International Commission on Illumination
Commission Internationale de l'Eclairage
Internationale Beleuchtungskommission

OP23

INNOVATIVE APPROACHE TO COMBAT HEALTHCARE-ASSOCIATED INFECTIONS USING STANDARDS DEVELOPED THROUGH INDUSTRY AND U.S. FEDERAL COLLABORATION

C. Cameron Miller et al.

DOI 10.25039/x46.2019.OP23

from

CIE x046:2019

Proceedings
of the
29th CIE SESSION
Washington D.C., USA, June 14 – 22, 2019

(DOI 10.25039/x46.2019)

The paper has been presented at the 29th CIE Session, Washington D.C., USA, June 14-22, 2019. It has not been peer-reviewed by CIE.

CIE Central Bureau
Babenbergerstrasse 9
A-1010 Vienna
Austria
Tel.: +43 1 714 3187
e-mail: ciecb@cie.co.at
www.cie.co.at

INNOVATIVE APPROACHE TO COMBAT HEALTHCARE-ASSOCIATED INFECTIONS USING STANDARDS DEVELOPED THROUGH INDUSTRY AND U.S. FEDERAL COLLABORATION

Miller, C.C.[1], Larason, T.C.[1], Poster, D.L.[1], Obeng, Y.[1], Postek, M.T.[2], Cowen, T.E.[3], Martinello, R.A.[4]
[1] National Institute of Standards and Technology, Gaithersburg, MD, USA
[2] College of Pharmacy, University of South Florida, Tampa, FL, USA
[3] Vision Based Consulting, Bethesda, Maryland, USA
[4] Yale School of Medicine, New Haven, Connecticut, USA

c.miller@nist.gov

DOI 10.25039/x46.2019.OP23

Abstract

Nationwide, healthcare-associated infections (HAIs) infect one in every 25 hospital patients, account for more than 99,000 deaths and increase medical costs by more than $35 billion, each year. Ultraviolet-C (UV-C) antimicrobial devices are shown to reduce the incidence of many of these HAIs by 35% or more, through the deactivation of the pathogen's DNA chain by irradiating it with a wavelength of ~254 nm. The methodology works, but, the adoption of UV-C technology by the healthcare industry has been sporadic. This is largely due to the lack of definitive knowledge and uniform performance standards or measures for efficacy to help healthcare managers make informed, credible investment decisions. The levelling of the playing field with scientifically certifiable data of the efficacy of antimicrobial devices will enhance acceptance by the healthcare industry and public, at large, as well as facilitate science-based decision making.

Keywords: Antimicrobial, Healthcare-Associated Infections, Ultraviolet-C

1 Introduction

Healthcare-associated infections (HAIs) are one of the leading causes of death in the United States (U.S.). HAI statistics are difficult to obtained. HAI are not as newsworthy as other causes of death, until a facility is closed for sanitation reasons. Nationwide, HAIs infect about one in every 25 hospital patients. (CDC 2018) Each year this translates to approximately 1.7 million HAIs occurring in U.S. hospitals, resulting in approximately 100,000 or more unnecessary deaths and an estimated $20 billion in U.S. dollars in healthcare costs. (SRT&SOCS 2014) The overall direct cost of HAIs to hospitals can be as high as $45 billion (Stone 2009) and costs due to operational or occupational losses of productivity are estimated at more than $100+ billion, yielding more than $145 billion per year of economic impacts on the U.S. economy alone with the understanding that full societal costs have never been fully measured or reported. (Marchetti 2013).

Comparing these economic data to information obtained from the U.S. Centers for Disease Control and Prevention shown in Figure 1, the deaths from HAIs place HAI deaths nearly at the level of those attributed to Alzheimer's disease and above the seventh leading cause of death in the U.S., that is, above diabetes. (CDC 2017) In 2015, diabetes claimed 79,535 deaths, which is only about three-quarters of the deaths attributed to HAIs. The U.S. currently recognizes an "Opioid Crisis" where in 2016, about 63,000 drug overdose deaths in the US were reported, while terrible is lower than those attributed to HAIs. (Hedegaard 2017) (Steenhuysen 2017)

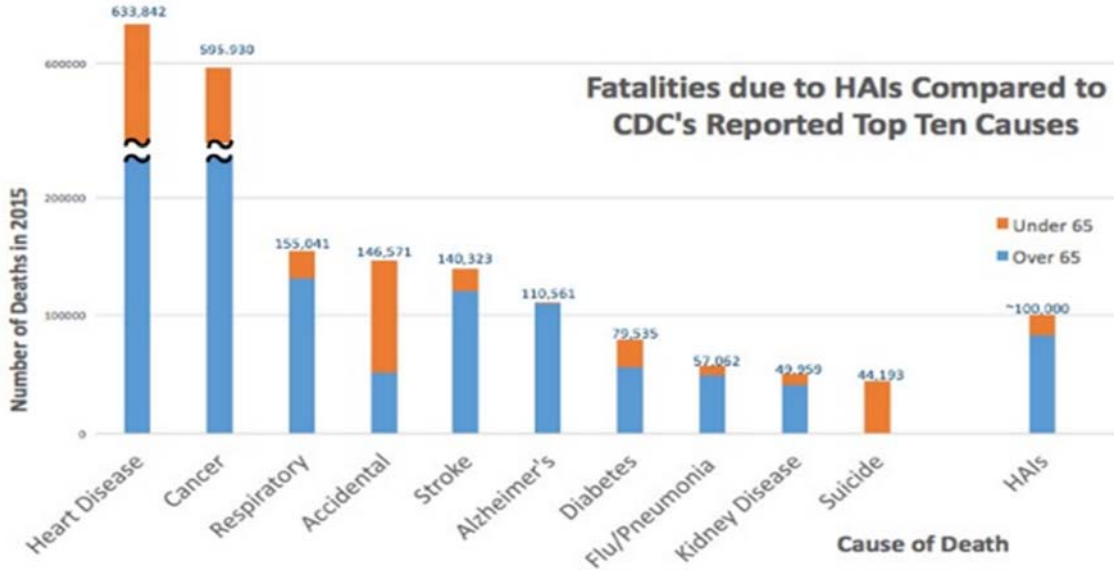

Figure 1 - CDC reported top ten causes of death in 2015 (CDC 2018) compared to the reported number of HAI fatalities (SRT&SOCS 2014)

2 Potential Solution

The deadly problem of HAIs, the technologies to combat HAIs, and the identification of barriers and research opportunities to improve the effective and efficient treatment of HAIs, have recently been explored. (Cowan 2018) (Martinello 2018) Efficient and effective use of ultraviolet-C (UV-C) in healthcare settings is essential to the widespread adoption of UV-C in healthcare. Moreover, the implementation of standard industry metrics for devices holds a significant promise to create a safe environment for patient care and mitigate the risk for HAIs. Here we examine the issues with HAI control and the role the National Institute of Standards & Technology (NIST) hopes to have in implementing UV surface disinfection in healthcare settings.

In 2016 the U.S. CDC concluded that the incidence of HAI-causing organisms can be reduced by up to 35% after adding antimicrobial UV-C emitting devices to standard cleaning strategies. (Anderson 2017) It was demonstrated in the terminal room disinfection study that automated UV-C emitting devices decrease the harmful pathogens in hospital rooms. Clinical case reductions of 30% to 70% in *Clostridium difficile* (*C. diff.*) have been reported, with similar results for methicillin-resistant *Staphylococcus aureus* (*MRSA*). (Rutala 2010) The methodology works, but, the adoption of UV-C technology by the healthcare industry has been sporadic. This is largely due to confusion and low confidence resulting from the lack of definitive knowledge and uniform performance standards or measures for efficacy to help healthcare managers make informed, credible investment decisions. Multiple UV light source technologies and disinfection mechanisms at multiple wavelengths (Table 1) contribute to the confusion and difficulty in comparing devices. Levelling of the playing field with scientifically certifiable data of the efficacy of antimicrobial devices will help facilitate science-based decision making.

The lack of a standard laboratory efficacy test method has resulted in manufacturers using different approaches to make efficacy claims. This lack of standardization has led to the confusion in the healthcare industry. While many manufacturers have excellent data to support disinfection claims, there are no efficacy standards, metrics or uniform testing methodologies for comparing one device's data against others, making it a "Wild West" in the healthcare market. The lack of regulation and standards has led to the development and introduction of very special testing and evaluation programs throughout the industry, often with the use of different pathogens, concentrations, testing methodologies and efficacy criteria. The over-abiding result is that there are no clear-cut paths for comparing one unit against another easily, thus often allowing cost to be the deciding factor for a hospital administrator.

Table 1 – UV-C light sources for disinfection and antimicrobial devices

Primary UV light source	New wavelengths of interest
• Mercury-based o primarily low pressure (254 nm) • Xenon-based o broad spectrum • LED o variety of output wavelengths	• Vacuum-UV o 100 nm – 200 nm, 205 nm, 222 nm o often portable, hand-held devices • Blue light o 405 nm, long-term exposure

3 Documentary Standards

In collaboration with NIST, International Ultraviolet Association (IUVA) and RadTech are exploring ways to reduce these discordant market conditions and answer the healthcare industry's questions surrounding standards and measures of device disinfection efficacy, as well as reliability, operations, efficacy, and durability. The Associations sought to draw from NIST's collaborative partnerships experience with manufacturers, their associations, academia, and the public sector in standards development and are looking for ways to establish a Federal-industry-public sector initiative in this technical area. It is envisioned that the adoption of standardized UV technology in the healthcare industry is a solution to combating HAIs and saving lives. The conversation with NIST on standards development and partnerships has been a great place to start for realizing this vision.

It was clear from the IUVA 2018 America's Conference HAI panel discussions held in Redondo Beach, California that the development of UV light measurements and standards is critically needed to grow and expand UV technology in all phases of disinfection. Industry wide collaboration and cooperation is needed, which was a continued theme at the IUVA 2019 World Congress in Sydney, Australia (Poster et al., 2019) where a special technical session for UV for healthcare/HAI took place. Heterogeneity in the reporting of UVC surface disinfection interventions in medical literature is clearly a potential barrier to implementation of the UV technology in the healthcare sector. (Martinello, 2019) The first step is to identify the main needs and then determine positive solutions. Consensus-based measurements and standards are needed in the UV technology sector; they are infrastructural and if designed properly, pose no competitive advantage to one single company. Companies can openly and readily cooperate at this level.

The first proposed standard is a test method for the measurement of radiant flux of low pressure (LP) mercury tubes developed through an ANSI approved standards development process. This document has a scope describing the procedures to determine the total radiant flux (W) and/or the distribution of radiant intensity (W/sr) at a specific wavelength of 254 nm under standard electrical and operating conditions. Most of this work would leverage the process written by Lawal, et al - 'Method for the Measurement of the Output of Monochromatic (254 nm) Low-Pressure UV Lamps' published in the IUVA News. (Lawal 2017) Standard electrical and operating conditions include the tolerances on voltage waveforms, voltage regulation, ballast conditions, ambient temperature, and allowable air flow. Additional conditions are controlled including lamp orientation, seasoning, preburning, and stabilization time to increase the reproducibility among laboratories. The calibration and measurement procedures are described for using an integrating sphere system, a goniometer system, or using the Keitz formula. The difference between using a broadband measurement versus a spectroradiometer system are presented. Additional guidance is provided including measurement uncertainty considerations and information that should be provided in a test report.

The second proposed standard to develop is a test method for the measurement of radiant flux of medium pressure mercury tubes and xenon tubes. The document scope describes procedures to determine the total spectral radiant flux (W/nm) and/or the distribution of radiant intensity (W/sr) over a wavelength range of 200 nm to 400 nm under standard electrical and operating conditions. Many of the conditions and the guidance presented in the LP mercury tubes document would be similar. More emphasis would be placed on calibrating the spectroradiometer within the measurement system.

The third document is a test method for the measurement of radiant flux of LED packages. The document scope describes procedures to determine the total spectral radiant flux (W/nm) and/or the distribution of radiant intensity (W/sr) over a wavelength range of 200 nm to 400 nm under standard electrical and operating conditions. The electrical and thermal management of the LED in a standard condition is significantly different than mercury tubes. The IES has published a measurement method for LEDs identified as LM-85-14 - Approved Method: Electrical and Photometric Measurements of High-Power LEDs. (IES 2014) While this document focuses on the 380 nm to 780 nm wavelength range, the protocol and techniques discussed in the standard can be extended to cover the 200 nm to 400 nm range.

The first three proposed standards have dealt with the measurements of components that are installed into fixtures. The next two documents would cover a test method for the measurement of radiant intensity distribution (W/sr) of a UVC luminaire and a test method for the measurement of irradiance (W/m2) of a UVC luminaire at a specific distance. The data collected using these two methods would allow healthcare applications to be modelled.

While this is not a complete list of documentary standards for UV antimicrobial devices used to tackle HAIs and Multi-Drug Resistant Organisms (MDRO) pathogens in healthcare facilities, which is the mission of the Healthcare/UV Working Group formed by the IUVA, an additional proposed standard is the recommended practice for implementing surface UVC disinfection. The recommended practice would provide guidelines on the required amount of UVC light to accomplish inactivation of different pathogens. The practice may also describe modelling techniques such as establishing a scenario and then by using ray tracing software, the data collected for the UVC luminaire, and UVC reflectance data determine if the dose is large enough to accomplish the required task.

4 The Role of NIST

NIST is taking an active role by improving UV measurement scales and UV measurement facilities to support the application of the documentary standards. The Ultraviolet Spectral Comparator Facility (UV-SCF) is undergoing a significant upgrade to improve the calibration of UV sensitive detectors for the quantity of power responsivity and irradiance responsivity. Table 2 shows the current power responsivity expanded uncertainties and expected expanded uncertainties once the upgrades are complete. The improvements are based on better scale realization at NIST's Primary Optical Watt Radiometer (POWR), picometer level wavelength control of the monochromator, environmental control of the measurement, and new sources such as laser drive plasma sources.

Table 2 – UV-SCF Power Responsivity Expanded Uncertainty Now and Future

Wavelength (nm)	Current Expanded Uncertainty (*k*=2)	Expected Expanded Uncertainty (*k*=2)
200	4.7 %	0.50 %
250	1.8 %	0.30 %
300	1.0 %	0.20 %
350	0.8 %	0.20 %

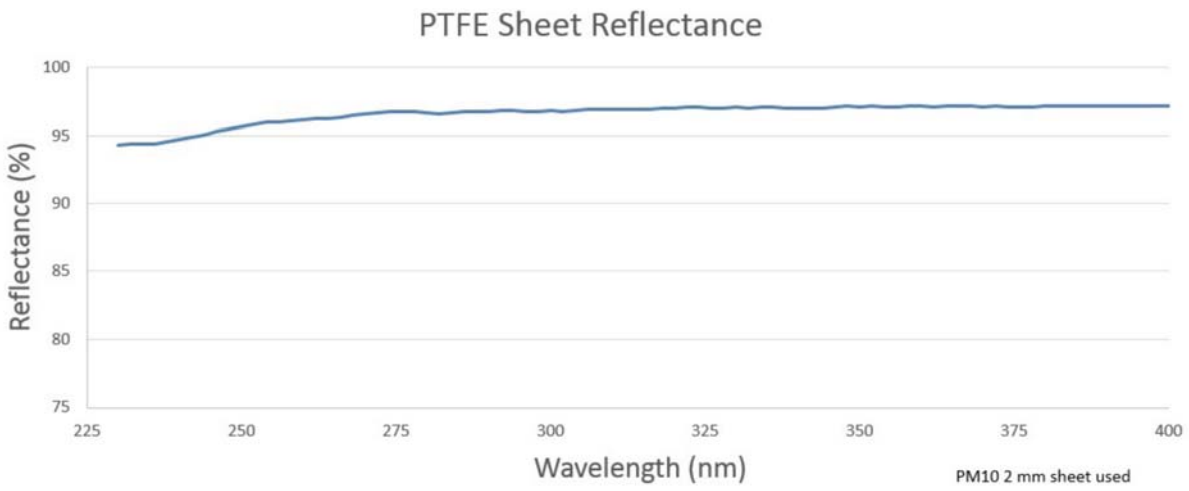

Figure 2 - Reflectance curve of PTFE Sheet used in UV water reactors

Using the calibrated detectors, spectroradiometer's are calibrated using a pulsed laser system which is discussed in another presentation at the CIE 29th Quadrennial Meeting (OP 77). (Zong 2019) which relies on the straylight correction method developed by Zong. (Zong 2006).The calibrated spectroradiometer is planned to be used in variety of applications including calibrating deuterium lamps for spectral irradiance. The laser calibration method will also be used to calibrate two sphere systems, a 30 cm diameter system mainly intended for LED measurements and 1.5 m diameter system mainly intended for customer products. The 1.5 m system is coated with a version of PTFE film intended for UV water reactors, shown in Figure 2. (Porex 2019) The development of these facilities will allow the dissemination of UV scales and artefacts to the measurement community to support UV disinfection.

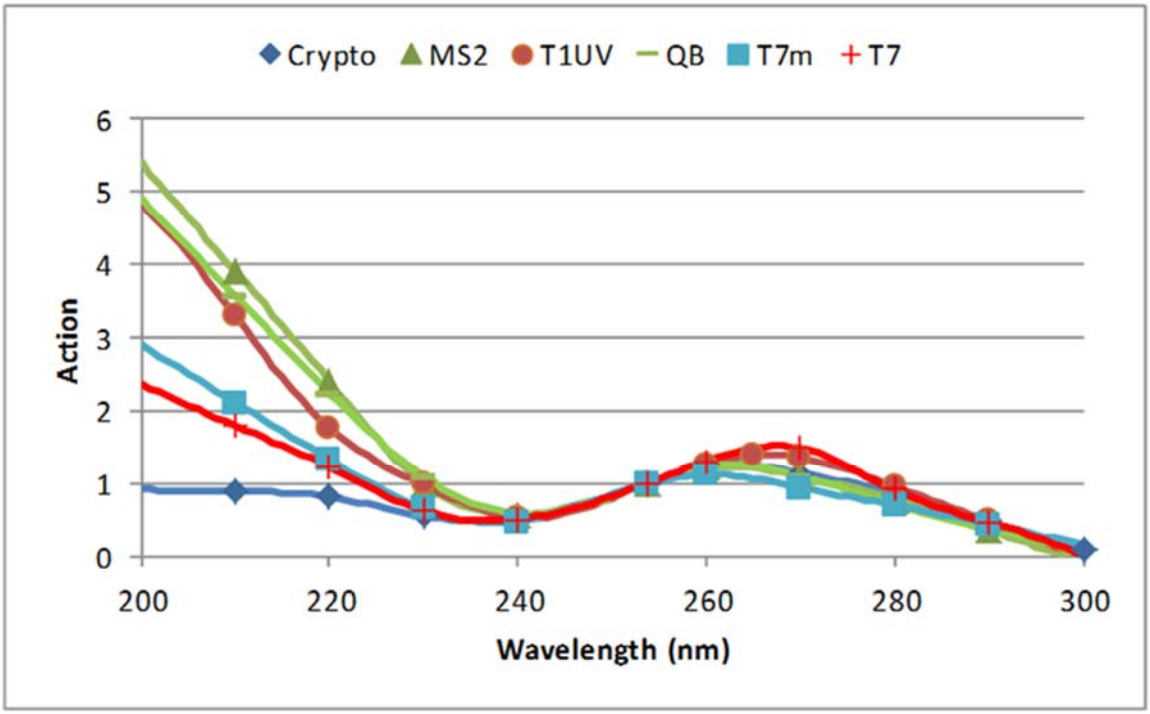

Figure 3 - Action spectra of Cryptosporidium and coliphages MS2, T1UV, Q beta, T7 and T7m

NIST is also taking an active role in determining the dose required for inactivation or disinfection of microorganisms. Previously NIST has collaborated to measure the spectral action spectra for a variety of pathogens, shown in Figure 3. (Linden 2013) Obeng et al. (2019) have also

explored inactivation of various bacteria species using broadband dielectric spectroscopy techniques as a new measurement tool to assess cell vitality. NIST plans to collaborate with external partners to continue this research into surface pathogens relevant to this project.

5 Summary

NIST has engaged with the IUVA and its member companies and affiliates to explore how standards and measures of device disinfection efficacy, reliability, operations and durability may help address these needs. Leveraging this partnership is essential to implement standards through federal participation in the development and use of voluntary consensus standards and in conformity assessment activities.

Clearly, the potential for this technology is huge. Industrial cooperation and coordination is foremost to develop the needed roadmap. There are many facets to this industry, but this is no different than other similar entities. Perhaps a consortium of the companies to coordinate these activities and provide the infrastructional guidance and roadmapping exercises is in order. Such a consortium can speak for the entire industry and provide leverage no single company can wield. Fundamental change can be affected through a path of advancing UV efficacy standards and testing protocols to demonstrate the advantages of UV for combatting HAIs while advocating its increased implementation through education and outreach programs targeting the Nation's healthcare sector.

References

Anderson, D. J., Chen, L. F., Weber, D. J., Moehring, R. W., Lewis, S. S., Triplett, P. F., Blocker, M., Becherer, P., Schwab, J. C., Knelson, L. P., Lokhnygina, Y., Rutala, W. A., Kanamori, H., Gergen, M. F., and Sexton, D. J., (2017) "Enhanced terminal room disinfection and acquisition and infection caused by multidrug-resistant organisms and Clostridium difficile (the benefits of enhanced terminal room disinfection study): a cluster-randomized, multicenter, crossover study," The Lancet, 89(10071), 805 – 814, https://doi.org/10.1016/S0140-6736(16)31588-4.

Centers for Disease Control and Prevention, (CDC) (2017) National Center for Health Statistics, "Health, United States, 2016: with chartbook on long-term trends in health," Library of Congress Catalog Number 76–641496, https://www.cdc.gov/nchs/data/hus/hus16.pdf#019.

Centers for Disease Control and Prevention, (CDC) (2018) National Center for Emerging and Zoonotic Infectious Diseases, "Healthcare-associated infections (HAI), HAI data and statistics," https://www.cdc.gov/hai/surveillance/index.html.

Cowan, T.E., (2018) "Healthcare acquired infection (HAIs): a deadly problem that is preventable: UV can help, what's holding it back?" Proc. SPIE 10479, 10479A-1 – 10479A-17 https://doi.org/10.1117/12.2288584.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) https://www.epa.gov/enforcement/federal-insecticide-fungicide-androdenticide-act-fifra-and-federal-facilities.

Hedegaard, H., Warner, M., and Miniño, A. M., (2017) "Drug overdose deaths in the United States, 1999 – 2016," Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/data/databriefs/db294.pdf.

Illuminating Engineering Society. (IES) (2014) LM-85-14, Approved Method: Electrical and Photometric Measurements of High-Power LEDs. New York.

Joint Hearing Before the Subcommittee on Research and Technology & Subcommittee on Oversight Committee on Science, Space, and Technology, (SRT&SOCS) (2014) House of Representatives, "Technology for patient safety at veterans' hospitals," 113th Congress, 2nd Session, Serial No. 113–83: p. 12; Washington, D.C., https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg89412/pdf/CHRG-113hhrg89412.pdf.

Lawal, et al; (2017) Method for the Measurement of the Output of Monochromatic (254 nm) Low-Pressure UV Lamps; IUVA News, Vol 19. No 1, Spring. (http://iuvahcuv.org/wp-content/uploads/2018/06/IUVA-Protocol-for-Measuring-the-Efficiency-of-a-low-pressure-UV-lamp-190101_LawalEtAl_Spring_2017.pdf)

Linden, K., Wright, H., Beck, S., Hargy, T., Larason, T., McCuin, R., (2013) Measuring the UV Action Spectra of Pathogens and Surrogates, presented at the IOA-IUVA 2013 World Congress & Exhibition

Marchetti, A. and Rossiter, R., (2013) “Economic burden of healthcare-associated infection in US acute care hospitals: societal perspective,” Journal of Medical Economics 16(12), 1399-1404, https://doi.org/10.3111/13696998.2013.842922.

Martinello, R. A., (2019) “Heterogeneity in the reporting of UVC surface disinfection interventions in medical literature - a potential barrier to implementation,” Presented at the 2019 International Ultra Violet Association World Congress, February 11, Sydney Australia.

Martinello, R. A., Miller, S. L., Fabian, M. P. and Peccia, J., (2018) "Identification of barriers and research opportunities to improve the effective and efficient application of adjunct UVC surface disinfection in healthcare," Proc. SPIE 10479, 10479B-1 – 10479B-8 https://doi.org/10.1117/12.2291091.

Obeng, Y. S., Papa, K. A., and Nablo, B. (2010) “Applications of Broadband Dielectric Spectroscopy (BDS) for Addressing Hospital Acquired Infections,” unpublished data.

Porex Filteration Group - https://resources.porex.com/Porex-Datasheet-High-Reflectivity-Components.pdf, Accessed April 30, 2019 - Any mention of commercial products within NIST web pages is for information only; it does not imply recommendation or endorsement by NIST.

Poster, D. L., Obeng, Y. S., Miller, C. C., Postek, M. T., Kasianowicz, J. J., Cowan, T. E., Martinello, R. A., (2019) “Minimizing healthcare-associated infections in the United States through the collaborative development of standards, metrology and technology,” Presented at the 2019 International Ultra Violet Association World Congress, February 11, Sydney Australia.

Rutala W. A., Gergen, M. F., and Weber, D., (2010) “Room decontamination with UV radiation,” Infection Control & Hospital Epidemiology, 31(10), 1025 – 1029 (2010) https://doi.org/10.1086/656244.

Steenhuysen, J., (2017) “Opioid crisis trims U.S. life expectancy, boosts hepatitis C: CDC,” Reuters, December 21, 2017, https://www.reuters.com/article/us-usa-healthcare-cdc/opioid-crisis-trims-u-s-life-expectancy-boostshepatitis-c-cdcidUSKBN1EF1TF.

Stone, P., (2009) “Economic burden of healthcare-associated infections: an American perspective,” Expert Review of Pharmacoeconomics and Outcomes Research 9(5), 417-422, http://www.tandfonline.com/doi/full/10.1586/erp.09.53.

Zong Y., Brown S. W., Johnson B. C., Lykke K. R., and Ohno Y., (2006) Simple spectral stray light correction method for array spectroradiometers, Appl. Opt., 45, 1111-1119.