

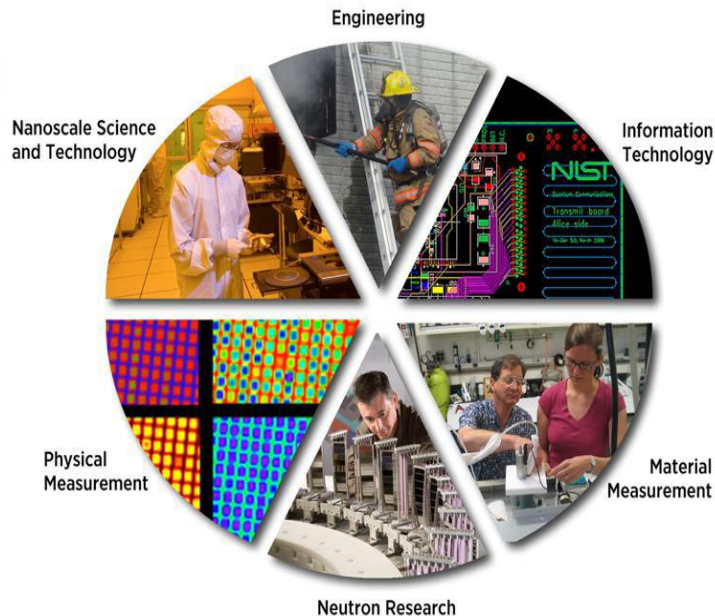
# NIST-FDA Genome Editing Workshop

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# NIST – Who we are today

## The National Metrology Institute

Global harmonization of measurement and traceability to the SI



## “Industry’s National Laboratory”

Non-regulatory agency partnering/serving industry to help maintain US leadership in science and technology products

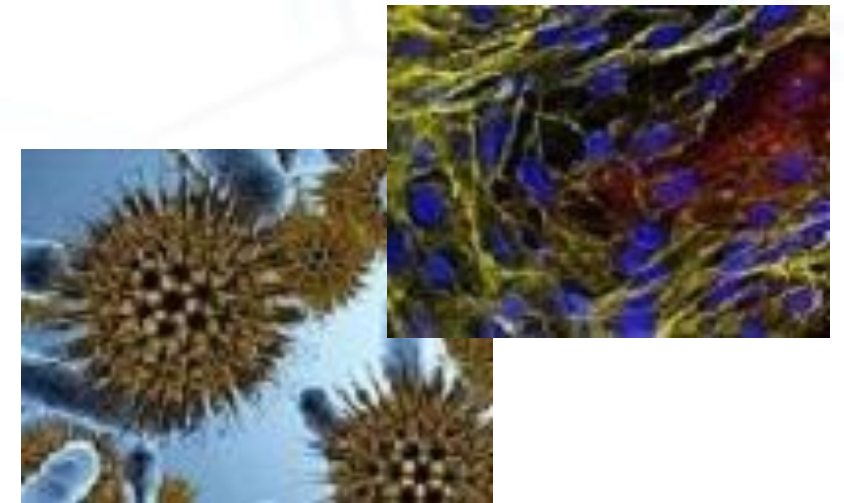
## Department of Commerce

developing standards to support international trade and commerce

# Bio at NIST

Develop measurement science, standards, data & technology to support development, manufacturing, & approval of product enabled by emerging biotechnology

- Works closely with stakeholders to identify key measurement problems and solutions
- Draws from a broad array of unique, cutting-edge expertise, resources, and facilities available at NIST
- Is a scientifically trusted “3<sup>rd</sup>” party that works to promote collaboration & sharing



# NIST Practices

## Measurements and Technology

- Develop advanced measurement capabilities
- Improve measurement quality and assurance

## Reference Materials /Standards

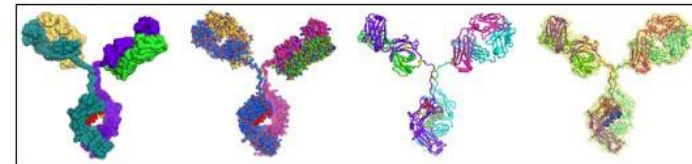
- Develop and certify NIST SRMs and RMs
- Generate reference data (e.g., chemical spectra)

## Standards

- Lead and contribute to documentary standards development through SDOs (e.g., ISO, IEC, ASTM, etc.)
- Conformity assessment
- Standards education



NIST synthetic RNA controls used in sequencing of Ebola virus genomes

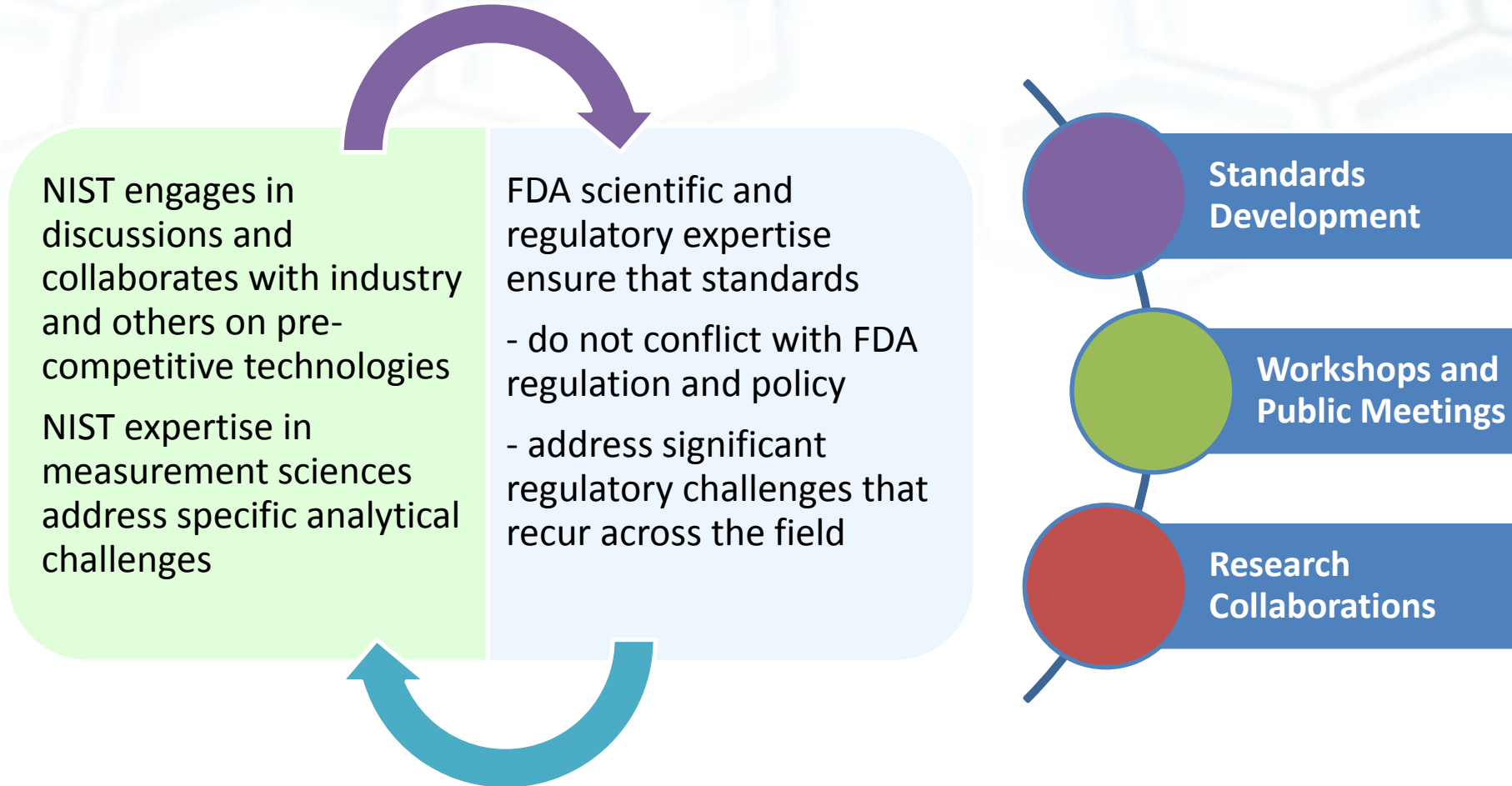


NIST Monoclonal Antibody Reference Material 8671



Yeast Cells as a Reference Material


# FDA-NIST Collaborations to leveraging unique expertise: Standards for Cell and Gene Therapy



# Selected recent workshops

**Bold represents Joint NIST-FDA Workshops**

May 2015	NIST Workshop: Strategies to Achieve Measurement Assurance for Cell Therapies Workshop
<b>Oct 2015</b>	<b>NIST-FDA Standards for Pathogen Detection via NGS workshop</b>
Feb 2016	CAR-T Biomanufacturing Symposium
May 2016	NIST Genome Editing Standards Workshop
Aug 2016	NIST Standards for Microbiome Measurements
<b>Apr 2017</b>	<b>NIST-FDA Cell Counting Workshop: Sharing practices in cell counting measurements</b>
<b>Aug 2017</b>	<b>NIST-DHS-FDA Workshop on Standards for Pathogen Detection</b>
<b>Oct 2017</b>	<b>NIST-FDA Flow Cytometry Workshop</b>



Workshop outcomes inform the development of documentary standards and reference materials

# Important roles of standards

## Standards

Many types of standards to accelerate R&D, product translation and commercialization



Common understanding  
(term, data interpretation)



Common practices



Traceable materials



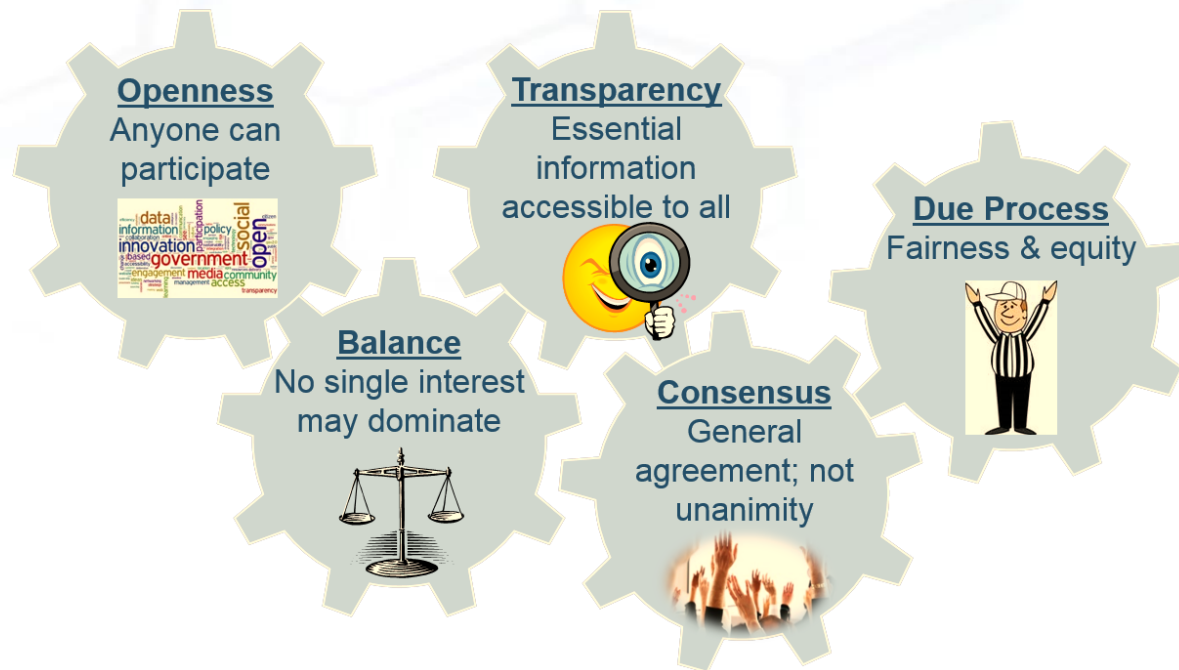
Common requirements



Common operational and management systems

# Standards Development Principles

## Documentary Standards (Voluntary Consensus)



## Reference Materials

Fitness for intended use

Reference to specified properties

Homogeneity

Stability



# Ongoing ISO/TC 276 Projects Relevant to Genome Editing and related Therapeutic applications

## Biobanking and Bioresources for R&D

- **Global overarching standard for ALL biobanks**
- Explanatory Document
- Validation & Verification

## Cell therapy Bioprocessing

- 3-Part Ancillary Materials
- Cell Transportation
- Cell Manufacturing Equipment

## Analytical Methods

- **Quality to oligo**
- **Genome synthesis**
- **Nucleic acid quantification**
- **NGS**
- Cell counting
- Cell characterization
- Cell authentication/identity

## Data Processing & Interoperability

- **Genome Compression**
- Requirements for data formatting and description

# Developers of documentary standards

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- ISO TC/276: *Biotechnology*
- ASTM
- *American National Standards Institute (ANSI) accredited SDOs: CLSI, ATCC*
  
- *Professional organizations*
- *Accreditation bodies*
- *Industry consortia*

**Coordination is required to avoid conflict and duplication**

**NIST**



**NEXIGHT GROUP**