

health. DEVICES



ENDOSCOPE REPROCESSING

Ensuring Its Effectiveness

MANAGING ANTI-
MALWARE SOFTWARE

ELASTOMERIC PAIN
PUMPS EVALUATED

ACHIEVEMENT AWARD
WINNER ANNOUNCED

PROBLEM REPORTING

Servo-i Support Arm Can
Compress Breathing Circuit

Smiths Medical Pumps Alarm
Inappropriately and Stop

Submitting Baxter Colleague
Certificates Correctly

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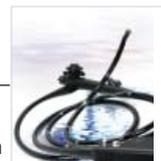
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CLEAR CHANNELS

INEFFECTIVE REPROCESSING OF FLEXIBLE ENDOSCOPES CAN HAVE DEVASTATING CONSEQUENCES FOR YOUR PATIENTS—AND FOR YOUR FACILITY'S BOTTOM LINE. PROTECTING YOUR PATIENTS AND YOUR INSTITUTION REQUIRES DEVELOPING AN EFFECTIVE REPROCESSING PROTOCOL, FOLLOWING THAT PROTOCOL WITHOUT EXCEPTION, AND SELECTING AND USING COMPATIBLE DEVICES AND METHODS. WE ILLUSTRATE THE KINDS OF PROBLEMS THAT CAN OCCUR AND DESCRIBE THE STEPS TO FOLLOW TO AVOID THEM.

In December 2008, U.S. Department of Veterans Affairs (VA) investigators discovered that staff at one of their facilities were not following manufacturer recommendations when reprocessing the auxiliary water tubing and other irrigation accessories on colonoscopes between patient procedures, creating the potential for contaminants from one patient to enter subsequent patients. This problem was even more alarming because, during at least some colonoscopies, tubing with an incorrect valve had been used to connect the colonoscopes to the flushing pump—an error that allowed backflow of body fluids into the irrigation system. This could further increase the contamination risk for the tubing that was not being properly reprocessed. Following the investigation, similar announcements were made by three other VA hospitals regarding inadequate reprocessing of certain endoscopes and accessories (ECRI Institute 2009 Apr 17, VA 2009).

Subsequently, more than 10,000 patients were informed that they might have been exposed to bloodborne pathogens during colonoscopies due to improper reprocessing of endoscopy equipment and accessories. The VA offered free

testing of notified patients, and over 50 patients tested positive for hepatitis B, hepatitis C, or human immunodeficiency virus (HIV). It is not known how many, if any, of these cases were the result of improper reprocessing.

More recently, officials at Palomar Pomerado Health System (PPHS) discovered during a routine internal oversight process that employees were repeatedly using expired disinfectant solution to disinfect certain endoscopic equipment. Investigation by state officials revealed that a delay in the arrival of new disinfectant solution had led employees to use expired solution, putting 45 patients at risk of infection (Clark 2010, Garrick 2010).

The events at the VA hospitals and PPHS are just recent examples of endoscope reprocessing problems that have plagued many healthcare institutions over the years. These incidents highlight the dangers of improper reprocessing of flexible endoscopes and their accessories. They also illustrate why such problems continue to occur: Put simply, reprocessing endoscopes is a complicated matter.

Ensuring Effective Endoscope Reprocessing



UNDERSTANDING THE PROCESS

Flexible endoscopes are used to perform minimally invasive diagnostic and therapeutic procedures. These devices can be guided through narrow winding routes, such as the digestive tract and blood vessels, to allow physicians to view and access internal body structures less invasively than would otherwise be possible. Because they are used within the body, flexible endoscopes become contaminated during use. Thus, between uses they must be reprocessed to reduce the risk of spreading infection among patients.

Reprocessing consists of cleaning followed by either sterilization or high-level disinfection (HLD). The choice of which process to use typically is made by the healthcare facility, taking into account clinical guidelines, manufacturer recommendations, and how the device is used.

The reprocessing protocol involves many steps that need to be followed diligently to ensure that an endoscope is reprocessed properly. The protocol involves, for example, multiple cleaning stages, leak testing, exposure to an appropriate sterilant

or disinfectant for a minimum duration and at an appropriate temperature, and appropriate rinsing and drying. Even the manner in which an endoscope is transported to the reprocessing room is a consideration.

Complicating matters is the fact that different models of endoscopes, even from the same manufacturer, might have different reprocessing requirements and guidelines. Furthermore, it is important to recognize that reprocessing just the endoscope is not sufficient. A variety of accessories—such as those used for irrigation or suction or to provide therapy—may also become contaminated during use and must be properly reprocessed or replaced.

Some steps in the reprocessing protocol can be automated by the use of devices that perform the desired function. Units that are dedicated to the HLD of flexible endoscopes are known as automated endoscope reprocessors (AERs). Alternatively, sterilizers—specifically those that employ low-temperature sterilization techniques, such as ethylene oxide (EtO), gas plasma, and liquid chemical sterilization—can be used. (The use of

STERIS SYSTEM 1E IS AVAILABLE

As users of the Steris System 1 (SS1) Sterile Processing System are aware, the U.S. Food and Drug Administration (FDA) recommended in December 2009 that hospitals begin developing plans to discontinue use of that system. Some of these users may be considering replacing the SS1 with the recently introduced Steris System 1E (SS1E) Liquid Chemical Sterilant Processing System. Although the SS1E was recently cleared by FDA, there has been some confusion over appropriate use of the new system. ECRI Institute is reviewing the issues affecting the SS1E and will discuss them in an upcoming issue of *Health Devices*.

low-temperature techniques is required to prevent damage to an endoscope's heat-sensitive components.) Common design features and factors of use for endoscope reprocessing units are described in the box on page 353.

Terminology note. For simplicity, we sometimes refer to both AERs and sterilizers by the more generic term “endoscope reprocessors,” or simply “reprocessors.”

AVOIDING THE PITFALLS

If flexible endoscopes and all associated accessories are used and maintained properly, and if all the required reprocessing steps are followed diligently, the risk of patient infection is very low. To help ensure that endoscopes are being reprocessed effectively, we recommend that healthcare facilities perform the steps outlined below. Each step is discussed in more detail in the sections that follow.

1. Develop and adhere to an effective reprocessing protocol—It is imperative that healthcare facilities have in place protocols with model-specific guidelines and instructions for reprocessing endoscopes and their accessories.
2. Select and use endoscopes and endoscope reprocessors or reprocessing methods that are compatible—Reprocessing endoscopes in an incompatible reprocessor or using an incompatible method can compromise the reprocessing procedure and cause damage to the endoscope.

3. Implement a comprehensive quality assurance (QA) program—Such a program can help ensure adherence to the proper reprocessing procedures and ensure the continuing quality of the reprocessing protocol. A comprehensive QA program will address, for example, regular training of personnel involved in reprocessing flexible endoscopes, monitoring of staff compliance with established protocols and procedures, periodic review of the protocol to ensure that it is still relevant in the current environment (e.g., that it doesn't include obsolete workflows or equipment/chemicals that are no longer in use at the facility), and documentation requirements to help you identify affected patients if a problem with the reprocessing procedure is later identified.

Components of a Reprocessing Protocol

The specific reprocessing requirements for individual endoscopes can differ from one model to the next. However, a flexible endoscope reprocessing protocol will typically incorporate the following steps.

Precleaning. This step is typically performed in the room where the procedure was performed, beginning immediately after the use of the endoscope. Precleaning begins the process of removing gross contamination—such as blood, feces, and respiratory

secretions—before it dries on the endoscope. This step involves wiping the exterior of the endoscope and irrigating all the channels with an enzymatic detergent solution. Personnel performing the cleaning should wear appropriate protective equipment, such as gloves, chemical-resistant gowns, goggles, and face shields.

Between patients, personnel should also clean any surfaces in the procedure room that came in contact with contaminated endoscopes or accessories, using a hospital-grade disinfectant.

Transport from the procedure room to the reprocessing room. Once precleaned, the endoscope needs to be taken to the reprocessing room, where the remaining reprocessing steps will be performed. The precleaned endoscope should be transported in an enclosed, leakproof container to minimize the risk of any airborne or droplet contamination being dispersed into the environment or contacting personnel. The container should be large enough to allow loose coiling of the endoscope to prevent damage to its internal structures and reduce the risk of endoscope puncture. Detachable components and accessories should be transported separately to prevent damage to the endoscope. It is important that the transport case for precleaned (but still contaminated) endoscopes be different from the carrying case used to transport clean and reprocessed endoscopes.

If a reusable case is used to transport precleaned endoscopes, the case should be cleaned with a germicidal agent between transports. The case should be constructed

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ENDOSCOPE REPROCESSING UNITS: AN OVERVIEW

Devices that are designed to reprocess flexible endoscopes can automate some of the steps required in the reprocessing protocol; such devices can help ensure consistent reprocessing each time. Endoscope reprocessors may either sterilize flexible endoscopes or subject them to high-level disinfection (HLD); the latter devices are known as automated endoscope reprocessors (AERs). Some of the available units can reprocess only a single endoscope at a time, while others can accommodate multiple endoscopes simultaneously.

Individual device designs vary. An endoscope reprocessor may include, for example:

- ▷ A basin with a lid—The endoscope is placed in the basin for reprocessing.
- ▷ Channel tubing with adapters—These components are used to irrigate the endoscope channels.
- ▷ A timing mechanism—This mechanism is used to control the soaking and channel irrigation times of the reprocessing phases.
- ▷ Fluid pumps and air pumps—These pumps circulate fluid (such as germicidal solution, water, or alcohol) and air as required.
- ▷ A heater—The heater maintains appropriate temperature parameters as recommended by the germicidal agent vendor.
- ▷ A reservoir for storing the germicidal agent.

Most endoscope reprocessors incorporate a dwell phase, during which the endoscope is exposed to a germicidal agent for a particular time and at a particular temperature, to achieve adequate reprocessing (either sterilization or HLD). All channels and valves are also exposed to the germicidal agent. However, after the dwell phase, some units also include a water rinse phase, during which the endoscope is rinsed with filtered water to remove any germicidal agent residues. In addition, some units include steps such as a detergent cleaning phase (before the germicidal agent exposure) and

an automated alcohol flush and forced-air drying phase at the end of the cycle (mostly AERs).

A few factors to consider when using endoscope reprocessors are:

Endoscope-model-specific requirements. Endoscopes vary in design based on the model type and function, and these design variations can lead to different reprocessing requirements. To ensure effective reprocessing of endoscopes, reprocessing staff must be trained to recognize the differences between models. This is true for both manual and automated reprocessing protocols. For example, the elevator wire channel of most duodenoscopes is not properly disinfected by many AERs and must therefore be disinfected manually.

Correct channel adapters. Each endoscope model might require unique channel adapters to ensure adequate reprocessing by an automated reprocessing unit (mainly for AERs and liquid chemical sterilant processing systems). The different adapters might look similar, and it is important that the staff recognize which adapter is required and that they connect the right one to the endoscope. The connection of a wrong adapter might affect fluid flow through the channel, leading to improper reprocessing of the endoscope. These adapters must fit snugly with no leaks. They should also be examined for cracks and poor fit and replaced as needed.

Filter replacement. Some reprocessors (mainly AERs and liquid chemical sterilant processing systems) contain a tap-water filtration system with a bacterial filter to prevent bacteria from coming in contact with the endoscope during rinsing. These filters need to be checked for proper operation and replaced periodically based on the reprocessor manufacturer's recommendations. It is important that the personnel who maintain the automated units be aware of the need to inspect and replace these filters.

of material that permits cleaning (e.g., it should not include foam or other materials that may soak up blood) and be able to withstand repeated cleaning. The same care should be taken regarding the cleaning of the cart used in the transport.

Leak testing. This step helps detect damage to an endoscope before the device is immersed in any detergent solution. Reprocessing a damaged endoscope could lead to the cleaning solution coming into contact with endoscope surfaces that are not designed for fluid exposure, leading to further endoscope damage that might require extensive repairs. Additionally, a damaged endoscope might not be able to

be adequately reprocessed; for example, there is a chance that organic debris could get into areas of the endoscope that are not usually exposed to reprocessing solution and that this debris could be flushed into a patient during the next use.

During the leak test, the endoscope is pressurized with air and submerged in water. If air bubbles appear in the water, the endoscope is damaged. Some endoscope manufacturers require that a “dry leak test” be performed first. In this test, the endoscope is pressurized with air but not immersed in water; large leaks can be identified by looking for decreases in pressure over time. If large leaks are detected,

the endoscope should not be submerged in water to avoid fluid damage.

Automated leak testing is available as an option on some endoscope reprocessors.

Manual cleaning. After it has been tested for leaks, the endoscope needs to be manually cleaned with an enzymatic detergent; this continues the process started by the precleaning step, which removes some but not all of the gross contamination. Manual cleaning is a more elaborate process than precleaning. Without meticulous manual cleaning, it would not be possible to fully decontaminate an endoscope. Traditional endoscope reprocessors cannot

remove gross contamination, nor can the germicidal agents used in these processes reliably penetrate the debris to disinfect/sterilize the surfaces below.* Also, organic material can deactivate some of the germicidal agents used.

Manual cleaning involves the following:

- ▷ Immersing the endoscope in the detergent solution—To allow the solution to contact all the endoscope surfaces, all detachable parts are removed. The disposable parts are discarded, and all removable, reusable parts are cleaned separately. The ratio of water to detergent and the required water temperature are specified by the detergent manufacturer.
- ▷ Brushing and wiping the debris from the device's exterior surface.
- ▷ Cleaning individual endoscope channels with a brush—Reusable brushes should be cleaned and disinfected between uses, and damaged brushes should be discarded.
- ▷ Connecting endoscope-manufacturer-supplied cleaning adapters to the endoscope (to permit adequate flow of solution) and flushing all the channels with a detergent solution.
- ▷ Soaking the endoscope in the detergent solution—The duration of the soak period is specified by the detergent manufacturer.
- ▷ Rinsing the endoscope with water.

An additional step in manual cleaning might be to use forced air to remove excess water from the endoscope before disinfecting or sterilizing it.

High-level disinfection/sterilization. After manual cleaning, the endoscope undergoes

either HLD or sterilization. Typically, the decision whether to sterilize or disinfect an endoscope is made by the healthcare facility, considering clinical guidelines and the use of the device, although sometimes endoscope manufacturers specifically recommend either HLD or sterilization for a particular endoscope. HLD or sterilization can be performed manually or using endoscope reprocessors.

If this process is to be performed manually, the endoscope and its detachable components must be soaked in a germicidal agent for a minimum duration and within a specified temperature range. Endoscope manufacturers typically provide a list of germicidal agents that can be used to decontaminate their endoscopes, and germicidal agent vendors usually provide the temperature and duration of exposure required to obtain adequate disinfection or sterilization.

If, instead, an endoscope reprocessor is to be used, the above-mentioned steps are automated. That is, the unit exposes the endoscope to the germicidal agent at a particular temperature and for a particular duration to achieve adequate decontamination. If the detachable components of an endoscope cannot be placed in an endoscope reprocessor, they must be separately exposed to a suitable germicidal agent. Each automated method/system has its own specific requirements. For example: AERs may require specific channel connectors to ensure adequate reprocessing of all channels in an endoscope. Sterilizers, on the other hand, may require dry instruments, may be limited to use with instruments with specific lumen sizes, or may require that instruments be wrapped.

It is also important to note that while some reprocessor units are sold with specific germicidal agents (provided by the same manufacturer), others might be compatible with multiple agents provided by an independent vendor. However, the exposure parameters may vary for different agents, and thus the reprocessor

manufacturer may need to make changes to the system (e.g., adjusting the time and temperature of exposure) so the unit can be compatible with the agent chosen by the healthcare facility.

Some germicidal solutions can be reused—that is, after exposure of one endoscope, the same solution can be used for another endoscope. In such cases, the germicidal agent vendors indicate the maximum reuse period. Reuse is allowable until the minimum effective potency/strength level is no longer met or until the reuse period expires, whichever comes first. The germicidal agent vendor will provide test strips to test the strength of the solution; users are required to test the solution periodically (typically before each use). Some chemical germicides may require specific pH ranges to maintain the efficacy of their solution. Healthcare facilities should make sure that their water is tested and falls within the pH range for any germicide it uses.

Rinsing and drying. When a liquid chemical germicide (LCG) has been used, the endoscope is typically rinsed with filtered water after exposure to the LCG to remove any chemical residue. This may be done manually or by an endoscope reprocessor, if one is used. For endoscopes that have undergone HLD, the channels are then flushed with 70% to 90% ethyl or isopropyl alcohol and dried using forced air. This should be performed manually if HLD is performed in an AER that does not include an alcohol flush and air purge cycle.

Storage/handling. Storage and handling instructions usually depend on the type of device used or the type of reprocessing method. Proper storage and handling are important to ensure that the endoscope can be reused without the risk of infection.

Typically, endoscopes subjected to gas sterilization processes are wrapped for storage (to maintain sterility) and unwrapped only within a sterile environment (e.g., in the OR). Some reprocessor manufacturers may require that sterilized

* However, ECRI Institute is aware of one AER that has been granted marketing clearance by FDA with a clinical indication stating that certain manual cleaning steps are not required if certain rinse/wash cycles are used. Data assessing this unit's ability to perform effective cleaning has been recently made available. For more information, see: www.biomedcentral.com/content/pdf/1471-2334-10-200.pdf.

endoscopes be used immediately after sterilization and may contraindicate storage of the endoscopes.

Endoscopes subjected to HLD must typically be stored in a moisture- and humidity-free environment, thus discouraging microbial growth. The endoscopes should be hung vertically, without touching each other, in a dust-free and well-ventilated storage area. To prevent recontamination of reprocessed devices, it is recommended that the storage area be located outside the procedure and reprocessing rooms. All the detachable accessories should be removed and stored separately.

Selecting Compatible Endoscopes and Reprocessors

Even the best reprocessing protocol can be undermined if the equipment and processes being used are not compatible. Incompatibilities between any of the three components involved—the endoscope, the endoscope reprocessor, and the germicidal agent—can prevent the endoscope from being adequately decontaminated or can cause expensive damage to it.

For proper and adequate reprocessing,

1. the endoscope must be chemically compatible with the germicidal agent—that is, the agent should not damage the endoscope material—and
2. the endoscope must be physically compatible with the reprocessor—that is, the endoscope should fit in the unit, and the reprocessor should offer the correct adapters for that particular model of endoscope, when applicable, to ensure reprocessing of all its channels and surfaces.

Compatibility of devices and methods will be considered when a reprocessing protocol is established, but it also needs

to be periodically reassessed—specifically when

1. a healthcare facility is looking to purchase a new endoscope,
2. a healthcare facility is looking to purchase a new endoscope reprocessor, or
3. an endoscope or reprocessor manufacturer changes its guidelines or recommendations. (Manufacturers do occasionally make changes; users should be aware of any such changes and update their own reprocessing practices accordingly.)

Depending on the range of endoscopic procedures performed at a healthcare facility and the size of the endoscope inventory, verification of compatibility can be a daunting task. The manufacturers of the endoscope and the reprocessor—and, if applicable, the supplier of the germicidal agent—will all have their own recommendations and guidelines regarding reprocessing. The hospital has the task of trying to ensure that the recommendations are all consistent and achievable and that any discrepancies are resolved.

SOURCES OF COMPATIBILITY INFORMATION

As mentioned, the germicidal agent supplier and the equipment manufacturers all have a part to play in establishing the compatibility of the various devices and processes. Below we describe the roles and responsibilities of the vendors involved.

Germicidal agent vendor. It is the responsibility of the germicidal agent vendor to state the conditions required to obtain adequate reprocessing using its agent. The germicidal agent vendor typically provides the following information:

- ▷ Exposure time (how long any device needs to be exposed to the agent).
- ▷ Temperature of the agent at the time of the exposure.

- ▷ Reusability of the agent and, when applicable, the maximum number of reuses and/or the reuse period.
- ▷ When applicable, the minimum effective strength/potency of the agent required to obtain adequate reprocessing (and a means to assess agent potency).

Endoscope reprocessor manufacturer. It is the responsibility of the reprocessor manufacturer to ensure that its system meets the necessary conditions (e.g., time and temperature of exposure) to achieve adequate reprocessing as stated by the suppliers of the germicidal agents for which the reprocessor is specified to be compatible. Reprocessor manufacturers typically provide the following information:

- ▷ The germicidal agent(s) to be used in the unit (some units can use multiple agents, although the unit may need different settings with each agent).
- ▷ When applicable, the required temperature for incoming water. If the incoming water is too cold, the device's internal heater may not be able to heat it to the appropriate temperature or may take too long to do so.
- ▷ Whether the unit is able to recover the agent for multiple uses.
- ▷ Compatibility of various endoscope models with the system. The reprocessor manufacturer tests various models of endoscopes to confirm compatibility—typically physical compatibility. That is, the manufacturer confirms that the endoscope fits and that the appropriate parts of the endoscope are exposed to the agent for the right amount of time. In cases for which a single company makes both the agent and the reprocessor, the company may also make claims for material compatibility. (Sterrad and Steris are two companies that do this.) When required, the reprocessor manufacturer provides the

appropriate connectors and adapters for the compatible endoscopes.*

Endoscope manufacturer. Endoscope manufacturers typically provide the following information:

- ▷ Material compatibility of their endoscopes with various generic reprocessing methods/agents.
- ▷ Instructions for cleaning and manual processing.

Endoscope manufacturers almost never recommend the use of a specific endoscope reprocessor. They provide only a list of germicidal agents that can be used with their endoscopes. They might occasionally recommend against using a particular reprocessor, but that usually occurs only when the reprocessor uses an agent that may be incompatible with their endoscope.

THE NEED FOR FURTHER ANALYSIS

The hospital must ensure that the endoscope, the endoscope reprocessor, and the germicidal agent work together to adequately reprocess the endoscope without damaging it. To do this, the hospital must rely on information obtained from the endoscope and reprocessor manufacturers. Under certain conditions, however, ensuring compatibility can be more complicated than simply obtaining compliance statements.

First of all, it is important that the facility correctly interpret the information it obtains. For example, endoscope and reprocessor manufacturers sometimes use expressions like “listed as not compatible” and “not listed as compatible” when referring to a germicidal agent or an endoscope model. Users need to understand the difference between the two statements. The

former indicates that the agent/model was tested and found incompatible, while the latter typically indicates that the agent/model was not tested and thus information regarding its compatibility is indeterminate.

Second, the healthcare facility may find that the recommendations of the endoscope manufacturer contradict the recommendations of the reprocessor manufacturer. For example, while a reprocessor manufacturer might confirm the compatibility of its unit with a specific endoscope model, the endoscope manufacturer might either recommend against the use of that reprocessor, based on incompatibility of the germicidal agent with the endoscope material, or simply not provide compatibility information (e.g., if it hasn’t tested its endoscopes for the agents used in that unit).

In cases in which an endoscope manufacturer does not provide compatibility information, the manufacturer might suggest that using the “unlisted” agent may lead to endoscope damage, which might not be covered by its warranty. Such situations place the hospital in an awkward position, especially if the reprocessor being considered offers significant workflow or other advantages over other alternatives.

There often is not a simple best answer. However, the following recommendations can guide your decision:

- ▷ If the reprocessor supplier states that the endoscope is not compatible, the reprocessor should not be used for that endoscope.
- ▷ In cases where the reprocessor supplier lists the endoscope as compatible:
 - If the endoscope supplier lists the endoscope as “not compatible,” we generally recommend against using the reprocessor for that endoscope.
 - If the endoscope supplier does not provide compatibility information or recommendations, the hospital will need to decide

whether to use the reprocessor, taking into consideration that the endoscope could possibly be damaged by the agent and the endoscope manufacturer may claim that such damage is not covered under warranty.

- If the endoscope supplier lists the endoscope as compatible, then the reprocessor can be used with that endoscope.
- ▷ If the reprocessor supplier does not offer a compatibility statement, ask the supplier to test that endoscope model for compatibility, and follow the above recommendations based on the supplier’s findings. If the supplier does not perform testing and compatibility information is not available, then the reprocessor should not be used for that endoscope.

RECOMMENDATIONS WHEN PURCHASING NEW EQUIPMENT

When buying a new endoscope, healthcare facilities should check the compatibility of the endoscope with the reprocessors currently in use at the facility. Users should also verify that they have the proper channel connectors (when applicable) and reprocessing accessories required to adequately reprocess the endoscope.

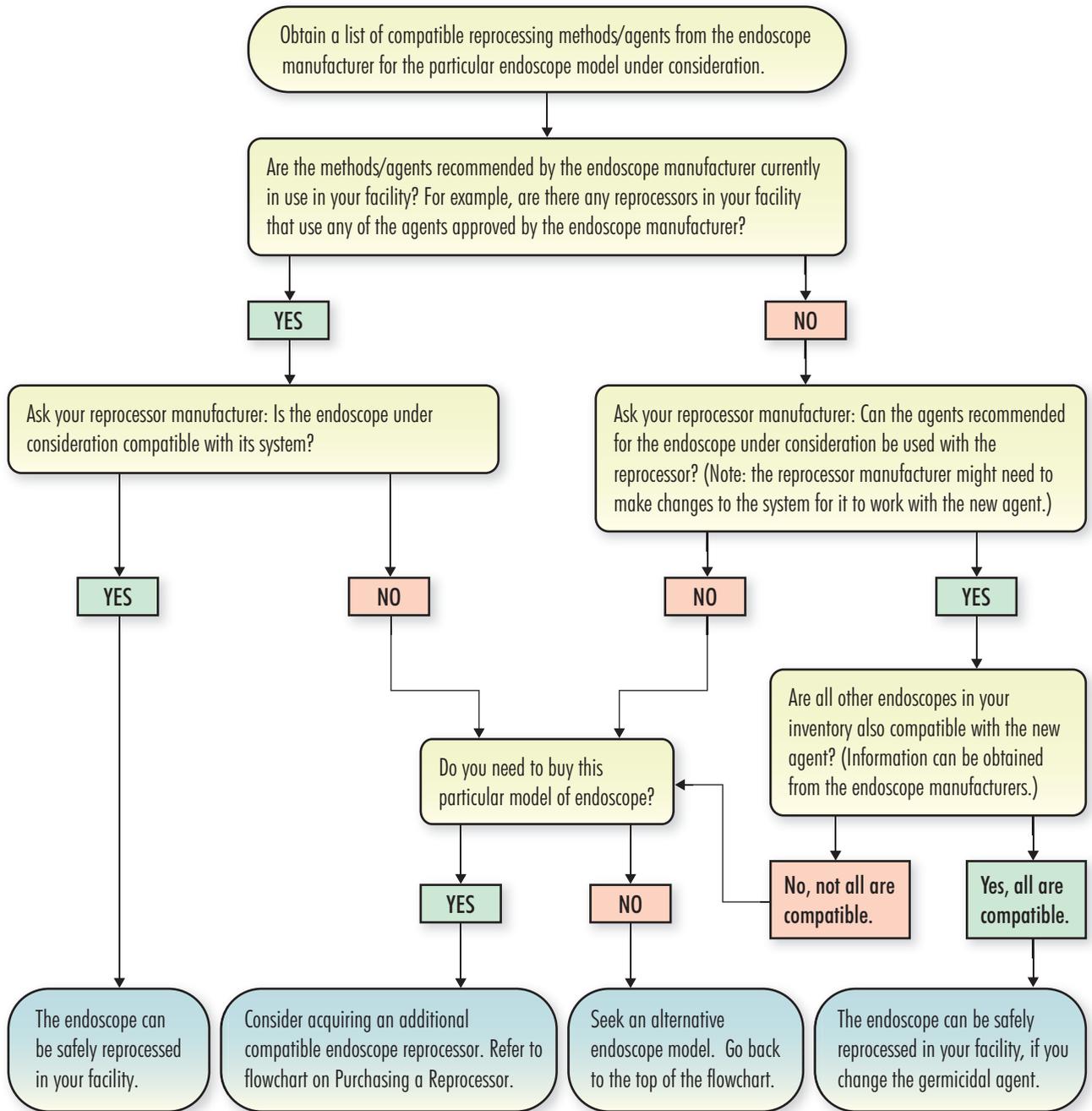
Similarly, when buying a new reprocessor, facilities should ensure that the unit is compatible with the bulk of their endoscope inventory.

We present two flowcharts to guide users through the process of verifying compatibility claims between the various components to ensure the adequate reprocessing of endoscopes. The first chart applies when purchasing a new endoscope (see page 357); the second applies when purchasing a new reprocessor (see page 358).

* Reprocessor manufacturers may maintain a list of endoscope models compatible with their systems. However, the list is rarely distributed to users or made public. Healthcare facilities looking for compatibility information are typically required to provide specific endoscope model numbers to the manufacturer, who will confirm compatibility with its endoscope reprocessors.

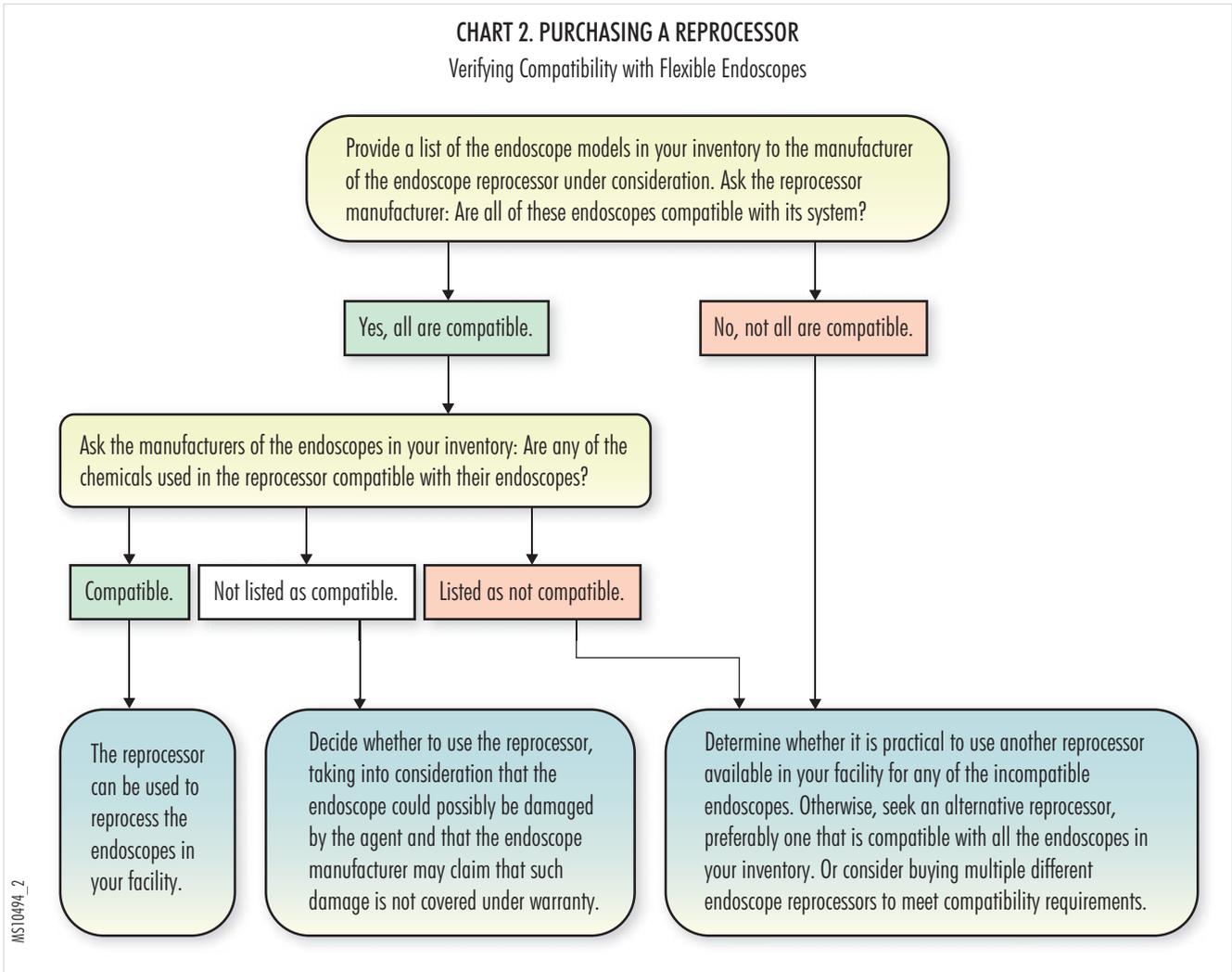
CHART 1. PURCHASING A FLEXIBLE ENDOSCOPE

Verifying Compatibility with Reprocessors



MS10494_1

CHART 2. PURCHASING A REPROCESSOR
Verifying Compatibility with Flexible Endoscopes



MS10494_2

Characteristics of a Quality Assurance Program

A comprehensive QA program can help ensure the quality of the reprocessing protocol and adherence to the proper reprocessing procedures. In addition, data collected as part of the program can facilitate the identification of at-risk patients in the event that a problem with the reprocessing procedure is discovered.

A comprehensive endoscope reprocessing QA program should incorporate the following measures:

- ▷ Ensuring compatibility between the endoscopes in your inventory and the reprocessor used. As discussed above, the reprocessing of endoscopes in an incompatible reprocessor can compromise the reprocessing procedure and/or cause damage to the endoscope.
- ▷ Training all employees on the current and correct reprocessing procedures and providing them with information on maintaining a safe environment, handling germicidal agents/detergents, disposing of wastes, etc. Training should occur at regular intervals, and each worker involved in endoscope reprocessing should be given an initial and annual competency review. Be sure to document the training and review processes.

- ▷ Ensuring competent supervision of reprocessing personnel by a knowledgeable individual.
- ▷ Ensuring that the staff has access to written, device-specific reprocessing instructions for every model of endoscope and that the instructions are in accordance with the guidelines and recommendations of the reprocessor and endoscope manufacturers.
- ▷ Assigning responsibility for monitoring compliance with the reprocessing protocol.
- ▷ Ensuring adequate documentation of endoscope use and reprocessing. In the event that it is discovered that an endoscope hasn't been adequately reprocessed, thorough documentation of an endoscope's clinical use—that is, patients on whom the endoscope was used—and decontamination process can facilitate identification of at-risk patients. Medical records may not identify the particular endoscope used on a patient or the endoscope reprocessor used to decontaminate the endoscope. It is up to the individual healthcare facility to implement processes that capture appropriate identifying information.
 - Documentation of the endoscope's clinical use should include patient identification information along with the date of the procedure, the type of procedure, the responsible physician's name, and a unique identifier (e.g., serial number, facility-assigned endoscope identification number) for the endoscope used.
 - Documentation of the reprocessing procedure should capture the endoscope model number, a unique endoscope identification number, the reprocessing steps performed on that endoscope, a unique identifier for the endoscope reprocessor, and all key cycle parameters (temperature, time of exposure, the chemicals or methods used, etc.). Some reproprocessors provide

a printout of some of the information, but users will need to document other information to obtain a full record. It is important to maintain records of each reprocessing cycle for each endoscope.

Note that some reproprocessors available on the market have features that facilitate automatic documentation of endoscope use and reprocessing. Using radio-frequency identification (RFID) or bar coding to capture patient and endoscope identifiers, these reproprocessors can be networked to a PC or an information system to automatically capture an electronic record of the reprocessing cycle.

Recognize that a healthcare facility might face some challenges when trying to implement good documentation practices. Some of these challenges include inaccurate recordings, changing inventory, changing personnel, and clinician resistance.

- ▷ Establishing a process for reporting reprocessing-related infections or lapses in reprocessing procedures to the facility's infection control department and, as appropriate, to public health agencies—such as FDA and the U.S. Centers for Disease Control and Prevention—and the reprocessor and endoscope manufacturers.
- ▷ Ensuring that sufficient reprocessing supplies are available at all times.
- ▷ Establishing a preventive maintenance program for endoscope reproprocessors.
- ▷ Periodically reviewing and updating the reprocessing protocols.
- ▷ Ensuring that the facility has processes in place to allow rapid response to hazards and recalls.

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