Safety Concerns Associated with 3D Printing and 3D Printed Consumer Products

May 6, 2020

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1 EXECUTIVE SUMMARY

The rapid development of 3D printing and additive manufacturing (AM), hereinafter, 3D/AM, is expected to change significantly product design, manufacturing and distribution. 3D/AM is a process of building products (including consumer products), and parts for products, by adding material generally in a vertical layering process.

What began as a technology that provided a quick method to produce prototype products, or parts for products, 3D/AM is rapidly growing in industrial and consumer product uses, due, in part, to widespread adoption of computer-aided design software, availability of open-source software, and a wider selection of materials for 3D/AM.

3D/AM offers many advantages to product designers and manufacturers over traditional manufacturing techniques. It opens up opportunities for significant improvements in the ability to customize products to customer preferences, as product manufacturing can be adapted without major retooling. 3D/AM can reduce costs and lead times because highly complex parts can be produced on demand. Product designers are no longer limited by considerations of traditional machining or materials. Suppliers can produce component parts, as needed, and in a non-traditional manufacturing setting, or via "distributed manufacturing" sites.

Staff has identified two broad hazard areas for 3D/AM: (1) hazards posed by use of a 3D/AM process, and (2) hazards posed by the printed products. Each of these hazard areas includes potential fire and combustion hazards, electrical hazards, chemical hazards, and mechanical hazards. In addition, staff has concerns that 3D/AM consumer products–particularly children's products–may not meet applicable regulations or voluntary standards, due to the 3D/AM manufacturer's potential unfamiliarity with federal regulations and voluntary standards applicable to those products, especially for small and micro-producers that are new entrants to the market.

Staff also has concerns about the potential health effects of materials used for 3D/AM and the potential for consumer exposures. To this end, staff is working along multiple fronts, including voluntary standards development and research. Staff has developed interagency agreements with our federal partners to investigate the potential health effects of materials used in, and chemical and particulate (including nanoparticle) emissions from, 3D/AM and potential consumer exposure.

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2 INTRODUCTION

The rapid development of 3D/AM technology has the potential to alter significantly consumer product manufacturing, both in commercial applications, and in the home. 3D/AM has many advantages over traditional manufacturing processes.

On the commercial side, 3D/AM processes allow broader design flexibility for component parts, or entire products, which may be built without consideration of machining tool accessibility, including milling and drilling operations required for traditional manufacturing processes. Cost savings are achieved through more efficient designs, reduction in the use of raw materials, and fewer processes needed to manufacture a product or a component of a product. This flexibility has enabled greater customization, as products can be varied to meet the needs of customers at levels not previously possible.

For consumers, 3D/AM is expanding from novelty- and hobby-related uses to more functional applications. Using relatively inexpensive 3D/AM technology and readily available open-source software and computer-aided design, consumers can design, customize, and print products, such as toys, kitchen utensils, and shoes, as well as many other products, at home.

2.1 TERMINOLOGY

The terminology used for 3D/AM is not universally defined. Staff generally uses the terminology, "3D printing," in reference to printing using small-scale printers intended primarily for home use. In contrast, staff typically uses the terminology, "additive manufacturing," in reference to industrial-scale production. The National Institute for Occupational Safety and Health (NIOSH) uses the term, "distributive manufacturing," to describe the use of more advanced 3D printers by small businesses or entrepreneurs to create a manufacturing site in a residence or commercial space. The intent, in general, of "distributive manufacturing" is to produce products for an individual for distribution in commerce directly, or logistical efficiency of a larger production operation, which can be closer to the point of product assembly.

2.2 WHAT IS 3D/AM?

3D/AM is a process of building consumer products, and parts for products, generally, by adding material in a vertical layering process (printing).[1] Several methods and materials can be used for 3D/AM, depending on the application. Fused filament fabrication (FFF), also known as the

[1] *3D printing* and *additive manufacturing* are synonymous terms for the process of producing parts through the addition of material in layers. "Additive manufacturing," or "AM," is the CPSC staff term used in the industrial and manufacturing areas; while "3D printing" is generally used to refer to smaller-scale consumer products.

fused deposition model (FDM)[2], is a process commonly used for low-volume production by consumers and businesses in low-cost printers. However, the technology available to the consumer is rapidly evolving, due to significant research and development investments for more advanced printers and starting materials, such as selective laser sintering (SLS) and UV-cured liquid photopolymer resins, which are becoming more affordable. Entrepreneurs and small business owners will often purchase more advanced devices to rapidly produce products that will be commercialized. The term, "distributed manufacturers," describes the use of more advanced printers in non-traditional "manufacturing" sites, such as consumer's homes, for commercial production.[3]

Manufacturers are currently using additive manufacturing to produce parts for consumer products, because it may simplify the manufacturing process and allow new, innovative designs that were previously impossible to produce using traditional manufacturing methods. Currently, limitations such as materials, speed, and equipment cost, limit the size and practical applications of printed parts, but these hurdles are expected to be overcome as the technology advances.

3 METHODS OF 3D/AM

The methods used in 3D/AM processes continue to develop and improve as more applications and materials are identified. Each process has specific characteristics that make it better suited for use in certain applications.

3.1 3D/AM PROCESSES

There are several types of 3D/AM processes.[4][5] The type of process selected is typically a function of the equipment available to the hobbyist or firm, the materials used, and the cost, speed, and the design requirements of the printed product. Printer cost is usually a function of part quality and production speed. The main processes used today include:

[2] https://lawitm.com/3d-printing-law-trademarks-why-fdm-isnt-for-everybody/

[3] *Distributed manufacturing.* Production of consumer products in the home environment intended for commercial use or distribution. Industry to produce and distribute products (e.g., machine parts, medical devices (FDA) locally.

[4] https://wohlersassociates.com/technical-articles.html.

[5] Industrial and Consumer Uses of Additive Manufacturing. A Discussion of Capabilities Trajectories, and Challenges. H. E. Quinlan, T. Hasan, J. Jaddou and A. J. Hart. Department of Mechanical Engineering, Massachusetts Institute of Technology, Cambridge, MA, USA. www.wileyonlinelibrary.com/journal/jie

Technology	AM Process	Typical Materials	Advantages
Fused Filament Fabrication (a.k.a. Fused Deposition Model)	Material extrusion	Thermoplastics	Good dimensional accuracy and fair surface finishes
Stereo lithography	Vat polymerization	Liquid photopolymer composites	Complex geometries, detailed parts, good surface finishes
Digital Light Processing	Vat polymerization	Liquid photopolymer	Complex shapes and sizes, high precision
Liquid Crystal Display	Vat polymerization	Liquid photopolymer	Complex shapes and sizes, great detail
Selective Laser Sintering	Powder bed fusion	Plastic, paper, metal, glass, ceramic, composites	Requires no support structure, high heat and chemical resistant, high speed
Direct Metal Laser Sintering	Powder bed fusion	Stainless steel, cobalt chrome, nickel alloy	Dense components, intricate geometries
Selective Laser Melting	Powder bed fusion	Copper, aluminum, stainless steel, tool steel, cobalt chrome, titanium and tungsten	Complex geometries and structures with thin walls and hidden voids or channels
Electron Beam Melting	Powder bed fusion	Titanium powder, cobalt chrome	Speed, less distortion of parts, less material waste

3.2 3D Printing Pens

3D printing pens are handheld 3D printing devices. A number of these products are marketed to children for creating 3D-like drawings. Many school districts are implementing 3D printing programs that provide instruction on the use of these devices for elementary and high school students. Given the proximity to the body, and often, intended use by children, the potential exposure to the hazards and effects identified for 3D printers may be greater for these handheld products. The products in this category generally cost less than $100.00. Staff considers 3D printing pens to be a separate product from typical 3D printers found in homes. Staff continues to collect information on these products and to consider a standard specifically for these types of 3D printers.

4 HAZARD AREAS OF CONCERN

Staff has identified several potential hazards associated with 3D/AM across the product lifecycle, including the safe storage and use of raw materials, the fabrication of a consumer product from the material during the printing process, and the end use of the product by the consumer. These hazards are of particular concern for 3D printing in consumers' homes, where the environment and expertise are more likely to be inadequate in comparison to AM used in industrial settings. Staff has categorized the hazards into two broad product development process areas, namely the hazards associated with: (1) 3D/AM materials and processes, and (2) end use of 3D/AM objects in or as consumer products.

4.1 3D/AM PROCESS HAZARDS

Hazards with 3D/AM processes include thermal, fire and combustion, electrical (shock), mechanical, and chemical (including chemical and particulate emissions) hazards. Thermal, fire and combustion, electrical, and mechanical hazards associated with 3D/AM printers can be mitigated with adherence to the appropriate voluntary standard, which may be demonstrated by printer manufacturers through product certification. Identified 3D/AM process hazards are summarized below.

4.1.1 Thermal, Fire, and Combustion Hazards

Thermal runaway may occur when the heater sensor is not reporting temperature accurately, or due to other control failures, which allow the buildup of additional heat and an uncontrollable temperature increase. Fire and combustion hazards may include fire and contact-burn hazards from thermal runaway, accessibility of hot parts, maximum and minimum temperature check failure, cooling fan failure, lack of fire suppression and detection at the printer location, and combustible/explosive dust generation. Staff anticipates limited user supervision of 3D/AM, because the 3D/AM processes generally take considerable time with little user involvement. Lack of fire suppression and detection at the printer location can lead to ignition of, and/or fire propagation to, nearby combustibles. Printing certain materials may also create combustible/explosive gases or dust that may ignite as a result of overheating of heating element components. This may be exacerbated by improper or lack of ventilation systems.

4.1.2 Electrical Hazards

Electrical hazards from 3D/AM printers may result from the lack of insulators, barriers, or improper spacing between conductive surfaces in the printer to prevent user access to live electrical components. Because 3D/AM printers have moving components, electrical wiring components need to have flexible wiring that withstands adequate flexing cycles for the life of the product. 3D/AM printers require electrical sensors and short-circuit protection to address moving components and wiring hazards.

4.1.3 Mechanical Hazards

Moving and heated components may cause physical or thermal burn hazards if barriers and proper warning labels are not put in place. This is especially true for large-scale 3D/AM printers.

In both home use and commercial applications, 3D/AM removes design and manufacturing barriers, which is encouraging to new entrants to the market, who may not have the technical expertise, including safety expertise, of traditional manufacturers. Product designs in these processes have the potential to condense and simplify aspects of manufacturing that, if using traditional manufacturing methods, would require multiple areas of technical expertise. For example, 3D/AM users may not have the same level of knowledge, skills, or abilities as established traditional manufacturers to perform failure analyses or select safe and appropriate raw materials for the intended purpose. Users thus may have readily available part designs for use, without verifying mechanical performance of the parts.

Good manufacturing processes and post-processing of parts are also concerns for product safety, and new micro-manufacturers may not have the QA/QC experience or knowledge to ensure safety. Given that 3D/AM is a relatively new technology, mechanical performance of produced parts is not well understood at this time and can have mechanical properties that differ from similar parts produced using traditional methods. In summary, printed parts makers have the potential to omit safeguards built into the traditional manufacturing process.

4.1.4 Chemical Hazards

Chemical hazards may occur from the materials used in printing. 3D/AM users and consumers are unlikely to understand the potential toxicity of the various types of materials and processes used in 3D/AM processes. Materials such as metals, nanomaterials, and thermoplastics are potential inputs to the process, depending on the 3D/AM technology used. Staff is concerned that, particularly in consumer uses, materials must be properly stored and packaged and that the storage environment is well ventilated. Chemical exposure to consumers may occur during production, because toxic emissions may accumulate in indoor environments with inadequate ventilation. When 3D printers are used in the home environment, it is also important to consider how the devices and materials will be properly stored, such that they are inaccessible to children or other occupants of the home who cannot safely operate or handle these products or the raw materials.

Staff is generally concerned about the inhalation of compounds and particulates released from these devices during printing. 3D/AM processes often involve high heat and a wide range of potential compounds to make products, in addition to substances that are produced as a result of the printing process. Understanding the specific compounds released, and the quantities to which consumers may be exposed, is a critical step in identifying the health effects that may occur to exposed individuals. However, general concerns for health effects include the exacerbation of existing conditions, such as asthma, or the development of acute illnesses, such as lung irritation.

Developing robust methods for testing is a critical step in understanding the potential health effects of these products. Once these test methods have been developed, and research on the releases of chemicals is complete, scientists and regulators will have the data needed to adequately assess the potential health risks for consumers, and will be able to provide guidance on best practices to reduce exposure to chemicals released during 3D printing.

4.1.5 Children's Product Hazards

Small-scale 3D printing has gained popularity in Science, Technology, Engineering, and Math (STEM) education. 3D printing is widely used in schools and libraries. It is likely that every student will be exposed to 3D printing in the future, and this raises concerns about chemical exposure during the printing process, which can take several hours. Staff is also concerned about the safe storage of raw materials used for 3D printing, particularly for home and school.

5 3D/AM Products and Potential Hazards

Although we have no data on injuries from 3D/AM printed products, we believe that the lack of data is due to limitations in the reporting. For example, reports may not identify products as manufactured via 3D/AM, and chemical hazards, especially chronic hazards, are often difficult, if not impossible, to identify in incident reports. Staff has concerns about potential hazards created by 3D/AM printed consumer products. Again, these fall into thermal, fire and combustion, electrical, mechanical, chemical, and children's product hazards.

5.1.1 Thermal, Fire and Combustion Hazards

Thermal and fire and combustion hazards may result from 3D/AM printed components and consumer products having unsuitable fire and combustion properties for their intended uses. For example, consumers may unknowingly use flammable 3D/AM printed products in or near potential sources of fire.

5.1.2 Electrical Hazards

Electrical hazards are likely if components or products are printed using improper materials. Products or components printed for protecting electrical circuits or mechanical moving components require careful selection of materials, such as flame-retardant materials that are needed near high-voltage circuits and heating elements; UV inhibitors, where the printed components may be subject to sunlight; and mechanical strength or flexing properties may be needed to protect moving components.

5.1.3 Mechanical Hazards

Staff is concerned about the structural integrity and other design considerations regarding 3D/AM objects used in and as consumer products. 3D/AM objects and materials may not fit their intended uses, resulting in breakages and potential impact, sharp edge, and small parts hazards.

5.1.4 Chemical Hazards

Consumers and manufacturers may be unaware of the toxicity of 3D/AM printed products, potentially resulting in dangerous uses of the products and the uptake of toxic chemicals by consumers.

5.1.5 Children's Product Hazards

Staff is concerned that printed consumer products intended for use by children may not meet the regulations applicable to children's products, due to the 3D/AM user's potential unfamiliarity with federal regulations applicable to those products. For example, there are regulations to prevent aspiration and choking deaths, including small balls (FHSA 1500.18(a)(17), pacifiers (FHSA 1500.18(a)(8)), toys with small parts, points and sharp edges (FHSA 1500.18(a)(9) and 1501), and others. Typically, retailers, sellers, and manufacturers of children's products are subject to inspection and testing requirements. Staff is concerned that these safeguards will be bypassed by 3D/AM.

6 DATA SECURITY

Because 3D/AM printers may be connected to the internet for remote access, downloading open-source software and monitoring software performance, it is important for these printers to have adequate data security protection to safeguard the software and safety of the printer. "Data Security," as used in an Internet of Things (IoT) product, concerns all of the data stored in, or moving in or out of, a connected product, which could impact the safety of the product. These include:

- Operational instructions (software)
- Consumer-originated data (biometrics, settings and preferences, multiple-user identification)
- Environmental metrics (*e.g.*, location, temperature, atmosphere, energy)
- Manufacturing/product data (*e.g.*, serial numbers across products)

Data Security, and the concept of product "hazardization" are described in greater detail in the recent staff document, *Status Report to the Commission on the Internet of Things and Consumer Product Safety*.[6]

[6] Status Report to the Commission on the Internet of Things and Consumer Product Safety. September 2019. https://www.cpsc.gov/s3fs-public/Status-Report-to-the-Commission-on-the-Internet-of-Things-and-Consumer-Product-Safety.pdf.

7 STAFF ACTIVITIES ON 3D/AD AND PRINTED PRODUCTS

Staff has conducted and continues to engage in a range of activities focusing on 3D/AD and printed products. A brief summary of staff's efforts is below.

7.1 PUBLIC BRIEFING TO THE COMMISSION

- Public briefing to the Commission on the potential hazards and risks with 3D printing processes and 3D printed products, held on October 30, 2019.

7.2 STAKEHOLDER OUTREACH

- Public meeting with Hewlett Packard (HP) on 3D printing technology and consumer products, held on July 16, 2018.
- Meeting between staff and Underwriter Laboratories (UL) on October 23, 2019. Thomas Fabian, Ph.D., Research & Development Manager, Polymer Material Science, presented UL's work on 3D printing and concerns about mechanical properties of 3D printed products.
- Interagency meeting sponsored by staff to discuss 3D printer research, held in August 2019, at the CPSC's National Product Testing and Evaluation Center in Rockville, MD. Participating agencies included the National Institute of Occupational Safety and Health (NIOSH), the National Institute for Standards and Technology (NIST), the U.S. Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). The meeting focused on the latest advances in testing and areas for further collaboration.
- Investigation initiated by Underwriters Laboratories (UL) to determine the potential health implications of 3D printing. UL has supported health and safety research. UL developed an advisory board to provide input and guidance on health and safety research. In February 2017, CPSC staff participated in the 3D printing advisory committee meeting, in addition to the Safety Science of 3D Printing Summit.[7] This important research focuses on the emissions of chemicals during the 3D printing process and the potential health effects of these compounds. This information is being used to develop the proposed UL/ANSI Standard Method for Testing and Assessing Particle and Chemical Emissions from 3D Printers.
- Presentation by staff during the 2020 annual meeting of the International Consumer Product Health and Safety Organization (ICPHSO). The presentation provided an overview of the hazards associated with 3D printers.

7.3 RESEARCH ACTIVITIES AND COLLABORATIONS WITH FEDERAL PARTNERS

For staff, understanding the material science, base materials, and manufacturing processes used in the various 3D/AM technologies (*e.g.*, FDM, Vat polymerization, Powder Bed Fusion) has

[7] http://ulchemicalsafety.org/initiative/3d-safety-science-proceedings/

been a primary focus. The properties of these materials and manufacturing methods will impact the durability of the product and the potential chemical exposures to users of these devices. A lifecycle approach also includes assessing the mechanical properties of printed materials and whether they are as durable as traditionally manufactured products, and if not, what are the mechanical safety implications. Durability also has implications for chemical safety, where the accelerated degradation of the product may lead to elevated exposures to chemicals incorporated into the product during printing.

A summary of staff's research activities and collaborations is below:

- Staff has established interagency agreements (IAG) with federal partners to assess the potential release and exposures to consumers from 3D printers. A research study with NIST is near completion and addresses the use of carbonaceous nanoscale compounds incorporated into 3D printer filament. Staff is also jointly investigating potential research activities with other federal agencies, including EPA and NIOSH.
- Staff developed a study that included the use of predictive models to estimate the concentrations of chemical emissions and thresholds for safety. These preliminary assessment studies were presented as posters at the Society of Toxicology Professional meeting (Jackson S *et al*., Preliminary Human Health Risk Estimates from 3D Printer Emission, Poster #2433, Society of Toxicology Annual Meeting, Baltimore, MD, 2017).
- CPSC has purchased several 3D printers and sampling equipment to begin a screening program of the materials used in 3D printers and to assess the equipment for the release of chemical emissions during printing.
- Staff developed an interagency agreement with the National Institute of Standards and Technology (NIST), the Environmental Protection Agency (EPA), and the Department of Defense (DOD) on carbon nanotubes in 3D printers.
- Staff developed an interagency agreement for research on the toxicity of 3D printer materials with the Department of Defense, Army Corps of Engineers, Engineer Research and Development Center (DOD ACE ERDC) and the Duke University Center for Environmental Implications of NanoTechnology (CEINT).
- Staff is engaged in a research agreement with EPA and NIOSH to study the health effects of volatile organic compounds (VOCs), particulates, engineered nanomaterials, and metals emissions from 3D printers.
- Staff is developing a multifaceted program in FY 2020 to further identify and evaluate several hazard areas for 3D/AM end-use products, including assessing a variety of materials, printing equipment and printer controls, and product designs; and to assess hazards associated with printer and end product use.

7.4 Voluntary Standards Activities

Staff has participated in a number of voluntary standards activities addressing 3D/AM safety. Underwriters Laboratories established a research advisory group that transformed into a Standards Technical Panel (STP) designated as, UL STP 2904, and which developed the first edition of the ANSI/CAN/UL “Standard Method for Testing and Assessing Particle and Chemical Emissions from 3D printers.” A similar effort is supported by the ISO/TC261 JG68 Joint ISO/TC 261 – ASTM F42 Group: Environment Health and Safety for 3D printers. The Korean Agency for Technology and Standards (KATS) is the convener of this group. The standard includes test methods to determine particle and chemical emissions from 3D printing processes that are used in non-industrial environments, including homes, schools, and office spaces.

ASTM is the primary standards organization that CPSC staff works with on matters related to mechanical hazards associated with additive manufactured parts. ASTM Committee F42 for additive manufacturing technologies and the ASTM Additive Manufacturing Center of Excellence are focused on the development of standards related to the materials, process, and properties of additive manufactured parts. The majority of the standards activity is related to metallic parts. At this time, the majority of applications are non-consumer product related, but staff anticipates additive manufacturing will be increasingly adopted by manufacturers of consumer products. Currently, the ASTM committees are driven by medical, aerospace and defense applications, and associated interests. Current staff activity has been limited to participation in ASTM subcommittee F42.07.09 on Consumer Products.

UL 60950 *Standard for Information Technology Equipment – Safety- Part 1: General Requirements* is the ANSI approved standard for the safety of 3D/AM printers. During the past few years, UL has been transitioning to a hazard-based safety engineering standard format under UL 62368-1 *Standard for Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements*. The new approach is designed to allow manufacturers to get their products to market in a timely manner. Staff is monitoring the effects of the transition and harmonization of the IEC requirements to the UL/CSA version of the standard to ensure that safety is not compromised with the new standard.

8 SUMMARY

The advent of 3D/AM processes has accelerated new product designs, and the demand for production in small-scale, educational or consumer settings has also expanded. 3D/AM products have few limitations in design and distribution. Free, open-source software allows novice product designers and home-based manufacturers to design and produce consumer products. Direct 3D/AM can be inexpensive enough to reduce barriers to entry into manufacturing sectors without the expertise common in the traditional manufacturing process, which may lead to increased safety hazards and diminished compliance with applicable safety regulations and voluntary standards. Staff has identified a myriad of potential hazards associated with 3D/AM processes and end products, which may be addressed through standards development and educating 3D/AM users on good manufacturing, environmental, health, and safety practices.

9 REFERENCES

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