LEARNING OBJECTIVES:

1. Define endoscopy.

2. Describe the rules and regulations that have an impact on flexible endoscope reprocessing, including those of the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Health and Human Services (DHHS).

3. Know the professional guidelines that affect practice, including those of the Association for the Advancement of Medical Instrumentation (AAMI), the Association for Professionals in Infection Control and Epidemiology (APIC), the Association of periOperative Registered Nurses (AORN), the American Society for Gastrointestinal Endoscopy (ASGE), the Centers for Disease Control and Prevention (CDC), the Society for Healthcare Epidemiology of America (SHEA), and the Society of Gastroenterology Nurses and Associates (SGNA).

4. Understand the process of facility accreditation by such agencies as the Joint Commission (JC) and the Accreditation Association for Ambulatory Health Care (AAAHC).

5. Know how to perform flexible endoscope processing safely (e.g., avoiding exposure to chemicals, preventing allergic reactions to latex, using proper ergonomics).

6. Understand the importance of environmental safety (e.g., fire safety, electrical safety, patient emergency equipment, waste management).

7. Understand the practice of ethics and its impact on patient safety.

WHAT IS ENDOSCOPY?¹

"An endoscopy involves examining the inside of a person's body using an endoscope. An endoscope is a medical device consisting of a long, thin, flexible (or rigid) tube which has a light and a video camera. Images of the inside of the patient's body can be seen on a screen. The whole endoscopy is recorded so that doctors can check it again. Endoscopy is a minimally invasive diagnostic medical procedure. It is used to examine the interior surfaces of an organ or tissue. The endoscope can also be used for enabling biopsies and retrieving foreign objects. Endoscopy is a noninvasive alternative to surgery for foreign object removal from the gastrointestinal tract.

"An endoscopy is often used to confirm a diagnosis when other devices, such as an MRI, X-ray, or CT scan are considered inappropriate.

¹ All of the information in this section is excerpted from "What is Endoscopy? What is an Endoscope?,” Medical News Today, June 12, 2009. This article is available at: http://www.medicalnewstoday.com/articles/153737.php.
“An endoscopy is often carried out to find out the degree of problems a known condition may have caused. The endoscopy, in these cases, may significantly contribute towards the doctor’s decision on the best treatment for the patient.

“The following conditions and illnesses are most commonly investigated or diagnosed with an endoscopy:

- Breathing disorders
- Chronic diarrhea
- Incontinence
- Internal bleeding
- Irritable bowel syndrome
- Stomach ulcers
- Urinary tract infections

“Endoscopies are commonly used for the diagnosis of cancer. They are used for biopsies — taking samples of tissue to find out whether it is cancerous. Thanks to an endoscope, biopsies of the intestines or lungs can be done without the need for major surgery. Colonoscopy is the most effective screening option for colorectal cancer.”

FLEXIBLE ENDOSCOPES

Flexible endoscopes are complex medical devices that are used in a variety of body cavities for diagnostic and therapeutic procedures. In the United States, at least 11 million gastrointestinal endoscopies are performed each year, and the number of procedures is increasing (Cullen et al., 2009). Because of the sophistication of their design, flexible endoscopes, which include gastrointestinal (GI) endoscopes and bronchoscopes, provide unique challenges for cleaning and high-level disinfection or sterilization.

“A risk of all endoscopy procedures is the introduction of pathogens or cross-contamination between patients. Failure to clean, disinfect, or sterilize equipment carries not only risk associated with breach of host barriers but also risk for person-to-person transmission of pathogens and transmission of environmental pathogens (e.g., Pseudomonas aeruginosa).” (ANSI/AAMI ST91). In addition, when a flexible endoscope is not processed correctly, the scope can be damaged, utilization of the scope can be reduced (it needs to be repaired), and chemical residues can cause toxic reactions in patients.

According to ANSI/AAMI ST91, “multiple peer-reviewed publications in several countries including the United States have documented breaches in processing that have led to patient exposure to improperly reprocessed flexible and semi-rigid endoscopes and have caused serious infections (Sanderson, 2010; Gonzalez-Candelas et al., 2010; Carbone et al., 2010; Aumeran et al., 2010; Holodny et al., 2012; CDC 2014). In nearly all of these cases, failure to comply with manufacturer’s written instructions for use (IFU) or established guidelines or malfunctioning equipment that was undetected has led to numerous outbreaks of infection due to improperly processed flexible and semi-rigid endoscopes.”
Between 2013 and 2015, there were outbreaks of infections with New Delhi metallo-β-lactamase (NDM) producing Carbapenem-resistant Enterobacteriaceae (CRE). The outbreaks were linked to contaminated endoscopes used to perform endoscopic retrograde cholangiopancreatography (ERCP). A total of 44 patients were infected (Rutala and Weber, 2014). Additional outbreaks linked to ERCP scopes occurred in Pittsburgh (McCool et al., 2012), Seattle (Aleccia 2015), and California (CDC, 2015a).

According to ANSI/AAMI ST91, the “effects of endoscopy-related infection outbreaks and other adverse patient reactions may include:

- “Microorganisms may be spread from patient to patient by contaminated or improperly processed flexible endoscopes or malfunctioning equipment (exogenous infections).
- “Microorganisms may spread from the GI tract through the bloodstream during an endoscopy procedure to susceptible organs, or may spread to adjacent tissues that are breached as a result of the endoscopic procedure (endogenous infections).
- “Microorganisms may be transmitted from patients to endoscopy personnel and/or from endoscopy personnel to patients.
- “Chemical substances can remain on devices from various chemicals used during the procedure or processing that can cause toxic reactions in subsequent patients.
- “Devices may be damaged or rendered difficult to use due to mishandling or inadequate processing.”

According to the Centers for Disease Control (CDC 2008), “minimizing these risks begins with the correct handling procedures in preparation for processing, to include precleaning steps at the point of use (e.g., bedside procedures), disassembly of parts, and safe transport. Cleaning according to the specific manufacturer’s written IFU is then required to ensure that patient soil and other materials are removed prior to the antimicrobial processes of high-level disinfection or sterilization. Cleaning is a multi-step process and is critical not only to ensure that subsequent processing steps can be effective but also to remove any potential toxic chemicals or other materials that can lead to adverse patient reactions. Cleaning is followed by disinfection or sterilization to reduce or completely remove microbial contamination. At a minimum, it is recommended that devices are subjected to high-level disinfection after each use. When possible and practical, flexible endoscopes should be sterilized due to the greater margin of safety built into sterilization. High-level disinfection is a multi-step process and is expected to be able to inactivate most pathogenic bacteria, viruses, and fungi but may not reliably inactivate certain types of microorganisms including bacterial spores. When these devices are used in sterile tissue procedures, sterilization is recommended.”

It should be noted that the term “infection control” is being replaced with the term “infection prevention.” Some of the references in this book might still use the older terminology but, moving forward, organizations are using the term “infection prevention” because that is the goal: to prevent infections from occurring.

**TRAINING, COMPETENCIES, AND CERTIFICATION**

The importance of competency in flexible endoscope reprocessing cannot be overemphasized. The majority of training is on-the-job. Many individuals do not have access to a formal training program. By studying textbooks like this one, flexible endoscope reprocessing technicians can help educate themselves on the principles and best practices of the profession. However, it is important to get hands-on experience within a GI/endoscopy department so that the principles
learned from this book can be applied to practice. Only fully trained personnel who have demonstrated competence in the care, handling, and processing of flexible endoscopes should perform the processing. The effective flexible endoscope reprocessing technician must clearly and thoroughly understand his or her roles and responsibilities. To achieve the necessary level of competence, the technician should study the various functions performed by flexible endoscope reprocessing technicians.

The competency of all individuals who process flexible endoscopes should be verified initially and annually for all aspects of reprocessing. If endoscope reprocessing is not performed competently, patient safety can be compromised and/or endoscopes can be damaged.

It is recommended that all personnel performing processing of endoscopes be certified as a condition of employment (ANSI/AAMI ST91). Personnel involved in endoscope processing should be provided with education, training, and complete competency verification activities related to their duties upon initial hire, annually, at designated intervals, and whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing. Processing activities should be closely supervised until competency is verified and documented for each processing task, from cleaning through storage of the endoscope. (ANSI/AAMI ST91)

Training for flexible endoscope reprocessing is a critical component of effective processing and should include the following:

- Facility policies and procedures for processing flexible endoscopes
- Infection prevention, attire, hand hygiene, and compliance with local, state, and/or federal regulations
- Workplace safety, including all relevant Occupational Safety and Health Administration (OSHA) standards related to chemical use, biological hazards in that department, and workplace safety processes and procedures related to endoscope processing
- Processing of each type, model, and generation of flexible endoscope, including GI endoscopes and bronchoscopes and those from different manufacturers
- Leak testing of endoscopes, when recommended in the manufacturer’s IFU
- Manual cleaning (including methods of verifying the effectiveness of the cleaning process), automated cleaning, and high-level disinfection
- Documentation of quality monitoring results
- Processing of all accessories
- Selection and use of detergents
- Selection and use of high-level disinfectants (HLDs)/liquid chemical sterilants (LCSs)
- Use of personal protective equipment (PPE), including correct donning and doffing of PPE
- Transport of used endoscopes
- Transport and storage of endoscopes that have been high-level disinfected
Competency verifications should be performed annually and should include the following (ANSI/AAMI ST91):

- Compliance with facility policies and procedures and the manufacturer’s written IFU for each type of endoscope processed at the facility
- Level of proficiency in processing procedures

Educational, training, competency verification, and other materials and information are available from endoscope manufacturers, automated endoscope reprocessor (AER) manufacturers, sterilizer manufacturers, manufacturers of chemicals (e.g., cleaning solutions, high-level disinfectants), professional associations, and professional journals (ANSI/AAMI ST91).

ECRI Institute (formerly the Emergency Care Research Institute) is an organization that has a foundation in independence and scientific research. ECRI Institute marries practical experience and uncompromising independence with the thoroughness and objectivity of evidence-based research. Each year, ECRI Institute lists the top ten health technology hazards.

Inadequate reprocessing of endoscopes and surgical instruments made number one on the list for 2016 (ECRI Institute, 2015). Unfortunately, reprocessing of endoscopes and surgical instruments was number four on the list in 2015 (ECRI, 2014) and number six on the list in 2014 (ECRI Institute, 2013), so the problem has become worse, not better.

In a 2010 job analysis survey performed by of the Certification Board for Sterile Processing & Distribution, Inc. (CBSPD), the following knowledge areas were identified by flexible endoscope reprocessing technicians:

- Rules, responsibilities, regulations, and safety
- Life sciences (infection prevention, anatomy, physiology, microbiology)
- Endoscopes and accessories for endoscopic procedures
- Handling and cleaning of endoscopes and accessories
- Processing of endoscopes and accessories
- Documentation
- Ethics

It is important to note the wide range of knowledge required for competent flexible endoscope reprocessing.

Working in a GI/endoscopy department requires the ability to take on multidimensional tasks and responsibilities that require specific knowledge and skills, including an understanding of the following:

- Decontamination, containment (if applicable), and handling of flexible endoscopes and accessories
- Processing and reprocessing of reusable products
- Storage and handling of flexible endoscopes and accessories
In addition, endoscope processing personnel should be knowledgeable about the various signs and symbols used on packages or containers of medical/surgical devices. This information helps ensure both employee safety and patient safety. See Appendix B.

The nature of the work performed in GI/endoscopy suites means that patient and personnel safety is paramount. As will be discussed in more detail later in this chapter, processing practices are highly regulated.

As previously discussed, all personnel performing flexible endoscope reprocessing must be properly trained to ensure their safety and the safety of the patients they serve. Orientation should include a review of regulations, reference materials, and all safety information. New flexible endoscope reprocessing employees should be assigned to an experienced mentor, who will monitor their progress. Orientation can take from 2 to 6 months, depending on the complexity of the services provided by the facility or department, the number and types of endoscopes being processed, the cleaning and disinfection process used, and the ancillary equipment used. The training process should be standardized to ensure that all employees are learning the same information in the same manner. It is recommended that an Orientation Guide be used to document all training.

The reprocessing technician should perform a “return demonstration” for each task to ensure that he or she is competent before moving on to another task. For example, after the leak-testing process is demonstrated, the trainee should repeat the procedure (return the demonstration) until it has been performed without error. Documentation of correct performance should be kept on file in the employee’s Orientation Guide.

The Joint Commission recommends that job evaluations and competency testing be performed every three years (Joint Commission, 2014). However, it is also recommended that ongoing education be provided to the staff. With training and education come competency assessments; therefore, competency assessments should be performed annually. In this testing, the department’s or facility’s nurse manager identifies specific activities to be evaluated (usually high-volume, problem-prone, or new processes or procedures), and a preceptor observes employees performing those tasks. The reprocessing technician should perform each of the specified tasks without error; otherwise, he or she must be retrained and retested. The results of all observations and evaluations should be documented on the Annual Competency Evaluation form (see Appendix A for an example). It is important that the person performing the competency assessments be knowledgeable about and competent in all aspects of flexible endoscope reprocessing.

Another change taking place is certification. The sterile processing profession has certification programs that recognize those individuals who have met professional standards. Attaining certification is an important personal and professional goal. In August 2004, New Jersey became the first state to require certification of all sterile processing professionals, including those who process flexible endoscopes. New York and Connecticut now also require certification for processing personnel. Attempts to pass certification legislation are occurring in other states as well.

In an “Interim Duodenoscope Surveillance Protocol” initially issued on March 11, 2015, the CDC stated the following:

“Staff Training and Competency. Ensure personnel performing reprocessing of duodenoscopes have received appropriate training with competency verification for reprocessing procedures. Competencies should be assessed at initiation of employee duties and at least annually and anytime a breach is identified or when a new technique or
equipment is introduced. Competency verification should include direct observation in addition to other assessments per facility policy (e.g., written tests). Personnel responsible for reprocessing endoscopes are encouraged to seek certification in flexible endoscope reprocessing.

All personnel performing cleaning, disinfection, and/or sterilization should be certified upon being hired or within two years of employment and should maintain that certification throughout their employment (ANSI/AAMI ST79). Ideally, staff should obtain certification as soon as they are eligible.

Certification for flexible endoscope reprocessing technicians is available through the CBSPD, located in Lebanon, New Jersey. Information about this certification program can be found at http://www.sterileprocessing.org. The SGNA offers a training certificate (not certification) program; visit their website at http://www.sgna.org.

ORGANIZATIONAL STRUCTURE

Within healthcare facilities, like most organizations, there is an “organizational structure,” which is often referred to as an organizational chart. The departmental organizational chart details the reporting and accountability mechanisms for the titles within the department, and the facility organizational chart details the reporting mechanism for administration.

ETHICS

CODES OF ETHICS

Steven Coughlin, author of “Ethical Issues in Epidemiologic Research and Public Health Practice,” asserts that healthcare professionals may face ethical issues such as conflicts of interest, distortion of medical facts, exorbitant or inconsistent billing, poor privacy and security of patient records and information, and compliance with local, state, and federal health regulations. (Coughlin, 2006)

Because noncompliance with healthcare legislation related to ethics can directly result in harm to patients, healthcare employers provide ethics training and policies for their workers. These courses and policies explain the ethical issues that healthcare workers might encounter, why they exist, and how to deal with them. The penalties for not following the guidelines set in these training courses and policies are sometimes severe: workers could face suspension, fines, loss of their medical license (if they have one), or lawsuits and jail time, depending on whether the worker violates employer or licensing body ethics policies or ethics legislation. (Coughlin, 2006)

Ethical actions are those that conform to accepted and professional standards of conduct. Deciding what is ethical can be complicated by an individual’s beliefs, knowledge base, and work ethic. Behaving ethically is important for the flexible endoscope processing worker.

The following is a suggested Code of Ethics for processing personnel:

- Always act in the best interests of the dignity, reputation, and good standing of the GI/Endo profession, applying professional judgment and acting responsibly in all matters related to patient care.
- Always act with courtesy and consideration to all those with whom you have to deal, including fellow professionals.
- Always comply with regulations and professional standards with regard to safety and processing issues.
• Communicate clearly and concisely; remember that communication is a two-way process and that listening is critical to the process.

• Always strive for the highest standards of excellence; never assume. Make sure that all devices are reprocessed as if they would be used on you or a family member.

• Practice competently. When in doubt, ask for advice from a qualified co-worker.

• Take responsibility for your work and make sure that it is completed on time and accurately.

• Maintain documentation of all your training. Maintain your continuing education and certification by attending continuing education programs and retaining certificates for verification of program content and of your attendance.

• Identify safety and/or risk management issues and report them immediately.

• Never disclose confidential information about a patient.

• Never disclose confidential information about happenings at the facility; there could be legal implications.

• If you make a mistake, try to minimize it and own up to it so that corrective action can be taken.

• Seek total quality management for all stages of a process.

• Report any instances of facility property damage or theft and do not participate in it.

• Treat co-workers with dignity and respect as you would like to be treated.

• Accept constructive criticism as part of your professional growth.

• Accept changes in work schedules when they are dictated by patient needs.

ETHICAL ISSUES
Many types of ethical issues can arise in the workplace:

• Work ethic
• Patient confidentiality
• Hospital property
• Sales representatives
• Employee behavior
• Employee safety

Work ethic: The healthcare environment is a diverse workplace; people from many cultures work together. Differences in cultural beliefs or behaviors can create misunderstandings. Part of a good work ethic is to learn as much as possible about how cultural differences affect work
practices and incorporate those differences into departmental functions without compromising the products that are being produced. Understanding these differences promotes the teamwork needed for a properly functioning department.

**Patient confidentiality:** The reprocessing technician has access to confidential patient information through the GI/Endo or operating room (OR) schedule, computerized records, the issuing of equipment, and charge systems. All patient information is highly confidential and should never be discussed with anyone at any time unless it is required for the direct care of the patient. All healthcare facilities must comply with the Health Insurance Portability & Accountability Act (HIPAA), which provides for the confidentiality and security of health information. Each facility has procedures regarding the destruction of confidential records.

**Hospital property:** Stealing or damaging hospital property is also an ethical issue. Sometimes when personnel witness such activity, they do not want to “get involved.” Ethically, however, the right thing to do is to report it.

**Sales representatives:** When sales representatives provide inaccurate information about their products, it is an ethical issue. Did the representative not really know, or was the sale more important than patient safety?

**Employee behavior:** Sometimes employees feel that they “do not want to get involved,” so they do not report problems such as a staff member leaving the workplace for several hours or not reporting for work at all but getting paid because he or she “forgot” to punch in or punch out.

**Employee safety:** Ethics also involves reporting noncompliance with wearing PPE, failure to adhere to all reprocessing protocols, and any other instances of noncompliance with policies and procedures. These issues relate to employee and patient safety and must be reported. Each facility has a corporate compliance policy; some facilities have a hot-line that can be used to anonymously report any compliance issues.

The guiding principle of healthcare ethics is the Hippocratic Oath, the ideal of doing no harm to another person. This means that ethical arguments related to health care revolve around whether the beliefs or actions of the healthcare worker affect any patient in a negative way. It is important to remember that ethics means doing the right thing.

**REGULATIONS, STANDARDS, AND RECOMMENDED PRACTICES**

An endoscope reprocessing technician’s work is of paramount importance because it affects the safety of patients, device users, and other endoscope reprocessing personnel. It is for this reason that endoscope reprocessing in healthcare facilities is subject to many regulations, standards, and recommended practices:

- A **regulation** is a principle, rule, or law designed to control or govern behavior. Compliance with a regulation is mandatory (i.e., required by law). Examples of agencies that issue regulations are the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and individual state health departments. For example, the FDA requires medical device manufacturers to provide instructions for use, which must be followed by healthcare personnel.

- In the context of flexible endoscope reprocessing, a **standard** is an established norm determined by opinion, authority, research, and/or theory. Examples are the American National Standards developed by the Association for the Advancement of Medical Instrumentation (AAMI). Although compliance with AAMI standards is not legally
required (except when an individual state health department adopts these standards as regulations), AAMI standards for chemical disinfection and other types of reprocessing are recognized as the primary measure of good practice in healthcare facilities, including GI/endoscopy suites. The CDC also publishes standards for infection control that include information on reprocessing practices. These guidelines are very important for infection prevention.

- **Recommended practices** are statements of sound principles of practice that are based upon scientific data and the opinions of experts. Again, compliance is not legally required, but recommended practices reflect accepted professional practices. Examples of recommended practices are the documents developed by the Society for Gastroenterology Nurses and Associates (SGNA), the Association of periOperative Registered Nurses (AORN), the American Society for Gastroenterology (ASGE), the Society for Healthcare Epidemiology of America (SHEA), and the Association for Professionals in Infection Control (APIC).

Although there are numerous professional organizations that provide guidance on the reprocessing of flexible endoscopes, some of the sources do not agree on the best practice, which causes confusion for those reprocessing endoscopes.

**PROFESSIONAL ORGANIZATIONS**

AAMI is the primary U.S. organization that develops consensus standards for decontamination, disinfection, and sterilization practices, and it coordinates the development of many international standards in these areas. AAMI also develops consensus standards for sterilization equipment and products, such as steam sterilizers, EO sterilizers, biological indicators, and chemical indicators. Of special relevance to flexible endoscope reprocessing are ANSI/AAMI ST91, ANSI/AAMI ST79, and ANSI/AAMI ST58. As noted earlier, AAMI standards are not the law (except in New Jersey), but they are widely recognized and accepted as best practice. Additional information about AAMI can be obtained at the AAMI website (http://www.aami.org).

Other organizations, such as ASGE, AORN, SGNA, SHEA, and APIC, also develop recommended practices and guidelines of importance to flexible endoscope reprocessing. AORN, for example, has published a recommended practice on the cleaning and processing of flexible endoscopes (AORN, 2015a). ASGE and SHEA, in collaboration with numerous professional associations and government agencies, have published a joint guideline on reprocessing flexible gastrointestinal endoscopes (ASGE/SHEA, 2011); and SGNA has published standards of infection prevention in reprocessing flexible gastrointestinal endoscopes (SGNA, 2015). APIC has published an infection prevention manual for ambulatory surgery centers (Bennett and Kassai, 2011).

**GOVERNMENT AGENCIES**

**ENVIRONMENTAL PROTECTION AGENCY (EPA)**

The EPA’s regulations affect several aspects of reprocessing. First, the EPA registers and regulates environmental disinfectants (disinfectants used on non-living things, such as tables
and floors). Second, the EPA controls emissions into the air (under the Clean Air Act) and into the water (under the Clean Water Act).

According to the EPA website (http://www.epa.gov), “Before a pesticide can be marketed and used in the United States, EPA must evaluate the pesticide to ensure that it meets federal safety standards for human health and the environment. Such evaluation is particularly important for antimicrobial pesticides (disinfectants, sterilants, and sporicides) which are used to reduce or eliminate microbial contamination. Once EPA determines that a pesticide meets federal safety standards, the Agency grants a license or ‘registration’ permitting its distribution, sale, and use according to approved label instructions.” Instructions for the disposal of pesticides must be followed in order to abide by the Clean Water Act.

FOOD AND DRUG ADMINISTRATION (FDA)
Overview: The FDA’s mission is “to promote and protect the public’s health by helping safe and effective products reach the market in a timely way, to monitor products for continued safety after they are in use, and to help the public get the accurate, science-based information needed to improve health” (http://www.fda.gov). The FDA website provides helpful information on medical products and devices.

The FDA originated in 1906, when the Food and Drugs Act was passed and President Theodore Roosevelt assigned implementation of the law to the Bureau of Chemistry of the U.S. Department of Agriculture. The Bureau eventually became the FDA, an agency residing in the U.S. Department of Health and Human Services. In 1938, Congress passed the Federal Food, Drug and Cosmetic Act, which, for the first time, required companies to prove the safety of new drugs before putting them on the market. It also provided for the regulation of foods, cosmetics, and therapeutic devices and updated existing laws to improve consumer protection.

“FDA's regulatory approaches are as varied as the products it regulates. Some products—such as new drugs and complex medical devices—must be proven safe and effective before companies can put them on the market. Other products—such as x-ray machines and microwave ovens—must measure up to performance standards. And some products—such as cosmetics and dietary supplements—can be marketed with no prior approval. These differences are dictated by the laws we enforce and by the relative risks that the products pose to consumers.” (http://www.fda.gov)

“The FDA safeguards the nation’s food supply by making sure that all ingredients used in foods are safe, and that food is free of contaminants—like disease-causing organisms, chemicals, or other harmful substances. The agency must approve new food additives before they can be used in foods. The FDA also monitors the safety of dietary supplements and the content of infant formulas and medical foods. Meat and poultry products, however, are regulated by the USDA [U.S. Department of Agriculture].” (http://www.fda.gov)

In addition, FDA regulates all medical devices, from very simple items like tongue depressors or thermometers to very complex technologies such as heart pacemakers and dialysis machines. The Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 progressively expanded and clarified FDA's authority over medical devices.

FDA Regulation of Healthcare Facilities: It is important to note that, in general, FDA does not directly regulate healthcare facilities; rather, it regulates the manufacturers of medical devices. There are two exceptions to this rule:
The medical device reporting (MDR) regulation requires medical device manufacturers and distributors to report patient deaths, serious injuries, and serious device malfunctions to FDA. The regulation also requires healthcare facilities to report device-related patient deaths to both FDA and the device manufacturer and to report device-related serious injuries to the device manufacturer. Healthcare facilities must also submit semiannual reports to FDA, summarizing all device-related patient deaths and serious injuries.

In 2000, FDA began regulating the reprocessing of single-use devices by healthcare facilities (hospitals) and third-party reprocessors (FDA, 2000). Essentially, such facilities are regulated in the same manner as medical device manufacturers and must submit to FDA the same kinds of information that device manufacturers do when they seek FDA clearance for introducing a new or modified device to the market. At this time, FDA does not regulate the reprocessing of opened but unused devices, pacemakers, or hemodialyzers (pacemakers and hemodialyzers are covered by other regulations), nor do the reuse regulations apply to ambulatory surgery facilities.

Instructions for Use: The FDA requires that medical device manufacturers provide end-users in healthcare facilities with specific IFU on how to clean and sterilize their products. This information should be obtained for every device processed at the facility and maintained in a binder. (It is advisable to have two binders, one for the scope cleaning area and one for the high-level disinfection area.) If a manufacturer fails to provide this information, the healthcare facility should document and report the problem using FDA’s MEDWATCH program (http://www.fda.gov/Safety/MedWatch/default.htm).

The sophistication of today’s medical devices makes it critical that IFUs be obtained and available for all devices being reprocessed, regardless of how long a device has been in use. Many manufacturers regularly update their IFUs; therefore, to ensure the safety of the device, it is essential that endoscope reprocessing technicians have the most current information. The best approach is to obtain the IFU before a device is purchased so that it can be verified that the processing equipment and any recommended accessories are available at the facility. If the device is new (it’s never been used in your facility before), ensure that in-servicing, according to the IFU, is performed. Thereafter, require an IFU each time a device is purchased. When the device is received, review the IFU and compare it to the information on file. If the IFU has been updated, reprocessing personnel should receive in-service training on the changes, and the new, dated IFU should be placed in the reference binders. If the IFU is the same, no action needs to be taken.

Instructions for use should be updated at least every two years because of the constant updating of IFUs by manufacturers. The use of posters or other reference materials from the manufacturer can serve as a valuable resource for staff. It is the responsibility of reprocessing personnel to obtain and continuously update the manufacturer’s IFU. It is recommended that a policy and procedure be established for routine updating of this information. The IFU should be dated when received to document when the company should be contacted for updates.

Some healthcare facilities use an on-line service for IFUs. However, what happens when the system is down or when power is lost? Do staff members know how to access the information? If a manual system is used (e.g., the IFUs are in a binder), how does staff locate the information? How is compliance with IFUs monitored? Noncompliance is not an option.

It is important that flexible endoscope reprocessors remember that the device manufacturer’s IFU must be followed exactly as written, each and every time the device is processed.
Noncompliance with IFUs creates patient safety, standard-of-care, and legal issues for the healthcare facility.

There are two important terms that need to be understood: validation and user verification. AAMI TIR12 (Designing, Testing, and Labeling Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers) defines these terms as follows:

- **Validation**: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification. **Validation is performed by MANUFACTURERS, not end users.** [emphasis added]

- **User verification**: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.” (Users are facility personnel who reprocess or use the device.)

The FDA requires medical device manufacturers to validate their product label claims of reusability and to provide complete and comprehensive written instructions for cleaning, disinfection, testing, packaging, sterilization, drying, and aeration (if applicable).

At the time of receipt, the IFU should be reviewed to ensure the following:

- The decontamination recommendations provide for thorough cleaning and define microbial lethality.

- The procedures can be performed in the healthcare facility using commonly available chemicals, supplies, and equipment.

- The procedures can be duplicated by healthcare personnel.

- The procedures can be easily understood by the user. (For example, diagrams and step-by-step instructions are helpful to personnel.)

- The procedures are in alignment with the recommendations of professional organizations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens (21 CFR 1910.1030).

- The instructions include a method by which users can verify effective decontamination.

- The instructions for use for the cleaning agent include the dilution/concentration that should be used, the temperature, the water quality (e.g., pH, hardness), and the exposure time (soaking or contact).

- The type and necessary quality of the water are specified (e.g., distilled water, deionized water, reverse osmosis water, filtered water, hard or softened tap water).

- The type and quality of cleaning agents and cleaning accessories that should be used are specified.

- There are instructions for the handling and preparation of the device for cleaning.
• Instructions are provided for the manual or mechanical method that should be used for cleaning, rinsing, and drying.

• The time-at-temperature and water pressure parameters for mechanical cleaning equipment are specified.

• Instructions are provided for any necessary testing of function and cleanliness that should be performed after the decontamination process.

• Any necessary additives (e.g., lubricants) that should be used in reassembly are specified.

• The compatibility of packaging with device materials is described (if applicable).

• Instructions are provided for the use of packaging materials commercially available to healthcare facilities.

• The compatibility of the packaging technique with existing packaging practices is described.

• The compatibility of the wrapped device with the planned sterilization process is described.

Healthcare personnel are responsible for ensuring that the cleaning, packaging, and sterilization methods recommended by the device manufacturer can be duplicated in their environment and that the manufacturer’s instructions are followed correctly. Healthcare personnel should follow regular and documented preventive maintenance and calibration programs for the equipment used in reprocessing. Documentation of the performance of maintenance and calibration activities and of the results should be maintained.

Reprocessing personnel should work proactively with vendors and manufacturers of medical devices to ensure that IFUs are current and to provide training for reprocessing personnel. Training should be on-site (preferred) and hands-on and provide for return demonstration. It is the facility’s responsibility to make sure that competency verification is performed and that it covers all aspects of processing.

**FDA Clearance:** Chemical sterilants, AERs, and chemical HLDs/LCSs are all within FDA’s purview. All such products must be cleared by FDA, based on applications submitted by the manufacturer, before they are marketed for the first time.

**Recalls:** Sometimes manufacturers must recall a product because of a problem. Healthcare facilities are usually notified by FAX, e-mail, or other method. It is important for reprocessing technicians to understand the importance of a recall. All recalled products (usually identified by item name, catalog number, and lot number) must be located, retrieved, and documented.

This is the end of Module 1.

There will be a quiz after Module 2.