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Personal Protective Equipment for Endoscope Reprocessing: Regulations, Standards & Responsibilities

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LEARNING OBJECTIVES

1. Discuss the difference between a regulatory requirement and a voluntary recommendation
2. Review regulatory standard 29 CFR 1910.1030 and its requirements regarding personal protective equipment and compare to voluntary recommendations
3. Discuss whether requirements/recommendations differ for processing endoscopes versus other instrumentation
4. Discuss personal protective equipment responsibilities of the employer and employee

Processing flexible endoscopes is one of the biggest challenges facing reprocessing departments today. Those challenges include delayed reprocessing, issues of inadequate manual cleaning, inadequate or non-existent cleaning verification, among others. One aspect of flexible endoscope reprocessing that shouldn't be challenging, yet often is, is the selection and use of personal protective equipment (PPE).

Staff member safety in the decontamination area has always been and will always be an area of high concern. Each reprocessing department should have in place a PPE policy that addresses these concerns. Unfortunately, even with the appropriate selection of PPE and a policy defining its use, non-compliance issues are still found during surveys and audits. A lack of understanding the requirements, and efforts to keep departmental costs low can lead to shortcomings regarding proper use of PPE. Also, the often-uncomfortable nature of some PPE can lead to improper use or lack of use. This lesson will address PPE requirements and recommendations, and the difference between the two; whether processing flexible endoscopes requires the same level of PPE as when reprocessing other instruments; and the responsibilities of the employer and employee regarding PPE use.

Objective 1: Discuss the difference between a regulatory requirement and a voluntary recommendation

In the reprocessing world, many professional organizations exist that outline best practice recommendations for processing instrumentation. Organizations like the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN) are examples of groups with broad-scope recommendations, which include many subjects related to instrument handling and processing, whereas the Society of Gastroenterology Nurses and Associates Inc. (SGNA) has a specific focus on gastrointestinal (GI) endoscopes. Regardless of their focus, all of these organizations' recommendations are voluntary and offer guidance to help reprocessing departments ensure the best patient outcomes. Many reprocessing duties are covered by these recommendations, including bloodborne pathogen safety and PPE; however, when worker safety is part of the equation, regulatory requirements – such as those from the Occupational Safety and Health Administration (OSHA) must be followed. The following definitions will help clarify why.

Voluntary standards: Guidelines or recommendations for best practices to provide better patient care. Industry, non-profit organizations, trade associations and others develop voluntary standards. These standards may become enforceable by surveyors if a healthcare facility states that they comply with that standard or if a state adopts the standard as a law, such as what has happened with AAMI standards in certain states.

Regulatory standards: A comparison benchmark that is mandated by a governing agency. Noncompliance with regulatory standards may lead to citation and legal penalties. In short, a voluntary recommendation is one a facility can volunteer to abide by (meaning if the facility devises an alternative policy or procedure, that may be followed instead of the voluntary standard/recommendation, as long as it doesn't violate any laws). Regulatory requirements, on the other hand, are laws and noncompliance with these laws can result in loss of reimbursement for services, and liability risk.

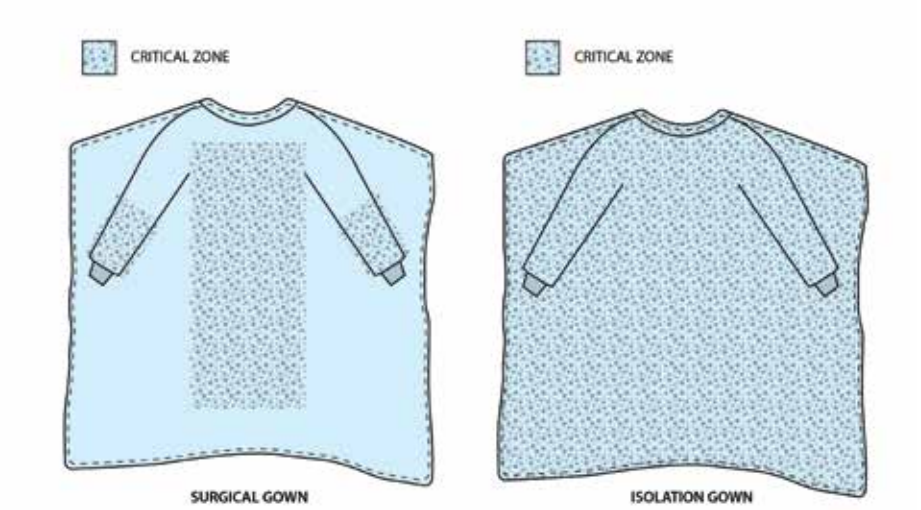

Figure 1: Example of gown designs

Objective 2: Reveiw regulatory standard 29 CFR 1910.1030 and its requirements regarding personal protective equipment and compare to voluntary recommendations

With flexible endoscopes' complex design and multitude of steps required to properly process them, it's no wonder making these devices safe for patients is an industry priority. While patient safety should be a high priority, the same should be true for endoscope reprocessing staff. OSHA's Bloodborne Pathogens standard, 29 CFR 1910.1030, is a regulation that must be followed. The standard provides requirements to ensure staff members are safe when handling contaminated items.

The Bloodborne Pathogens standard, as amended pursuant to the Needlestick Safety and Prevention Act of 2000, prescribes safeguards to protect workers against health hazards caused by bloodborne pathogens. Its requirements address items such as exposure control plans, universal precautions, engineering and work practice controls, PPE, housekeeping, laboratories, hepatitis B vaccination, post-exposure follow-up, hazard communication and training, and recordkeeping. The standard places requirements on employers whose workers can be reasonably anticipated to contact blood or other potentially infectious materials (OPIM), such as unfixed human tissues and certain body fluids. *Note: For the purpose of this lesson, only PPE will be addressed specifically in regard to 29 CFR 1910.1030.*

The standard emphasizes the requirement of providing PPE of the correct barrier level, size and fit to protect employees as they perform their reprocessing duties. A gown designed for surgery or for use during

AAMI	AORN	SGNA
Liquid-resistant covering with sleeves (e.g., a backless gown or surgical gown)	Fluid-resistant gown with sleeves	Gowns to protect skin and/or clothing
General-purpose utility gloves	Gloves (e.g., general-purpose utility gloves with a cuff that extends beyond the cuff of the gown	Gloves to protect hands
Fluid-resistant face mask	Mask	Masks to protect mouth/nose
Eye protection	Eye protection or a full-face shield	Goggles/eye shields to protect eyes
		Face shields to protect face, mouth, nose and eyes
Surgical-type hair covering	Clean surgical head cover	Head and shoe covers
Liquid-resistant shoe covers	Shoe covers or boots designed for use as PPE	

Figure 2: A comparison of PPE recommendations

decontamination processes should have reinforcement in the front and on sleeves to protect against liquid permeation and strike-through (see Figure 1).

As OSHA's Bloodborne Pathogens standard states, PPE will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. The standard goes on to define each piece of PPE that may be necessary to provide this protection. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate PPE, such as but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices.

Even though recommendations from voluntary organizations don't have legal implications for non-compliance, they are considered by survey organizations and do provide evidence-based best practices that give proven advice for protecting staff against biohazards. Figure 2 compares PPE recommendations from three major organizations: AAMI, AORN and SGNA. As can be seen from this side-by-side comparison, the recommendations from these three organizations align with the requirements set forth in the OSHA Bloodborne Pathogens standard.

Objective 3: Discuss whether requirements/recommendations differ for processing endoscopes versus other instrumentation

Much of the instrumentation used in hospitals is reprocessed in a central location, most often the Central Service/Sterile Processing (CS/SP) department. Flexible endoscopes, on the other hand, may be processed in multiple locations throughout a facility. Clinic settings, such as Endoscopy, Ear Nose and Throat, and Urology, may be cleaning and high-level disinfecting flexible endoscopes. A misconception exists in some of these departments that flexible endoscope processing is somehow different and, therefore, less hazardous than processing other types of instrumentation. It is clearly demonstrated by the alignment in the PPE requirements and recommendations from the aforementioned organizations, including SGNA whose focus is primarily GI, that there is no difference between the level of PPE protection required to process a flexible endoscope than for any other surgical instrument.

Each group expresses the need for proper barrier protection and coverage requirements that PPE should provide when the potential for exposure to blood and body fluid can be expected. Anyone who has ever processed an endoscope knows that such potential exists when processing flexible endoscopes; therefore, use of isolation gowns and/or wrists-length exam gloves as PPE for decontamination processes is not recommended or acceptable. As stated in ANSI/AAMI ST91, processing personnel should use a style of glove that prevents contact with contaminated water. Gloves that are too short, do not fit tightly at the wrist, or lack cuffs might allow water to enter when the arms move up and down. Exam gloves should not be used for decontamination. General purpose utility gloves fitted at the wrist or above should be used. ANSI/AAMI ST91 also addresses gowns. In situations that require the

highest level of protection (e.g., there is a possibility that attire can become soaked with blood or other potentially infectious material, as when items are being washed by hand), a Level 4 gown (as defined by ANSI/AAMI PB70) should be used. Level 4 is the highest barrier protection rating for gowns and drapes.

Objective 4: Discuss personal protective equipment responsibilities of the employer and employee

While the employer holds much of the responsibility for PPE, it is a shared responsibility between the employer and their employees, and its proper use requires cooperation and communication to produce the best safety outcomes and avoid potential legal issues.

Any facility where instruments (in this case, flexible endoscopes, specifically) are reprocessed will need to review and understand the requirements of OSHA 29 CFR 1910.1030. Those requirements are broken down the following ways:

Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate PPE.

Use. The employer shall ensure that the employee uses appropriate PPE.

Accessibility. The employer shall ensure that appropriate PPE in the appropriate sizes is readily accessible at the worksite or is issued to employees.

Cleaning, Laundering and Disposal. The employer shall clean, launder and dispose of PPE as required by paragraphs d and e of the OSHA standard, at no cost to the employee.

Repair and Replacement. The employer shall repair or replace PPE, as needed, to maintain its effectiveness, at no cost to the employee.

While not addressed in this section of the standard, training and yearly competence in donning (putting on) and doffing (removing) procedures must also be verified by employers.

With the employer covering all aspects – from acquisition of PPE to its disposal and replacement – one might ask, "what is the employee's role?" Their primary role is to wear it – and wear it properly. Anyone who has worked in a reprocessing area knows how hot and, often, uncomfortable head-to-toe PPE can be. Nevertheless, it is necessary to protect oneself from the biohazardous dangers reprocessing presents. Adherence to proper donning and doffing procedures provided by the PPE manufacturer(s) will ensure the items perform as intended and offer maximum protection from exposure.

Conclusion

While the necessity for PPE to protect healthcare workers has long been known, questions around its selection and issues with its consistent and proper use remain. Consideration for employee comfort must be balanced with meeting the requirements of keeping staff safe while performing their job. Good communication between those in the facility who must wear the PPE and those who must purchase and maintain it will help ensure the appropriate PPE is always available and worn. C

RESOURCES

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5. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91: 2015. *Flexible and semi-rigid endoscope processing in health care facilities.*
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7. Society or Gastroenterology Nurses and Associates. 2015. *Standard of Infection Prevention in the Gastroenterology Setting.*