— documentation of physical and chemical monitoring; and

— adherence to device, LCS/HLD, and automated processing equipment manufacturers' written IFU.

b) **Gaseous and vapor chemical sterilization processes.** Performance measures should include, but are not limited to, the following:

— verification of training and continuing education;

— correct loading of items into the sterilizer chamber;

— selection of chemical sterilization cycle parameters;

— selection and use of CIs and BIs;

— accurate load records;

— documentation of physical, chemical, and biological monitoring; and

— adherence to device and sterilizer manufacturers' written IFU.

c) **Handling and transfer.** Performance measures should include, but are not limited to, the following:

— selection and use of attire;

— correct techniques for unloading the sterilizer, automated processing equipment, or solution container; and

— correct techniques for transferring items to the point of use.

A root cause analysis should be completed when a patient safety event occurs (not primarily related to the natural course of the patient's illness or underlying condition) results in death, permanent harm, or severe temporary harm (Joint Commission, 2015 [188]).

Rationale: Controlling variables in the system can help to ensure quality and process efficacy. Ensuring that high-level disinfection or liquid or gaseous and vapor chemical sterilization has been achieved will minimize the potential risk to patients. Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Analysis of this information provides a method of identifying problems or shifts in activities and making improvements in the system.

13.14.6 Functional areas for product and process improvement

13.14.6.1 Workplace design

Optimization of product and process performance relies on efficient workplace design. Problems such as cross-contamination, excessive processing costs, product failures, inefficient time usage, and so on can be created or exacerbated by poor workplace design. Workplace design encompasses the following:

a) the physical layout of the processing area;

b) the functional workflow patterns;

c) the physical facilities (e.g., the mechanical and electrical systems, lighting, plumbing, ventilation, environmental controls); and

d) the types and locations of processing equipment and supplies.

13.14.6.2 Processing policies and procedures

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process. The review of records and of documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process. Written procedures should be reviewed, and current practices should be audited for compliance in the areas included in the CQI program. Examples of CQI program areas include the following:

a) training, continuing education, and competency verification;

b) product identification and traceability (i.e., lot control numbers and load records);

c) monitoring cleaning effectiveness;

d) monitoring manual processes that use LCSs/HLDs;

e) monitoring automated processes that use LCSs/HLDs;

f) monitoring gaseous and vapor chemical sterilization processes;

g) product testing;

h) product recalls; and

i) workplace safety training (including safe use of chemicals and safe handling of biohazards).

13.14.6.3 Product use

Evaluating the performance of products that have been or will be used can offer important feedback on the effectiveness of the process and the products selected. Performance measures can come from internal evaluations, end-user feedback, supplier testing, and repair records:

a) **Internal evaluations.** Internal evaluations can be used to audit the quality of finished products. For example, instruments can be checked for functionality, packaging, and delivery. Preprocessing decontamination can be evaluated by visually examining instruments for contamination. Product recalls can be evaluated by reviewing records of actions following documented chemical sterilization or high-level disinfection process failures. Periodic product monitoring can be evaluated on the basis of the loads or cycles tested and the actions taken as a result of failures.

b) **End-user feedback.** A formal documented system to log, investigate, and resolve complaints and product failures should be established. Issues such as patient infections, PPE failures, and malfunctioning endoscopes should be documented, monitored, and tracked over time. A procedure should be established for investigation and remediation of serious and repeat problems.

c) **Supplier testing.** The manufacturer should thoroughly analyze concerns relative to the performance of products or supplies through testing or other means. Processing personnel should make a written request to and receive a response from any vendor whose products, supplies, or services are in question. All correspondence should be filed with the corresponding complaint, including details of the investigation, the findings, and any actions taken by the vendor to resolve the problem.

d) **Repair records.** Review of instrument repair records might show a pattern. Once identified, the cause for the repair can be reviewed, corrected, and then monitored to ensure that the problem has been resolved.

13.14.6.4 Implementation of product and process improvements

There is no single right way to implement a CQI program. The program should be customized to the individual facility. However, a team approach has been proven to be successful because it allows direct input from multiple employees and results in a superior program.

Employees who are actively involved in and responsible for the day-to-day functions outlined in the plan should be members of the team. This approach should generate input from those most knowledgeable in methods of effectively improving the program. Additionally, such involvement may promote a sense of ownership that may lead to a higher degree of commitment on the part of those endoscope processing team members implementing the program.

The single most important issue for those charged with implementing a CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the CQI program). The frequency and type of information generated will vary depending on the level of control established in the documentation plan. Facilities with processes that are uncontrolled or highly variable will require increased process monitoring and documentation, which can be reduced over time as the program brings these processes under improved control.

Occupational safety is symbiotic with patient safety and is a key part of the quality system. Occupational safety records that should be kept as part of the quality system include

a) maintenance records such as exhaust air flow checks;

b) exposure records from gas monitors;

c) employee safety training (chemicals used on-site, OSHA Hazard Communication Standard, emergency procedures, work instructions for safe use of equipment); and

d) medical evaluation of personnel using respirators.

The CQI program should assess all components of chemical sterilization and high-level disinfection processes for the ongoing ability to achieve the desired outcome of consistently delivering an efficacious product to the user. Performance improvement plans, when needed, should be implemented to enhance chemical sterilization and high-level disinfection processes on the basis of this assessment. Examples of measures to be considered when assessing chemical sterilization and high-level disinfection processes include trending data over a defined time period related to

a) the number of items processed;

b) the number of failed cleaning verification tests, if applicable;

c) the number of BI tests, if applicable;

d) the number of BI failures for each chemical sterilization process, if applicable;

e) the number of physical parameter failures;

f) the number of failed CIs, if applicable;

g) the number of spore test strips, if applicable;

h) the number of spore test strip failures, if applicable;

i) the number of solution test strip or chemical monitoring device failures for processes that use LCSs/HLDs;

j) competency verification (the percentage of endoscope processing team members successfully completing education, training, and competency verification activities);

k) timing and completeness of preventive maintenance of gaseous and vapor chemical sterilizers and automated processing equipment;

l) ability to locate all items during recalls;

m) completeness of test records;

n) results of microbial surveillance culturing, if applicable; and

o) occupational safety records.

For more information about implementing a quality management system approach, see ANSI/AAMI ST90 [18].

14 Device repair and loaned endoscopes

14.1 General considerations

Flexible and semi-rigid endoscopes and accessories shall be carefully inspected to identify defects or malfunctions during each step of processing and prior to patient use. Defects and malfunctions identified during use shall be clearly described as to the location and nature of the defect or malfunction and reported according to facility procedure. Routine preventive maintenance should be addressed in each facility policy and procedure. Processing staff should be aware of endoscope preventive maintenance and repair strategies.

Transport or shipping is done following decontamination and disinfection or sterilization procedures, including drying, for damaged endoscopes. A device to be shipped for repair should be placed in a securely sealed, leak-proof primary container. If the endoscope is considered contaminated, the package must be clearly identified as contaminated material and must be packaged, labeled, and shipped in accordance with the manufacturer's written IFU, the requirements of the carrier (U.S. Postal Service or private carrier), and the applicable U.S. Department of Transportation (DOT) regulations (49 CFR 170–178). Endoscopes that are processed are packaged, labeled, and shipped in accordance with the manufacturer's written IFU, the requirements of the carrier (U.S. Postal Service or private carrier), and with the applicable U.S. DOT regulations (49 CFR 170–178). The shipper is responsible for correct packaging and labeling.

A facility-specific policy and procedure shall be in place with details on communication and method when a defect or malfunction is detected at the point of use. The policy and procedure should specify the:

a) responsibility and accountability for defect and/or malfunction documentation;

b) processing procedures for repair handling;

c) records to be kept, including repair information;

d) review of repair records to determine trends; and

e) review of repair records to identity endoscopes and/or accessories requiring replacement or follow-up.

Regulatory reporting can be required.

14.2 Point of use detection and communication

At the point of use, an endoscope and/or accessories in need of repair should be clearly identified before processing and removed from service until processed, repaired, and processed before reuse. For removal from service and transport, the endoscope and/or accessories should be placed in a containment device to prevent additional damage.

For a device identified as defective or malfunctioning at the point of use, a tag should be affixed and include the following information:

a) flexible or semi-rigid endoscope serial number or unique identifier;

b) date of occurrence;

c) time of occurrence;

d) department or procedure room where procedure was performed (e.g., Procedure Room 3);

e) endoscopist;

f) a clear description of the malfunction or defect (e.g., “foggy” view, unable to articulate distal end, irrigation not flowing, suction not working, unable to pass biopsy forceps through channel); and

g) name of individual completing the report.

14.3 Processing area detection and communication

Flexible and semi-rigid endoscope and/or accessories identified for repair should be placed in a designated location to be processed, following the manufacturer’s written IFU for damaged endoscope processing, before additional examination, repair, or shipping to another facility for repair.

Following processing, the damaged endoscope and/or accessories should be delivered to the designated location for repair.

Additional information should be added to the defect/malfunction tag initiated at the point of use:

a) failed or passed leak test, for endoscope to be repaired;

b) condition of all channels (e.g., cleaning brush passed easily, channel easily flushed);

c) condition of accessories (e.g., suction valve cannot be inserted);

d) condition of external surface (e.g., head of endoscope scratched in area of biopsy port);

e) date of processing;

f) time of processing;

g) process used to achieve high-level disinfection or sterilization;

h) name of individual completing the processing; and

i) name of individual completing the report.

14.4 Health care facility point of repair transfer

The facility’s designated process should be in place to notify the repair person or vendor.

Documentation should include the tracking number or identification of the individual picking up the items for repair, the date, and the time.

14.5 Return to health care facility from repair

Documentation from the repair service should include the following:

a) method, date, and time of return;

b) decontamination procedure performed by repair facility;

c) type of service performed;

d) parts replaced; and

e) recommendations for future prevention of damage.

Upon return from repair, the endoscope and/or accessories should be carefully inspected by the receiving facility for defects or malfunction prior to return to service.

The endoscope and/or accessories returned from repair shall be fully processed in accordance with the health care facility processing policy before patient use.

14.6 Loaned endoscopes

14.6.1 Policy and procedure

There should be a facility policy and procedure for lending or borrowing flexible or semi-rigid endoscopes**.** The policy should be developed in conjunction with infection prevention and control, risk management, materials management, perioperative services, GI/endoscopy, clinical engineering, and other personnel as deemed necessary. Personnel should be knowledgeable in the facility's policies and agreements for loaned endoscopes. A request for a loaned endoscope to be used during the repair period should be made only after facility policies established to maintain records, including patient traceability, are considered. The policy and procedure should address the following:

a) Upon receipt, inspect the loaned endoscope for damage and consistency with the original endoscope.

   1) Ensure that the manufacturer's written IFU have been provided for the specific loaned endoscope.

   2) If any differences are noted in the loaned endoscope compared to the endoscope it replaces (e.g., it has an additional channel), in-service all staff members, with competencies verified, in processing the endoscope.

   3) Confirm that correlating processing accessories and connection adapters are available for effective processing.

   4) If any damage is noted in the loaned endoscope, contact the facility or company that loaned the endoscope to report the damage and request a replacement.

   5) Document the loaned endoscope by manufacturer, model, date received and serial number.

b) Completely process the loaned endoscope, according to the manufacturer's written IFU, before use.

c) Prior to return, completely process the loaned endoscope.

d) Inspect the loaned endoscope for damage. Document the condition of the endoscope and date of return.

For more information on management of loaned instruments, see AAMI TIR63 [24].

14.7 Use of loaned endoscopes during microbial surveillance

It might be necessary for health care facilities performing microbial surveillance to use loaned endoscopes while awaiting culture results from quarantined endoscopes. The same policy and procedures outlined in 14.6.1 apply.

14.8 Quality measures for repairs

Repeated failed cleanliness testing and/or persistent positive microbial culture surveillance results could be an indication of a damaged endoscope. The device should be removed from service and examined by a trained repair technician.

Failed functional testing (e.g., failed leak testing, angulation issue) is an indication of a damaged endoscope. The device should be removed from service and examined by a trained repair technician.

Repair history documentation should be reviewed on a periodic basis to identify trending by the following:

a) model of endoscope;

b) individual endoscope (serial number or unique identifier);

c) type of repair;

d) processing method;

e) individual(s) performing processing;

f) individual performing clinical procedure; and

g) procedure type in which the endoscope was used.

A preventive maintenance program should be in place to plan thorough inspection of all channels and working mechanisms of endoscopes and accessories for function or defects.

Infection prevention and control, processing, clinical engineering, and procedure area personnel should be part of the quality review team to:

a) review repair documentation;

b) maintain a perpetual physical inventory of semi-rigid and flexible endoscopes;

c) review competency testing results; and

d) make recommendations based on trending.

15 New product evaluation

15.1 General rationale

Periodically, new products enter the market for which AAMI does not offer guidance for application. Some products do not fall within AAMI's purview. For those that do, AAMI applies a rigorous consensus review process that includes committee discussion, balloting, public review, and subsequent publication; this consensus review process can be quite lengthy. When any product is being considered for use within a facility, it is the responsibility of the intended users to evaluate the product using a systematic process of product evaluation and to establish policies and procedures that reflect this process and that are appropriate to the health care organization. This is especially true when the health care organization is considering a product for which there are no guidelines from AAMI or other similar professional organizations.

15.2 Considerations

The following are considerations associated with conducting a product evaluation:

a) Establish a multidisciplinary committee with representation from those who will be affected by the new product. For example, for a product related to steam, low-temperature, or chemical sterilization, representation could include, but not necessarily be limited to, infection prevention and control, operating room, sterile processing, endoscopy, risk management, and staff development/education personnel.

b) Collect and distribute to the multidisciplinary committee information related to the product. Such data should include, but not necessarily be limited to, the following:

   — FDA clearance documentation, if applicable;

   — relevant research articles published in peer-reviewed journals;

   — literature and written IFU from the device, equipment and/or chemical manufacturer;

   — experts' opinions; and

   — reports from peers who are using or have trialed the product.

c) In addition to evaluating the product's intended application, consider the following:

   — ease of understanding the manufacturer's written IFU;

   — contribution to patient and employee safety;

- any legal implications associated with use of the product;
- cost/value analysis (return on investment);
- personnel education necessary to implement use;
- ease of use of the product;
- related safety issues;
- compatibility of the product with existing equipment and products;
- environmental impact;
- availability of ongoing support from the vendor for such services as maintenance; and
- impact on standardization of product inventory.

d) If a product trial is indicated, consider the following guidelines:

- establish a time limit for the trial;
- identify the personnel and departments that should trial the product;
- establish the amount of product that should be evaluated;
- evaluate the manufacturer's written IFU;
- develop evaluation tools through the multidisciplinary committee identified above;
- determine and implement the education and demonstrations needed for the trial;
- define the desired outcome; and
- analyze the data and compare the actual outcome with the desired outcome.

For more comprehensive information on the evaluation of new products, see AORN (2018f) [41].

Annex A
(informative)

Alternatives for keeping cool in the processing environment

A.1 Introduction

The healthy human body maintains a core temperature of about 98.6 °F (37 °C). Core body temperature will stay basically the same no matter what the temperature of the surrounding area might be or what the activity level of the person might be. A healthy safe core temperature is between 98 °F and 100 °F for most people. Some individuals might naturally have a core temperature that is slightly lower or higher than 98.6 °F. If a person is exposed to an environment that is very warm or very cool, the body will take steps to bring the core temperature back to the healthy range. The process of regulating core temperature is called thermoregulation.

The hypothalamus controls thermoregulation. When core temperature becomes too high or too low, the hypothalamus issues instructions to muscles, organs, glands, and the nervous system. If the body needs to cool down, the instructions will cause sweating and vasodilation to occur. As sweat evaporates, it will cool the skin, which will help lower core temperature. The central nervous system can cause the capillaries under the skin to open or dilate, which increases blood flow to the skin surface and allows the body to release heat.

There are steps that can be taken to heat or cool the body as needed. In winter, people wear additional layers of clothing, and in summer people wear lighter-weight clothing. In addition, eating cool foods like ice cream or iced drinks and cooling the pulse points of the body can help to cool the body. The opposite is also true. Eating warm foods and warming the body's pulse points will help to warm the body.

The American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) has a standard on thermal comfort, ANSI/ASHRAE 55-2013, *Thermal environmental conditions for human occupancy* [33]. This standard provides information on working in various environmental conditions and what most people would consider to be comfortable. The University of California Berkeley Center for the Built Environment has developed a tool to assist companies in determining whether the environment in a particular room meets this standard. This tool can be found at no cost on the Internet. The tool measures thermal comfort based on sustained activity for one hour. Functionality to evaluate comparisons of different variables is available. Several variables can be addressed in the tool. Detailed help information on how to use the thermal comfort tool is available through a help link on the tool's website. Information on determining the metabolic rate to be used can be found in ISO 8996, *Ergonomics of the thermal environment—Determination of metabolic rate* [48]. Information regarding the impact of clothing can be found at ISO 9920, *Ergonomics of the thermal environment—Estimation of thermal insulation and water vapour resistance of a clothing ensemble* [49].

It is possible that the protective attire worn in the decontamination area could cause workers to feel overheated and to perspire. Lowering the ambient temperature might not be an efficient mechanism for reducing body temperature. This Annex discusses alternatives for how personnel can keep cool in the sterile processing environment.

A.2 Decontamination environment

The temperature and relative humidity of the decontamination area/room of the sterile processing department is controlled to minimize potential growth of bacteria, fungi, and molds and to provide a comfortable working environment. The personal protective equipment (PPE) required to be worn when working in the decontamination area/room can be uncomfortable even when the temperature of the decontamination area is within the recommended range. Some individuals might feel overheated when working in this area and wearing PPE. Lowering the room temperature is not effective in lowering the body temperature of individuals wearing PPE because not enough skin is exposed to the air for perspiration to evaporate and cool the body. More effective alternative measures can be taken to make workers comfortable.

A.3 Protective attire

Protective attire worn in the decontamination area might be uncomfortable because it does not allow the body to disperse heat that is generated while working. Many of the protective gowns and aprons used in the decontamination area are made of plastic or other fluid-resistant materials. The plastic or other fluid-resistant material provides an excellent barrier to bloodborne pathogens, but it does not allow for the body to disperse any excess heat that might build up. This heat can cause employees to sweat, which can be uncomfortable.

A.4 Alternative cooling methods for personnel working in the decontamination area/room

Rather than being exposed to heat for extended periods of time during the course of the job, workers should, wherever possible, be permitted to distribute the workload evenly over the day and incorporate work/rest cycles. Work/rest cycles give the body an opportunity to get rid of excess heat, slow down the production of internal body heat, slow down the heart rate, and provide greater blood flow to the skin. In the evaluation of an appropriate work/rest schedule, shorter work periods and more frequent rest periods should be considered:

a) as temperature rises;

b) as humidity increases;

c) when there is no air movement;

d) when protective clothing or gear is worn; and

e) for heavier work.

In general, more frequent, shorter periods of exposure to heat are better than fewer longer exposures. Individual requirements can vary greatly (OSHA, 2019 [225]).

It is important that a person is well hydrated before donning PPE. Hydration will help to keep the body cool. Employees can take breaks to maintain hydration.

Cooling devices worn under PPE could provide additional comfort. Cooling devices can be reusable or single-use and include:

a) cooling bandanas, skull caps, or head bands;

b) cooling neck scarfs or towels; and

c) cooling vests.

Frequent breaks might also be needed so that cooling devices or cool water can be applied to body pulse points. Pulse points include the back of the neck, the inside of the wrists, the inside of the elbows, the back of the knees, the inside groin area, and the head, between the temple and ear. Applying cool water or ice to these areas can help to cool the body.

Because no two facilities or individuals are the same, it is important to establish policies and procedures to provide for the comfort and safety of the personnel working in the SPD decontamination area/room environment.

a) The plan should address the preferences of the individual worker in relation to environmental temperature and humidity and the design and capacity of the HVAC system.

b) A multidisciplinary team that includes at least representatives from infection prevention and control, facilities management, risk management, human resources, and SPD should establish the policies and procedures.

c) All staff working in the decontamination area/room should receive education and training in the dynamics of cooling the body and measures that can be taken to work comfortably while wearing PPE in the decontamination area/room.