DECIPHER THE MAZE OF REGULATIONS
Operating in Compliance

Regulations, compliance, and laws oh my! Even the famous Wizard of Oz could not have envisioned the maze of requirements in place for institutional laundries today. It’s no wonder we become confused over what we must do, what we should do, and what we have to do! Operating in compliance with state laws, regulations, and voluntary industry standards has become a full-time occupation in order to keep up with the ever-changing marketplace.

This informational piece is designed to help laundry managers sort through some of the alphabet soup of organizations to identify their areas of focus, what power and/or authority they may wield, and how this may impact institutional laundry operations. Hopefully, this simplified guide will help you to identify the requirements that apply to you, areas you can look to for explanation, and how to gauge their applicability to your operation.
The Centers for Disease Control and Prevention (CDC)

Their title pretty well sums it up; CDC scientists are constantly scrutinizing areas where our safety may be in peril, be it in our work environment, at homes, or while traveling. The CDC was formed in 1946, and at that time stood for the “Communicable Disease Center.” While the acronym hasn’t changed, this governmental organization’s role now extends far beyond the realm of communicable diseases. The CDC impacts global health, bioterrorism, disability, occupational health, and even environmental health concerns and issues.

The CDC’s work today is known for its global efforts towards conducting research and investigations, as well as its action-oriented approach to resolutions. This organization is widely known for its quick response to public health emergencies, as best noted in the recent anthrax mail scare, response to the SARS outbreak, and other bioterroristic concerns.

Guidelines and recommendations developed for specific issues related to public health are published by the CDC. Those impacting our industry would include recent publications, such as “Guidelines for Environmental Infection Control in Health-Care Facilities” (6/6/2003 / Vol. 52 / No. RR-10) and “Guideline for Hand Hygiene in Health-Care Settings” (10/25/02 / Vol. 51 / No. RR-16). While these guidelines are often perceived as regulatory, they have no regulatory authority of themselves. However, as a highly recognized and credible authority, the CDC guidelines and recommendations are often implemented in voluntary accreditation requirements, such as The Joint Commission on Accreditation of Healthcare Organizations.

Recent CDC recommendations have addressed infection control measures as related by: 1) the encouraged use of alcohol-based hand scrubs and in the use of chlorhexidine gluconate (CHG), 2) the recommendation that facilities may eliminate covers on contaminated textile hampers in patient care areas, 3) the guidance to avoid sorting/pre-rinsing contaminated textiles in patient care areas, and 4) the confirmation that providing hygienically-clean textiles to intensive care neonatal units is an acceptable practice as opposed to requiring sterile textiles for patients in the NICU.

National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA)

Both created by the Occupational Safety and Health Act of 1970, signed by President Richard M. Nixon 12/29/70. NIOSH is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the CDC and comes under the jurisdiction of the U.S. Department of Health and Human Services.

On the other hand, OSHA is a division of the U.S. Department of Labor. OSHA aims to ensure worker safety and health in the United States by working with employers and employees to create better working environments. Since its inception in 1971, OSHA has helped to cut workplace fatalities by more than 60% and occupational injury and illness rates by 40%.

The Occupational Safety and Health Act of 1970 encouraged states to develop and operate their own job safety and health programs. OSHA monitors state plans and provides 50% of an approved plan’s operating costs. There are currently 22 states and jurisdictions operating complete state plans that cover private, state, and local government employees. These states must set job safety and health standards that are “at least as effective as” comparable federal standards.

STATES & JURISDICTIONS OPERATING COMPLETE STATE PLANS


*Please note: the Connecticut, New Jersey, New York, and Virgin Islands plans cover public-sector employees only.
Under the Bush Administration, OSHA focused on three strategies: 1) strong, fair, and effective enforcement; 2) outreach, education, and compliance assistance; and 3) partnerships and cooperative programs.

**Enforcement**

What are OSHA's inspection priorities? Top priority are reports of imminent dangers or accidents about to happen. Second are fatalities or accidents serious enough to send three or more workers to the hospital. Third are employee complaints followed by referrals from other government agencies and employers reporting a high injury and illness rate. Penalties from OSHA can range from $0 to $70,000, depending on the seriousness of the violation and its likelihood to result in serious harm to employees.

**Compliance**

OSHA's main premise: the General Duty Clause states that an employer is responsible for providing a workplace free of occupational hazards. OSHA develops a set of written standards specific to those potential occupational hazards and compliance documents (CPL) are developed to interpret the standard. Probably the best known standard within the healthcare industry is the 1991 Bloodborne Pathogens rule that remains in the forefront of operational practice today.

Recent changes in OSHA provided for the creation of the targeted approach by focusing compliance inspections on injuries of frequent occurrence and serious in nature. Other requirements include reporting/recording of occupational illness and/or injury and often provide a good source for laundries to identify areas where continued education may be necessary.

**Partnership**

Current OSHA trends in the laundry industry have focused on the identification, training, and application of the confined spaces regulations. In the past, ALM developed a partnership with OSHA to focus on developing specific informational packets and training opportunities specific to our industry and a confined spaces fact-sheet packet was first on the list of educational products to be developed through the ALM–OSHA alliance.

NIOSH research, information, education, and training in the field of occupational safety and health comes under the jurisdiction of the U.S. Department of Health and Human Services. Their most recent work impacting institutional laundries would be the NIOSH Alert on “Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings” (pub. #2004-165, September 2004).

NIOSH publications result from gathering information, conducting scientific research, and translating the knowledge gained into products and services. Organizations, such as OSHA, may either accept or reject the recommendations submitted by NIOSH. Otherwise, they carry no regulatory or enforcement authority.

**Food and Drug Administration (FDA)**

While the FDA is the federal agency responsible for ensuring that food is safe, it is also responsible for assuring that biological products and medical devices are safe and effective, and that these products are honestly, accurately, and informatively represented to the public. Surgical healthcare textiles have been identified as medical devices. For facilities that process healthcare textiles, the FDA develops, implements, monitors, and enforces standards for textiles used in surgical procedures as a medical device.

The Medical Device Act (1974) required that medical devices be classified. In 1990, the Safe Medical Device Act expanded the authority of the FDA to include detailed reporting of incident failure related to medical devices. According to the Association for the Advancement of Medical Instrumentation (AAMI) in their published standard, processing of reusable surgical textiles for use in healthcare facilities and laundry facilities processing sterile or non-sterile surgical textiles for their own facility/entity should “comply with the industry standards of practice and guidelines and should be aware of FDA's quality system regulation.” More stringent standards are in place for institutional laundries who process surgical textiles for facilities not owned by the facility and for facilities that provide the sterilization/autoclave process.
**Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**

Established in 1915 by setting standards in hospitals. Over time, this organization has broadened its accreditation base beyond acute care facilities to include skilled nursing facilities, home health, durable medical equipment companies, assisted living facilities, clinical laboratories, and more. JCAHO publishes standards and scoring guidelines annually and awards a three-year accreditation based on a Periodic Performance Review and a survey of the facility. JCAHO standards often mirror the CDC guidelines, NIOSH recommendations, and other applicable industry standards, state and federal health department statutes, as well as regulatory requirements by OSHA, FDA, and others.

JCAHO's new survey process that utilizes a “tracer methodology” will most likely lead survey teams to the laundry operations when textile processing or the provision of adequate patient and/or clinical staff textile needs are not being met, or they interrupt the provision of care in a timely fashion.

These bodies, both required and voluntary, are designed to provide healthcare services in a safe manner for the public while maintaining a safe workplace for employees. Recent activities within the industry have recognized a need for voluntary standards within the institutional laundry industry for facilities that process textiles used in healthcare facilities. A joint effort of leading industry associations are currently at work defining practice standards. Once published, these standards may set the bar for healthcare laundry operations and provide the purchasing public with guidelines whereby they can more accurately measure compliance, service, and quality. Moves such as these are often designed to postpone and/or avoid mandatory government regulations and benefit the dedicated laundry operations with the recognition of achievement/quality.


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**Decipher the Maze of Regulations**

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