

David F. Goldsmith, MSPH, PhD, LLC
9504 Crosby Road
Silver Spring, Maryland 20910

August 28, 2015

Ms. Angela D. Freeman
Manager, Certification Programs
Textile Rental Services Association
1800 Diagonal Road, Suite 200
Alexandria, VA 22314

Dear Ms. Freeman:

I have prepared a review of TRSA's "Hygienically Clean" program with the purpose of examining its value for public health and for its business benefits. Specifically, I will address the following: Defining TRSA's Hygienically Clean Program; Methods for attaining standardized clean levels for bedding and providers' uniforms; Certification and testing of cleaned textiles for levels of infectious agents; Workplace safety and health standards for employees of TRSA member companies; Impacts on patients, care givers and broad public health by adoption of Hygienically Clean standards; Potential for marketing Hygienically Clean standards to hospitals and to clinic providers; Possible survey of member companies regarding their experiences with TRSA's Hygienically Clean program; Improving Hygienically Clean program to lower concentrations of infectious agents and other potential hazards in cleaned textiles; Conclusions and recommendations for 2016 and beyond. I have used materials TRSA supplied to me and I have conducted my own evaluation obtained from the National Library of Medicine's Pubmed, its online link with the world's published research studies.

In my assessment of the Hygienically Clean program, it is clear that the required testing is reasonable and adds public health and business value to the certification process.

My Research and Professional Background

I am an occupational and environmental epidemiologist, having earned my MSPH and PhD degrees in epidemiology from the University of North Carolina in 1977 and 1983, respectively. I am now a Professorial Lecturer in the Department of Environmental and Occupational Health in the George Washington University Milken Institute School of Public Health in Washington DC. I also hold an adjunct Associate Professor rank at the Georgetown University in the Department of Human Science in the School. In 2014 I was Fulbright Visiting Research Chair in Science, Technology, Engineering or Math at the University of Manitoba, School of Medicine in Winnipeg, Canada. I have teaching and research experience in the area of occupational and environmental health, dermal epidemiology, risk assessment, reproductive health, and application of epidemiology to medical-legal disputes, including the history of silica dust

exposure and the science of causation. My specialty within environmental epidemiology is and has been for 25 years lung cancer and other pulmonary health effects related to a variety of toxins. I was a member of the science panel of the Institute of Medicine (IOM) examining the evidence of health of veterans serving in the Gulf War. I have been qualified as a health expert in proceedings before Federal courts, State courts, and I have acted in a professional capacity as an advisor to many Federal, State, and international agencies. Those agencies include the U.S. and California Environmental Protection Agency (EPA), National Institutes of Health, National Institute for Occupational Safety and Health (NIOSH)--Centers for Disease Control and Prevention (CDC); Consumer Products Safety Commission (CPSC); and the Occupational Safety and Health Administration (OSHA). I have provided expert opinions on toxic hazards in Canada, Japan, Israel, and Uzbekistan. I was a member of the World Health Organization (WHO), International Agency for Research on Cancer (IARC) panel assessing the carcinogenicity of silica in 1986. In 2014 I testified on behalf of the proposed crystalline silica dust standard.

I have acted as a peer-reviewer for many professional journals in public health; I have been a member of the Board of Editors for American Journal of Industrial Medicine and for Journal of Toxicology and Environmental Health. I am currently an Executive Editor for the Archives of Environmental and Occupational Health. I have been a member of many grant review panels for the National Institutes of Health (NIH), EPA, National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), Agency for International Development (USAID) and National Institute for Occupational Safety and Health (NIOSH). I have served as an expert in many legal/medical cases throughout the U.S. related to exposures as varied as pesticides, foundry dusts, asbestos, silica dust, cryogenic medical devices, diesel exhaust, World Trade Center exposures, and solvents.

In my career I have examined many issues related to respiratory and dermal health including surveys of rice farmers exposed to silica in soils, farmworkers exposed to pesticides, studies of the pulmonary disease risks from the inhalation of silica and asbestos dusts, and lung cancer hazards from a mixture of smoking and other inhaled toxins. In my career I have studied the health effects of cutaneous exposures to pesticides. I was from 2006 to 2008 and in 2012 a Study Section member for Centers for Disease Control and Prevention-NIOSH Agricultural Health and Safety Centers. I have been a member of the National Institutes of Health (NIH) Study section--Infectious Disease, Reproductive Health, Asthma, and Pulmonary Epidemiology (IRAP)--examining grant proposals linking environmental exposures to pulmonary and skin conditions. When I was seconded to the Veterans Administration from 2009 to 2011, I had responsibility to review scientific evidence related to lung disease health effects from military exposures to Agent Orange, to combustion hazards from burn pits, and to hazardous oil field exposures from the Gulf War. I previously sent you my resume summarizing my academic experience and publications.

What is TRSA's Hygienically Clean Program?

There has long been concern about residual infectious and blood-borne agents presenting risks for secondary infections from the reuse of bedding and the rewearing of healthcare provider garments. This can be true for all reusable textiles, including but not limited to hospital curtains, drapes, upholstery, towels, and patient apparel as well. Blaser et al. (1984) found the most commonly detected microorganisms on hospital textiles include gram negative bacteria, coagulase negative staphylococci, *Bacillus* sp, and typical skin flora (Blaser et al., 1984). Fijan and Turk (2012) reviewed many examples of surviving pathogens in hospital textiles after laundering, including some risky laundry cleaning conditions (Fijan and Turk, 2012). There are two recent cases of laundry contamination, one in Hong Kong and another in New Orleans that demonstrates how critical it is to adhere to cleanliness methods to prevent mold related illnesses (in New Orleans this contamination led to five adolescent fatalities) [Cheung 2015; Duffy et al, 2014]. It was for the potential risks of transmission of infectious organisms that TRSA adopted test methods to be used by commercial laundries to measure cleanliness and safe handling of soiled textiles, a sufficient wash process with industrial strength detergents and bleach, sufficient drying of textiles, and returning the cleaned laundry to the clinics and facilities where they would be reused (TRSA, 2015a).

It is noteworthy that there are no federal or state standards or performance regulations for microbiological testing of hospital or clinical textiles; TRSA Hygienically Clean Program grew from the industry agreeing to impose upon itself the chore of setting performance regulations. The foundations for TRSA's Hygienically Clean program stand on three pillars: recommendations by the CDC that commercial laundries use water temperatures of 160 F (71 C) and 50-150 ppm chlorine bleach for at least 25 minutes, also recognizing that lower water temperatures and time can be utilized in the wash process; CDC also urges laundries to use common-sense washing practices for processing and storage of linen rather than proscribed rules and regulations (CDC, 2003 and 2011); the work of the Certification Association for Professional Textile Services Administration (CAPTSA). CAPTSA collaborated with European Union to develop the first regulations that established the operational standards in the 1980s—less than 20 colony-forming units (CFU) per square decimeter of washed material (TRSA, 2015b). In 1995 the Quality Indicator Study Group targeted the U.S. market to adopt the <20 CFU standard for nosocomial infections (Quality Indicator Study Group, 1995). Since 2004, TRSA has established scientifically-based standards for commercial cleaners to adopt a regulatory quality for cleaning reusable textiles used in healthcare. This standard was adopted when TRSA's Healthcare Committee developed the Healthcare Laundry Accreditation Council (HLAC) to provide the specific performance practices for certified laundries to meet. In 2012, TRSA launched the Hygienically Clean certification program that matched the international standard <20 CFU per square decimeter of material. Achieving this level of cleanliness is the heart of TRSA's Hygienically Clean standard, and the means to attain these goals are left to the expertise of the commercial laundry. Third Party inspectors are given the authority for laundry plant evaluations. They verify strict adherence and compliance with requirements outlined within the Hygienically Clean standard for facilities, housekeeping, the laundry process, and OSHA regulations. TRSA adds an operational layer to this regulation by requiring laundry performance that is checked by

independent laboratory compliance before achieving certification and ongoing quarterly testing by independent laboratory methods for maintenance of cleanliness (TRSA, 2015b). The degree of testing is used to continuously validate the laundry process up to the Hygienically Clean standard, and it alerts laundry officials when there are issues in the washing or drying or handling procedures.

Certification and Testing of Cleaned Textiles

Under TRSA's Hygienically Clean program the target of <20 CFU per square decimeter of laundered material has to be met for the first three months once a laundry has entered into the certification process. Once that is achieved, there is mandatory retesting every quarter. In all cases the analysis is conducted by independent laboratories having no affiliation with the laundry. This sort of testing is often called "continuous quality assessment," and it is focused on product quality assurance rather than service performance. Attaining these regulatory standards provides the laundry the opportunity to label their finished products in conformance with TRSA's Hygienically Clean program. Microbial testing follows the methods adopted by RODAC, total aerobic microbial count (TAMC), which meets the <20 CFU per square decimeter of laundered material and the United States Pharmacopeia (USP) 62 microbial examination tests (TRSA, 2015b). When the pathogens are tested, they include staphylococcus aureus, pseudomonas aeruginosa, *E-coli*, *candida albicans* salmonella, bile tolerant gram negative bacteria, and *clostridium* sporogenes. If laundries fail a test, there are avenues for retesting, with TRSA inspections and guidelines, to achieve compliance (TRSA, 2015b). Laundries are mandated to maintain records of all inspections and regulatory fabric testing for the length of the contract with TRSA, plus five years (TRSA, 2015b).

Workplace Safety and Health for Employees of TRSA Members

TRSA member laundries have established procedures that provide a high quality of workplace safety and health. They achieve that by complying with OSHA regulations and by making protection of their employees' health a hallmark of their operation. Specifically, Hygienically Clean certified companies adhere to OSHA's regulations on bloodborne pathogens, hepatitis B vaccinations, hazard communication, and guidelines for employer compliance. Hazard communication is essential because there is a great deal of social heterogeneity and language skills in an industrial laundry workforce. The managers and supervisors at certified facilities must make sure that all workers know the importance of safety and health in their operations. Most recent data from the Textile Services Industry Safety Report from 2010 to 2014 showed that TRSA member companies' total recordable (accident) incident rate fell 27.3% versus 9% for all private U.S. industry. The days away from work, restricted or transfer rate was 25.6% for TRSA members versus 8.3% for all U.S. industry (SafeTRSA, 2015). Hygienically Clean laundries focus on making sure all workers are aware of the essential nature of two paths within the plant: soiled linens and clean garments and textiles. All workers must have vaccinations for blood borne pathogens (including hepatitis) and wear protective masks, gloves, and use work smocks to protect against transmission of infectious materials. All work clothes remain in the laundry where they are washed for reuse. The ideal is to have employees handle soiled linens as little as possible; there are

significant opportunities for automation at this end of the laundry process. It is essential that all carts and laundry bags be regularly cleaned so that hygiene in the plant can be maintained.

The Hygienically Clean standard provides guidance for the laundry process, including cycle times, water use and rinse levels, temperature for washing for bleaching and adding other chemical disinfectants. Drying the washed linens must be controlled and monitored in order that bacterial recontamination cannot occur. Cool-down drying, pressing, and folding temperatures are part of effective employee health procedures so that burns are prevented among workers. Lastly clean and dried products must be packaged, transported and stored for restocking at the healthcare site.

Impacts on Patients, Care Providers, and Public Health of Hygienically Clean Standards

Laundries' adherence to Hygienically Clean standards has meaning for the customers using these clinical textiles. Hospitals and their staff all know and can clearly communicate to patients that the sheets, pillows, towels, and curtains have a very high degree of cleanliness. Health care providers, including nurses, physicians, technicians, food service workers, and assisted living and hospital staff all know the garments they use are reliably clean and disinfected. Furthermore, with Hygienically Clean regulations in place, this adds confidence that there is very low likelihood of microbial transmission of infectious agents from the wearing of any clinical garment, and when there are infectious blood, urine, fecal matter, or skin, there will be no further transmission to other patients or staff. Hygienically Clean standards have a very large and positive impact on public health in general because they set the scene to lower the overall community infectious agent risk burden. Advocates of Hygienically Clean regulations should conduct research studies in order quantify how much infectious risk can be removed by the switch from facility-based washing to commercial laundry handling of linens and uniforms. I looked for this sort of data in Pubmed, but did not find any published studies demonstrating the health benefits of adopting Hygienically Clean procedures.

Potential for Marketing Hygienically Clean standards

Hygienically Clean certified companies have a serious marketing advantage versus competitor laundries who do not have the Hygienically Clean certification. The reasons for this are manifold:

- Established performance standards
- Use of independent laboratory evidence for demonstrating compliance
- Focus on patients and clinical staff safety and hygiene
- Emphasis on laundry employee health and safety benefiting all the laundries' customers
- Clear set of cleanliness and public health markers
- Leadership in the absence of Federal or state regulations.

All these are positive attributes of TRSA's Hygienically Clean standards, and companies should be emphasize these attributes in marketing campaigns. One way to increase broad knowledge of TRSA's Hygienically Clean standards would be to attend large public health professional meetings where a

booth could demonstrate the effectiveness of these efforts. An example would be the American Public Health Association (APHA) annual meetings (in 2015 APHA meets in Chicago at the end of October).

Surveys of Member Companies Regarding Experiences with TRSA's Hygienically Clean Program

TRSA shared with me eight surveys of member companies from 2014 about their perceptions of survey of TRSA's Hygienically Clean program. Although this limited survey gives an overall positive assessment, the small sample size limits the applicability to the industry as a whole. One respondent in reply to the question 'What has been your customer reaction (to hygienically clean)?' this was: "For some customers, it means nothing. But for other customers it is very important component of our service. But I think businesses also do not give enough credit to your own employees' reaction. It is almost more important for your own employees to know that you take the extra effort to achieve certification. It makes them feel better about their career, and gives them confidence when someone asks them why they work for you. Certification is certainly a quality benchmark, but it also a marketing initiative, both for external and internal customers." Many respondents noted that their Hygienically Clean certification brought them new business accounts (though the question did not ask how much Hygienically Clean might have improved the companies' bottom line). I believe conducting a larger survey would be an excellent member benefit and would provide some added information for the larger health community with a stake in cleaner textiles. Doing an expanded survey would fit the philosophy of Mr. Joe Ricci, President and CEO of TRSA, who noted that measuring various aspects of laundry performance can provide insight where the industry could be headed (Ricci, 2015)

Improving Hygienically Clean Program to Lower Concentrations of Infectious Agents

To improve the power and marketing impact of TRSA's Hygienically Clean program, there are at least two routes to take. Both take account of the development of new technologies. One approach is to determine if certified laundries can achieve a target below 20 CFU per square decimeter of laundered material. That could become feasible if newer detergents or steam cleaning processes or some other technical improvement would meet a <15 CFU standard. International cleanliness standards might change if new technologies were introduced in the EU or Japan, and that might be the basis for lowering the current TRSA standard. The other means to that end would be to design new fabrics that resist infectious biomaterials and could be washed at lower temperatures or using less bleach. Another approach would be to design new fabrics that are treated with novel antimicrobials or nanoparticles. These new technologies must also consider worker risks as well as wastewater and environmental treatment methods as part of the process for improving future Hygienically Clean procedures. The antimicrobials could include triclosan, silane quaternary ammonium compounds, zinc pyrithione and silver nanoparticles (Windler et al., 2013)

Conclusions and Recommendations for 2016 and Beyond

It is clear that TRSA's Hygienically Clean Program has created a regulatory platform that benefits patients, clinical care staff and public health. TRSA has done so by adopting transparent and defensible regulations that provide industrial linen and uniform laundries with scientific methods for controlling levels of infectious agents to <20 CFU per square decimeter of laundered material. In this assessment of the Hygienically Clean program, it is clear that the required testing is reasonable and adds public health and business value to the certification process. We have discussed the importance of Hygienically Clean Program for hospitalized patients, for healthcare staff, and for overall workplace safety and health. Expanded surveys of TRSA members would provide a better picture of the business impacts of the Hygienically Clean program. It also appears that Hygienically Clean label can have a major impact on marketing in this field. Thus, TRSA should consider bringing its ideas and leadership to a wider public health audience by sponsoring a booth at the annual American Public Health Association (APHA) meetings. A similar endeavor at international infectious disease research meetings may be equally beneficial. Lastly, improving technologies for current washing and drying techniques as well as the development of novel textiles with antimicrobial properties can advance the current field and lead to reduced water use, lowered bleach and detergent needs as well as improving drying procedures.

I appreciate the opportunity to examine TRSA's Hygienically Clean regulatory program and to offer some of my insights.

Yours truly,

David F. Goldsmith, PhD

References

- Blaser M.J. et al. (1984) Killing of fabric-associated bacteria in hospital laundry by low-temperature washing. *J Infect Dis.* 149:48-57.
- Burden M. et al. (2011) Newly cleaned physician uniforms and infrequently washed white coats have similar rates of bacterial contamination after an 8 –hour workday: A randomized control trial. *J Hosp Med* 6:177-182.
- CDC (2003) Guidelines for Environmental Infection Control in Health-Care Facilities-- Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), Atlanta GA. Available at http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf
- CDC (2011) Centers for Disease Control and Prevention. Laundry washing infected material. Atlanta, GA. Available at <http://www.cdc.gov/HAI/prevent/laundry.html>.
- Cheung E. (2015) Hong Kong hospitals face linen shortage amid fungus scare. *China Morning Post*, July 22.
- Duffy J. et al. (2014) Mucormycosis outbreak associated with hospital linens *Ped Infect Dis J* 33: 472-476
- Fijan S and Turk SS (2012) Hospital textiles, Are they a possible vehicle for healthcare associated infections? In *J Environ Res Public Health* 9: 3330-3343
- Mitchell A. et al. (2105) Role of healthcare apparel and other healthcare textiles in the transmission of pathogens: A review of the literature. *J Hosp Infect* 90:285-292.
- Quality Indicator Study Group (1995). Approach to the evaluation of quality indicators of the outcome of care in hospitalized patients with a focus on nosocomial infection indicators. *Infect Control Hosp Epidemiol* 16:308-316.
- Ricci J (2015) A better way to measure the impact of laundry. *Hotel Business Review* (http://hotelexecutive.com/business_review/4300/a-better-way-to-measure...)
- SafeTRSA (2015) Commercial Laundry Safety Improvement Outpaces National Industrial Averages (<http://www.safetrsa.org/>) May 26.
- TRSA (2015a) Nothing Left Behind: Quantifying Hygienically Clean Removes All Doubt. Alexandria VA, June. pp1-8.
- TRSA (2015b) Standard for Producing Hygienically Clean Reusable Textile for use in the Healthcare Industry, Alexandria VA June pp1-17.
- Windler L. et al. (2013) Comparative evaluation of antimicrobials for textile applications. *Environ Int* 53: 62-73.