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Responding to COVID-19 with Additive Manufacturing

In response to COVID-19, many companies are working to create the equipment needed to treat patients and protect healthcare workers. Medical device companies are quickly scaling manufacturing operations, while other manufacturing companies are adapting their operations to assist. Some companies are experiencing difficulty in getting parts and tooling necessary for their operations, as suppliers and transportation networks adapt to containment measures for COVID-19.

Introducing additive manufacturing into the supply chain will help organizations overcome some of these challenges.

Managing Uncertainty with Additive Manufacturing

- Flexibility to increase short-term production capacity with shorter changeover and no additional capital expenses
- Shorten production ramp for conventional manufacturing with AM tool
- Manufacture parts closer to point of use, reducing impact of disruptions to transportation
- Additive Manufacturing capacity can be added without new capital expenses by identifying conventional suppliers with AM capabilities or adding AM-exclusive service bureaus to your supply chain
- Enable supply chain disintermediation by reducing components when you follow Design for Additive Manufacturing (DfAM) guidelines to take advantage of unique AM features

COVID-19 Applications

Personal protective equipment (PPE)
- Face shield
- Face mask
- Respirator

Ventilator components
- Air exchanger
- Filter adapter
- In-line filter housing
- Pneumotachometer
- Ventilator splitter
- Flow restriction device

Rapid tooling
- Shorten production ramp for conventional manufacturing

Additive Manufacturing Technologies

Note: the following terms/definitions are based on "ISO/ASTM 52900: Standard Terminology for Additive Manufacturing - General Principles - Terminology"

	Typical Process Features	
	MATERIALS Metals Polymers Ceramics	PART SIZE S M L
Material Extrusion Material is selectively dispensed through a nozzle or orifice	■	● ● ●
Material Jetting Droplets of build material are selectively deposited	■	● ● ○
Vat Photopolymerization Liquid photopolymer in a vat is selectively cured by light-activated polymerization.	■ ■	● ● ○
Directed Energy Deposition Focused thermal energy is used to fuse materials by melting as they are being deposited.	■	○ ● ●
Powder Bed Fusion Thermal energy selectively fuses regions of a powder bed.	■ ■	● ○ ○
Binder Jetting A liquid bonding agent is selectively deposited to join powder materials.	■ ■ ■	● ● ○
Sheet Lamination Sheets of material are bonded to form a part.	■ ■	● ● ●

For more information

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COVID-19 EMERGENCY RESPONSE

Design for Additive Manufacturing

In response to the COVID-19 emergency, many individuals/organizations are willing to help by sharing medical part designs.

Designers working on products to be fabricated with Additive Manufacturing (AM) should be aware of the unique capabilities and limitations of these processes. This brief guide draws from AM standards to provide guidance for designers responding to the needs of healthcare workers and patients during COVID-19.

The ultimate objective is to increase the quality of designs submitted (to the America Makes portal and other potential channels) and shorten the design review/selection process.

Benefits of Design for Additive Manufacturing (DfAM)

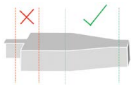
- Reduce Costs
- Decrease Production Time
- Improve Part Performance
- Improve Material Performance
- Reduce Part Mass
- Reduce/Eliminate Post-Processing
- Reduce/Eliminate Assembly

Common Design Issues

Selected extracts from ISO/ASTM 52910:2018 (Clause 7. Warnings to designers)

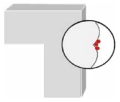
DETAIL LOSS (POST-PROCESSING)

Small features on parts can become degraded during part removal from the machine or during post-processing.



ABRUPT THICKNESS TRANSITIONS

Abrupt thickness transitions can cause distortions or accuracy problems



CLEANLINESS

Loose residual material can remain on the part; in some applications additional cleaning measures may be required.

TRAPPED VOLUMES

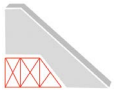
Design access to internal features to release trapped material

DETAIL LOSS (PART FILE)

Common file types define geometries by surface triangles. Triangle sizing has a significant impact on surface smoothness and accuracy.

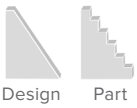
UNITLESS PART FILES

Common file types are unitless, and under or oversized parts may be produced if units are not successfully communicated.



BUILD ORIENTATION

Orientation of the part relative to the build plane influences the support structure, productivity, material usage, and part performance.

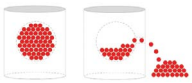


LAYERING/STAIR STEPS

The layer-based process often leaves small surface transitions along the part surfaces.

Recommendations

Reference AM standards for guidelines and recommendations.



Design slots or holes for material removal. Ensure post-processing includes thorough part cleaning and plug any holes at this stage, if needed.

Use the standardized .AMF part file which describes an object for AM processing in more detail than .STL ISO/ASTM 52915:2016(E).

Communicate with the additive manufacturing engineer to orient the part in the build chamber to minimize the impact of these features.

Design for Additive Manufacturing Standards (ASTM F42.04)

ISO/ASTM 52900:2015
Standard Terminology for Additive Manufacturing – General Principles – Terminology

ISO/ASTM 52915:2016
Standard Specification for Additive Manufacturing File Format (AMF) Version 1.2

ISO/ASTM 52910-1:2018
Additive manufacturing — Design — Requirements, guidelines and recommendations

ISO/ASTM 52911-1:2019
Additive manufacturing — Design — Part 1: Laser-based powder bed fusion of metals

ISO/ASTM 52911-2:2019(E)
Additive manufacturing — Design — Part 2: Laser-based powder bed fusion of polymers

ISO/ASTM 52901:2016
Standard Guide for Additive Manufacturing – General Principles – Requirements for Purchased AM Parts

Following DfAM guidelines and communicating with AM process specialists is critical to the success of the final parts. Published AM standards can provide more detailed guidance and additional considerations not covered here, such as:

1. **Process limitations**
   minimum feature sizes, surface finish
2. **Materials**
   safety, permeability, recycling
3. **Thermal effects**
   shrinkage, distortion, residual stress
4. **Productivity**
   nesting, process optimization

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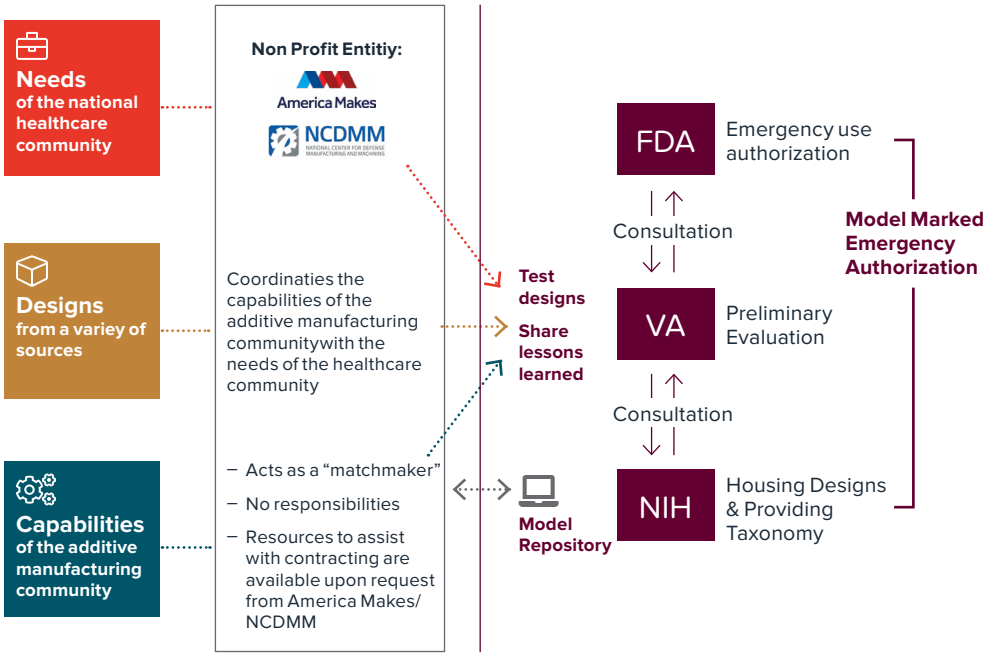
Additive Manufacturing Community Response to COVID-19

America Makes

America Makes is maintaining a portal to submit your organization's AM capabilities, AM designs, or health care PPE needs to help match manufacturing capabilities with needs.

LEARN MORE
www.americamakes.us/statement-on-covid-19/

ASTM International publishes voluntary consensus standards for a wide range of materials, products, systems, and services including additive manufacturing, medical devices, and personal protective equipment. These standards provide requirements, guidelines, and recommendations that can accelerate the design review and validation.



FDA

The Federal Drug Administration (FDA) has published a FAQ on 3D Printing Medical Devices, Accessories, Components, and Parts during the COVID-19 Pandemic

LEARN MORE
www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic

ASTM INTERNATIONAL

ASTM International is providing no-cost public access to important ASTM standards used in the production and testing of personal protective equipment - including face masks, medical gowns, gloves, and hand sanitizers - to support manufacturers, test labs, health care professionals, and the general public as they respond to the global COVID-19 public health emergency.

LEARN MORE
www.astm.org/COVID-19

- F42: Additive Manufacturing Technologies
- F04: Medical and Surgical Materials and Devices
- F23: Personal Protective Clothing and Equipment
- D11: Rubber and Rubber-like Materials
- E35: Pesticides, Antimicrobials, and Alternative Control Agents

CENTER of EXCELLENCE
Research to Standards

ASTM Additive Manufacturing Center of Excellence (AM CoE) brings together industry, government, and academia to optimize the AM R&D and standards development processes. By tightly coupling these processes, standards get into the hands of those who need them faster, drastically reducing AM time to market and increasing widespread adoption.

- Establish standards, certification, and qualification for repeatable, consistent parts and processes
- Prevent gaps and duplication of work in a dynamic, fast-paced technology space
- Identify challenges that can be solved with technological improvement

LEARN MORE
www.amcoe.org

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ASTM Standards and COVID-19

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Visit **www.astm.org/COVID-19** to access these standards through the ASTM Reading Room.

Masks

ASTM F2299/F2299M-03(2017 — Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

ASTM F2101-19 — Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

ASTM F2100-19 — Standard Specification for Performance of Materials Used in Medical Face Masks

ASTM F1862/F1862M-17 — Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

ASTM F1494-14 Standard Terminology Relating to Protective Clothing

Medical Gowns

ASTM F2407 - 06(2013)e1 — Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities

ASTM F1671 / F1671M - 13 — Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

ASTM F1868 - 17 — Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate

ASTM D751 - 19 — Standard Test Methods for Coated Fabrics

ASTM D1683/D1683M-17(2018) — Standard Test Method for Failure in Sewn Seams of Woven Fabrics

ASTM D1776/D1776M-20 — Standard Practice for Conditioning and Testing Textiles

ASTM D5034-09(2017) — Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

ASTM D5587-15(2019) — Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

ASTM D5733 - 99 — Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure (Withdrawn 2008)

ASTM D6701-16 — Standard Test Method for Determining Water Vapor Transmission Rates Through Nonwoven and Plastic Barriers

ASTM F1494-14 — Standard Terminology Relating to Protective Clothing

Gloves

ASTM D6319-19 — Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D3578-19 — Standard Specification for Rubber Examination Gloves

ASTM D5250-19 — Standard Specification for Poly(vinyl chloride) Gloves for Medical Application

ASTM D6977-19 — Standard Specification for Polychloroprene Examination Gloves for Medical Application

Hand Sanitizers

ASTM E2755-15 — Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults

ASTM E1174-13 — Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations

ASTM E3058-16 — Standard Test Method for Determining the Residual Kill Activity of Hand Antiseptic Formulations

Respirators

ASTM F3387-19 Standard Practice for Respiratory Protection