

a white paper from



As Manufacturing Moves to 3D Printing Technology, Product Safety Standards Still Apply

With the advent of 3D printing technology, the way we look at conventional manufacturing may never be the same. 3D printing is beginning to impact almost every phase of manufacturing, regardless of product type, and as the technology continues to evolve, it is certain to change nearly every industry and transform the way we do business.

However, the expression, “The more things change, the more they stay the same,” also applies—regardless of new manufacturing techniques, the same safety and quality regulations and standards still apply to finished products.

The Evolution of 3D Printing

3D printing has already started a revolutionary change in the way companies are looking at design and manufacturing. As 3D printers become more robust and less expensive, parts manufactured from 3D printing technology could become the norm, instead of the exception.

Several industry publications, like 3D Printing Industry (www.3dprintingindustry.com) and 3D Printing and Additive Manufacturing (www.liebertpub.com/3dp),

regularly highlight new and innovative applications for 3D technology, including ways that 3D printing has penetrated many product areas, including:

- ▶ Medical devices (e.g. prosthetic creation)
- ▶ Pharmaceutical (e.g. tablet manufacturing)
- ▶ Toys (e.g. novel image and structure of figurines)
- ▶ Food (e.g. Hershey's creating chocolates; Barilla creating novel pasta shapes)
- ▶ Automotive (e.g. car part fabrication)

Many of the companies driving this technology are not household names. While large organizations like Hewlett-Packard and GE are players in this space, new companies like 3D Systems, Mcor Technologies, Stratasys, Materialise and EnvisionTEC have emerged. Some offer their own unique printers for specific applications and others provide the 3D printing services or materials (referred to as filament or additive) to these growing firms.





What Companies Can Do

As these new entrants in the 3D market build their businesses, they will need to assure their customers that the products made with their 3D printers and printing materials comply with the required regulations; they will need to prove to their customers that they have “done their homework.” It is the product manufacturer that must demonstrate regulatory compliance and ensure product safety and quality.

To ensure that your organization is aware of and in compliance with all applicable standards, seek out a credible third-party organization, such as NSF International, to advise you on the regulations that impact your business, provide guidance on the necessary steps to demonstrate compliance and help you inform the marketplace that your product(s) are verified as compliant, differentiating you from an ever-growing field of competitors.

NSF International is well versed in all of these standards, and can support you in making sure your organization, and its equipment and materials, meet safety regulations and standards when applying this new technology. Whether you are producing food, water, personal care or medical device products, you can benefit from regulatory guidance, testing, auditing and consulting services. Engaging this kind of “technical insurance” can help ensure that your products and customers are protected and have minimized business risk.

Copyright © 2015 NSF International.

This document is the property of NSF International and is for NSF International purposes only. Unless given prior approval from NSF, it shall not be reproduced, circulated or quoted, in whole or in part, outside of NSF, its committees and its members.

Cite as: NSF International. November 2015. As Manufacturing Moves to 3D Printing Technology, Product Safety Standards Still Apply. NSF: Ann Arbor, MI.

Same As It Ever Was

In the push to create these systems, the focus has been on innovation and technology. Now that 3D printers are being more widely adopted, the next phase in their evolution needs to be addressed: the applicable regulations that exist for specific product sectors. Consumer safety remains a priority and the established safety and purity standards for all industries still apply.

In fact, food, drug, cosmetic and medical device products made with any of the 3D printing technologies (printers, additive/filament materials) **must** comply with the appropriate U.S. Food & Drug Administration (FDA) regulations. For example, chocolate made by a 3D printer is no different than chocolate made in traditional production – it must still comply with all food safety and health regulations outlined in the U.S. Code of Federal Regulations.

However, many of the new entries in the 3D printing world (as well as many of the well-established corporations) have not previously worked in this field of regulatory oversight. With changes in manufacturing methods, these companies are now subject to a myriad of new requirements that may cause unplanned delays and additional unbudgeted costs to their product launch. **Essentially, the way the game is played may have changed, but the rules have not.**



NSF International

789 N. Dixboro Road, Ann Arbor, Michigan 48105 USA

+1 (800) NSF MARK | +1 (734) 769 8010 | info@nsf.org | www.nsf.org