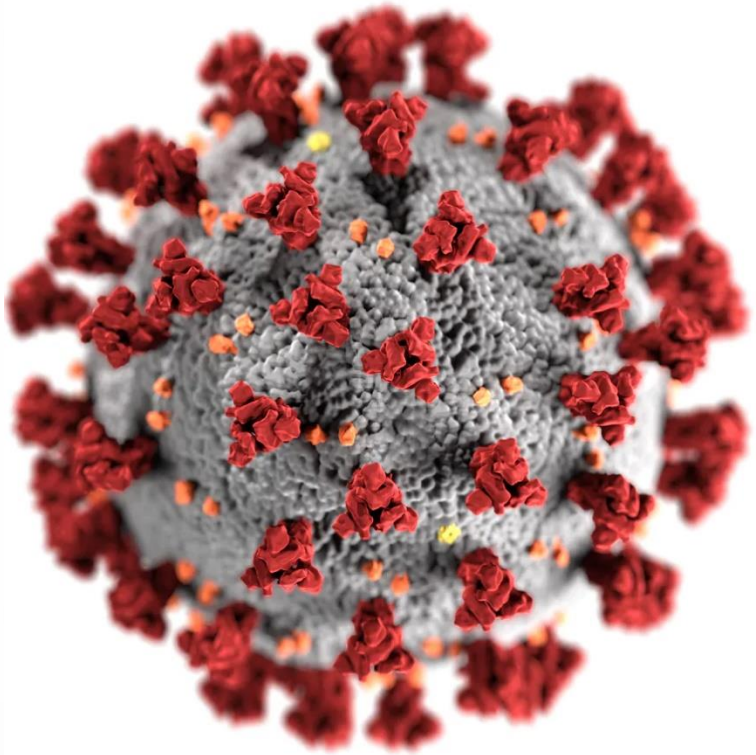

Surface Disinfection by UVC

Bench Scale Study and Field Implementation Considerations

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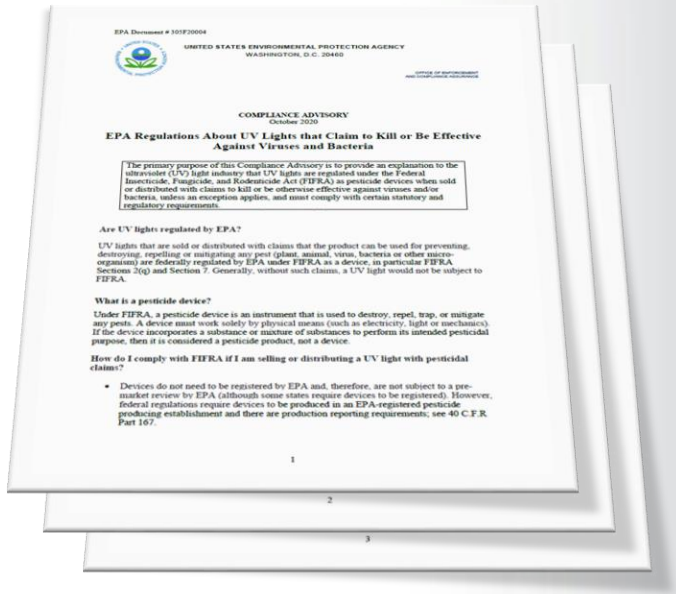
IUVA Webinar Enhancing the New Normalcy with UV Disinfection - Transportation

EPA – FIFRA and UV Lights

UV lights are federally regulated in the U.S. by EPA under FIFRA as a device if sold/distributed with claims for its use for preventing, destroying, repelling or mitigating any pests

Must comply with certain statutory and regulatory requirements

- UV device claims must be supported by testing with that specific device including testing for any pathogens they list
- EPA does not accept general claims like “germicidal” or unqualified “germ” claims
- False or misleading claims cannot be made


EPA Document # 305F20004

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

COMPLIANCE ADVISORY
October 2020

EPA Regulations About UV Lights that Claim to Kill or Be Effective Against Viruses and Bacteria

The primary purpose of this Compliance Advisory is to provide an explanation to the ultraviolet (UV) light industry that UV lights are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as pesticide devices when sold or distributed with claims to kill or be otherwise effective against viruses and/or bacteria, unless an exception applies, and must comply with certain statutory and regulatory requirements.

Are UV lights regulated by EPA?

UV lights that are sold or distributed with claims that the product can be used for preventing, destroying, repelling or mitigating any pest (plant, animal, virus, bacteria or other micro-organism) are federally regulated by EPA under FIFRA as a device, in particular FIFRA Sections 2(q) and Section 7. Generally, without such claims, a UV light would not be subject to FIFRA.

What is a pesticide device?

Under FIFRA, a pesticide device is an instrument that is used to destroy, repel, trap, or mitigate any pests. A device must work solely by physical means (such as electricity, light or mechanics). If the device incorporates a substance or mixture of substances to perform its intended pesticidal purpose, then it is considered a pesticide product, not a device.

How do I comply with FIFRA if I am selling or distributing a UV light with pesticidal claims?

- Devices do not need to be registered by EPA and, therefore, are not subject to a pre-market review by EPA (although some states require devices to be registered). However, federal regulations require devices to be produced in an EPA-registered pesticide producing establishment and there are production reporting requirements; see 40 C.F.R. Part 167.

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Problem Definition

- Growing interest in UVC for surface and aerosol disinfection as a result of pandemic
- Emerging UVC products are being widely marketed
- Increasing technical support requests for evaluating UVC technologies (e.g., from public transportation agencies)
- Feasibility of UVC in complex environments is relatively unknown

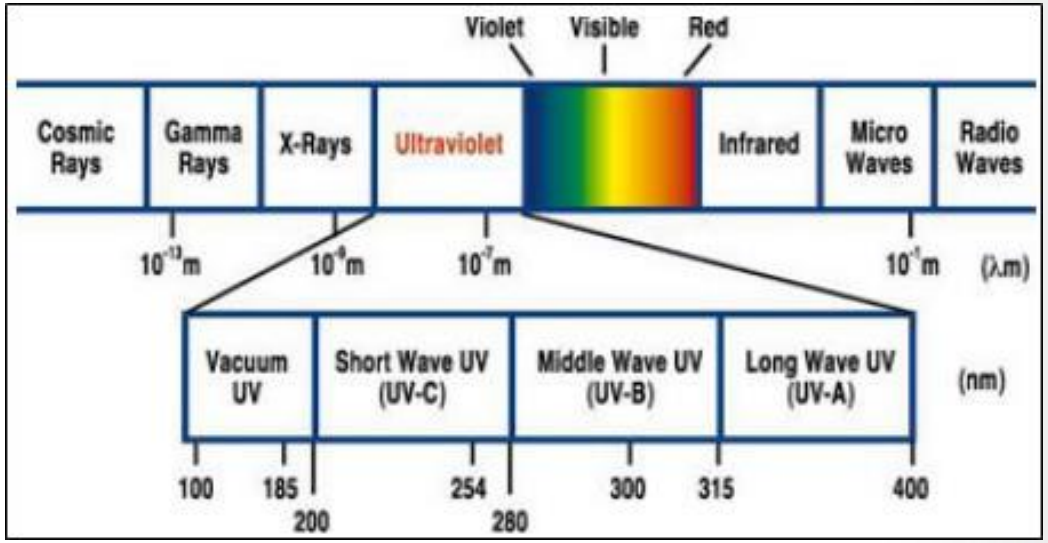
New York Metropolitan Transport Authority invested $1 million on devices from Puro Lighting for their trains and buses

Problem Definition (cont.)

- UVC can be an effective approach to reduce exposure to virus on
  - Surfaces
  - Aerosols

- Complementary to regular disinfection and/or cleaning procedures

- Not all UV is equal
  - Single wavelength
  - Broad wavelength
  - Continuous vs Pulsed/Flash



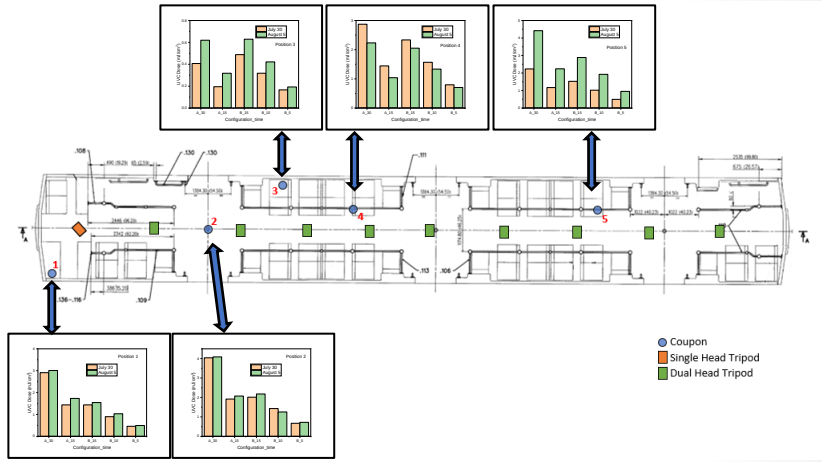
UV radiation is classified as a human carcinogen by US Department of Health and Human Services and the World Health Organization

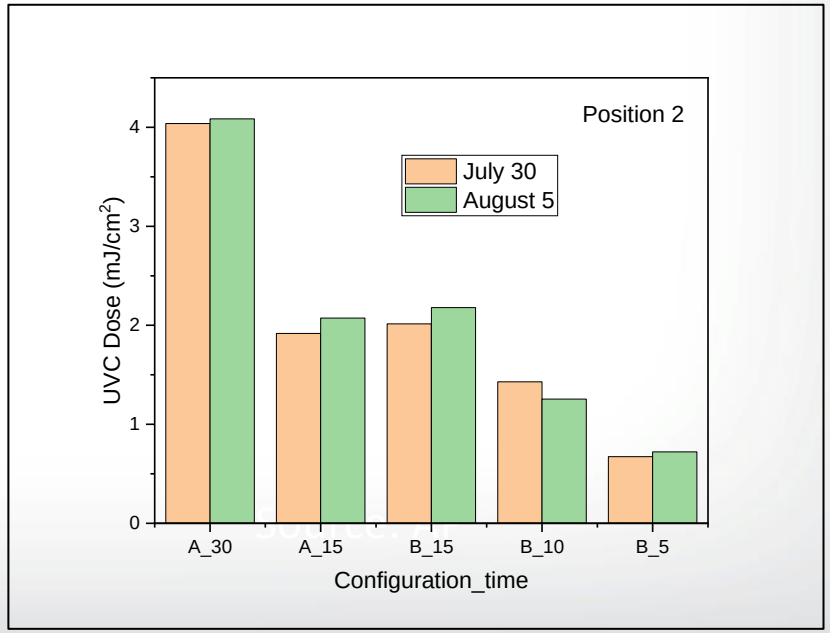
Research Questions

- Is UVC effective in inactivating SARS-CoV-2?
  - Can we consider surrogate (viruses)
- What parameters impact efficacy?
  - Dose (Intensity, distance, and time)
  - Material
  - Dry / wet droplets
  - Saliva composition
- What UVC doses are achievable in the field?

LA Metro Field Test

- LA Metro field study (August 2020)
  - Evaluate practicality of a UV-C emitted pulsed xenon light: ease of use, setup time, durability, electrical load, functionality
  - Evaluate dose in field testing
- EPA supplied MS2-inoculated stainless-steel coupons to incorporate in field test
- LA Metro measured UV dose for each coupon location / exposure





LA Metro Field Test Results

- Measured range of UVC doses in LA Metro tests: ≤ 4.0 mJ/cm^2
- Lowest doses at locations outside of direct line of sight or at large distances
- Highest dose for location at ~60” directly in front of light, 30 min exposure time
- *No significant reduction in MS2* on coupons exposed to UVC in LA Metro test*
  - Laboratory tests needed to understand this lack of virus inactivation

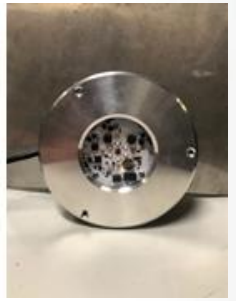
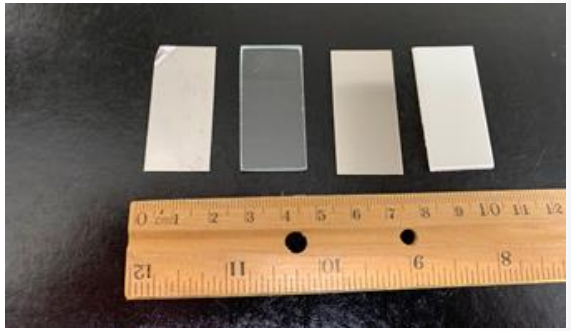
Source: AP

* MS2: Non-enveloped bacteriophage; BSL-1 organism; high resistance & persistence, fast and easy analysis

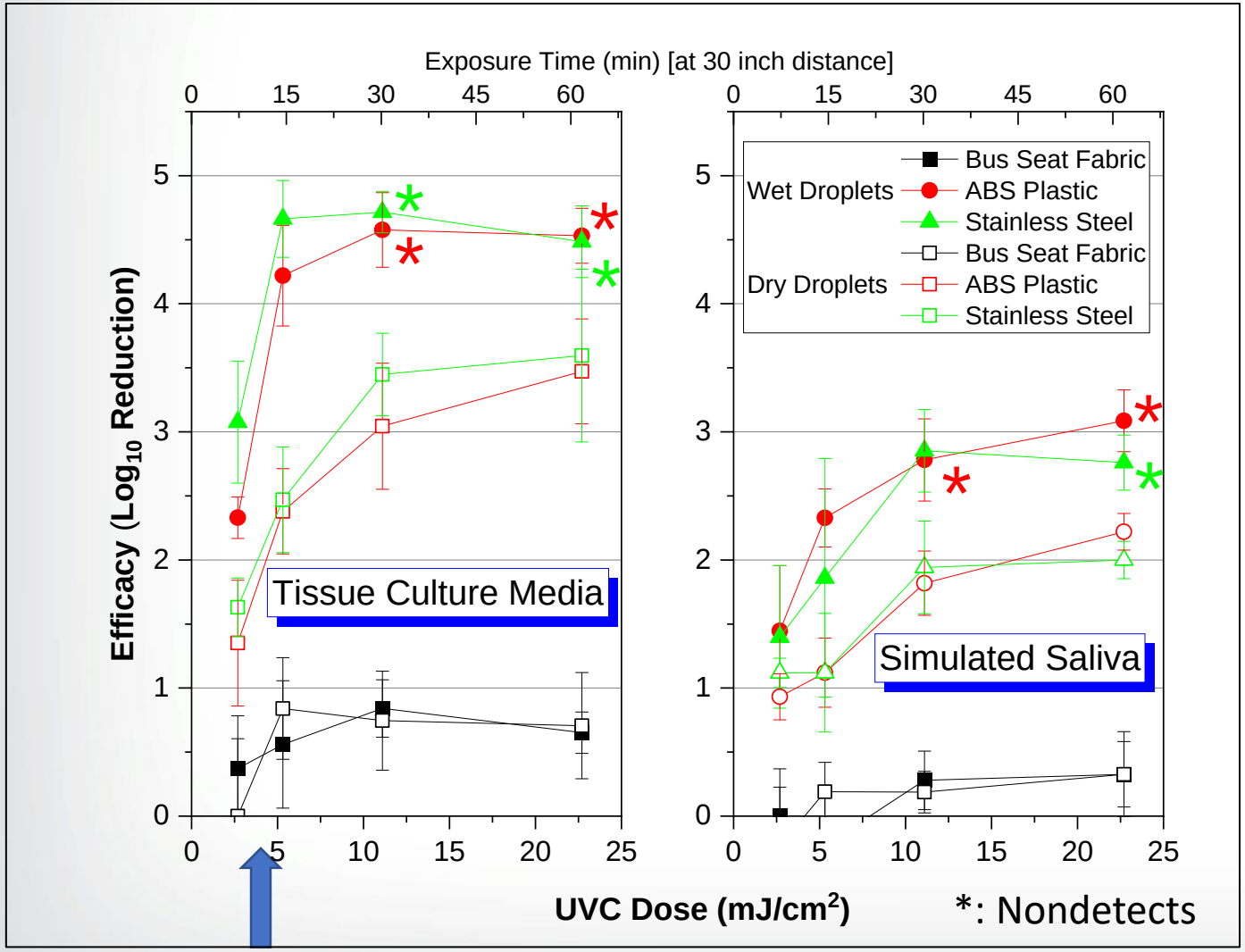
Laboratory Research Approach

- Field study with stakeholders (LA Metro)

- Bench-scale studies:
  - Determine efficacy of UV-C light emitting devices against SARS-CoV-2 virus
    - Pulsed Xenon light
    - UV-C LED (275 nm)
  - Materials: ABS plastic, stainless steel, bus seat fabric
  - Assess efficacy in applied settings

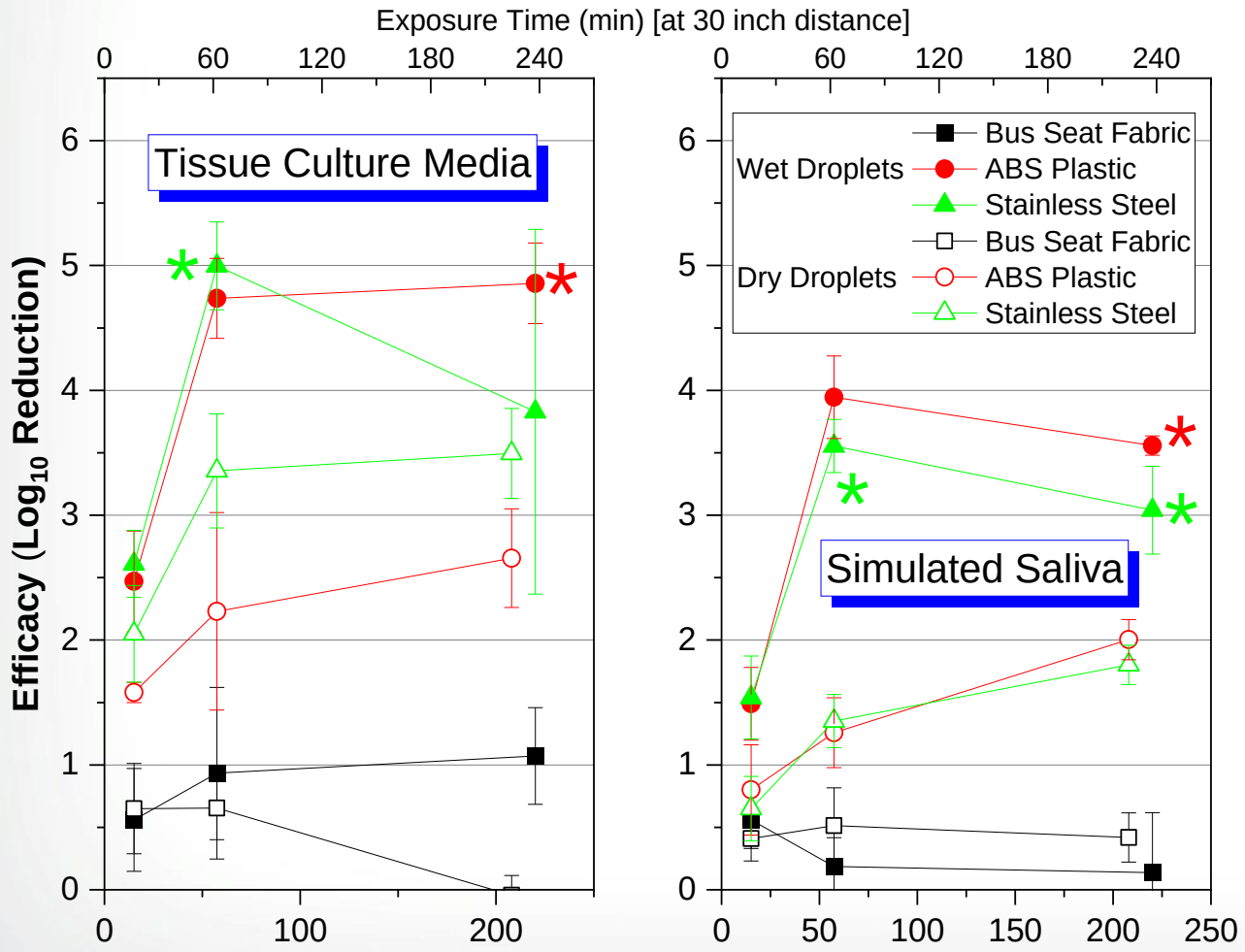
SARS-CoV-2 Efficacy Results Pulsed Xenon



LA Metro dose (at 30 min, ~60")

- High log reductions for smooth materials (ABS plastic and stainless steel)
- Low log reductions for rough, porous surface (bus seat fabric)
  - Virus shielded from UVC light within material fibers
- SARS-CoV-2 in a dried saliva is most difficult to inactivate
  - Absorption of UVC light in saliva may explain this difference
- LA Metro's highest UVC dose recorded for a surface at 60" distance from a light and a 30 min exposure time was 4.0 mJ/cm^2

SARS-CoV-2 Efficacy Results LED



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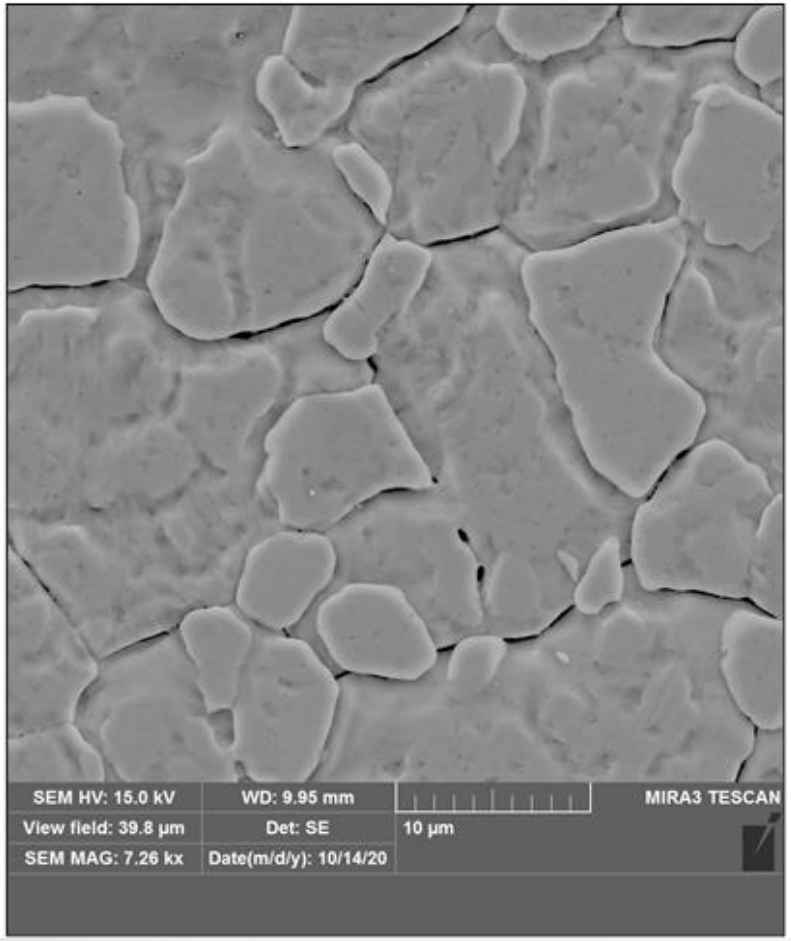
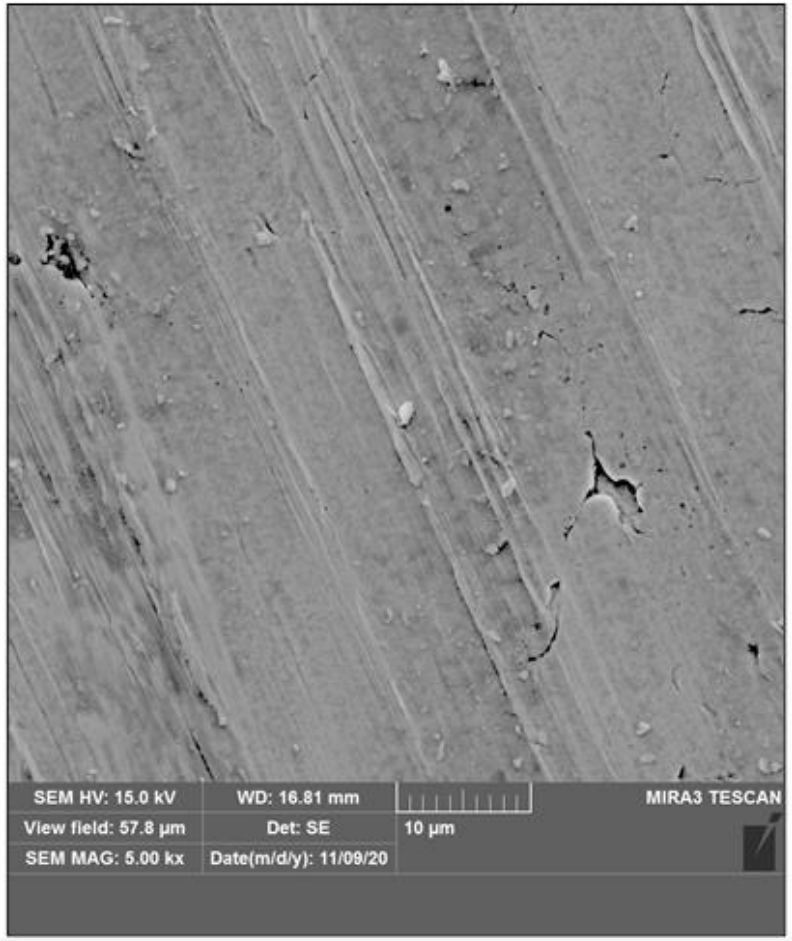
A closeup of some of the materials

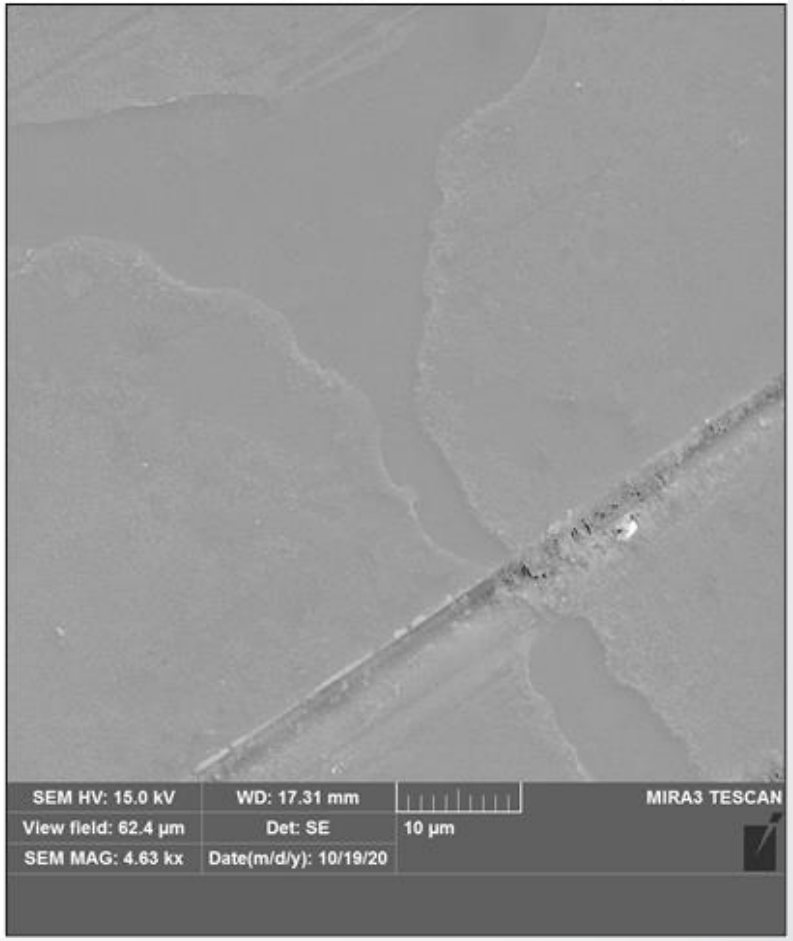
Milled 304 Stainless Steel (MS2/Phi6 study)



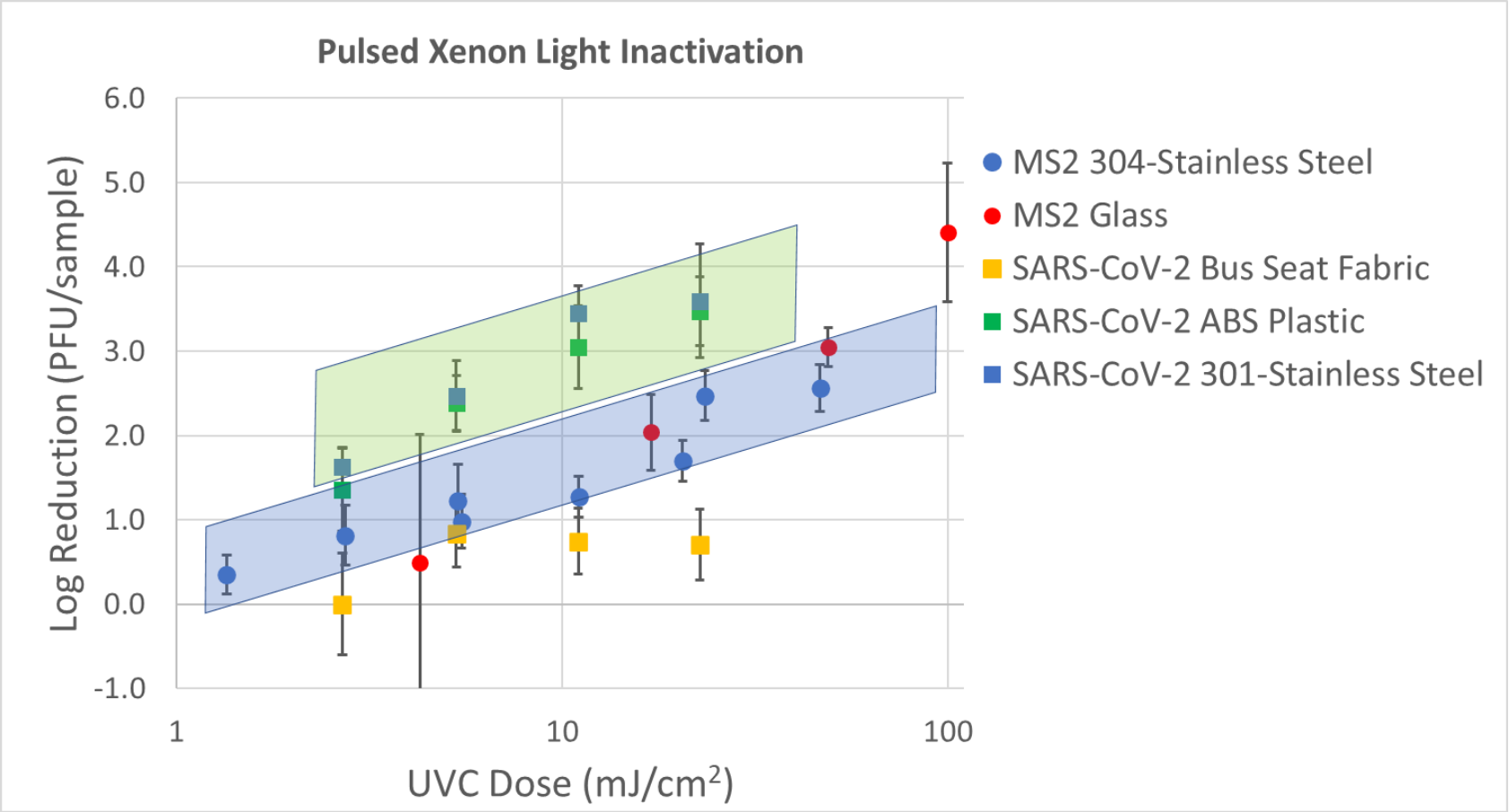
301 Stainless Steel (SARS-CoV-2)



Glass Coupon (MS2/Phi6 study)



SARS-CoV-2 Surrogate Research



- Conducted UVC disinfection research with two potential surrogate bacteriophages, MS2 and Phi6
- MS2 is a good surrogate in that it is more difficult to inactivate than SARS-CoV-2

UVC Summary

- Summary of bench scale research
  - We estimated UVC doses needed to achieve various log reductions of SARS-CoV-2, and other surrogate viruses, with two light sources
  - UVC dose conditions depend on multiple variables
    - Lack of established methods makes direct comparisons with (new) literature challenging
  - For the tested light sources, the required doses for 3 log reduction (99.9%) could only be obtained at relatively short (30” or shorter) distances for operationally feasible exposure times (<60 min)

UVC Applications

- Considerations for surface disinfection
  - Implementation of UVC requires design and engineering solutions to deliver effective doses
    - Challenge to do this in complex environments with permanent fixtures
    - Use of multiple lights at various angles or moving lights may overcome single light approaches
  - Inactivation of a virus on non-smooth surfaces (fabric, carpet etc) will remain a challenge
    - Viruses may still be able to “hide” in crevasses or canyons on otherwise smooth surfaces

Acknowledgments

- SARS-CoV-2 studies:
  - Battelle: William Richter, Michelle Sunderman, Megan Howard
- MS2 and Phi6 studies:
  - Jacobs Technology Inc.: Ahmed Abdel-Hady, Mariela Monge, Denise Aslett, Dahman Touati
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  - Shawn Ryan, Worth Calfee (ORD/CESER)
  - Yvette Hopkins (Office of Enforcement and Compliance)
  - Diane Isbell (Office of Pesticide Programs)

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ORD/CESER/HSMMD

https://www.epa.gov/healthresearch/research-covid-19-environment