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Benefits and Advantages of Process Driven Accreditation

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Executive Summary

Laundries accredited by the Healthcare Laundry Accreditation Council (HLAC) are the recipients of many advantages and benefits. The key benefit is process accreditation which provides assurance that the entire process with which the textile has come into contact with has been reviewed.

HLAC accreditation examines the process using a detailed checklist of standardized criteria supported by recognized state, federal and international agencies as well as industry standards.

Internationally, there is some reliance on biological testing of healthcare textiles after laundering, however, no accepted protocols or definition of what is acceptable was found in the literature, nor was there a universally understood definition of what is hygienically clean. Scientifically sound testing programs can support infection prevention initiatives with information about a specific point in time. The credibility of these snapshots in time is dependent on the test being used and the soundness of the sampling program being utilized including testing frequency, implemented controls and the delivery of textiles to the point of use. Currently, there is no consensus from the Centers for Disease Control and Prevention (CDC) or Environmental Protection Agency (EPA) on a standard test method for textile hygiene.

Product testing programs may enhance the HLAC process if they are used for quality assurance (i.e., process development and control) and for end product testing as an indication of the results expected. However, HLAC believes that the highest level of assurance can only be provided with a correctly designed and managed laundry and linen program. The process centered focus of HLAC accreditation is based on fundamentally sound principles intended to provide the highest level of ongoing assurance. The focus on the "process" and the reduced reliance on the "end product testing" mirror recommendations of both the ISO 9000 Series and the FDA 820 Quality Systems Regulations. HLAC Accredited Laundries provide their healthcare customers the highest level of assurance that their healthcare textiles have been produced and delivered in a hygiene manner capable of supporting their facilities' Infection Prevention initiatives.

Accreditation, like the process employed by HLAC, is designed for organizations, associations and entities, and is based on specific published, recognized standards or practices; while product testing is designed for the individual snapshot in time situation.

Introduction

There has been ongoing discussion with respect to the most effective manner to inspect and accredit healthcare laundries. The issue surrounds whether or not it is relevant or sufficient to test in a laboratory a sample or samples of the end product to determine whether or not the laundry is doing the right things or is it more important to test the overall process itself?

The question is how best to assure that laundered healthcare textiles are delivered in a state that can support their customers Infection Prevention initiatives, especially in the light of the issue of Hospital Acquired Infections (HAIs). HLAC has been accrediting healthcare laundries since 2005 based on the highest standards for patient safety and infection prevention.

Background

Historically, in the hierarchy of the healthcare system, laundry has been considered by many to be at the bottom of the healthcare "totem pole". Laundry services were known to be labor intensive, and believed to be populated, for the most part, with unskilled labor. Often, the department was relegated to a "land locked" section of the hospital basement where expansion, growth or the introduction of new technology was not possible due to space and barriers constraints. When the Joint Commission panel members inspected the hospital, visits to the laundry, if they happened at all, were often abridged and superficial. Laundry ceilings tended to be low, much of the equipment was basic and often there was a wet wash floor. The flat floor was usually congested with rolling stock and while the layout may have made production sense, little priority was given to bio-burden or infection control concerns.

Many laundries had limited time or budget to ensure soiled-to-clean separation barriers, a proper infection control regiment, or strict cleaning guidelines. Because there were no mandated performance standards, the process of swabbing areas for bio-burden did not routinely happen and, for the most part, laundries

were left to their own initiative and devices to stay clean, ship out clean linen and avoid re-contamination of textiles.

This situation changed significantly for the better in 2005 when a consortium of concerned operators, infection control professionals, product vendors and healthcare professionals created what is now known as the Healthcare Laundry Accreditation Council (HLAC). HLAC is a non-profit organization formed for the purpose of inspecting and accrediting laundries processing healthcare textiles for hospitals, nursing homes, and other healthcare facilities. It is a voluntary process governed by a voluntary board of 12 directors, half of whom are operators and their association representatives, while the other half are healthcare professionals and their association representatives. Its mission is to raise laundry processing to the highest standard for patient safety and infection prevention.

The HLAC process is an all-inclusive, on-site inspection of the facility, its processes and procedures, and protocols. On-site inspectors are experienced healthcare professionals who review and observe the operation, inspect its policies, and question both managers and production staff on the job. The day-long inspection observes operations, equipment, building design, infrastructure systems and delivery methods. Some empirical testing is also conducted during the inspection, such as ironer chest temperature, safety equipment and air flow.

Recently, alternative protocols for inspecting laundries based primarily upon the inspection of end product textiles have been in use. A laundry may be deemed certified by relying heavily upon a third party laboratory testing the end product to ensure that microbiological standards are met. This type of product testing raises many questions; for example what happens if the cart where hygienically clean laundry is placed on has bioburden or the cart is not wrapped and exposed to environmental contaminants while waiting or during delivery to Customer. HLAC Accreditation directly examines the process and addresses these matters providing added value to the users of the linen that the entire process will ensure they receive hygienically clean linen.

Literature Search

A review of the literature concludes that "continued compliance with existing environmental infection control measures will decrease the risk of healthcare associated infections among patients."[1] Much of the discussion presented in this section has been adapted from the "Laundry and Bedding" and "Environmental Sampling" sections of the CDC's "Guidelines for Environmental Infection Control in Health-Care Facilities."

The Centers for Disease Control and Prevention (CDC) in the U.S. reports that although contaminated textiles and fabrics in healthcare facilities can be a source of substantial numbers of pathogenic microorganisms, reports of healthcare associated diseases linked to contaminated fabrics are so few in number that the overall risk of disease transmission during the laundry process likely is negligible. When the incidence of such events are evaluated in the context of the volume of items laundered in healthcare settings (estimated in 1980 to be 5 billion pounds annually in the United States),[2] existing control measures (e.g., standard precautions) are effective in reducing the risk of disease transmission to patients and staff. Therefore, use of current control measures should be continued to minimize the contribution of contaminated laundry to the incidence of healthcare-associated infections. The control measures are based on principles of hygiene, common sense, and consensus guidance; they pertain to laundry services utilized by healthcare facilities, either in-house or contract, rather than to laundry done in the home.

Hygienically clean laundry carries negligible risk to healthcare workers and patients, provided that the clean textiles, fabric and clothing are not inadvertently contaminated before use. OSHA defines contaminated laundry as "laundry which has been soiled with blood or other potentially infectious materials or may

[1] "Guidelines for Environmental Infection Control in Health-Care Facilities, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), U. S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, GA, 2003;ii. (http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf)

[2] Mallison GF, Central services and linens and laundry. In: Bennett JV, Brachman PS, eds. Hospital infections. Boston, MA: Little, Brown & Co., 1986;251-6.

contain sharps."[3] They go on to state that the purpose of the laundry portion of the standard is to protect the workers from exposure to potentially infectious materials during collection, handling and sorting of contaminated textiles through the use of personal protective equipment, proper work practices, containment, labeling, hazard communication, and ergonomics.

The laundry facility in a healthcare setting should be designed for efficiency in providing hygienically clean textiles, fabrics and apparel for patients and staff. Guidelines for Environmental Infection Control state that the key to clean laundry is partially related to laundry design. A review indicates that the design and engineering standards for existing facilities are those cited in the Facility Guidelines Institute edition in effect during the time of the facility's construction.[4]

Much has been written about testing of laundry textiles, however, no standard was found to exist in our review. Research indicates that "in the absence of microbiologic standards for laundered textiles, no rationale exists for routine microbiologic sampling of cleaned healthcare textiles and fabrics."[5] The report goes on to say that sampling may be used as part of an outbreak investigation if epidemiologic evidence suggests that textiles, fabrics or clothing are a suspected vehicle for disease transmission.

Before 1970, U. S. hospitals conducted regularly scheduled culturing of the air and environmental surfaces (e.g., floors, walls, and table tops).[6] Microbiologic sampling of air, water and inanimate surfaces (i.e., environmental sampling) is an expense and time-consuming process that is complicated by many variables in protocol, analysis, and interpretation. It is therefore indicated for only four situations.[7] The first is to support an investigation of an outbreak of disease or infections when environmental reservoirs or fomites are implicated epidemiologically in disease transmission.[8, 9, 10]

The second situation for which environmental sampling may be warranted is in research. The third indication for sampling is to monitor a potentially hazardous environmental condition, confirm the presence of a hazardous chemical or biological agent, and validate the successful abatement of the hazard.

The fourth indication is for quality assurance to evaluate the effects of a change in infection-control practice or to ensure that equipment or systems perform according to specifications and expected outcomes. Any sampling for quality-assurance purposes must follow sound sampling protocols and address confounding factors through the use of properly selected controls. Results from a single environmental sample are difficult to interpret in the absence of a frame of reference or perspective.

Other examples of sampling for quality-assurance purposes may include commissioning newly constructed space in special care areas (i.e., ORs and units for immunosuppressed patients) or assessing a change in housekeeping practice. However, the only types of routine environmental microbiologic sampling recommended as part of a quality-assurance program area a) the biological monitoring of sterilization processes by using bacterial spores[11] and b) the monthly culturing of water used in hemodialysis applications and for the final dialysate use dilution.

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[3] U. S. Department of Labor, Occupational Safety and Health Administration, Occupational Exposure to Bloodborne Pathogens: final rule (29 CFR 1910.1030). Federal Register 1991;56:64004-182.

[4] Facility Guidelines Institutes. Guidelines for design and construction of hospital and health care facilities, 2010. Chicago, IL; American Society for Healthcare Engineering; 2010.

[5] Ayliffe GAJ, Collins BJ, Taylor LJ. Laundering. In: Wright PSG, ed. Hospital-acquired Infection: principles and Prevention. Bristol, UK: 1982;101-6.

[6] Litsky BY. Results of bacteriological surveys highlight problem areas in hospitals. Hospital Management 1966;101:82-8.

[7] Gröschel DHM. Air sampling in hospitals. Ann NY Aca Sci 1980;353:230-40.

[8] McDonald LC, Walker M, Carson L, at al. Outbreak of *Acinetobacter* spp. Bloodstream infections in a nursery associated with contaminated aerosols and air conditioners. Pediatr Infect Dis J 1998;17:716-22.

[9] Barbaree JM, Gorman GW, Martin WT, Fields BS, Morrill WE. Protocol for sampling environmental sites for legionellae. Appl Environ Microbiol 1987;53:1454-8.

[10] Eickhoff TC. Microbiologic sampling of the hospital environment. Health Lab Sci 1974;11:73-5.

[11] Bond WW, Sehulster LM. Microbiological culturing of environmental and medical-device surfaces. In: Garcia LS, Miller JM, Bell, M, ed. Clinical microbiology procedures handbook, 3rd Ed., section 13. Washington, DC; American Society for Microbiology Press, 2010.

As a result of this understanding, most experts agree that conducting quality-assurance sampling on an extended basis, especially in the absence of an adverse outcome, is usually unjustified.

In conclusion, the key recommendation on the microbiologic sampling of textiles is summed up when the Centers for Disease Control (CDC) recommended that laundries should "not conduct routine microbiological sampling of clean textiles."[12, 5]

Regulatory Bodies and Standards

"By 1970, the Centers for Disease Control, (CDC) and the American Hospital Association (AHA) were advocating the discontinuation of routine environmental culturing because rates of health-care associated infection had not been associated with levels of general microbial contamination of air or environmental surfaces and because meaningful standards for permissible levels of microbial contamination of environmental surfaces and air did not exist."[13, 14, 15] The CDC has since been clear in their determination that routine microbiologic testing is not necessary.

Internationally, the German Certification Association for Professional Textile Services RAL – Hygiene Certificate Program includes mandatory microbial testing of textiles[16] and in Australia; the institute for Sustainability and Hygiene International's Certification Standards for Processing Reusable Linen Certified Sustainable Hygienic Linen Standards (CSHLS) program also requires mandatory microbial testing.[17]

HLAC Approach

The key premise behind the HLAC methodology for accreditation is to focus on the process. Inspecting the processes at the laundry to ensure that it meets a predetermined standard is viewed as the best method of ensuring that the product being shipped from the laundry is clean and free from any danger to the patient.

The process is extensive and includes a review and inspection of the following elements, to mention a few:

- Textile specifications, maintenance and inventory,
- Laundry facility design, ventilation and chemical management,
- Contingency planning, back-up and protocols,
- Equipment, preventive maintenance, and operations,
- Personnel qualifications, hygiene and training,
- Customer policy, contact and complaint procedure,
- Quality control, assurance and monitoring, and
- Universal precautions, handling, storage and transportation.

Laundries can spend considerable time preparing for an HLAC inspection to ensure that they are in compliance with every aspect of the process. The preparation standards require a multi-disciplinary approach to laundry operations because beyond actual production methods it includes aspects of Customer Service, Transportation, Maintenance, Housekeeping, Chemical distribution, Human Resources, Safety and Training as well as Textile Selection. Production staff are interviewed and questioned as to what is done, how it is done and their role in keeping laundry clean.

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[12] Garner JS, Favero MS. Guideline for handwashing and hospital environmental control. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1985. Document No. 99-1117 (Also available at Infect Control 1986; 7:231-43).

[13] Eickhoff TC. Microbiologic sampling. Hospitals 1970;44:86–7.

[14] American Hospital Association Committee on Infections Within the Hospitals. Statement on microbiologic sampling in the hospital 1974;48:125–6.

[15] Rafferty KM, Pancoast SJ. Brief report: bacteriological sampling of telephones and other hospital staff hand contact objects. Infect Control 1984;5:533–5.

[16] German Certification Association for Professional Textile Services, RAL-GZ 992/2 – Hospital Linen, Bönnigheim, Germany

[17] Institute for Sustainability and Hygiene International, *Certification Standards for Processing Reusable Linen,* MacKenzie, Brisbane, Queensland, Australia, April 2011

For Laundries to receive accreditation they will have to be built right, equipped properly and staffed with qualified and trained personnel in the appropriate manner in which to process product, interact with customers and vendors and generally maintain operations in a clean and aseptic manner.

In every visit inspectors are guided by the following:

- Is the facility set up appropriately to deliver clean linens to customer?
- Is the staff following appropriate protocol to deliver clean linens?
- Does the laundry have policies and procedures in place that maintain requirements?
- Is the facility clean?
- Does the facility comply with all local, state, and federal guidelines and regulations as laid out by the appropriate professional standards bodies?
- Are the carts, tubs, washers, dryers, conveyors, bins and trucks maintained and cleaned?
- Is there separation at all times between soiled and clean product?

Summary and Conclusions

To summarize, it is accurate to state that no universally accepted microbiological standard or protocol was found in our search to exist for the testing of textiles being processed for healthcare facilities. The Centers for Disease Control and Prevention (CDC) and the American Hospital Association (AHA) have never advocated for textile sampling within healthcare laundries.

It is true that Germany and Australia do include some testing; however, each country is employing different protocols and standards. Further, there is no universally accepted definition of hygienically clean.

The U.S. FDA Quality Systems Regulations and the ISO 9000 Quality Series support the fundamental basis for HLAC accreditation, i.e. process-centric focus and reduced reliance on end-product testing. Testing programs are certainly used when these quality systems are applied, but their value is based on the accuracy of the test method being used and the sampling plan being utilized. There are no CDC or EPA recommended test methods. The sampling program used by a product testing program should extend through transportation and delivery of products which is an area of high risk for environmental contamination.

HLAC concludes that any inspection of a healthcare laundry needs to review and place significant weight on factors such as design, equipment, procedures, training, protocols and adherence to regulatory body requirements as essential requirements for accreditation.

A thorough review and inspection of the laundry textile process from receipt of the soiled linen to delivery of the clean product to the final user provides assurance to the customer and the end user of a hygienically clean product. It is important to note:

- There are currently over 170 laundries in the United States and internationally that are HLAC accredited which provides the laundries with the added value of having their processes accredited to ensure consistent delivery of hygienically clean linen.
- The HLAC Accreditation Process ensures a laundry has the processes in place to provide hygienically clean linen not just once but every time.
- HLAC Accreditation substantiates a laundry's operational processes have been independently inspected and adhere to professional recognized infection prevention and control policies.
- HLAC's industry leading standards, jointly developed in cooperation with several industry advocacy groups, include every step of the textile processing cycle. These rigorous standards undergo continuous evaluation to keep pace with industry norm and infection control requirements.
- The achievement of HLAC accreditation ensures process driven excellence for the Best healthcare laundries.