



Nothing Left Behind: Quantifying Hygienically Clean Removes All Doubt

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REUSABLE TEXTILES & APPAREL

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Efforts to ensure optimal disinfection in healthcare environments are extending beyond addressing hard, non-porous surfaces to softer ones that may be at risk for microbial contamination or could contribute to nosocomial disease transmission. Greater attention to this realm can be part of any medical facility's quest to find new ways to improve the climate of patient safety in a facility. Patients' fear of healthcare-associated infections (often unspoken) is their greatest concern, necessitating measures to ease their minds about the cleanliness of their rooms.

TRSA's Hygienically Clean certification is in lock-step with this objective. This designation assures the safety and cleanliness of textile products rather than certifying only laundry processes.

Inspired by other professional associations, consumers and thought leaders, as well as regulatory and accrediting bodies, Hygienically Clean is a scientifically based initiative that recognizes the many patient safety stakeholders' need to maximize the synergy of shared interests and resources to further control infection.

DEFINING HYGIENICALLY CLEAN

This is no mystery: Hygienically Clean is an established threshold that guides the reduction of pathogens on textile products to levels that pose no threat of human illness, according to the Certification Association for Professional Textile Services Administration (CAPTSA), which has served its 400 members in 15 European countries, Japan, China and United Arab Emirates for nearly 50 years.

The microbial levels established by CAPTSA and the European Union (EU) for laundered textiles **30 years ago** [20 colony forming units (CFU) per square decimeter for healthcare] serve as the basis for Hygienically Clean certification. Adoption of such a clear and universal maximum is the best way to introduce to North America the protocols of the EU, which require testing at various stages of laundering to indicate that clean textiles are free of pathogens in sufficient numbers to cause human illness.

The following research provides scientific, quantitative definitions that explicitly establish and validate levels that define hygienically clean; and documents the emerging importance to the U.S. healthcare industry of quantifying and verifying textile hygiene.

TRSA's acceptance and support of these international standards reflect its members' steady pursuit of continuous improvement, whether through increased productivity, reduced cost through energy and water conservation or simply working to deliver a better final product. TRSA members have a long history of pursuing various professional certifications that quantify and verify performance in many aspects of their operations.

HYGIENICALLY CLEAN IS THE RIGHT DIRECTION

When TRSA's Healthcare Committee initiated the Healthcare Laundry Accreditation Council (HLAC) and its certification program in 2004, it was long acknowledged that proper commercial laundering formulas (calibrated time, temperature, chemistry, mechanical action) produce clean, safe reusable textiles. TRSA invested in developing HLAC to define best healthcare laundry practices.

TRSA Hygienically Clean reflects the evolution of healthcare laundry certification in light of growing global concerns about infection control, with the ultimate objective of the complete elimination—nothing left behind—of potentially harmful microbial content with the caveat that potential elimination is meaningless unless properly measured and documented.

The Hygienically Clean label is trustworthy because it does not certify a facility simply on the basis of following all proper policies and procedures to prevent contamination; it requires consecutive months of independent laboratory testing before certification and ongoing testing to maintain the designation.

With HLAC's legacy of approving processes and TRSA now verifying their effectiveness, healthcare providers can be confident they receive hygienically clean linen by using certified laundries (enforced as a contract provision) and/or certifying their on-premises, central or co-op laundries. Hundreds of laundries processing healthcare and other linens are already certified; any large, central laundry processing any reusable textiles is a good candidate for Hygienically Clean certification.

MEASURING OUTCOMES MATTERS

Outpatient and hospital settings and the length of time patients are exposed to textiles vary, requiring launderers to

assure healthcare providers that laundered, reusable textiles pose no risk of infection. This underscores the importance of verifying performance to a cleanliness standard. Any such wavering is unacceptable to laundry customers who demand accountability and cannot afford the risk of a launderer speculating that its textiles are sanitized. Microbial measurement of clean laundry is the only assurance.

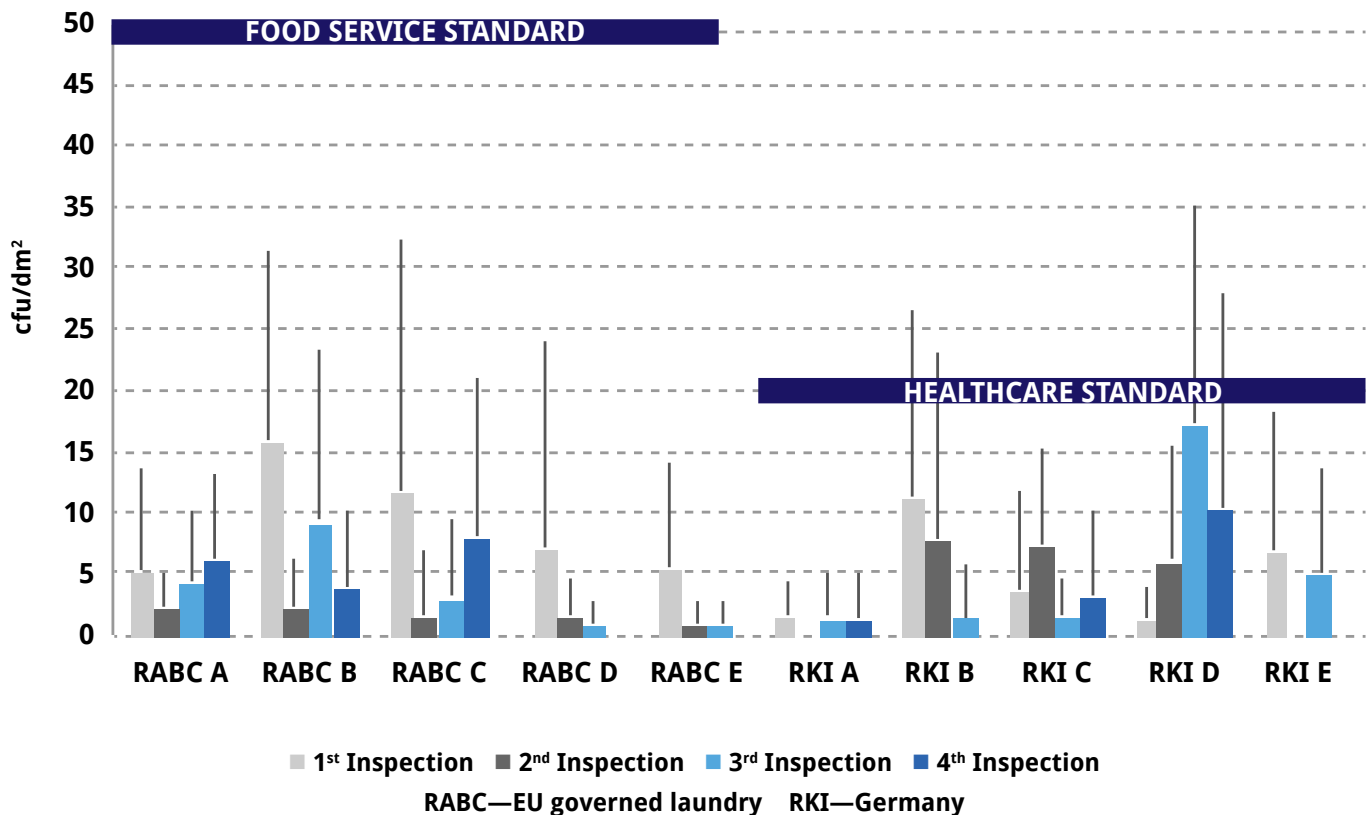
In 2011, WFK Cleaning Technology Institute, Krefeld, Germany, reported the findings of year-long quarterly testing of 10 laundries in Europe required to comply with the 20 CFU standard for healthcare¹. All succeeded in all quarters. A total of 10 samples were tested from each laundry in each inspection. In just one quarterly sampling (assessment of 10 samples at one laundry), the limit was not met in all 10. The other 39 samplings were perfect 10-for-10s (Figure

1). In fact, in more than half the samplings, the laundries scored 5 CFU or less.

WFK concluded these results demonstrate that laundries subjected to limits “can guarantee the microbiological quality of their expedition (ready for shipment) textiles.”

Half the laundries in this study are international-association-certified; the other half are EU certified. Both certifiers enforce the 20 CFM healthcare limit. But the EU is more prescriptive, requiring not only microbiological testing of expedition textiles, but similar measures in various stages of laundry processing (Table 1). “The microbiological quality achieved from the dry expedition textiles did not depend on whether the laundry was operated in accordance with the (German) criteria or had introduced the (EU) system with relevant limit values and control procedures,” WFK said.

Figure 1 Cleanliness levels of laundered textile samples



1. Heintz, M, Bohnen, J. “Hygiene in Commercial Laundries.” Hyg Med, 36-7/8, 292-298, 2011.

Table 1 Microbiological requirements for test points in laundries

Test point	RKI (only healthcare sector)	RABC requirement (healthcare sector)	RABC requirement (food industry)	DIN 10524 (only food industry)	Drinking Water Reg. 2001 [21]
Disinfection efficacy of washing processes	All test bacteria killed	All test bacteria killed	All test bacteria killed	–	–
Expedition textiles	20 cfu/dm ² ^a	20 cfu/dm ² ^b	50 cfu/dm ² ^b	50 cfu/ dm ² ^a	–
Water	Consult Drinking Water Reg.	100 cfu/ml, no <i>E. coli</i> , enterococci or coliform bacteria in 100 ml	100 cfu/ml, no <i>E. coli</i> , enterococci or coliform bacteria in 100 ml	–	100 cfu/ml, no <i>E. coli</i> , enterococci or coliform bacteria in 100 ml
Moist textiles	^a	30 cfu/dm ² ^{od}	100 cfu/dm ² ^{od}	–	–
Surfaces close to textiles	^a	100 cfu/dm ² [*]	100 cfu/dm ² [*]	–	–
Hands of personnel	^a	100 cfu/dm ² [*]	100 cfu/dm ² [*]	–	–
Air	–	–	–	–	–

^a No specifications, but tests needed [10, 20] to ensure that the hygiene conditions are such that the probability of health risks and damage to patients and staff are reduced to an unavoidable minimum when the pertinent hygiene standards are maintained
^b In nine out of ten samples as well as absence of human pathogenic microorganisms
^c In four out of five samples
^d Action limit value
^e Orientation value

The researchers also noted that “it is not visible that differences in the air content of microorganisms correlated with the presence of a constructional separation” between clean and soil areas, proving that such a division “is not a prerequisite for the hygienic reprocessing of textiles.”

INTEGRAL TO ENSURING PATIENTS’ SAFETY

With patients’ health at stake and healthcare providers under financial and compliance pressures to cost-effectively deliver services, quantifiable certification is an important tool to measure performance. A May 2013 analysis by the Robert Wood Johnson Foundation and Urban Institute² observes that “there is a consensus that scientifically rigorous and valid measurement of performance can be instrumental in improving value in U.S. healthcare. Measures have altered the culture of health care delivery for the better. Nevertheless, despite notable successes and the recent cultural change, substantial shortcomings in the quality of U.S. health care persist.”

Quoting the *New England Journal of Medicine*³, the Institute/ Foundation observes that “the United States is about 25

years into efforts to bring performance measurement into medicine.” The analysis cites this long-held hierarchy of such measurement⁴:

Structural measures include requirements imposed by customers and regulators, such as specifications for the physical plant and management systems. Applied to laundry certification, this has historically included specifying *exactly how*:

- Soil and clean should be separated
- Washing machines should be tested
- Records for equipment performance should be kept

Process measures determine whether evidence-based guidelines are followed, but do not indicate attainment of a guideline’s goal (i.e., they don’t verify or quantify cleanliness):

- Verifying proof-of-delivery of wash chemistry
- Monitoring rewash rates
- Grading textile product quality

2. Berenson, RA, Krumholz, HM, Pronovost, PJ. “Achieving the Potential of Health Care Performance Measures.” *Timely Analysis of Immediate Health Policy Issues*, Robert Wood Johnson Foundation and Urban Institute, May 2013
 3. Relman AS. “Assessment and Accountability: The Third Revolution in Medical Care.” *New England Journal of Medicine*, 319(18): 1220–2, 1988.
 4. Donabedian A. “Evaluating the Quality of Medical Care.” *The Milbank Memorial Fund Quarterly*, 44(3): 166–206, 1996.

Outcome measures determine whether desired results are achieved, per TRSA Hygienically Clean:

- 20 CFU of microbial content per square decimeter of fabric (RODAC plate test)
- Complete elimination of bacteria harmful to human health (USP 62)

Hygienically Clean sets a precedent for U.S. laundry certification by **adding** these *outcome measures to structural and process measures* long mandated, regulated or suggested by public and private authorities:

- Occupational Safety & Health Administration
- American National Standards Institute (ANSI)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Centers for Disease Control and Prevention (CDC)
- Center for Medicare and Medicaid Services (CMS)
- The Joint Commission (TJC), formerly the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

NO BETTER VERIFICATION THAN MICROBIAL TESTING

A recent white paper, “What’s Left Behind,” states that the differences between HLAC and Hygienically Clean are “largely immaterial” and that independent laboratory testing “may not be strictly necessary, but can serve to provide additional piece of mind.” This only stands to reason as TRSA created HLAC and Hygienically Clean builds upon requirements such as documentation and inspection while adding quantifiable testing.

But U.S. healthcare authorities are recognizing the value of outcome measures as opposed to structural and process measures and this trend has extended to laundry. In January 2013, a CMS memo⁵ clarified and revised the agency’s guidance involving:

Laundry detergents. “Advances in technology allow modern-day detergents to be much more effective in removing soil and reducing the presence of microbes than those used in the past when much of the research on laundry processing was first conducted. The CMS in collaboration

with the CDC has determined that facilities may use any detergent designated for laundry in laundry processing. Further, laundry detergents used within nursing facilities are not required to have stated anti-microbial claims.”

Water temperatures and chlorine bleach rinses.

“Laundry processing conducted within facilities typically occurs in a low water temperature environment. Many laundry items are composed of materials that cannot withstand a chlorine bleach rinse and remain intact. The chlorine bleach rinse is not required for all laundry items processed in low temperature washing environments due to the availability of modern laundry detergents that are able to produce hygienically clean laundry without the presence of chlorine bleach.”

Maintenance of equipment and laundry items.

“Facilities are not required to maintain a record of water temperatures during laundry processing cycles” but must follow manufacturers’ instructions for:

- Washing machines, dryers, detergents, rinse aids, other additives
- “Clothing, linens, and other laundry items to determine the appropriate methods to use to produce a hygienically clean product.”

CMS also indicates that facilities “should have written policies and procedures which should include training for staff who will handle linens and laundry,” but does not prescribe such policies or procedures.

The healthcare community and large, centralized laundries are best served by independent, third-party certification programs such as Hygienically Clean and HLAC. The trend, internationally as well as domestically, is moving toward microbial testing of reusable textiles for use in healthcare facilities⁶. In addition to the concept’s long-standing European presence, the Institute for Sustainability and Hygiene International’s Certification Standards for Processing Reusable Linen⁷ (CSHLS) require it.

TRSA does not believe lack of mandatory testing under federal or state regulations in the U.S. is a compelling reason not to include mandatory microbial testing in our certification program. Requiring independent, third-party testing provides our customers with tangible evidence that

5. Director, Survey and Certification Group, to State Survey Agency Directors. “Clarification of Interpretive Guidance at F Tag 441-Laundry and Infection Control.” Centers for Medicare & Medicaid Services, Ref: S&C: 13-09-NH, January 25, 2013.

6. TRSA. Standard for Producing Hygienically Clean Reusable Textiles for Use in the Healthcare Industry. TRSA, Alexandria, VA, February 12, 2013.

7. Institute for Sustainability and Hygiene International. *Certification Standards for Processing Reusable Linen*. MacKenzie, Brisbane, Queensland, Australia, April 2011

the textiles they are using are hygienically clean, and verification that the commercial laundry process does what it is recognized by the CDC to do—result in production of hygienically clean reusable textiles.

The frequency of microbial testing selected for this certification program is not based on any federal or state regulatory requirements because none exist. No testing regimen selected would have a statistical basis as there is no database to draw from. With the existing paradigm for laundry certification, any testing frequency is an improvement over the status quo of no testing. In the Hygienically Clean program, testing is conducted in each of the first three months of certification, followed by semiannual testing if all testing in the first three months passes the established criteria.

Testing is a must to gauge cleanliness because it is a measure of *product* quality, not *service* quality. Good service meets customers' expectations for consistent, reliable and timely provision of service, politely and respectfully, with communications they can comprehend⁸. Thus, service quality is often assessed using *qualitative* measures.

A product's quality typically is associated with measures such as defects per unit produced, how many are returned, warranty claims per units sold and number of quality certified suppliers who produce it⁹. The roots of product quality lie in the producer's ability to deliver high volumes according to expected specifications (customer requirements, in accordance with technical and regulatory requirements). Thus, *quantitative* tools are frequently used to measure product quality.

Here's how Hygienically Clean fits these criteria:

1. **Quantifiable** – only certification that requires linen to be tested by an independent lab to verify they are hygienically clean
2. **Objectivity** – only certification using *internationally recognized standards, independent inspection and ongoing testing* as the ultimate judge of hygiene
3. **Continuous** – only certification requiring laundries to pass *ongoing* microbial testing demanding consistent performance
4. **ISO Guidelines** – The International Organization for Standardization (ISO) states that production *processes*

are not reliable indicators of product quality, only *product-specific testing* can earn certification

5. **Internationally Recognized** – based on established international standards that can be applied around the world across all textile services customer markets

Under ISO, a laundered product cannot be considered hygienically clean because the cleaning process is certified. The product itself must be subjected to a certification standard. Only then may the product's labeling or packaging be embellished with a certification conformity mark.

NO HIGHER STANDARD THAN TRSA PRODUCT QUALITY

TRSA is pleased with North American textile services operators' acknowledgment that laundered products should be held to a cleanliness standard as evidenced by the reception to the new certification. A total of 25 laundries will be certified Hygienically Clean within in the next two months, representing a 130 percent increase in the number of certified facilities since April, when 11 plants had earned the designation.

This reception is not surprising; given the knowledge base on business-to-business laundering effectiveness TRSA has built since 1912. A century of unparalleled research and professional education on best practices, developed by member companies who have shared expertise for decades, led to the creation of stringent Hygienically Clean standards:

- Complex inspection/audit criteria of laundry operations
- TRSA created all major specialty procedures developed for U.S. healthcare laundry work, including HLAC

While Hygienically Clean focuses on outcome measures (test results), it encompasses structural and process measures by allowing laundries in compliance with federal, state and professional standards to use documented standard operating procedures (SOPs) for sorting, handling, processing and finishing reusable linens and garments:

- Quality control manuals and other best business management practices
- Functional separation of clean from soil

8. Miller, E. *Handbook for Measuring Customer Satisfaction and Service Quality*. U.S. Transportation Research Board, National Research Council, January 1999

9. Wisner, J., Tan, K-C, Keong-Leong, G. *Principles of Supply Chain Management: A Balanced Approach*. Cengage Learning, Independence, KY, 2008.

- Washing procedures, formulas and temperatures for chemical use, rinsing, extracting and finishing
- Equipment maintenance, cleaning and housekeeping

With an operations history rooted in customer satisfaction and regulatory compliance having generated a wealth of effective processes in use throughout the textile services industry, TRSA has established Hygienically Clean as a means for industry operators to answer to today's "higher calling" for business transparency, sustainability and cost-effectiveness.

Hygienically Clean is the only tool for launderers to implement the first recommendation for the healthcare industry in the Robert Wood Johnson Foundation/Urban Institute report:

- **Decisively move from measuring processes to outcomes**

"The operational challenges of moving to producing accurate and reliable outcome measures are daunting but worth the commitment," the report points out. Patients, payers, policy-makers and providers care about end results—not the technical approaches taken to achieve desired outcomes that can vary across different organizations.

Focusing on outcome measures, the report continues, sparks engagement in broader approaches to quality improvement activities, "ideally relying on rapid-learning through root cause analysis and teamwork rather than taking on a few conveniently available process measures that are actionable but often explain little of the variation in outcomes."

Hygienically Clean encompasses these concepts without ignoring the contribution of specific processes that are associated with achieving better outcomes. The program views every structure and process as an internal tactic, part of a comprehensive approach to achieving good outcomes, rather than as an end in itself.

Every healthcare facility should strongly encourage that their laundry, regardless of whether it is a commercial, co-op or on-premise laundry, verify compliance and quantify cleanliness by requiring continued certification in their RFPs and laundry service contracts. Hundreds of laundries in virtually every regional healthcare market across the United States and Canada are currently maintaining their certifications, shouldn't your laundry?

KEY PROVISIONS FOR MICROBIAL TESTING OF LAUNDERED HEALTHCARE TEXTILES

7.3. Probationary Period

7.3.1. The probationary period ends when three consecutive months of bacteriological testing meet Minimum Microbiological Performance Specifications and the plant has passed inspection. Bacteriological testing on textile items (flat and terry) will be conducted in each of the first three months. After initial samples meet microbiological criteria, textile samples shall be selected on a rotating basis such that in the first three months, six different textile items are tested. Plants will be allowed to resubmit/re-test one failed test result in the probationary period. If a failed test result is received, the plant must immediately resubmit the same item for testing to the same test lab.

7.4. Quality Control Microbial Testing

7.4.1. After successful completion of the precertification period, microbial testing will be conducted on a quarterly basis.

7.4.2. Four times yearly, three textile items will be submitted by plant personnel to an approved laboratory for bacteriological testing. Samples shall be selected on a rotating basis, with a goal of testing twenty-eight (28) different textile items at least once in the first three-year period.

7.4.3. Should any textile item fail quarterly bacteriological testing, TRSA may require that product to be one of the textiles tested quarterly until it is reasonably assured there are no compliance issues.

8.1 Quality Control Microbial Testing

All testing shall be done by a TRSA-approved laboratory that is accredited by any accreditation body recognized under the ILAC MRA (Mutual Recognition Arrangement) or recognized by federal or state agencies for microbiological testing. Examples of acceptable third-party accreditation bodies include the International Accreditation Service (IAS), American Association of Laboratory Accreditation (A2LA), and ANSI-ASQ National Accreditation Board doing business as ACLASS. Laboratories recognized by federal or state agencies such as EPA, FDA, Department of Agriculture, CDC, CPSC, and OSHA are also approved.

8.2. Minimum Microbiological Performance Specifications

Microbial testing shall be performed using the following test methods: RODAC Plate count quarterly and United States Pharmacopeia (USP) 62 semi-annually. United States Pharmacopeia (USP) 62 – Microbiological Enumeration of Nonsterile Products: Microbial Examination Tests. See current pass/fail criteria below. Methods and criteria are continuously reviewed and subject to revision.

RODAC Plate Test	Pass/Fail Criteria
Total aerobic microbial count (TAMC)	Acceptance criterion for microbiological quality: ≤ 20 cfu per square decimeter
Test Method USP 62	Pass/Fail Criteria
Specified Microorganisms	Acceptance criterion for microbiological quality: Absent

From TRSA's *Standard for Producing Hygienically Clean Reusable Textiles for Use in the Healthcare Industry*, January 2015