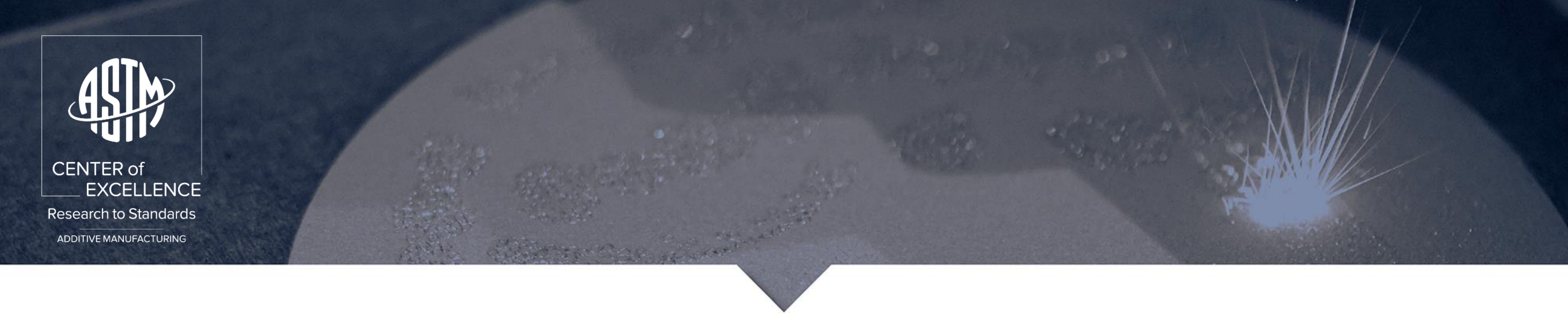


ASTM INTERNATIONAL
Additive Manufacturing Center of Excellence

Role of Additive Manufacturing in PPE Shortage Mitigation

Kirstie Snodderly
February 23, 2022

www.amcoe.org

Agenda

- Introduction
- ASTM AM Center of Excellence
- PPE Shortages
- Community, Industry, Government Response using Additive Manufacturing
- ASTM Response
- Collaboration

Responding to COVID-19
with Additive Manufacturing

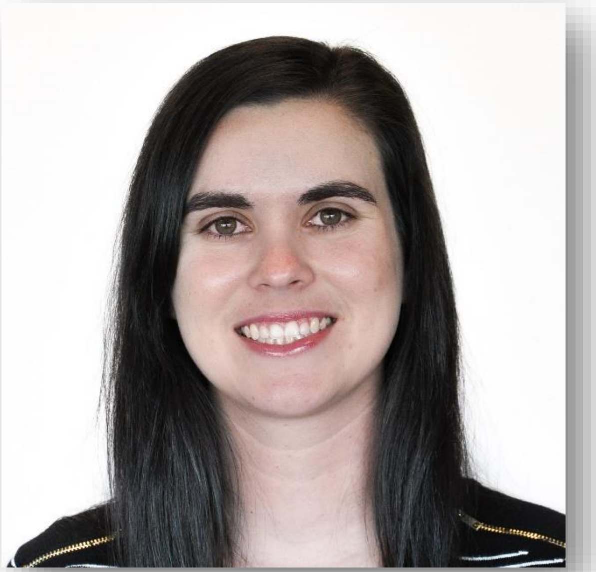
Introduction

- Additive Manufacturing R&D Project Engineer, ASTM International

- 5 years of experience in additive manufacturing for medical applications

- Former Additive Manufacturing Engineer for the Additive Manufacturing of Medical Products (AMMP) Lab at the US FDA – Food and Drug Administration

- Master of Engineering and Bachelor of Science in Bioengineering from the University of Maryland



ASTM AM CoE – Research to Standard

- **ASTM formed Additive Manufacturing Center of Excellence (AM CoE) in 2018**

Mission

The Center bridges standards development with R&D to better enable efficient development of:

- Standards
- Education and training and
- Certification and proficiency testing programs

Vision

The Center facilitates collaboration and coordination among government, academia, and industry to:

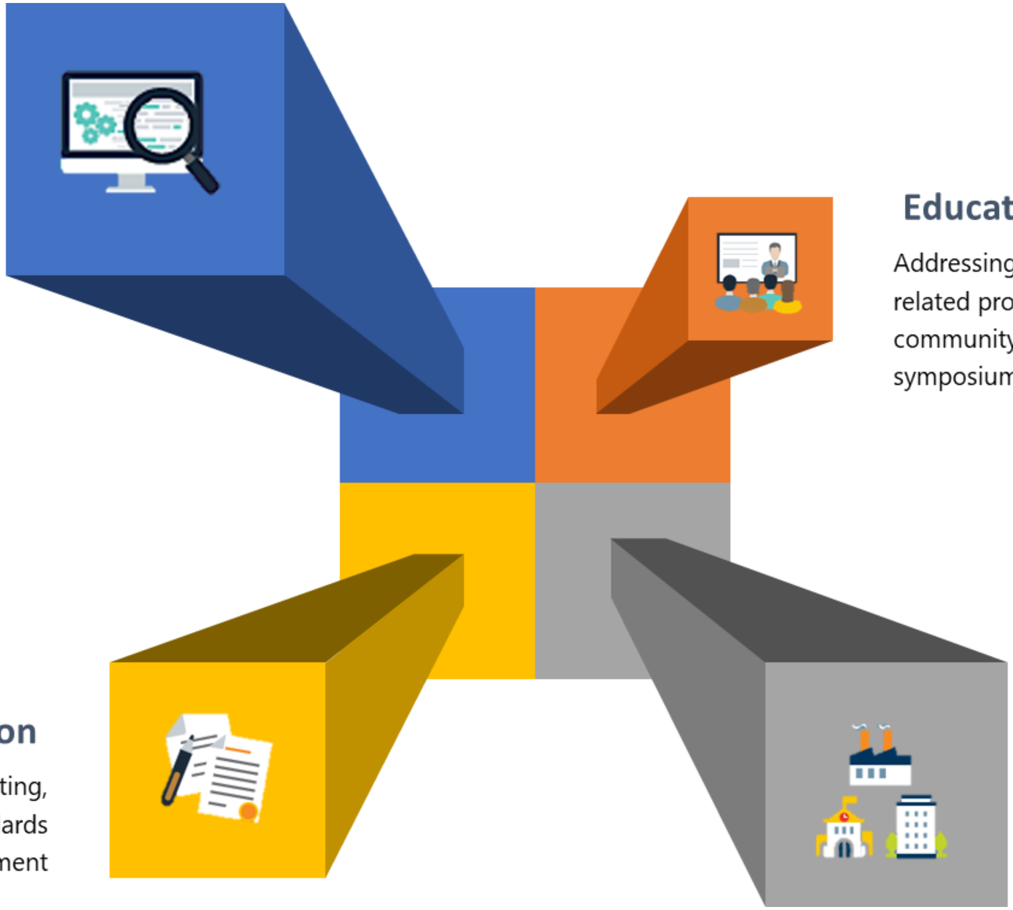
- Advance AM standardization
- Expand ASTM International's and our partners' capabilities.

ASTM Committee F42 is dedicated to AM and has technical subcommittees focused on the development of consensus-based standards. This is happening in partnership with ISO TC261.

ASTM AM CoE is a collaborative partnership among ASTM and organization representing government, industry, and academia that conducts strategic R&D to advance standards across all aspects of AM in addition to create E&WD and Certification Programs.

ASTM AM CoE Focus Areas

CENTER of EXCELLENCE
Research to Standards
ADDITIVE MANUFACTURING



Research & Development

Leverage R&D to significantly accelerate standards development.

Education and Workforce Development

Addressing standards and standards related program gaps of the AM community via webinars, workshops, symposiums and conferences.

Standards and Certification

Benchmarking materials, testing, processes and machinery for standards development

Industry Consortia

Serving as a consortium platform for all industry sectors leveraging AM technologies

CENTER of EXCELLENCE
Research to Standards
ADDITIVE MANUFACTURING

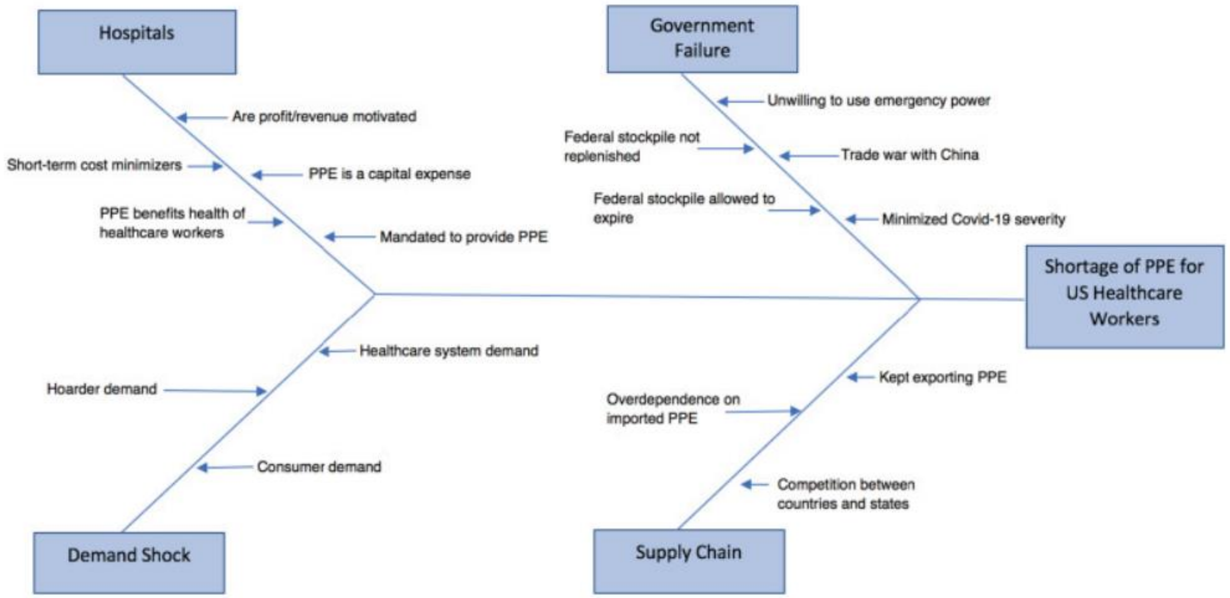
PPE Shortages during the COVID-19 pandemic

U.S. FOOD & DRUG ADMINISTRATION

Medical Device Shortages During the COVID-19 Public Health Emergency

- The US FDA has created and maintained a list of US medical device shortages which include PPE such as:
    - Face masks
    - Respirators
    - Medical Gowns
    - Gloves

- Why shortages exist in the US:
    - Hospitals
    - Government
    - Demand Shock
    - **Supply Chain**



Cohen, J., & Rodgers, Y. (2020). Contributing factors to personal protective equipment shortages during the COVID-19 pandemic. *Preventive medicine*, *141*, 106263. https://doi.org/10.1016/j.ypmed.2020.106263

CENTER of EXCELLENCE
Research to Standards
ADDITIVE 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

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

★ Most Common for PPE fabrication

Why Additive Manufacturing

Benefits of Additive Manufacturing

- Flexibility
- Design Freedom*
- Rapid Prototyping – Short turnaround time
- Part Integration
- **Supply Chain Mitigation**: manufacture parts closer to point of use
  - Reducing impact of disruptions to transportation

* Compared to Traditional Manufacturing

Community and Industry Response

- Individuals began to sew fabric masks and donate them to health care and essential workers
- Community members created social media pages to connect individuals who wanted to help
- Industry, Academia, and other organizations called for community help to address shortages by providing designs or creating design challenges:
  - **Open-source designs for door openers, face shields, face makes, etc.**
  - **America Makes: Fit to Face AM Mask Design Challenge**

A Sewing Army, Making Masks for America

With overrun hospitals facing an acute shortage of masks, people are pulling out their sewing machines to fill the void.

3D printed face shields for medics and professionals

Open-source face shields anyone with a 3D printer can help produce. Join the community-driven effort to help professionals in your area.

America Makes Announces Top Designs of Fit to Face—Mask Design Challenge

https://www.prusa3d.com/page/covid-19_379/
https://www.nytimes.com/2020/03/25/business/coronavirus-masks-sewers.html
https://www.americamakes.us/america-makes-announces-top-designs-of-fit-to-face-mask-design-challenge/

ASTM Response

- ASTM International is providing **no-cost** public access to **29** important ASTM standards, used in the production and testing of personal protective equipment (PPE)
    - Face masks
    - Medical Gowns
    - Gloves
    - Hand Sanitizers
    - Respirators

- **Target Audience**: Manufacturers, test labs, health care professionals, and the general public as they respond to the global COVID-19 public health emergency

ASTM AM Response

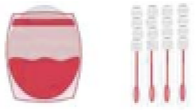
COVID-19 EMERGENCY RESPONSE

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.

- Development of a design guide for Additive Manufacturing
- Identified devices that could be designed and fabricated using AM <u>including PPE</u>
- **Objective:** Increase the quality of designs and shorten the design review/selection process.



COVID-19 Applications

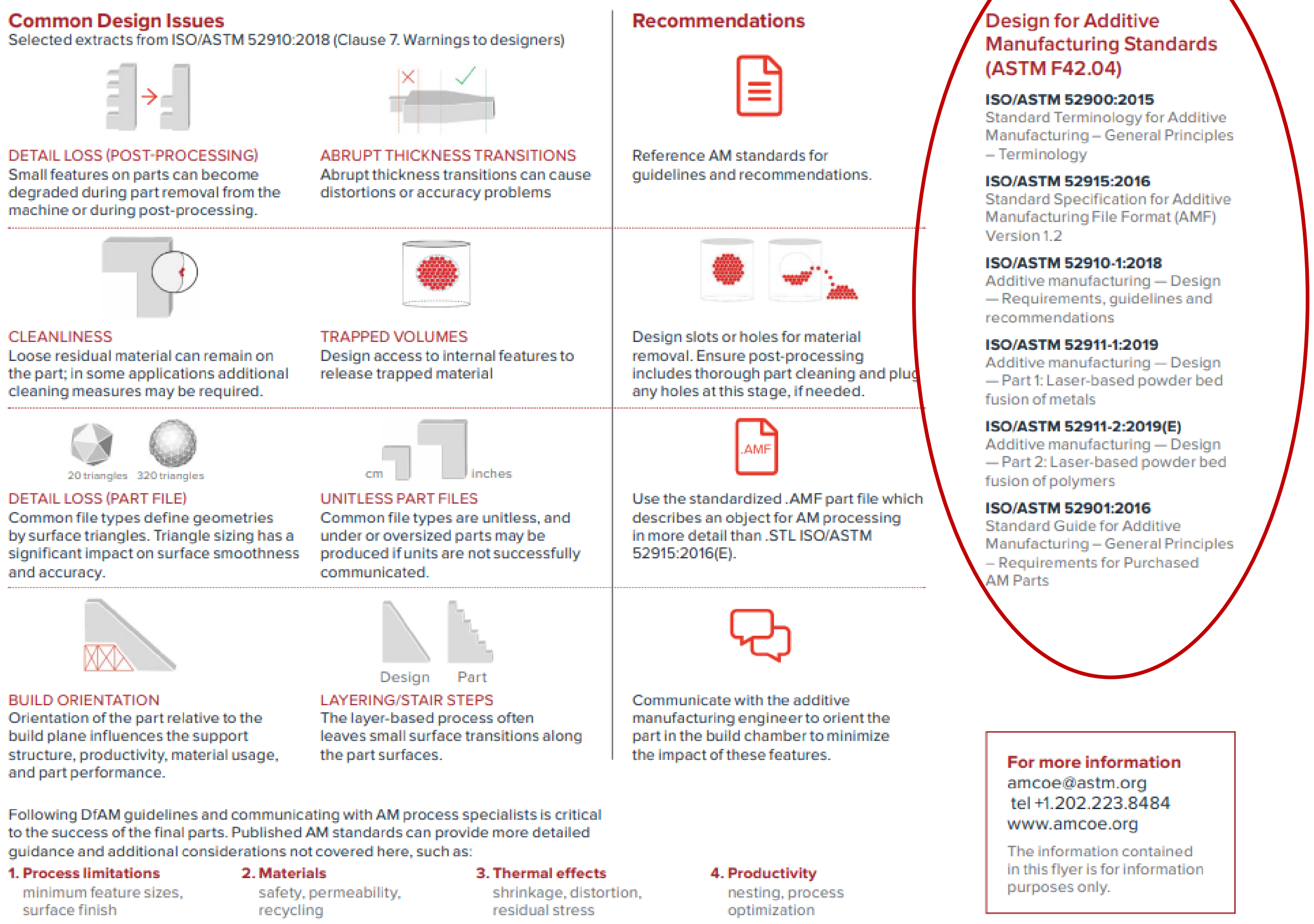
Personal protective equipment (PPE)
- Face shield
- Face mask
- Respirator

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

Rapid tooling
- Shorten production ramp for conventional manufacturing

ASTM AM Response

- The design guide covers potential design-related issues in AM and provides recommendations for mitigation of these design issues based on existing Design for Additive Manufacturing Standards (ASTM F42.04)
- Decreases the possibility of receiving low-quality (feasibility) designs for PPE submitted to America Makes portal and the NIH print exchange



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.

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

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

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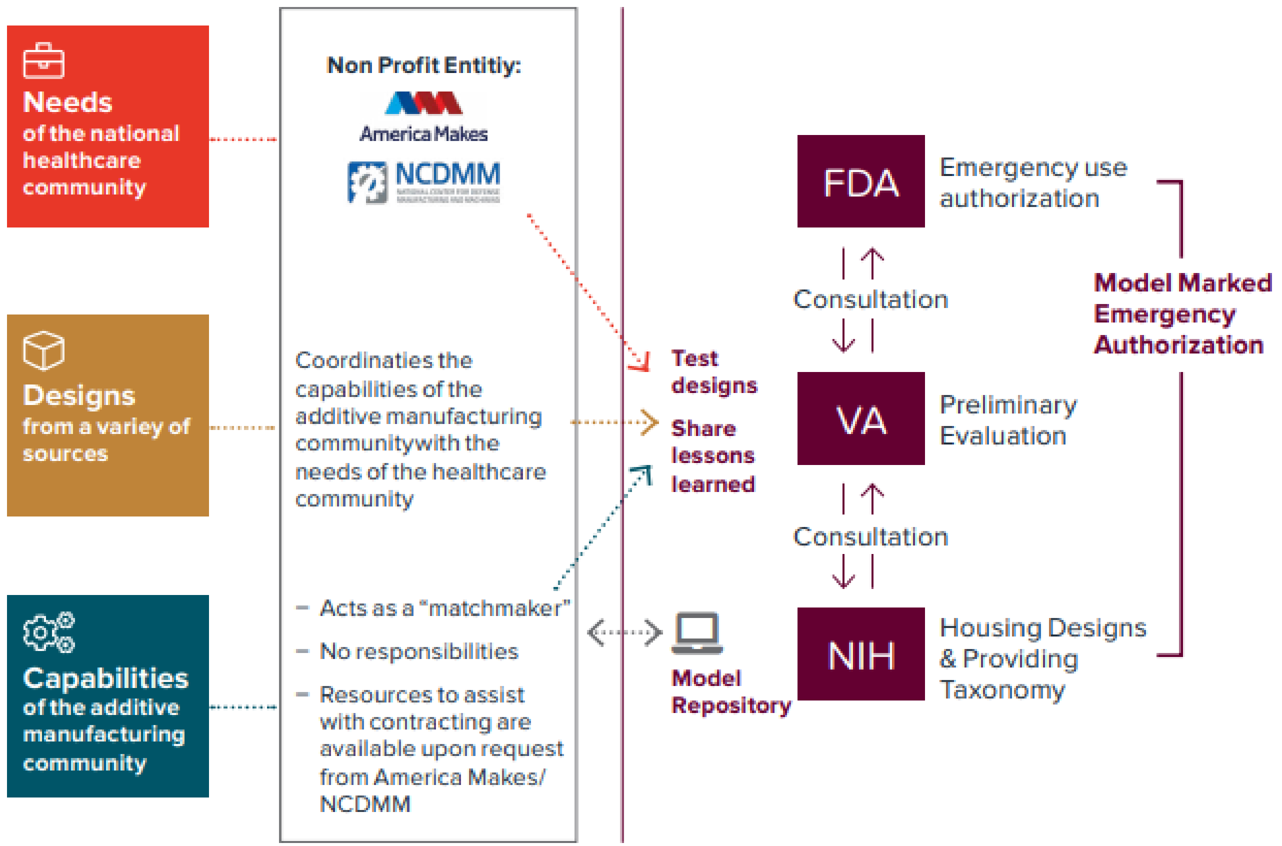
The information contained in this flyer is for information purposes only.

Collaborative Effort

- US FDA, VA, and National Institutes of Health (NIH) MoU
  - Community members provided the designs
  - NIH controls the use of data or model
  - VA evaluated and tested the designs: clinical and bench testing

- Challenge America and the Veterans Health Administration Innovation Ecosystem 2nd call, maker challenge – asked the community to submit designs for PPE, specifically, respirators



Collaborative Effort

- Additive Manufacturing can provide a stopgap for certain PPE items when traditionally manufactured PPE is limited or unavailable such as:
  - Face Masks
  - Face Shields

Traditional Manufacturing

Additive Manufacturing

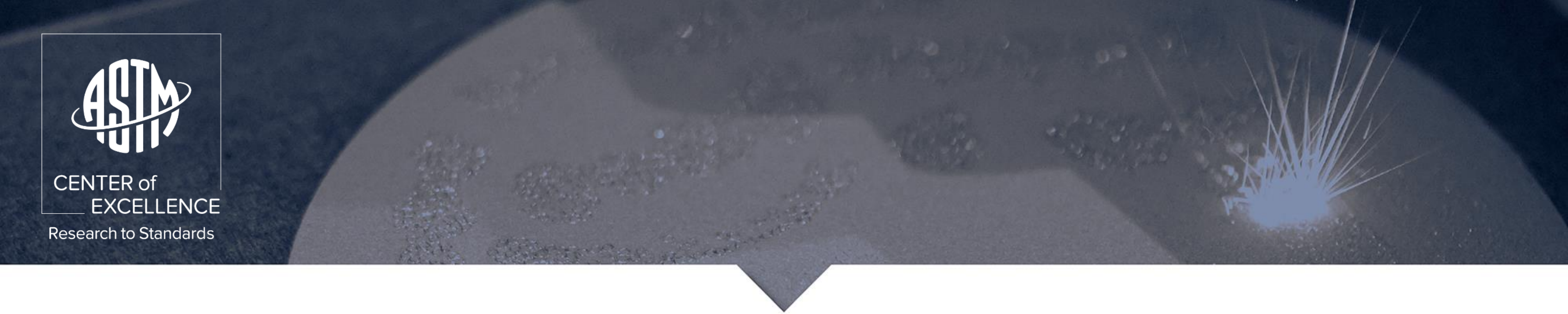
Traditional Manufacturing

Additive Manufacturing

https://3dprint.nih.gov/collections/covid-19-response

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

https://assets.researchsquare.com/files/rs-63872/v2/16735c17-bebe-4938-8ac4-064e854c0645.pdf?c=1631862553



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Thank you.

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