# Regulations that Impact Disinfection and Sterilization Processes

## ALPHA Patrol: Keeping Health Care Safe for Everyone

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**KEYWORDS**

• Disinfection • Sterilization • Regulatory agencies

''Time out'' no longer means a corner for placement of errant children. Communication, continuous quality improvement, safer patient care, and integration of services are a day-to-day reality. Every clinical service depends, at some point while providing patient care, on the Sterile Processing and Materiel Management (SP/MM) department. All reusable instruments, mobile equipment, and disposable supplies are facilitated in some way by SP/MM. They enable clinicians to provide the highest quality care. They are a vital link in bringing health to patients.[1]

The operating room (OR) suite historically was a ''closed environment.'' Other than employees and patients, not many ventured beyond the OR's double doors. Through the 1980s, surveyors from the Joint Commission on Accreditation of Hospitals (JCAH) met with upper management and department heads in conference rooms. They talked at length and reviewed committee meeting minutes and records.[2] Over time, this reality has changed. Evolution and education of the public have increased the scrutiny of the activities performed inside the OR.

Today the Joint Commission, as they have been known since 2007,[2] uses a more physical and widespread survey process. Surveyors actually walk about the facility, question workers to validate education and ongoing quality improvement participation, and interview patients to validate their participation in improving their quality of life through health care. The Tracer Methodology[3] of survey and institution of

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unannounced surveys has bought the surveyors directly into the operating rooms and other procedures locations. Direct observation and personal contact with everyone involved in patient care is the new experience.

## APLHA PATROLS WHO KEEP A GUARDIAN EYE ON THE PRACTICES OF DISINFECTION AND STERILIZATION

Functions of the SP/MM department are regulated and monitored by a variety of overseers beyond the Joint Commission. Although participation in JC accreditation is technically voluntary, facilities who desire payment for providing services to Medicare and Medicaid clients must first be JC accredited.[4] Other agencies, referred to in this article as the ALPHA Patrol, providing oversight and having established mandatory regulations include the Occupational Safety and Health Administration (OSHA), Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and Agency for Healthcare Administration (AHCA).

OSHA, established in 1970 by the US Department of Labor, works to ensure safe work places for all employees.[5] The statutes established are law, therefore mandatory. Noncompliance with these statutes can cause severe fines to be levied against the facility and endanger JC accreditation. They are well recognized in health care facilities for the Bloodborne Pathogens Standard established in 1991 and Needlestick Safety and Prevention Act in 2001.[6] The statute regulating the use and monitoring of ethylene oxide (ETO) for sterilization is known as Title 29 of the Code of Federal Regulations (CFR) Part 1910. 1047.[7]

The US Department of Health and Human Services (HHS) was established in 1980. The mission is to protect the health of all Americans and provide essential human services.[8] The department includes more than 300 programs, with several agencies that impact hospitals. These include CMS, FDA, and CDC.[8]

In 1970, the EPA was established by the US government.[9] Their impact on SP/MM includes the chemicals used to clean, disinfect, and sterilize products as well as the product's disposal stream. The chemicals are hazardous to the environment if used or disposed of incorrectly. Strict adherence to the labeled practices of use and disposal are required. In some instances, even the shipping containers must be rendered harmless before disposal.[10] Many hospitals elected to discontinue use of facility-operated incinerators, further complicating the waste disposal stream and increased expense. Maintaining a central file of the Material Safety Data Sheet and manufacturer's instruction for storage, use, and disposal of all products helps ensure education and compliance of staff. A master file may be established and maintained with the facility's designated safety division; however, a central department file is most helpful when staff can access it easily in the event of an exposure or spill.

The FDA, established in 1906, regulates among other items, medical products. It is illegal to alter a medical device. This includes the device being sterilized and the sterilization device.[11] Reuse of devices labeled for "single use only" is also regulated by the FDA.[12]

Another federal entity active in SP/MM is AHCA. All health care facilities are required to be licensed by the government. Although AHCA's primary function is inspection of new and renovated facility constructions, annual facility inspections are also performed. This annual Life Safety Inspection works with OSHA to help ensure that facilities continue to be safe for workers and patients.[13] For example, if your facility elected to install a new ETO sterilizer, permits, inspections, and/or testing would be required by 4 agencies: AHCA, OSHA, EPA, and FDA.