National Institute of Standards and Technology

NIST

Additive Manufacturing for Health

A Perspective of the National Institute of Standards and Technology

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Additive Manufacturing at NIST: Not an Isolated Effort

- Engineering Laboratory
- Material Measurement Laboratory
- Physical Measurement Laboratory
- NIST Center for Neutron Research
- Information Technology Laboratory
- Other agencies and
- Industry

"If you can not measure it, you can not improve it."

Lord Kelvin

Measurement Assurance : Confidence in Measurements for Decision Making

NIST is the Nation's Measurement Laboratory

❖NIST mission: As part of DoC, promote U.S. innovation and industrial competitiveness by advancing **measurement science, standards**, and technology

❖Basic research and technology development in measurements.

❖NIST does not impose standards; standards are accepted by consensus.

❖NIST is not a regulatory agency; serves as neutral ground for industry consortia, standards development organizations, public workshops, interlaboratory comparability testing, etc.

❖ **>100 years: focus on physical measurements and science. ~25 years in Biosciences**

Role of NIST Research Laboratories

- Infrastructural non-proprietary metrology methods for a broad class of measurement challenges
- Emphasis on rigorous procedures to characterize measurement uncertainty
- Long-term commitment, expertise, and neutrality essential for harmonized and unbiased national and international standards
- Leverage NIST core competences for advancing manufacturing systems, processes, and equipment

➢ **Measurements and Standards**

Additive Manufacturing Materials and Processes

- Variety of Material Types:

  Polymers, ceramics, metals, composites, paper, etc.

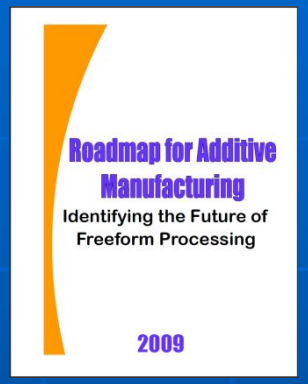
- Variety of Material Forms:

  Filaments, resins, powders, sheets, rods, etc.

- Variety of Processes:

  Many systems: different approaches, different materials, different capabilities, different purposes

Interacting with NIST



2009 AM Industry Roadmap

America Makes / National Additive Manufacturing Innovation Institute

Public-Private Partnership
National AM Roadmap

AM Needs and Priorities

Additive Manufacturing Consortium (AMC)

Precompetitive Technology Development

ASTM Committee F42 on Additive Manufacturing Technologies

Standards Development

NIST Workshop: Measurement Science for Metal-Based AM

Needs, Priorities, and Action Plans (Dec. 2012)
http://events.energetics.com/NIST-AdditiveMfgWorkshop

Substantial Collaborations and Stakeholder Interactions

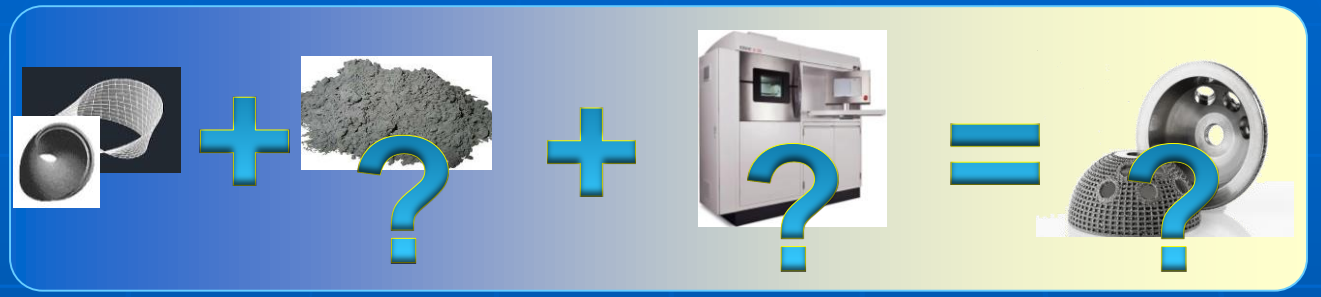
Joint research, site visits, events, etc.

From Road Map: Barriers that Prevent Broad Adoption of Metals-Based Additive Manufacturing

- Limited material types and unknown / non-uniform properties
- Lack of process repeatability and inconsistent system performance
- Insufficient part accuracy
- Insufficient surface finish (e.g., for contoured surfaces)
- Many needs for AM standards (materials, process, machine, quality)
- Need for improved non-destructive evaluation methods for complex defects and part geometry
- Requirements for post-processing (e.g., heat treatment, surface treatment, support removal, finish machining, sterilization)
- Lack of AM-specific design tools / design guidelines

Also apply to soft material

Uncertainties in Additive Manufacturing



Uncertainties in Input Materials

Uncertainties in Equipment and Process Performance

Uncertainties in the Final Parts

Digital Thread

Metrics and Models

Material Characterization

Process Monitoring and Control

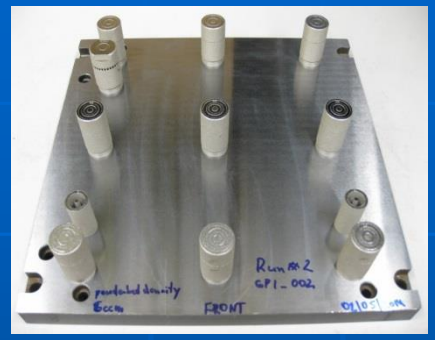
Qualified Part

Measurement Science and Standards
Drive Innovation and Reduce Risk of Adoption

AM Powder Characterization : Starting Materials

Measurement methods

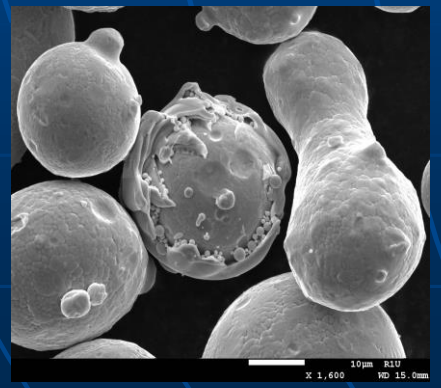
- SEM (size, morphology)
- Quantitative X-Ray Diffraction (chemical composition)
- Laser Diffraction (size distribution)
- X-Ray Computed Tomography (morphology)
- X-Ray Photoelectron Spectroscopy (elemental chemical states)



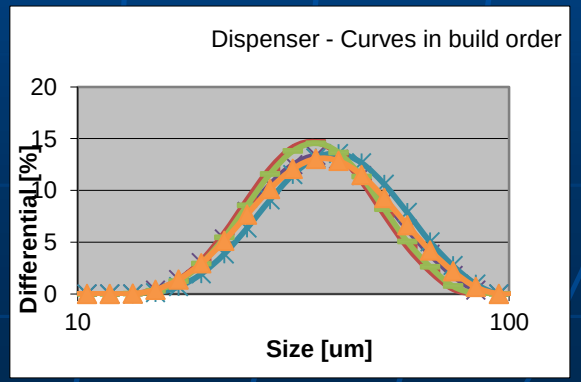
Powder bed density measurements

Recent ASTM standards

- ASTM F3049-14 Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
- ASTM F3122-14 Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes



Effects of powder reuse / recycling

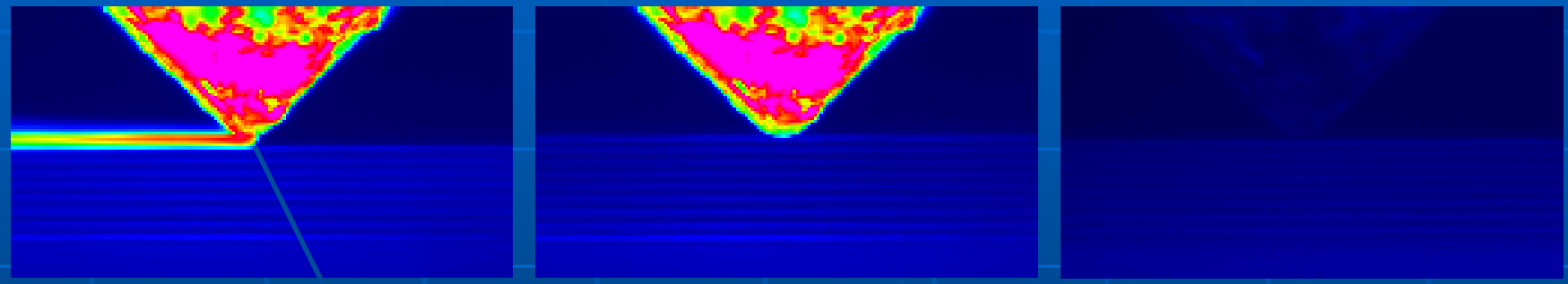


SOFT MATERIALS
Technologies for Following Quality of Printing

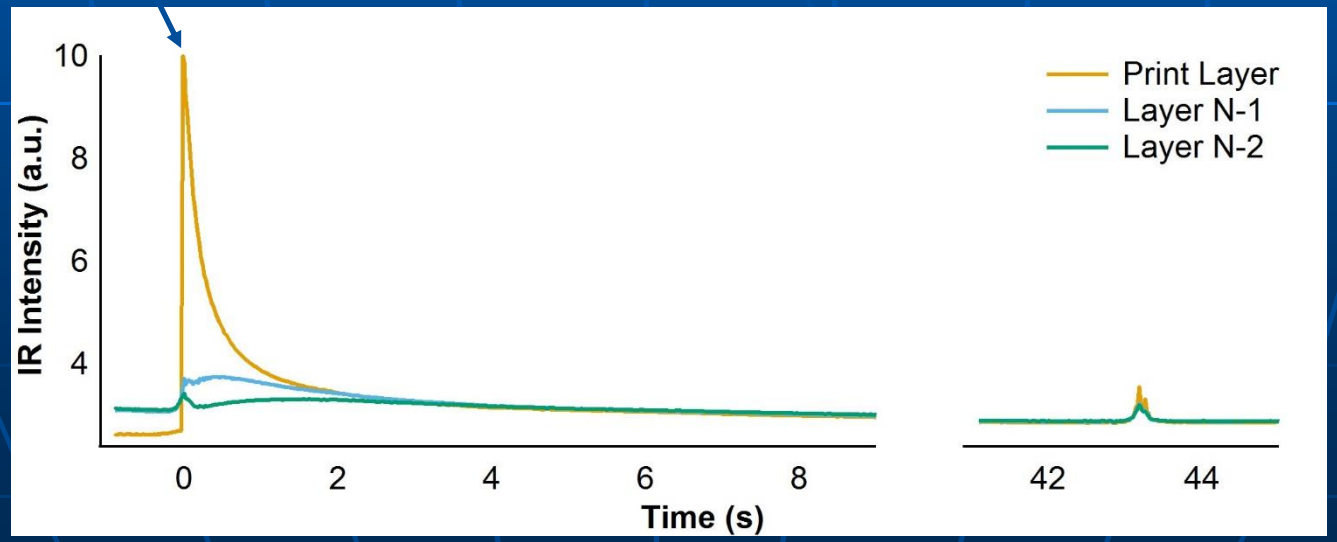
Printing Pass
Emission + Reflection

Non-Printing Pass
Reflection Only

Cold Pass
No Reflection



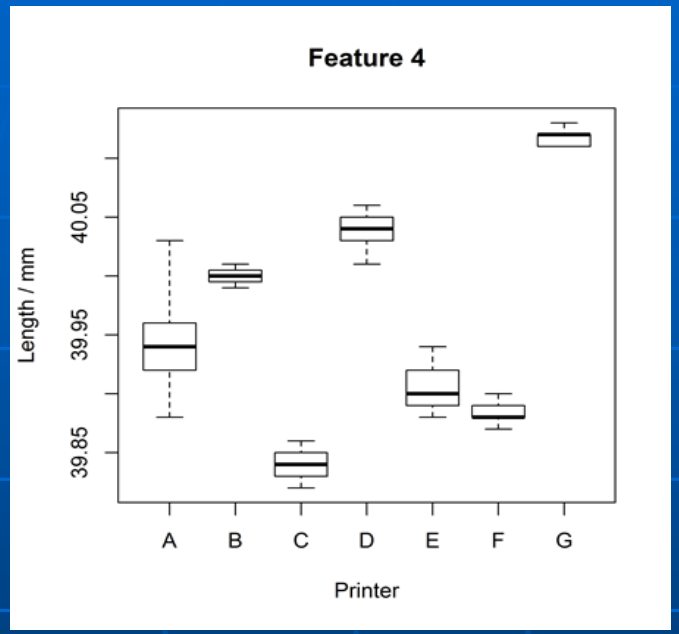
Kalman Migler

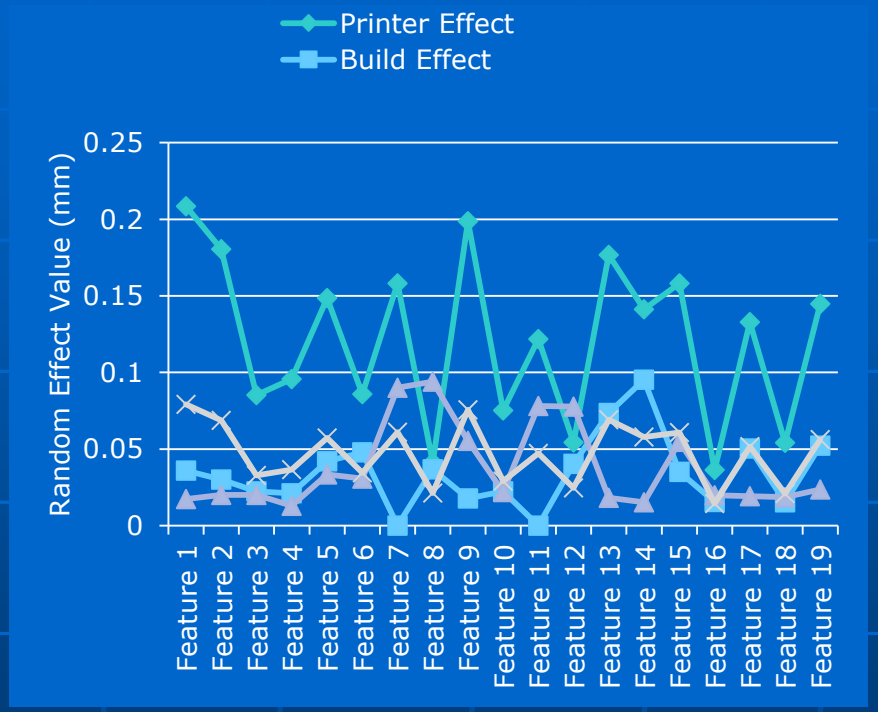


Reflection + Emission Intensity

Reflection Intensity

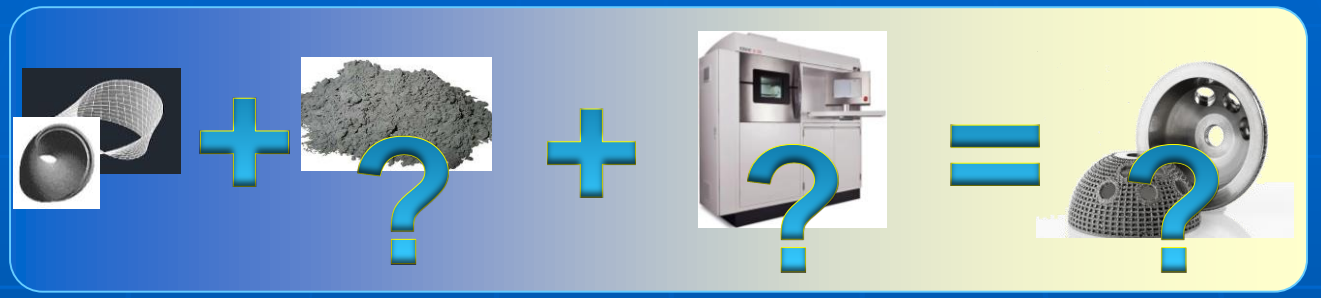
Interlaboratory Comparison





- Between laboratory variation is significantly larger than within laboratory (or between build) variability – “Printer effects” dominate
- Better results if increase the number of participating laboratories (rather than increase the number of samples manufactured by each lab)
- Detailed manufacturing plan is vitally important

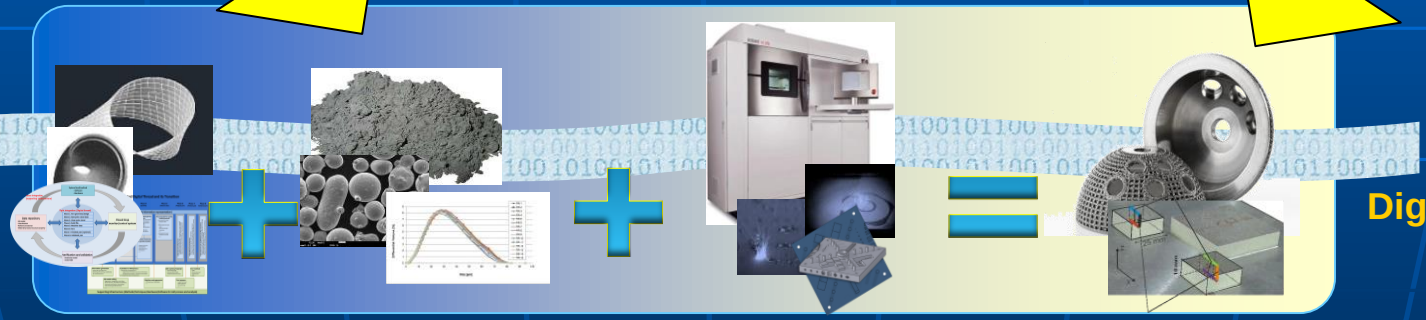
Uncertainties in Additive Manufacturing for Health



Uncertainties in Input Materials

Uncertainties in Equipment and Process Performance

Uncertainties in the Final Parts



Digital Thread

Metrics and Models

Material Characterization

Process Monitoring and Control

Qualified Part

Living cells + Active biological agents

Appropriate / safe complex biological function

Measurement Science and Standards
Drive Innovation and Reduce Risk of Adoption

AM Challenges in Regenerative Medicine Applications

Fundamental Challenges
For Cell Therapy Products

What are the product characteristics for clinical effectiveness and safety? How do starting materials and manufacturing process affect characteristics? Differences between individual donors/recipients.

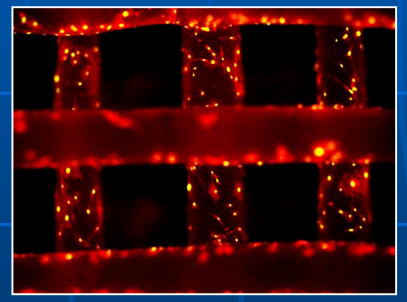
Additional Challenges
For Additive Manufacturing Products

Materials properties (mechanical and fabrication, sterility). Additional functionality (vasculature, bioactivity and response). Physical scale of product and complexity of bioreactors.

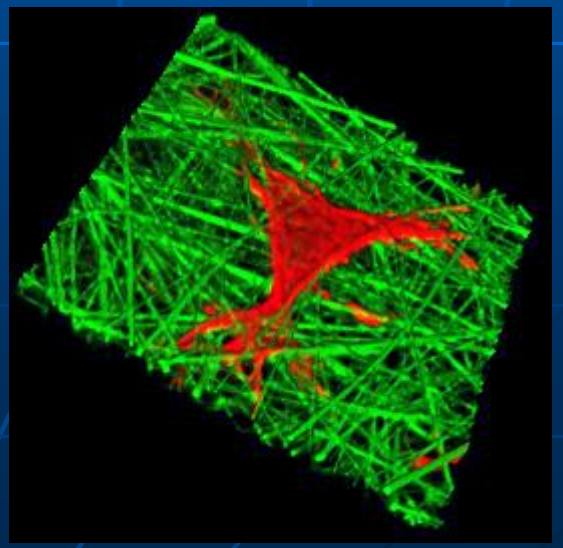
Reference Materials for Scaffolds for Tissue Engineering

- RMs 8395-8397
- to assess scaffold porosity measurements
- to assess measurements of scaffold strut diameter & strut spacing
- assess the variability in additive manufacturing processes

Reference material scaffolds for structural measurements

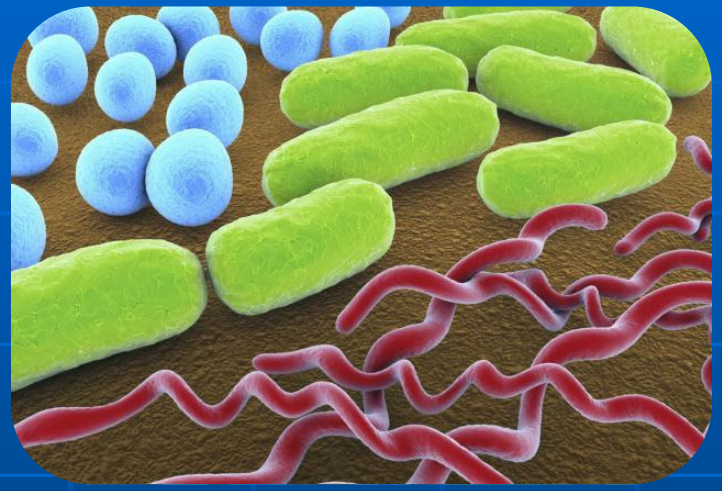


- Morris et al. used RM 8396 to develop guidelines for selecting optimal uCT image acquisition parameters for accurate imaging as required for mass manufacture
  - Morris DE, Mather ML, Simon Jr CG, Crowe JA (2012) Time-optimized X-ray micro CT imaging of polymer based scaffolds. Journal of Biomedical Materials Research Part B: Applied Biomaterials 100B, 360-367

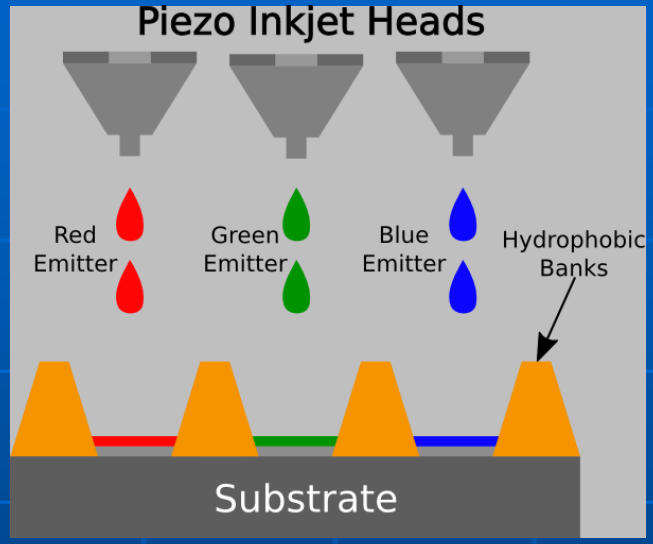


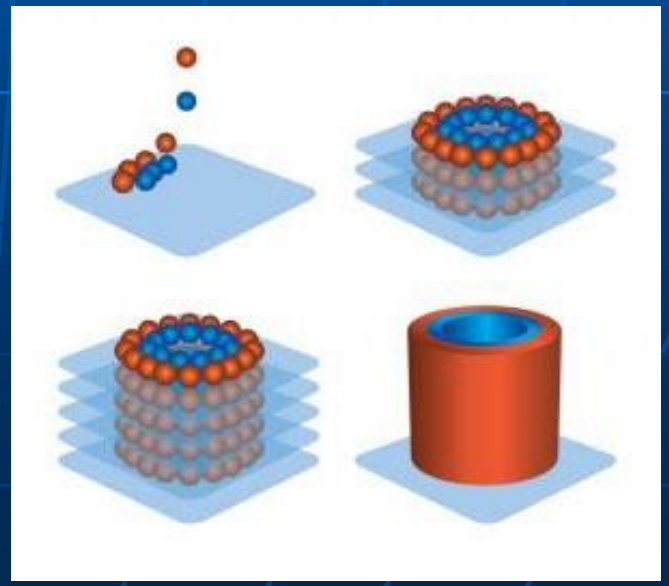
Carl Simon

Additive manufacturing for microbial test materials



- Reproducible starting materials
- Systematic studies of identify and location
- Dynamic measurements
- Predictive models





Scott Jackson

ASTM/NIST Workshop

- Goal : understand current NEEDS, BARRIERS, and SOLUTIONS to achieving more widespread use of metal AM for fatigue and fracture critical applications
- **May 4-5 San Antonio, TX**
- For Industrial (aerospace, medical, defense, etc), Academic, Government, Regulatory, and Funding Agencies
- Workshop Website
  - http://www.nist.gov/mml/acmd/structural_materials/am-fatigue-and-fracture-workshop.cfm
  - nik.hrabe@nist.gov

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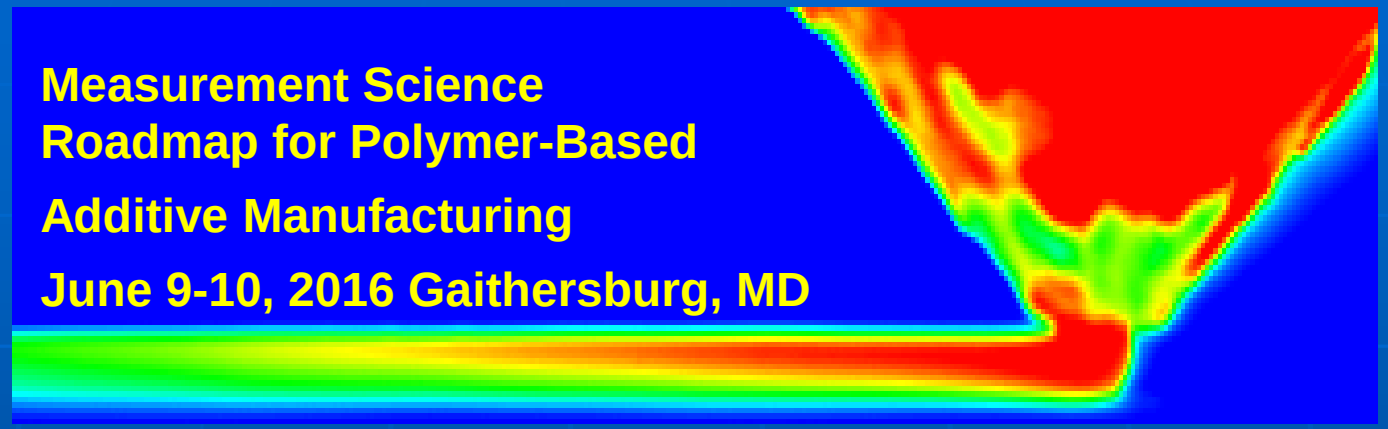
Measurement Science Roadmap for Polymer-Based Additive Manufacturing

June 9-10, 2016 Gaithersburg, MD



Goal: Develop roadmap that identifies the measurement science research and standards needed to accelerate the commercialization and adoption of polymers-based additive manufacturing

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Thank You