



Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation

Kathie Morgan, ASTM President

Dan Smith, ASTM Vice President

Jeff Stull, ASTM PPE Consultant

Guest speakers from National Research

Council Canada, U.S. Occupational

Safety and Health Administration, and

North Carolina State University



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Agenda

PPE Forum Meeting | March 7, 2022 | 9AM-10AM Eastern

1. Opening remarks (Kathie Morgan)
2. Agenda review (Dan Smith)
3. Presentation on PPE Laboratory Comparison Study by National Research Council Canada
4. Presentation on product differences between F2100 and F3502: Possible need for a hybrid product (OSHA and NCSU)
5. Planning for next ASTM International Global Forum Event
6. Questions & Answers
7. Adjourn



Presentation on PPE Laboratory Comparison Study

National Research Council Canada

Presenters: (1) Ralph Paroli, R&D Director (NRC-Metrology)

(2) Andy Oldershaw, Sector Leader, Measurement System Engagement

(3) Timothy Sipkins, Research Associate



Presentation on Product Differences Between F2100 and F3502 – Possible Need for a Hybrid Product

Presenters: (1) Andy Levinson, Deputy Director U.S. Occupational Safety and Health Administration

(2) Bryan Ormond, Assistant Professor, Textile Protection and Comfort Center, Wilson College of Textiles, North Carolina State University



Canadian interlaboratory comparison

Panel discussion
March 2022

Background

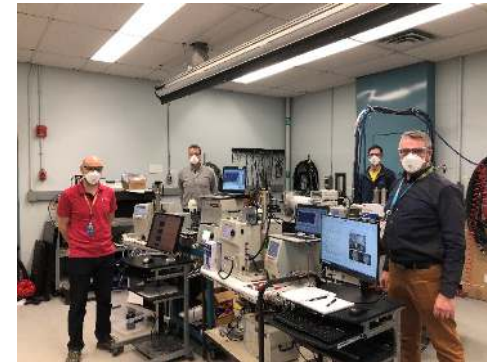
NRC Metrology is Canada's National Metrology Institute (NMI). Our expertise in measurement enabled the rapid development of PPE testing to address a critical gap in our national quality infrastructure, in response to the Covid-19 pandemic.

Initial response:

- Product testing – temporary, not our usual role.
 - More than 5,000 samples tested.

Current activity:

- **Support to the PPE quality infrastructure, our usual role:**
 - Metrological traceability
 - Measurement assurance
 - Standards development



Collaboration - Support to the PPE quality infrastructure

In collaboration with a network of laboratories, academics, manufacturers, health authorities and other laboratory stakeholders.

- 30 + members coast to coast including 20 test facilities, areas of interest include:
 - Proficiency testing.
 - Reference material development.
 - Test method development.
 - Accelerated aging.



Metrological traceability

As an NMI, metrological traceability is a core to our mission and vision.

Traceability directly to the SI (International system of Units) is not practicable.

ISO/IEC 17025 and International Laboratory Accreditation Cooperation policy on traceability (ILAC P10) allow alternatives.

Reference procedures or standards, supported by a suitable comparison can be accepted as a means for establishing metrological traceability.



Measurement assurance

ISO/IEC17025, 7.7 Ensuring the validity of results:

To assure the validity of their results, laboratories must:

- periodically monitor their results. This monitoring is to make sure within laboratory consistency.
Repeatability
- periodically compare their results with other laboratories. This comparison is to check laboratory to laboratory consistency.
Reproducibility



Standards development

Setting standards requires data from multiple sources:

- Linking standard methods, more consistency to the meaning of %PFE.
- Verifying and validating that standards provide the right information for decision makers.
- Verifying and validating compatibility laboratory capabilities.
- Making sure that conformity assessment to standards is practicable and accessible.

Interlaboratory comparisons - The cornerstone

Material testing

Targets material testing, which will remain a critical piece of standard moving forward.

Components

Pressure plates
Calibration media
Candidate ref. material
Respirator (with loading)

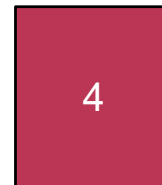
Participation

Included 17 systems spanning three categories.



TSI 8130A

The most common kind of filter tester in North America



Photomer

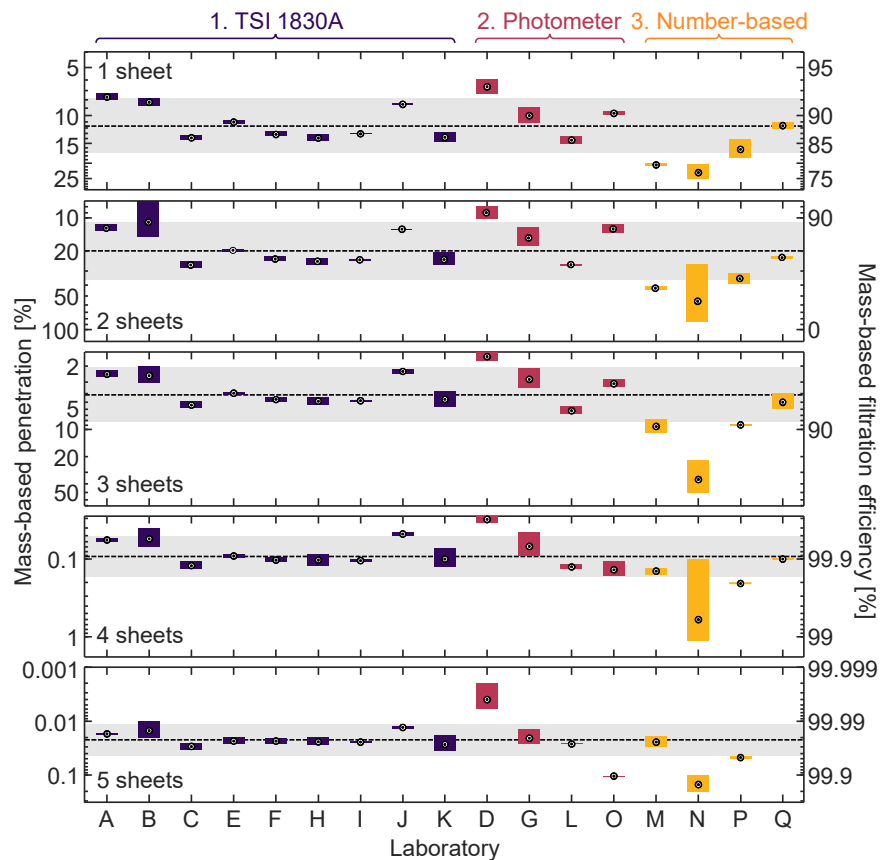
Similar operation but not the TSI 8130A (DustTrak, etc.)



Numer-based

Typically accompanied with size-resolved measurements.

Calibration (strongly-size dependent) media



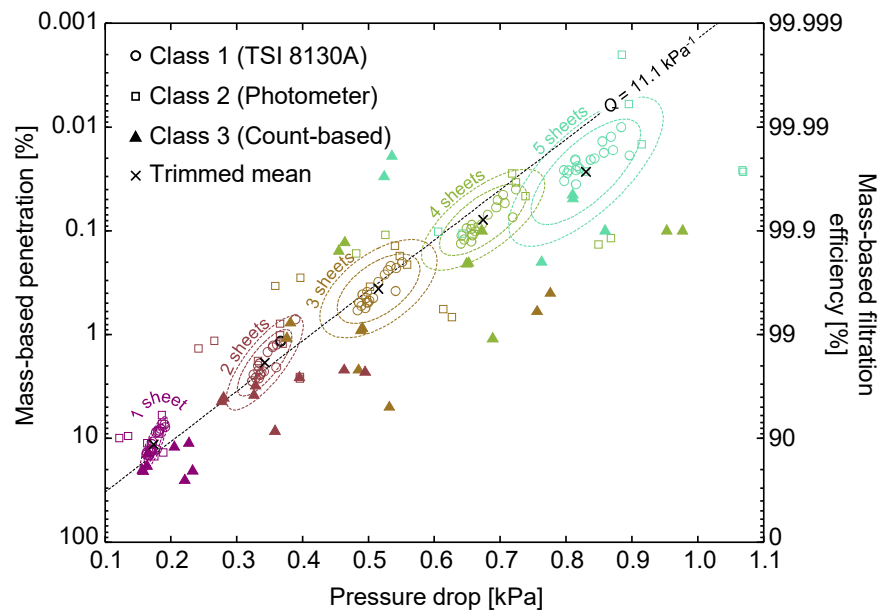
ILC results

Media was tested in multiple layers.

Uncertainties were dominated by differences between laboratories, rather than differences within a laboratory.

In large part differences between types of instruments was of a similar magnitude as those within a given class of instruments.

Calibration (strongly-size dependent) media

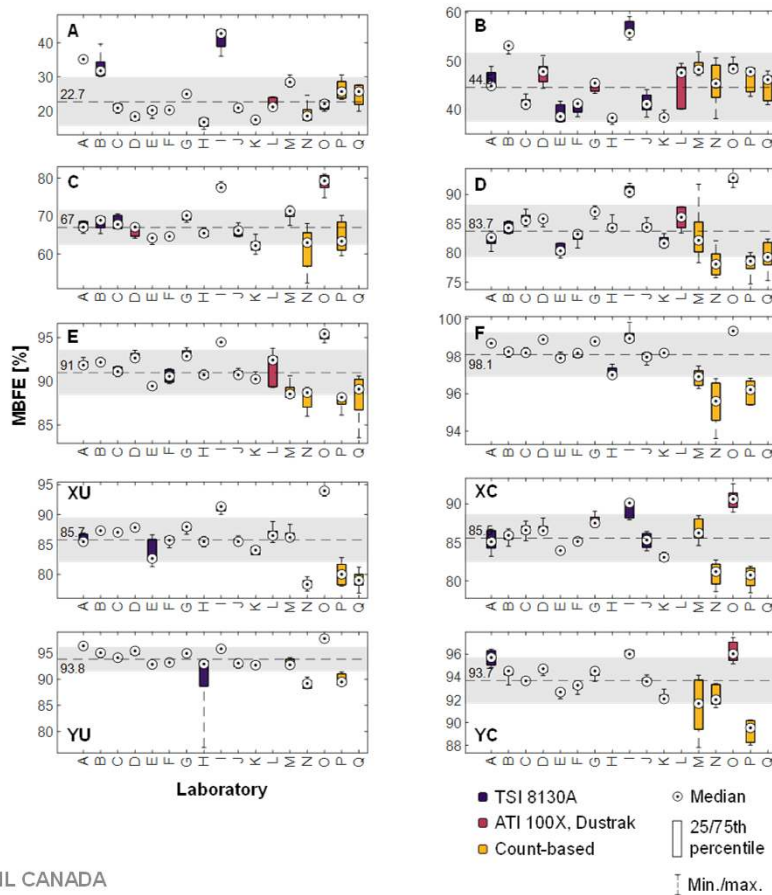


Adding pressure drop

Plenty of scatter about central trend of constant *quality*.

Outliers seem to correspond to number-based systems, perhaps still limiting comparison between the classes of systems.

Candidate reference material

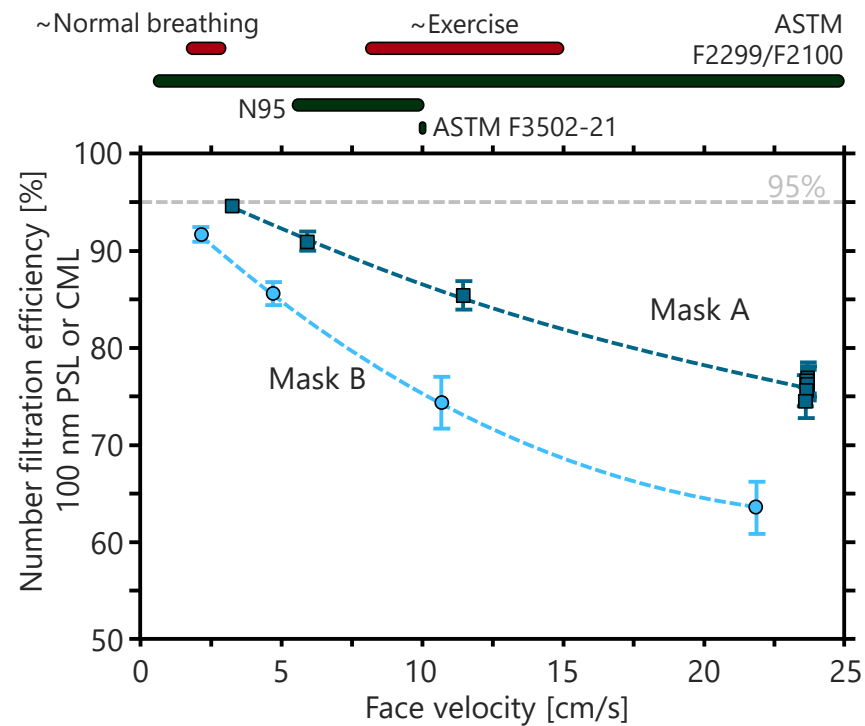


Reference material

Spans a much larger range of PFEs, in support of testing across a full gamut of materials (including individual layers)

Uncertainties are larger for poor filters, both for individual measurements and differences between laboratories

Systematic examination of parameters



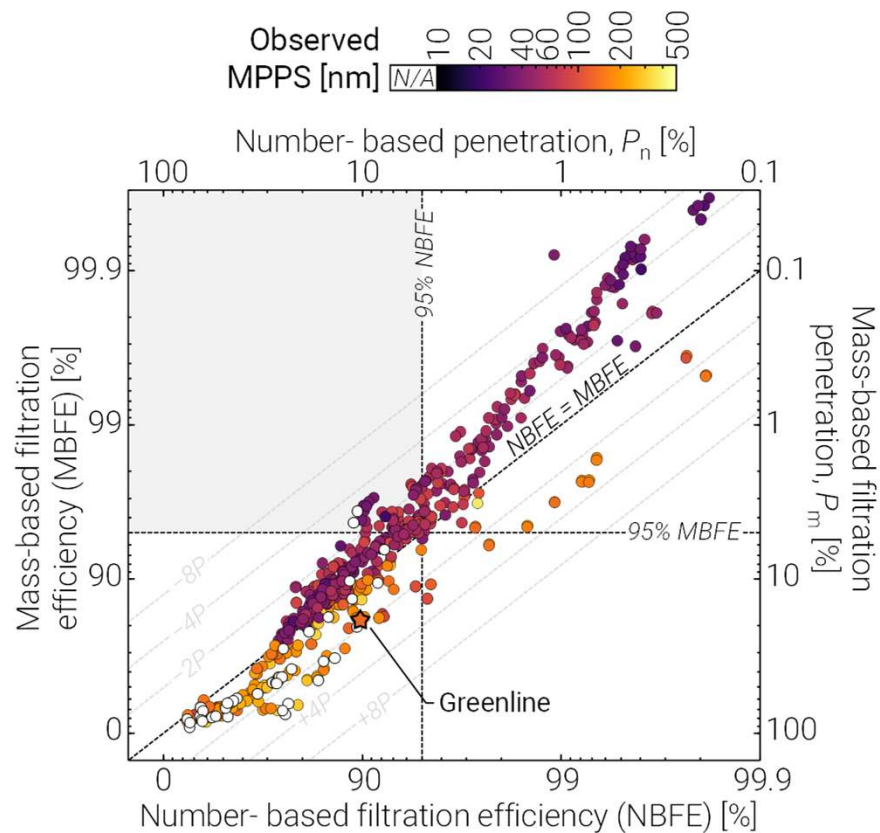
Parameters

- Face velocity (see left)
- Conditioning
- Neutralization (required!)
- Artifacts for PSL (move to NaCl to test against a broad range of sizes)

Movement towards more unified, robust standards

Corbin et al. Sci. Rep. (2021).
<https://www.nature.com/articles/s41598-021-01265-8>

Mass- v. number-PFEs



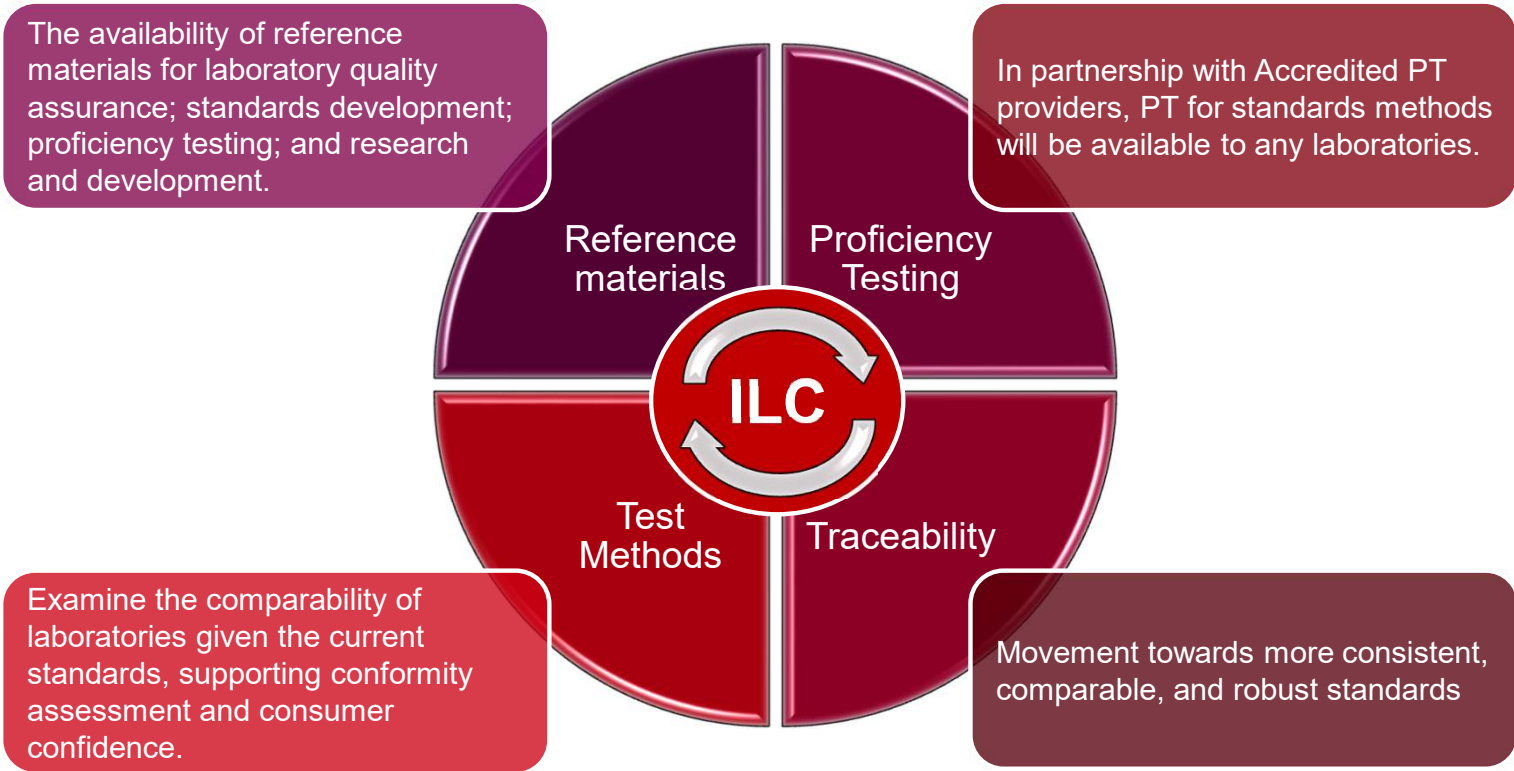
Differences, but commonalities

Understanding this relationship is critical to translating academic studies to practical standards

Sensitive to charge state of the material (via the most penetration particle size)

Sipkens et al. arXiv.
<https://arxiv.org/abs/2201.12446>

Anticipated outcomes



THANK YOU

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Potential Need for a Hybrid Mask Product for Healthcare Worker Protection Against Infectious Diseases

Andrew Levinson, MPH

Acting Director, Directorate of Standards & Guidance
U.S. Occupational Safety and Health Administration (OSHA)

March 7, 2022

OSHA and Infectious Diseases

- Bloodborne Pathogens Standard (29 CFR 1910.1030)
- Respiratory Protection Standard (29 CFR 1910.134)
- General PPE Standard (29 CFR 1910.132)
- Tuberculosis Compliance Directive
- Pandemic Influenza guidance

- COVID-19 ETS Healthcare (now being finalized)
- COVID-19 ETS Vaccination and Testing (overturned by SC)
- Regulatory Agenda – Infectious Diseases in Healthcare

Conventional Healthcare Worker PPE

Accessible version: <https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html>



2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

Last update: July 2019

Contact

- Gloves
- Gowns
- Eye protection*

Droplet

- Masks

Aerosol

- Respirators
- Eye protection*

Diseases by Transmission Type (Examples)

Contact

- Common: MRSA, Viral Hepatitis A
- Less common: Ebola*

Droplet

- Common: Influenza, Meningitis
- Less common: Pneumonic Plague

Aerosol

- Common: Tuberculosis
- Less common: Measles

* Some infectious diseases involve multiple transmission modes

Defining Minimum PPE Requirements



Examination Gloves

- ASTM D3578 (latex), D6319 (nitrile), D6977 (chloroprene)



Surgical/Isolation Gowns

- AAMI PB70 (barrier criteria)
- ASTM F2407/F3352 (other reqt's)



Medical Masks

- ASTM F2100
- Multiple levels



Respirators

- NIOSH-Approved APR or PAPR per 42 CFR Part 84

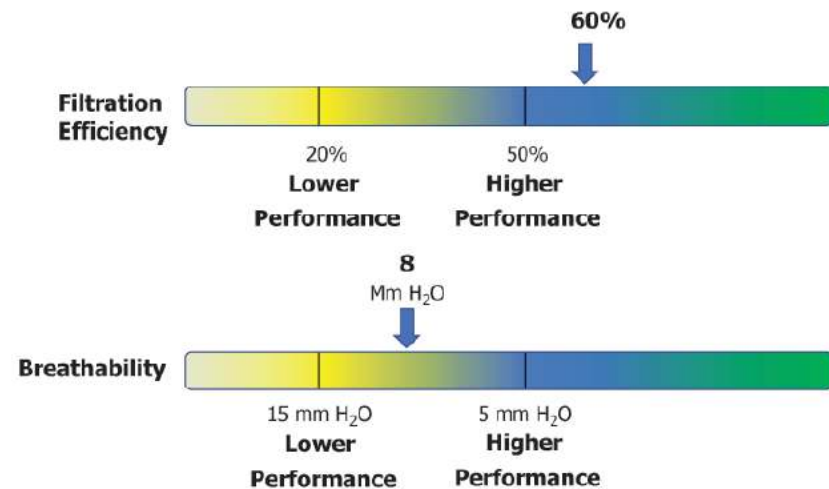
Use of Masks for Droplet Transmission

- Current Standard: ASTM F2100
- Intended Purpose:
 - Source control (defined as PPE by providing blood splatter resistance)
- Requirements
 - Filtration efficiency (bacteria/sub-micron particles)
 - Differential pressure (airflow resistance)
 - Blood penetration resistance
- Shortcomings
 - Standard addresses materials only
 - Does not account for potential leakage



New Barrier Face Coverings

- New Standard: ASTM F3502
- Intended Purpose
 - Address products for individuals (incl. workers) not required to wear either respirators or medical masks
- Requirements
 - Sub-micron filtration efficiency
 - Airflow resistance
- Positive Attributes
 - Optional: leakage assessment
 - Spans range of products



Possible Hybrid Mask Product

- Intended Purpose:
 - Define higher performing masks for high droplet transmission diseases
 - Also require passing performance per ASTM F1862 (blood spurt test method)
- Approach
 - Adopt CDC/NIOSH suggested guidance for higher performing face coverings
- Benefit
 - Establishes better-fitting, better filtering masks for non-respirator situations in healthcare

Type of Mask	Filtration	Breathability	Leakage*	Labeling
Workplace Performance Mask	ASTM F3502 Level 2 at $\geq 50\%$	ASTM F3502 Level 1	Leakage ratio of ≥ 5	MEETS WORKPLACE PERFORMANCE
Workplace Performance Plus Mask	ASTM F3502 Level 2 at $\geq 80\%$	ASTM F3502 Level 1	Leakage ratio of ≥ 10	MEETS WORKPLACE PERFORMANCE PLUS



Planning for Next ASTM International Global Forum Event

Dan Smith and Jeff Stull



For more information:
www.astmppecollaboration.org



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