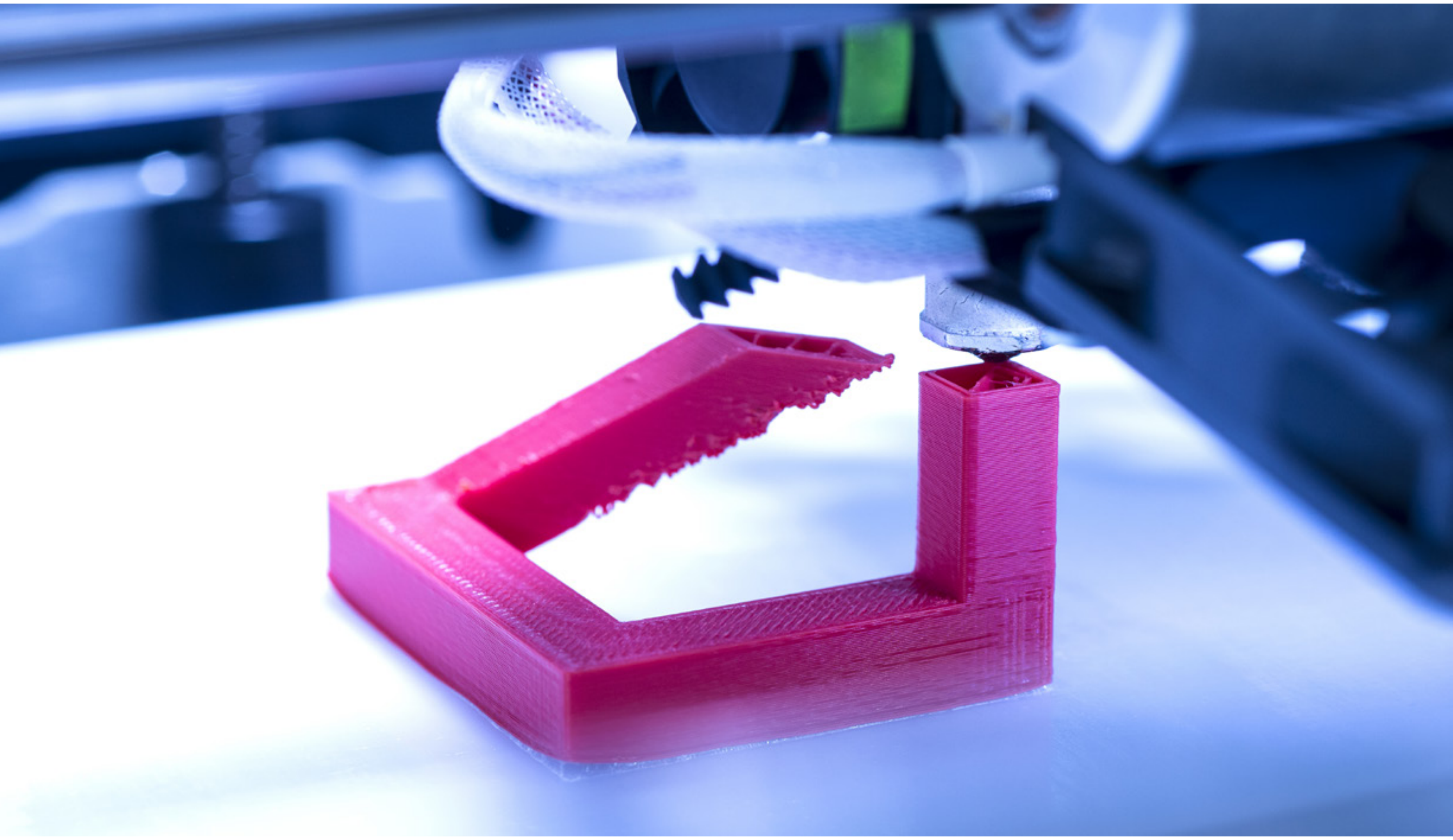
AIG EMERGING RISK RESEARCH

In collaboration with Praedicat

The Many Dimensions of 3D Printing and Additive Manufacturing



Executive Summary

In 2015, Adidas announced that it successfully produced a 3D printed running shoe. Adidas reported the "Futurecraft 3D" has a customized mid-sole based on a digital assessment of a runner's anatomy and running characteristics.[1] At the same time, General Electric reportedly produced a fuel nozzle for its LEAP jet engine via additive material layering which replaces traditional casting and fusing of twenty parts[2], with a nozzle that is 25% lighter and five times more durable than the traditional nozzle equating to roughly $3M of savings per aircraft, per year.[3] These examples paint a vibrant picture of future manufacturing - highly efficient, customized, localized, waste-minimizing, and technologically driven.

The rise of 3D printing, also known as additive manufacturing, will revolutionize global commerce. Companies will begin to shift away from standardized products, produced in massive factories, thousands of miles away from the point-of-sale. Retailers and consumers will likely take a bigger role – producing products in small batches on-demand, reducing unit costs, increasing customization and driving significant demand for software, hardware and production materials. The days of ordering a part and waiting for it to be produced by a far-flung factory, loaded on a ship or airplane and moved across the world are numbered.

As with any technological revolution, the benefits are balanced with risks. The risks of additive manufacturing can broadly be classified by stakeholder group – raw material suppliers, intermediate and finished goods manufacturers, software and hardware developers, workers, consumers, and communities. Much of the early research has focused on manufacturing quality, comparing 3D printed materials and products against more traditional methods. The core focus is material science and polymer physics to better assess physical properties such as shear, compression, durability and tensile strength.[4]

One area that has received limited attention thus far is worker safety. Additive manufacturing presents new angles on existing worker risks such as raw material exposure, the use of new machines, and handling of in-process and finished goods. In our discussions with leading additive manufacturers, some note that workers are exposed to "significant amounts of dust" via newly designed manufacturing processes. Risk managers are wrestling with this new exposure and seeking information and practices to reduce uncertainty and manage risk.

To address this concern, AIG partnered with Praedicat, an innovative data science company that uses algorithms to mine the scientific literature and score potential harmful agents. Using Praedicat's technology, we focused on commonly used additive manufacturing substances and assessed research on exposure and potential human health impacts. While the literature is still developing, there are early insights that can be drawn and used to better manage worker safety as additive manufacturers scale up.

Our research indicates that some commonly used additive manufacturing materials have the potential to cause worker injuries. This includes the inhalation of ultrafine metal and other nanoparticles along with volatile organic compounds (VOCs) that have the potential to cause adverse health impacts such as lung and nervous system injury, mental impairment, various forms of cancer, and hearing loss. While the science is in different states of maturity, some exposure and disease combinations are well-supported while others continue to develop.

Businesses using additive manufacturing can take a proactive approach to managing worker safety by reviewing the science and adjusting manufacturing processes accordingly. For example, elimination or substitution might be considered when the scientific evidence indicates the risk of using a specific agent is particularly high. For all agents, common worker safety processes and engineering controls can be applied to additive manufacturing such as proper ventilation, system enclosures, rotating worker shifts, and using proper respirator equipment. Businesses should also utilize proper disposal techniques to avoid environmental contamination and protect those workers charged with the disposal and removal of residue or equipment. These activities, in combination with a broader worker safety program, will address the most common worker safety risks.

AIG endeavors to continue its research and partner with the world's leading additive manufacturers. We are committed to leveraging science and engineering to reduce uncertainty and better manage this unique risk. The AIG-Praedicat partnership demonstrates this unique approach and we look forward to additional partnerships that foster the growth of additive manufacturing while managing its risks.

Overview

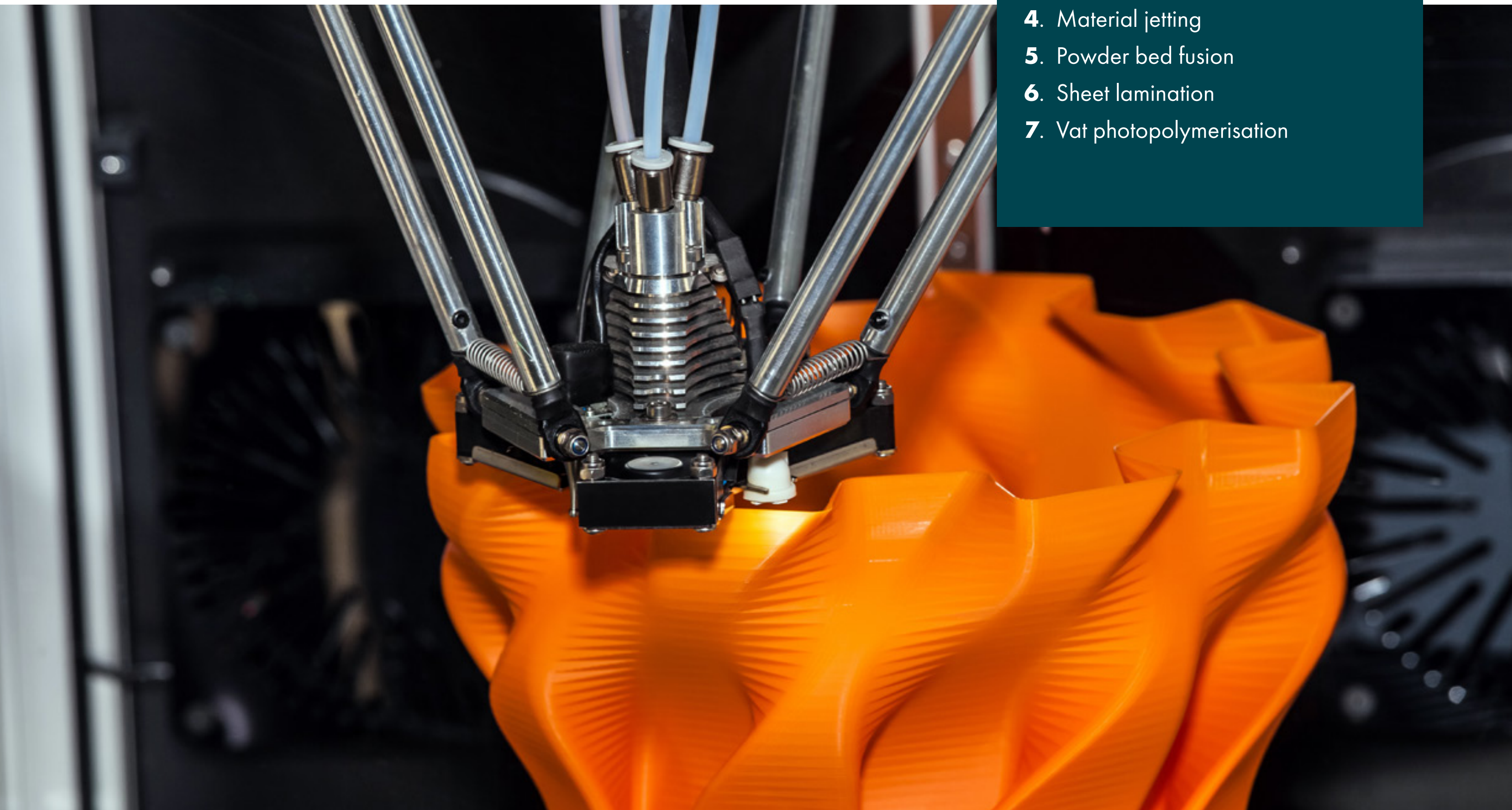
Additive manufacturing is the creation of a three-dimensional object using successive layering of materials. It differs from traditional manufacturing techniques that rely on the removal of materials to create a shape. Additive manufacturing is much more flexible and versatile than traditional manufacturing methods because nearly any shape can be printed using a relatively simple combination of hardware and software.

The technology and approach is not new. It has been used for decades, most often to make prototype parts. As the technology advanced, it moved beyond prototyping to standard production. The current and potential applications of additive manufacturing span virtually all industries including many sectors and businesses that were never previously involved in manufacturing. For example, Dubai-based construction firm Cazza is working with the UAE government to pursue a goal of 3D printing 25% of the country's buildings by 2030.[5]

As additive manufacturing has matured, the list of materials has also grown. For example, Fused Deposition Modeling™, the most popular type of material extrusion, commonly uses several plastics: acrylonitrile-butadiene-styrene, polylactic acid, nylon, polystyrene, and polyethylene terephthalate. Recently, material suppliers have added carbon nanotubes and graphene to material extrusion filaments and powder bed fusion materials to enhance material properties of the finished product.[6] Metals and their alloys are another main class of material, frequently using an alloy ground down to an ultrafine powder for use in powder bed fusion. These alloys are commonly based on titanium, stainless steel, nickel, aluminum, and cobalt-chromium.

The term additive manufacturing encompasses a variety of technological processes. The American Society for Testing Materials (ASTM) and ISO developed a joint standard (ISO/ASTM 52900) to categorize additive manufacturing processes:

1. Binder jetting
2. Directed energy deposition
3. Material extrusion
4. Material jetting
5. Powder bed fusion
6. Sheet lamination
7. Vat photopolymerisation



Industry outlook

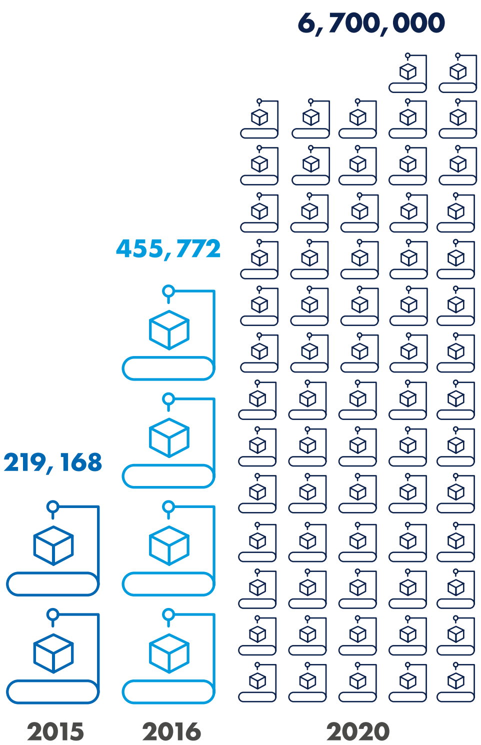
As industry applications grow and material science improves, we will continue to see 3D printing grow. There are several business factors that will continue to fuel the growth.

First, additive manufacturing may be more cost effective and flexible than traditional subtractive methods. Printing items on-site and on-demand will likely dramatically reduce the cost of carrying stock, while simplifying logistics operations and mitigating supply chain risks. Additive manufacturing also allows customers to customize products and enables its practitioners to reverse engineer obsolete or legacy equipment and parts to keep costs down.

Eventually, additive manufacturing may prove faster, less energy consumptive, and less wasteful than traditionally manufactured parts. Technological advances in the additive manufacturing ecosystem, from printers to software to materials, have allowed the speed of operations to approach levels needed for mass production. Larger-scale items are becoming easier to produce using additive manufacturing as printer manufacturers have been able to create and deploy ever-larger printers.

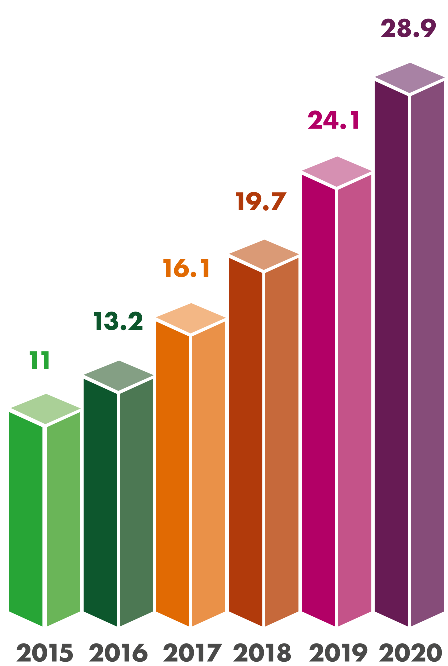
While market forecasts for additive manufacturers vary, nearly all project the market for 3D printing to grow dramatically in the next five years. With most rapid industrial growth, especially those driven by new technology, we expect new risks to emerge in short order. The remainder of this report discusses these risks and the measures that additive manufacturers could employ to address the risks.

Global unit shipments of 3D printers, 2015 - 2020



Source: Gartner, Global unit shipments of 3D printers from 2015 to 2020, October 2016

3D printing market size worldwide, 2015 - 2020 (USD billions)



Source: IDC, 3D printing market size worldwide from 2015 to 2020 (in billion U.S. dollars), January 2017

Risk Spotlight

- **Operational safety:** Additive manufacturing is already, and will increasingly be used, by non-traditional manufacturers. While traditional manufacturers commonly have risk mitigation measures in place, new additive manufacturers may have no such experience. Compounding this risk, additive manufacturing uses metals and plastics that can generate toxic exposures (as we discuss herein). Using additive manufacturing in public spaces (e.g. retail stores) may create occupational- and consumer-type risks for third parties who would remain unexposed from traditional processes.

- **Environmental:** One of the benefits of additive manufacturing is the reduction (or decrease) of by-product compared to subtractive manufacturing. There is still some residue, however, and depending on the materials used, specific disposal protocols may be required to comply with government environmental regulations and overall community safety standards.

- **Intellectual property/data integrity:** Additive manufacturing allows for relatively easy replication of existing objects, increasing the risk of counterfeiting. Whether intentional or accidental (e.g. via cyber-attack), changes to an object's digital model or the additive manufacturing software can result in changes to manufactured products, lead to product or printer failure, and result in several kinds of damage.

- **Product liability:** Under traditional product liability law, the persons or entities responsible for a defective product are those who manufactured or sold it. Additive manufacturing can create many possible defendants in a product liability lawsuit depending on how the definition of "manufacturer" is construed. Non-traditional manufacturers who print and sell products may be held liable as manufacturers. Plaintiff lawyers may also attempt to hold accountable the 3D model developers and/or software developers involved in a part's creation and the systems used to manufacture it.

- **Strategic risks:** Additive manufacturing may dramatically change the industrial ecosystem by shifting production away from low-cost labor centers to the point-of-sale. Many companies have large investments in highly-specialized production facilities that may need to be retooled in a similar fashion to the "mini-mill" revolution in steel production. Others in the supply chain such as shippers, wholesalers and retailers will have their business models called into question as more on-site production occurs. Enterprising retailers will form new business models, becoming mini-production centers rather than pure retail outlets. Software developers, additive manufacturing hardware manufacturers, and raw material suppliers, such as chemical companies, will see significant increases in demand.

Additive Manufacturing, Occupational Risks, and Worker Safety

Patterns of scientific publishing

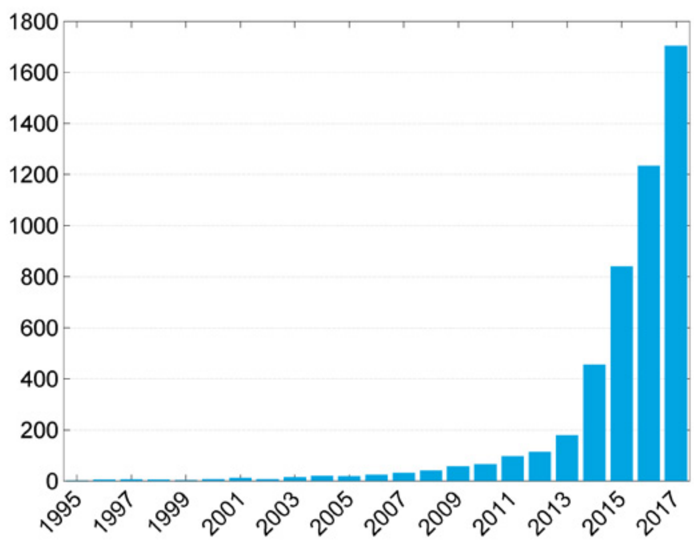
A key leading indicator of emerging risk is scientific literature. As additive manufacturing has grown, both with companies and consumers, the scientific literature discussing its risks and benefits has exploded, as shown below.

The vast majority of the published, peer-reviewed, scientific literature examines the potential benefits of additive manufacturing in various applications: prostheses, biomaterials, implants, wound healing, and other biomedical and engineering applications. This leaves a small minority of the remaining science – several dozen papers – to discuss the potential risks to people who use additive manufacturing technologies in their work or as a hobby. The majority of the bodily injury- and exposure-related literature was published in 2017, with the first papers appearing in 2015.

Only two papers directly investigated potential human harm from additive manufacturing, and they were published in August and November 2017. The first was a case report discussing a 28-year old man who became asthmatic after using Fused Deposition Modeling with ABS plastic.[7] The second studied the effects of 3D printer emissions from a Fused Deposition Modeling system on the rat cardiovascular system and found that they induced acute hypertension and microvascular dysfunction.[8]

Given the increased use of additive manufacturing and the scientific interest to date, one should expect that scientists will continue to investigate the resulting human exposures and health effects over the next several years. As one 2015 review[6] of additive manufacturing noted: "the potential toxicity, environmental hazards, and chemical degradability of materials and solvents in additive manufacturing remain a topic of considerable research potential."

Scientific articles about additive manufacturing



What is in additive manufacturing emissions?

Although a very wide range of materials are used in additive manufacturing, the exposure literature to date has focused on two primary issues:

- ultrafine (i.e. nanoscale) particles, and
- volatile organic compounds.

These two classes of emissions are not unique to any one additive manufacturing-related material or process but the composition of the emissions are. The adjacent box lists specific chemicals in additive manufacturing emissions that have been highlighted in the scientific literature. [9] [10] [11] [12] [13] [14] [15]

Much of the existing literature does not characterize the individual nanoparticles that are emitted during 3D printing. Instead, it focuses on particle size, amount, and concentration. [9] [11] There are two reasons for this:

- several effects are less dependent on particle composition than on exposure; and
- it can be difficult to identify the constituents of individual particles.

However, it is reasonable to assume that additive manufacturing using metals as input can result in the production of nanoparticles of the input material, its alloys, and related oxidized species.

Additionally, volatile organic compounds are used ubiquitously in industrial processes and are often incorporated into the types of polymers used in additive manufacturing. For example, ABS plastic, used in pipes and Legos™, is a copolymer consisting of acrylonitrile, butadiene, and styrene. When heated, some of the polymer can break down and/or residual amounts of the building blocks can be released. In contrast to agglomerated ultrafine particles, volatile organic compounds are often readily identified using precision laboratory equipment. Most of the identified compounds have rich literatures outside of their application in additive manufacturing that can help inform us about risk.

Materials cited in the scientific literature as being emitted from additive manufacturing processes

Ultrafine particles and nanoparticles

Titanium & titanium alloys
Aluminum & aluminum alloys
Soot
Iron & steel
Zinc
PM2.5

Volatile organic compounds

Styrene
Xylenes
Toluene
Benzene
Ethylbenzene
n-hexane
Acetone
Acetonitrile
Ethanol
Isopropanol
Acetaldehyde
Methyl methacrylate
Pyrene
Caprolactam
Lactide

How does material affect risk?

Each combination of input material and additive manufacturing process can present its own risks; due to the immense number of such combinations, the extent and characteristics of volatile organic compounds and ultrafine/nanoscale particle exposure remain largely unknown. Research is ongoing, both into potential human harms and the types of exposures to which additive manufacturers may be subjected. Researchers recognize that emissions vary across processes and have started to investigate multiple input material types and printing processes to discern the differences.

Nanoscale Particles

Nanoscale particles, such as those making up metal powders, may pose risks. Namely, they can easily infiltrate the respiratory tract and get lodged in the lungs. Combined with the increased surface area to volume ratio inherent in nanoparticles, their potential reactivity is many times greater than that of an equivalent amount of the corresponding micro- and meso-scale particles.

In 2013, the U.S. National Institute of Standards and Technology (NIST) compiled a technical report detailing the "lessons learned" while establishing an additive manufacturing laboratory.[15] They explain that raw metal input powders may present the greatest risk to machine operators because of the myriad safety issues they present. Aerosolized metal powders present an explosion risk, while body contact has the potential to cause irritation to eyes and skin. Furthermore, inhalation of metal powders may lead to pulmonary fibrosis from nonspecific immune responses while ingestion can cause gastrointestinal upset. The NIST report references aluminum powder specifically, and we note here that the science linking chronic aluminum exposure to bone demineralization and to mental impairment is very strong with a high degree of scientific consensus. There is also a substantial body of scientific literature linking aluminum exposure to pneumoconiosis while emerging literatures are tracking several other bodily injury hypotheses, including multiple cancers and neurodegenerative disease.

Extending this discussion to the other cited metal powders suggests that the risks presented by any of them ought to be considered. The increasing use of carbon nanotubes in additive manufacturing input materials also suggests the potential emergence of a new exposure. While carbon nanotubes embedded in composite materials rarely escape from the bulk substance, they can be released during finishing processes such as sanding and buffing. While the scientific consensus today remains low regarding the risk of lung damage or cancer due to carbon nanotube inhalation, it is common for new research to track potential new exposures. In the table below we use Praedicat's analytical engine to summarize the scientific consensus around the most important human harm hypotheses in the peer-reviewed scientific literature. One can think of harm hypotheses where the current scientific consensus is 'low' as emerging risks, with the possibility that future research may establish a stronger causal link. Similarly, harm hypotheses already rated 'high' are established risks.

Material	Potential Risk	Scientific Consensus
Aluminum	Mental impairment	High
Aluminum	Bone demineralization	High
Aluminum	Pneumoconiosis	Medium
Carbon nanotubes	Pneumoconiosis	Low
Carbon nanotubes	Lung Cancer	Low
Cobalt	Metallosis (medical implants)	High
Cobalt	Pneumoconiosis	High
Cobalt	Cardiovascular disease	Medium
Chromium(VI)	Lung cancer	High
Chromium(VI)	Gastrointestinal cancer	Medium
Nickel	Lung cancer	Low
Stainless steel	Lung cancer	High
Stainless steel	Nervous system injury	High
Stainless steel	Pneumoconiosis	Medium
Titanium dioxide nanoparticles	Pneumoconiosis & asthma	Low
Titanium-aluminum alloys	Osteolysis (medical implants)	Medium

Volatile Organic Compounds

While the list of volatile organic compounds detected during additive manufacturing processes is long, a small subset of identified volatile organic compounds are most commonly cited, including lactide, methyl methacrylate, and styrene. Lactide is a simple combination of two molecules of lactic acid, and has been cited as one of the primary emitted volatile organic compounds when the printed material is polylactic acid.[13] At the time of writing, there is no literature investigating the toxicology of lactide or any epidemiology specifically mentioning lactide as a suspected cause of disease. In fact, according to the biomedical literature, lactide is mainly used to build polylactic acid polymers for biomedical applications. It is important to note, however, that implantation uses of polylactic acid do not yield significant information regarding any potential inhalation risks of lactide.

Methyl methacrylate is used in a variety of materials, primarily as an input into various formulations of acrylic plastics. Methyl methacrylate is known to be flammable and to irritate eyes, skin, and lungs.[17] It is another major emitted volatile organic compound from printing using polylactic acid, with one study citing it as comprising 44% of total volatile organic compounds emissions.[14] Methyl methacrylate has been investigated for its potential to cause arrhythmias, hyposmia (a reduction in ability to detect odors), colorectal cancer and pneumoconiosis. Methyl methacrylate is an example of a potential emerging risk - none of these bodily injury hypotheses currently has more than a low degree of scientific consensus, nor are any of them projected to increase dramatically in the next seven years.

Styrene is a basic organic chemical used to build a variety of polymer resins, rubbers, and plastics, including ABS plastic, styrene-butadiene rubber, and expanded polystyrene foams. Styrene-based polymers are used to produce hundreds of products. Styrene also occurs naturally in the gasses emitted from burning organic matter and in a variety of foods. Styrene has repeatedly been found to be the most common volatile organic compound emitted from additive manufacturing using ABS plastic.[12 13 14] An already established risk, styrene exposure is consistently linked to the development of peripheral neuropathy, a condition where the nerves between the brain and the rest of the body are damaged resulting in weakness and numbness in the hands and feet. It is also strongly linked to speech-frequency hearing loss, although the research indicates that the combination of noise along with styrene exposure may be required to trigger this type of hearing loss. As different additive manufacturing setups likely have different noise profiles, one should not discount the possibility of research emerging investigating a link between it and hearing loss. In the table below we use Praedicat's analytical engine to summarize the scientific consensus around the most important human harm hypotheses in the peer-reviewed scientific literature.

Material	Potential Risk	Scientific Consensus
Lactide	None found	N/A
Methyl methacrylate	Arrhythmia	Low
Methyl methacrylate	Pneumoconiosis	Low
Styrene	Speech-frequency hearing loss	High
Styrene	Peripheral neuropathy	High
Styrene	Mental impairment	High
Styrene	Asthma	High
Styrene	Retinal damage	High

Risk mitigation

The risk of bodily injury from exposure to volatile organic compounds and nanoparticle emissions from additive manufacturing can be mitigated with standard protections and procedures, including: personal protective equipment and closed handling systems.[18 19] Differences between additive and traditional manufacturing will require experienced manufacturers to consider what changes are necessary to mitigate additive manufacturing's unique risks. The expansion of additive manufacturing to non-manufacturing environments also poses a new potential threat: exposures to third parties within a building or facility.

When it comes to worker safety and exposure control, practicing industrial hygienists rely on what's known as the hierarchy of controls:

(1) Elimination
(2) Substitution
(3) Engineering controls
(4) Administrative controls
(5) Personal protective equipment

The first two methods of control are elimination and substitution. This essentially means that if the hazard can be removed or a less hazardous material can be used in place of a more hazardous one, then that is the safest course of action. Of course, this may not often be feasible, since a substituted material has to meet the same performance requirements as the original to ensure the end product performs as required. In some cases, a dry product might be replaced by one in a liquid suspension to reduce particle volatilization and subsequent exposure.

The next step in the hierarchy, engineering controls, includes measures such as proper ventilation and system enclosures. For example, a printer could be isolated under negative pressure so that nanoparticles and volatile organic compounds generated during the printing process are vented out, away from employees and third parties. In another case, a downdraft ventilation system might be installed to draw contaminants away from machine operators. Researchers who assessed volatile organic compounds and particulate matter from a binder jetting 3D printer recommended "enclosure of the system..., operation next to a ventilation hood or open windows, wearing of appropriate respiratory protection if room ventilation is not sufficient and storage of the resin-like solution inside fume hood when the printer is turned off... to reduce the health exposure risk."[20] Even with isolation and ventilation, personal protective equipment may still be necessary in order to clean the machines and perform maintenance.* 3D printing with metals can generate films of fine particulates on flat surfaces, and these can accumulate if housekeeping is poor, leading to explosion hazards along with the hazards discussed above.

Administrative controls, unlike the three prior control methods, do not work to eliminate the hazard itself, but instead focus on limiting overall employee exposure by rotating tasks or exposure times. An example is limiting an employee to operating a 3D printer for half of a shift before rotating them to another task without any exposure.**

Personal protective equipment is the final rung in the hierarchy of controls. Employees that are provided personal protective equipment must be trained on how to effectively and safely use and maintain it. If respiratory protection will be used, medical clearance and fit tests are required. Some researchers caution that the ability of respirators to adequately protect against nanoparticle exposure is unknown, and additive manufacturing technology is too nascent to fully understand all of its potential risks. [21 22 23] Employers need to be proactive in applying best practices while researchers catch up.

Non-traditional manufacturers, such as retailers and service businesses, may lack familiarity with general manufacturing practices and the hierarchy of controls regarding worker safety and exposure control. Employers new to this field will need to investigate and implement the controls that will be most relevant to their additive manufacturing operations to minimize the risk to their employees and nearby third parties.

Selection of protective clothing, like respiratory protection, should be based on the specific nanoparticles or substances used in the process. Fit factors, proper seal, use and maintenance, and limitations of each type of respirator must be considered.

For gloves, the American Industrial Hygiene Association states that good quality, disposable gloves made from nitrile, neoprene, latex, or other chemical resistant material, should be used. Eye protection should also be a consideration if the respirators being worn do not provide eye protection. The American Industrial Hygiene Association also recommends tight-fitting dustproof safety goggles for use in high exposure scenarios. After use, personal protective equipment should be properly disposed of to prevent cross contamination of other work areas or employees' homes.

* NIST found that health risks appeared greatest when loading metal powder into the machine or manipulating powder inside the build chamber and mandated NIOSH-approved full face respirators or powered air purifying respirators with a P100 HEPA cartridge for any operator or employee involved in powder manipulation.[17]

**The need for training and recordkeeping becomes evident the further the topic is discussed. Previously untrained employees may now need to receive and understand general HAZCOM, respiratory protection & other PPE, and housekeeping training, as well as medical monitoring and fit testing. All of this means that employers, including small businesses, may need to implement Health and Safety programs, which outline these training programs and recordkeeping requirements as dictated by OSHA.

Wrap-up and Next Steps

Additive manufacturing will dramatically change the manufacturing sector in the next ten to fifteen years. This paper aims to increase the focus on worker safety research in parallel with more common materials research. A science-based analytical assessment can be used to highlight emerging risks to workers and measure the value of deploying controls to mitigate those risks. A sound risk management process will span all additive manufacturing activities, including, but not limited to, material selection, job set-up production facility design, cleaning and maintenance and worker safety training.

AIG will continue its research on additive manufacturing risks and looks forward to partnering with clients and research partners on these initiatives to ultimately reduce the level of uncertainty and risks associated with additive manufacturing implementation.

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