familiar with ongoing processes to update them.

FDA's laser performance standards have not been updated since 1985. FDA's outdated laser regulations pose a particular barrier to the emerging technology of laser-illuminated projectors (LIPs). This equipment represents a dramatic improvement over traditional movie and video projectors in terms of picture quality, reliability, and environmental impact.

This summer, FDA published a rulemaking proposal "to better harmonize" its laser regulations with those of IEC. The new rule would be effective no sooner than 2016. However, FDA proposed to conform its regulations to the 2007 IEC laser standards, although the IEC standards themselves are scheduled for significant revisions in early 2014.

Thus, rather than harmonize U.S. laser regulations with the rest of the world, FDA's proposal would, in the words of the National Association of Theater Owners, "apply an outdated laser standard that does not reflect the scientific results of modern laser safety research, while the rest of the international community will be using a new 2013 version based on extensive research and new computer modeling."

The FDA's outdated laser regulations are particularly ill-suited to regulating LIPs. The type of lasers used in some LIPs may require FDA approval, even though the laser light is internally manipulated and processed in such a way that the diffused light projected out of the LIP is indistinguishable from light emitted by traditional xenon-arc lamps. In other words, LIPs do not actually emit laser beams, but are regulated under FDA's

outmoded rules as if they do.

FDA received 38 public comments, almost all of which opposed the proposal and requested it be withdrawn. Many commenters asked FDA to simply adopt the upcoming IEC standards instead of the 2007 standards, and others asked that FDA adopt a policy of enforcement discretion whereby compliance with current IEC standards would be accepted even before those standards are officially adopted by FDA. Hopefully, the agency will respond favorably. But urging this outcome was only made possible by previous industry efforts to make sure the IEC standards are workable, and by carefully monitoring related governmental rulemakings.

There is a lesson here: Staying on top of those "voluntary" standards is critical.

*Claire Frezza is a law clerk at Wiley Rein and can be reached at 202.719.3752 or cfrezza@wiley.law.