5. New Equipment Planning

IMPORTANCE OF EQUIPMENT PLANNING

Understanding the purpose and performance expectations of the different types of reprocessing equipment available for use in SPD is a critical element of planning for new construction and frequently must be considered in SPD renovation projects. As noted in Section 3 (New Construction), once the SPD functional program is created and the reprocessing concepts have been selected, equipment planning and development becomes the primary focus as the space plan cannot be completed without it. Renovation projects are primarily driven by a focus on equipment replacement or on the addition of a new type of technology.

Annex F lists the major types of SPD equipment by functional area and might help managers be inclusive in their planning. This section of the book focuses on key features for planners to consider when comparing options and selecting the larger, more costly, and more complicated SPD equipment. Washing and sterilizing equipment requires special planning considerations related to space, circulation, utilities, ventilation, service area, workflow, functionality, infection prevention, equipment redundancy, installation, testing, and throughput capacity. Planners are encouraged to thoroughly review all of the various manufacturers' products available in each category to compare features and throughput and to estimate use and consumables costs. However, it might be a disadvantage to purchase equipment in the early stages of new construction planning; technologies and equipment features are continuously being updated, and committing SPD to a specific model is not recommended. Additionally, it might be tempting to lock in prices for a specific equipment mix at the early planning stages; however, this strategy also might provide to be disadvantageous. Some healthcare facilities taking this approach have installed equipment that was already three to five years old (with expired warranties and older technology) by the time the new SPD opened and the equipment was operational.

DETERMINING THE SPD EQUIPMENT MIX

There are many factors to consider in SPD equipment planning, and significant research and time might be required to balance effectiveness, efficiency, infection prevention and control, personnel factors, safety, cost, and space issues. In new construction, the project's SPD equipment planner might be part of the architect's consulting team, as noted previously. On the other hand, smaller renovation projects might not require a professional equipment planning consultant; a member of the healthcare facility's regular planning staff or an

interdepartmental planning team might be appointed to review options. Equipment vendors can also be a good source for throughput planning and for presenting the features of their company's products. Professional equipment planning consultants recommend that if vendors are used for throughput planning, the healthcare facility should invite multiple vendors to participate in the process to help ensure that the vendors do not "over-sell." Whatever approach is taken, the active involvement of the SPD manager (and SPD team, as appropriate) in the determination of equipment performance criteria and in the ultimate equipment selection is required.

Because many organizations select capital equipment under corporate purchasing or preferred-provider agreements, it is important that supply-chain management understand performance parameters and participate in the discussion. The healthcare facility's engineers can also provide valuable input during the equipment planning process for renovation projects by assisting planners in understanding maintenance, utilities, ventilation, plumbing, and steam supply requirements. The engineers' understanding of the current utility system might also be helpful if there are issues related to capacity. An assessment might be needed of SPD's peak operating hours, its utility requirements during this time, the requirements of other departments connected on the same steam and water lines, and the operational impact on SPD of the new equipment under evaluation. The infection preventionist's input is also desirable to ensure that the necessary infection prevention and control elements are incorporated.

There can be biases about equipment manufacturers because of experience with equipment made by the manufacturer, the manufacturer's reputation (e.g., history of product recalls), or interaction with the manufacturer's representatives. There might also be positive or negative attitudes related to the reliability of a new product, concerns about maintenance costs, or issues related to the prior service responsiveness of a particular manufacturer. It is helpful if the planning team members openly discuss their biases, past experiences, and observations, both positive and negative. These subjective elements are just as important to long-term product satisfaction as are objective factors such as equipment features or costs. The desire of the SPD team, surgeons, perioperative nurses, infection preventionist, and others to implement best practices is a key component of equipment planning for every healthcare facility. There is always the over-riding goal of accomplishing all reprocessing steps specified by the medical device manufacturers' IFU in concert with the reprocessing equipment manufacturers' IFU. Any equipment that cannot accomplish this goal should not be considered for the project. The use of appropriate equipment maintains the operational effectiveness of SPD reprocessing, as recommended by groups such as AAMI, AORN, and APIC and as required by state health departments and other accrediting agencies.

Once the equipment types required to carry out the scope of SPD's reprocessing responsibilities have been determined, the number of units necessary to meet current and projected future needs can be quantified. Some of the factors that are generally considered important to this analysis include the following:

- Current customers and workloads (as discussed in Section 3)
- Growth projections (as discussed in Section 3)
- Long-term facility planning for new services or product lines
- Desired hours of reprocessing and staffing factors
- The equipment's capacity to provide the desired process with a completed result in the shortest cycle
- Associated accessories or related equipment, such as manifolds, loading racks, and carriages
- The best use of space for multiple units of the same equipment type
- SPD's time goals for the complete reprocessing cycle (decontamination through terminal sterilization)
- STAT processing volume and fast-track capability
- Maintenance and downtime expectations
- Ergonomic and efficiency features such as automatic machine queuing and conveyor loading
- The need for redundancy of equipment that performs a key process and that might present a bottleneck to throughput if it is not available (e.g., ultrasonic cleaners)
- The ability of the equipment to contribute to the LEED process—which usually can be achieved by selecting equipment that has a lower or more efficient consumption of utilities

In addition to the items noted above, quality outcomes, personnel safety, ease of use, maintenance requirements, and workflow efficiency are all equally important considerations for determining the proper mix and number of individual units of SPD equipment.

MATERIALS REPROCESSING LIFE CYCLE

To achieve the quality outcomes for SPD reprocessing, it might be helpful to view each piece of equipment as having a specific, and yet interrelated, function that cannot be overlooked in the life cycle of materials reprocessing. Any missing equipment element, any nonfunctioning equipment element, and any short-changed process will compromise quality. For example, if the thermal disinfection expected as the process outcome of a washer–disinfector is not attained, personnel on the "clean side" (preparation and packaging) might be exposed to contamination. Furthermore, the number of microorganisms left on the device might be excessive for successful sterilization. And, if the sterilization cycle is not effective, a nonsterile device might be presented to the sterile field during the surgical procedure. Figure 2 illustrates the

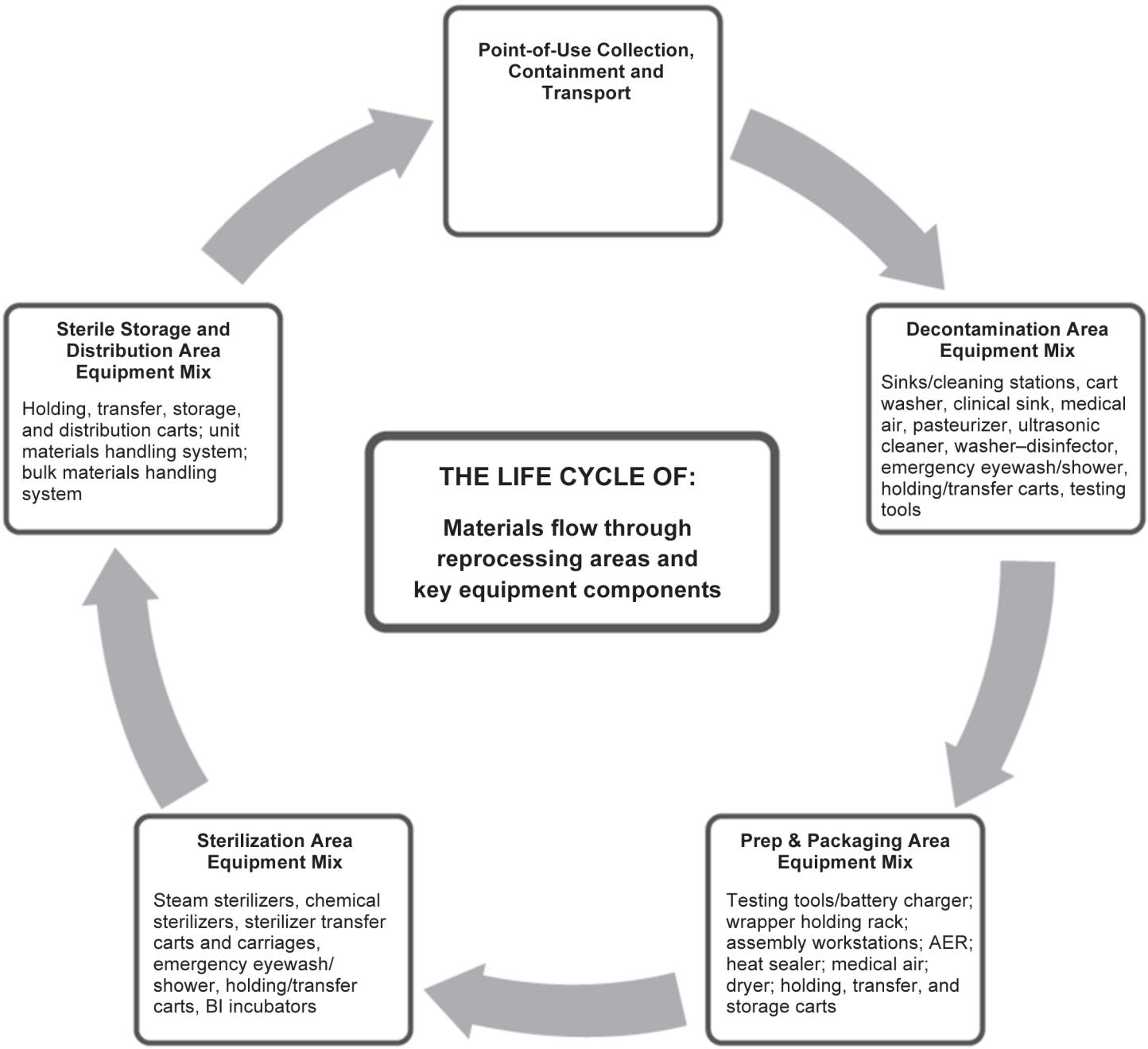

Figure 2—SPD Equipment Location and Materials Flow

importance of selecting and locating the proper equipment mix within each functional area. Each step and functional area is important for the effective reprocessing of medical devices according to the manufacturer's IFU. The flow of materials through each separate functional area and the throughput to the next step in the reprocessing cycle could be impeded by lack of sufficient equipment.

WATER AND STEAM QUALITY

Water Quality

The Impact of Water Quality

The quality of the water used in SPD processing equipment is an important consideration not only for proper interaction of the water with the cleaning chemistry, but also for maintaining equipment performance by preventing buildup of minerals and other deposits on medical devices and on the equipment itself. Water hardness has the greatest impact on chemical effectiveness, because it necessitates increasing the concentration of most chemicals for them to be effective. Other impurities, such as bicarbonates (e.g., sodium, calcium, magnesium), chlorides, sulfates, and silica, can diminish the effectiveness of water as a solvent and cause scale to form on the equipment. Some substances, such as oxygen, carbon dioxide, chlorides, sulfates, and suspended solids, are also corrosive. Suspended solids are easily redeposited on surfaces after cleaning. Water with a high pH (above 8.5) or an unusually low pH (below 5) also alters chemical efficiency by facilitating soil deposits and corrosion. Organic residues that remain after inadequate cleaning are of particular concern because they can reduce the effectiveness of a disinfectant by diluting it with excess moisture, inactivating it, or preventing the disinfectant from contacting all surfaces of the medical device being disinfected.[11]

Water for Use in Medical Device Reprocessing

In the preparation of water for use in medical device reprocessing, both the microbiological content and the inorganic and organic content of the water need to be considered. The level of microorganisms in treated municipal water varies, even if it has been subjected to chlorination to prevent microbial growth. Therefore, it is necessary to assess the microbial level of water used for device reprocessing in the SPD to ensure that it is acceptable. Microbial level is measured as the number of colony-forming units (CFU) per milliliter (mL) of water. The risk of adverse patient events associated with the number of microorganisms in the water depends on the type of device and its intended use. The risk is low for devices that contact only intact tissue and higher for devices that contact the patient's bloodstream or other sterile body sites. Contamination of water systems, particularly with bacteria such as *Pseudomonas* species, *Legionella* species, *Stenotrophomonas* species, and nontuberculosis mycobacteria species, poses a significant infection risk. Annex D of AAMI TIR34 addresses strategies for controlling bacterial contamination and proliferation in water systems.[11] This document also addresses the routine collection and monitoring of bacterial contamination in water systems.

In addition to considerations related to the growth of microorganisms, it should be noted that municipal chlorinated water can be expected to contain inorganic components that could damage medical devices during reprocessing. The levels of inorganic components also must be assessed to determine the necessary water treatment to remove them.

Four Categories of Water Quality

The four categories of water quality that might be required for medical device reprocessing are described in AAMI TIR34:[11]

- **Potable water.** Potable water (tap water) provided by the municipal water supply can vary considerably in type and levels of contaminants. Incoming potable water should be assessed for the presence and levels of contaminants and other characteristics that could affect medical device reprocessing.
- **Softened water.** Softened water is water that receives limited treatment (softening) to reduce scaling by replacing calcium and magnesium ions with more soluble sodium ions. This treatment process does not reduce microbial levels or remove organic material from the water. Storage of softened water should be minimized to maintain consistent quality levels. Storage and distribution systems for softened water should be made of materials that will minimize chemical and bacterial contamination. Also, softeners should be maintained to prevent inadequate softening or over-addition of exchange ions (e.g., chloride ions), which could lead to device damage.*
- **Deionized water.** Deionized water is water that receives limited treatment (deionization [DI]) to remove inorganic material from the water. This treatment process does not reduce microbial levels or remove organic material from the water. Storage of deionized water should be minimized

* In some cases, the entire hospital or clinic might have softened water supplied as potable water for general use.

to maintain consistent quality. Storage and distribution systems for deionized water should be made of materials that will minimize chemical and bacterial contamination. Also, deionizers should be maintained to ensure that when the resins lose their deionizing capacity, they will be replaced.

- **High-purity water.** This type of water is extensively treated (usually by a multistep treatment process that might include a carbon bed, softening, DI, and reverse osmosis [RO] or distillation) to ensure that the microorganisms, inorganic material, and organic material are removed from the water. Also, a final submicron filtration might be part of the treatment process. Bacteria can grow in water stored in tanks, thereby negating the microbial removal aspect of the treatment process and increasing microbial levels to unacceptable levels. Storage and distribution systems should be carefully controlled to maintain low microbial counts and endotoxin levels.

Water Quality for Processing Devices in Ultrasonic Cleaners

Ultrasonic cleaners are used to facilitate thorough cleaning of jointed, cannulated, and serrated stainless steel instruments and other difficult-to-clean medical devices. Ultrasonic cleaning typically is used after manual cleaning, which removes gross soil, and before the items are placed in medical washers or washer–disinfectors. Key water quality factors associated with the most effective ultrasonic cleaning include water hardness, water temperature, ionic contaminants (e.g., chloride, heavy metals), microbial level, and the presence of bacterial endotoxins. The temperature of the water is also an important factor in ultrasonic cleaning; the equipment manufacturer's IFU should be consulted for specific recommendations. The level of monitoring required for each factor varies with the type of equipment.

If the ultrasonic cleaner does not provide a final rinse, the medical device manufacturer's instructions for manual rinsing should be followed.

Water Quality for Processing Devices Requiring Pasteurization or Thermal Disinfection

Water of various qualities is required in the decontamination area to assist SPD in achieving the correct cleaning and disinfection outcomes. Depending on the stage of reprocessing, potable (tap) water might be of adequate quality (e.g., for precleaning), but the medical device manufacturer's IFU and the equipment manufacturer's specifications should be consulted to determine high-purity water requirements.

Table 6, excerpted from AAMI TIR34,[11] summarizes current recommendations that might be helpful for planning purposes. If a recent water analysis has not been completed, such an analysis is recommended so that the water hardness, dissolved solids, and other ion content are known.

Water Quality for Processing Devices Prior to Sterilization

Water that is not contaminated with endotoxins and that does not contain high levels of hard-water deposits is recommended for cleaning devices that will undergo subsequent sterilization. Final post-cleaning rinses with purified water are recommended, although water of lesser quality may be used for earlier cleaning and rinsing stages provided that it is compatible with the cleaning chemistry used.

Table 7, excerpted from AAMI TIR34,[11] summarizes current recommendations that might be helpful for planning purposes. If a recent water analysis has not been completed, such an analysis is recommended so that the water hardness, dissolved solids, and other ion content are known.

Water Treatment Methods

Several water treatment methods are used in healthcare facilities, including reverse osmosis, deionization, and distillation. Such treatments might also remove or reduce the chlorine levels and increase the ability of microorganisms to replicate so it is important to periodically monitor and maintain whichever process is selected. Annex A (Water treatment methods) of AAMI TIR34 summarizes the options.[11] The most frequently used water treatment methods that might be considered for SPD application are as follows:

- **Reverse osmosis.** RO systems are widely used in medical device water purification systems because they have the ability to remove dissolved inorganic solutes, bacteria, and bacterial endotoxins. RO is a membrane separation process. RO systems are sensitive to incoming water conditions that can lead to diminished performance so users are advised to carefully follow the manufacturer's instructions for incoming water treatment and monitoring to ensure that the RO system is operated within its design parameters. RO systems should be fitted with a variety of sensors to monitor the system's performance. Conductivity (or total dissolved solids) sensors in the incoming water and product water streams are used to monitor the ability of the membrane to remove dissolved inorganic solutes. Flow meters, usually in the product water and reject water streams, are used to monitor the output of the RO system. RO systems are also fitted with gauges to monitor the pressure at various points

in the system. Although not indicative of treated water quality, monitoring flow rates and pressures can help ensure that the system is operating within the manufacturer's specifications and thus will aid in ensuring RO reliability.

- **Deionization.** DI is an ion exchange process that removes both anions (negatively charged ions) and cations (positively charged ions) from water, resulting in pure water. Water treated by DI can have very high quality with respect to ionized contaminants, but the process has no capacity for removal of non-ionized substances, including bacteria and bacterial endotoxins. Systems that include DI as a component should also contain carbon adsorption and ultrafiltration elements to prevent formation of carcinogenic nitrosamines and to remove bacteria and endotoxins. The usual application for DI is as a polisher to RO or as a

Table 6—Water Quality for Processing Devices to be Pasteurized or Thermally Disinfected[11]

Stage in Process	Function	Water Quality*
1. Precleaning of patient-used medical device	Remove gross debris and ensure that soil is not allowed to dry on the device or inside lumens.	Potable water is acceptable, at a temperature not exceeding 45 °C (113 °F).
2. Cleaning with detergent	Remove patient organic and inorganic material (soil) that is not removed by simple precleaning (Stage 1).	Potable water is acceptable to dilute detergent if it meets the detergent manufacturer's specifications. The water temperature should not exceed 45 °C (113 °F).
3. Post-cleaning rinse	Remove detergent residues and any loosened soil.	Potable water is acceptable, at a temperature not exceeding 45 °C (113 °F). The water should be changed two or three times to ensure thorough rinsing. For each rinse, a sufficient volume of water should be used to completely immerse the device; if immersion is not used, then some other means, such as the washer–disinfector manufacturer's specifications, should document that the volume of water used is sufficient.
Subsequent to precleaning, cleaning, and rinsing, ONE of two methods of heat treatment is used.		
4a. Thermal disinfection	Kill microorganisms.	Potable water is acceptable if it meets the washer–disinfector manufacturer's specifications.
4b. Pasteurization	Kill microorganisms.	Softened, deionized, or high-purity water is preferred, but potable water is acceptable. The water used in the pasteurizer may need to be changed daily or after each load to reduce buildup and carryover of debris. The manufacturer's instructions should be followed.

* Ensure that potable water is compatible with the detergent manufacturer's recommendations. If the potable water in a specific geographic area is very hard (e.g., > 150 ppm $CaCO_3$), it is desirable to remove solutes by DI (acceptable) or RO (preferred) for all cleaning, rinsing, disinfection, and sterilization stages. Softened or deionized water can be used to prevent or reduce Ca^{++}, Fe^{++}, Fe^{+++}, and Mg^{++} deposits if removal of other ions is not needed.

standby process for use in the event of RO system failure, rather than as a primary means of purification. DI systems cannot remove certain low-molecular-weight, toxic, bacterial products.

- **Distillation.** Distillation is the oldest and simplest method of water purification, and the process is most beneficial in removing dissolved inorganic compounds, bacteria, bacterial endotoxins, viruses, and cysts. Distillation heats water to the boiling point (100 °C [212 °F]) in a vessel (still) and converts it into steam. The steam passes into a condenser, where it is cooled (condenses) back into the liquid phase (distillate) and collected in a reservoir. Inorganic salts, bacteria, viruses, and high-boiling organics remain behind in the still. In automated stills, fresh water is added continuously and a portion of the water is continuously sent to drain to help reduce mineral deposits. Pretreatment of incoming water is sometimes necessary to reduce system maintenance and to improve the quality of the distillate. All distillation units require descaling and removal of precipitated solids in order to maintain equipment efficiency. The water hardness and any pretreatment determine the frequency of descaling procedures; acidic chemicals are used to dissolve the scale without damaging the still and its heating elements.

Table 7—Water Quality for Processing Devices to be Sterilized by Steam or Low-Temperature Gas[11]

Stage in Process	Function	Water Quality*
1. Precleaning of patient-used medical device	Remove gross debris and ensure that soil is not allowed to dry on the device or inside lumens.	Potable water is acceptable, at a temperature not exceeding 45 °C (113 °F).†
2. Cleaning with detergent	Remove patient organic and inorganic material (soil) that is not removed by simple precleaning (Stage 1).	Potable water is acceptable to dilute detergent, provided that it is compatible with the detergent to be used. The water temperature should not exceed 45 °C (113 °F).
3. Initial post-cleaning rinse	Remove detergent residues and any loosened soil.	Potable water is acceptable, at a temperature not exceeding 45 °C (113 °F). The water should be changed two to three times to ensure thorough rinsing. For each rinse, a sufficient volume of water should be used to completely immerse the device; if immersion is not used, then some other means, such as the washer–disinfector manufacturer's specifications, should be used to document that the volume of water is sufficient.
4. Final post-cleaning rinse	Reduce likelihood of hard-water deposits or endotoxins on device.	High-purity water is preferred.§ One final rinse is adequate if there have been two to three changes of water during the initial post-cleaning rinse (with each rinse using sufficient water volume to completely immerse the device).

* Ensure that potable water is compatible with the detergent manufacturer's recommendations. If the potable water in a specific geographic area is very hard (e.g., > 150 ppm $CaCO_3$), it is desirable to remove solutes for all cleaning, rinsing, disinfection, and sterilization stages. Softened water can be used to prevent or reduce Ca++, Fe++, Fe+++, and Mg++ deposits if the removal of other ion contaminants is not needed.

† For flexible endoscopes, the precleaning at the bedside may be done using detergent diluted with potable water.

§ Manufacturers of ophthalmic surgical instruments recommend that devices used for cataract surgery be thoroughly rinsed with sterile distilled water (i.e., water equivalent to the high-purity water) before sterilization.

Questions that SPD planners and users should ask when selecting a water treatment system for new construction or renovation include the following:[11]

- Has the facility previously analyzed the tap water? If so, is this analysis available?
- Is the microbial level of the tap water known?
- Have organic and inorganic contaminants in the tap water been identified?
- Is there already a water treatment process for the tap water? If so, has it been prospectively monitored to ensure the quality of the treated water?
- Is the range of water temperature known?
- Is information available on the water quality requirements for each piece of reprocessing equipment or system?
- Is information available on the water quality requirements for each medical device to be reprocessed?
- Is there a plan for water use in terms of water quality requirements for each piece of reprocessing equipment or system?
- Do the available sources of water match the specified requirements for the reprocessing equipment?
- Are there means in place to monitor the water quality delivered for each different requirement?
- Has a specific individual been designated as responsible for ensuring proper water use?
- Are regular audits conducted to provide the responsible person with accurate, current data on the status of water quality?

Contemplation of these questions might assist planners, engineers, and architects in assessing the available water treatment methods and determining the space, plumbing (e.g., piping and drain connections), ventilation, and electrical requirements. When a new water treatment system is needed, the healthcare facility normally works with a water treatment specialist to design the system, because the specialist usually knows the quality of the potable water in the area. The water treatment specialist can recommend the options for water treatment devices needed to produce the water quality required by the healthcare facility and provide it to all applicable cleaning and sterilizing equipment in SPD.

Cost assessment should also play a role in the selection of a water treatment method. A 25-year life-cycle cost analysis of the new equipment and installation costs, including ongoing maintenance and replacement costs, is recommended for each method under consideration. In order to select the most appropriate and cost-effective water treatment process, planners should understand the water-quality and volume requirements of the reprocessing equipment. Manufacturers of washers and sterilizers can be consulted about the water use of their equipment. Sustainable (green) water conservation features are highly desirable for the final (high-purity) rinse water used in cart washers and washer–disinfectors. Planners can also assess the volume of high-quality water required for manual cleaning and rinsing (piped into the sink stations) by reviewing the IFU of the medical device manufacturers.

Water and Cleaning Chemistry

The detergent selected for use in the various types of reprocessing equipment located in SPD should be compatible with the potable water in the geographic region, because conditions vary widely. Detergent additives are formulated by manufacturers to compensate for variations in the hardness level of potable water. The detergent manufacturer's instructions should be consulted before softened, deionized, or high-purity water is used in main detergent wash stages. And, because the effectiveness of detergents is heavily influenced by water temperature, the detergent manufacturer's IFU should be followed closely.

The water used for an enzymatic prewash may be potable, softened, or deionized, but high-purity water is not required for this stage of cleaning. Enzymes, however, are biologically active proteins that are sensitive to various environmental conditions, including pH level and water temperature. Users should consult the product labeling for guidelines on water quality and temperature requirements. If the product labeling does not supply the optimal range of pH and temperature, the manufacturer should be consulted. Labeling also might indicate the pH and temperature at which complete deactivation of the enzymes occurs, so it is useful to check water temperature with a thermometer when cleaning medical devices manually.[11]

Steam Quality

Design of the Steam System

The design and construction of the steam system (e.g., the proximity of the steam boiler to SPD, the design of the piping) is a critical factor in its ability to produce and maintain the quality of steam required for the SPD's new sterilizers. In

some situations, point-of-use steam generation might be the best solution to providing quality steam, but it has a significant space impact. ANSI/AAMI ST79 contains an informative annex that can assist planners and the SPD manager in understanding the key factors associated with steam quality, including steam dryness, the level of noncondensable gases (NCGs), and how the physical installation of the steam distribution system affects quality.[4]

Steam pipework should be designed and installed in the following manner (Annex M of ANSI/AAMI ST79[4]):

- Piping should direct the condensate to flow by gravity in the same direction as the steam (except for any vertical rise between floors).
- There should be no dead legs of piping that can trap and hold condensate when the sterilizers are turned off.
- Air vents and steam traps should be fitted at each vertical rise.
- Care should be taken to design a system that traps, drains, and returns any condensate that might accumulate.

Steam Dryness

Quality is normally defined in terms of the dryness factor of the steam, as measured in percent by weight rather than volume, and the level of NCGs. The dryness factor can range anywhere between 0% and 100%, with 0% steam meaning that the fluid is water with no steam present and 100% steam meaning that the steam contains no water. Manufacturers of steam sterilizers recommend that steam for sterilization should be 97% to 100% dry. Steam that has too much water in it (i.e., the dryness factor is too low) is a reported cause of wet packs and damp loads. A minimum dryness value of 95% is recommended for a sterilizer load containing metal and a minimum dryness value of 90% is recommended for a sterilizer load containing textiles.[81]

On the other hand, sterilizing conditions might not be attained if the steam supply moisture content is insufficient to prevent it from becoming superheated when it expands into the sterilizer. Superheated steam has a higher temperature than its corresponding pressure indicates that it should be. Sterilizing with superheated steam is similar to sterilizing with hot air. Dry heat sterilization requires a much longer exposure time by comparison to saturated steam sterilization, so the usual exposure periods for saturated steam sterilization will not be effective if the chamber contains superheated steam. Superheated steam does not condense (lacks water) or create the energy needed for sterilization until its temperature drops to the point at which condensation can occur. The temperatures achieved by superheated steam also can result in damage to the devices (e.g., rubber components) and their packaging. From an operational standpoint, if paper or textile packaging looks scorched or charred, the conditions for superheated steam probably have occurred and corrective investigation must be undertaken. In a typical SPD steam sterilization cycle of 250 °F to 270 °F (121 °C to 134 °C), superheating below 9 °F (5 °C) is acceptable.[81]

Noncondensable Gases

The second measure of steam quality is the presence of NCGs in the steam that is released when the steam condenses onto cooler surfaces, such as instruments in a set or the sterilizer walls. The products that contain NCGs are typically introduced during the steam boiler water treatment and softening required to prevent scale formation and then they are added to the steam by the boiler feed water. An excessive presence of these gases affects air dilution in the sterilizer chamber and can create air pockets that block steam contact with the medical devices and interfere or prevent effective sterilization. The level of NCGs should be below 3.5% by volume and is expressed as mL of gas per 100 mL of condensate. NCGs at this level are not likely to cause any problems when mixed with steam in the sterilizer chamber.[81]

Monitoring

Because various contaminants can be present in steam for sterilization, periodic measurement is recommended to ensure that they do not corrode the sterilizer or the devices being sterilized. At installation, an assessment of steam quality should be made and documented. Condensate samples can be tested on a regular basis for the presence of the various contaminants and compared with the original readings. Appropriate treatment or changes to the system must be made to ensure that only allowable contaminant levels are present in the steam used for sterilization in SPD.[4]

INTEGRATED PROCESS FLOW

As mentioned previously, integrated process flow software applications are becoming increasingly appreciated and integral to accomplishing SPD's goals of improved efficiency and quality. Planners are advised to take advantage of the opportunity provided by remodeling or new construction projects to investigate and apply this technology to new decontamination and sterilizing equipment. Most major SPD reprocessing equipment manufacturers have options for integrating the various processes and improving

documentation. SPD equipment planners should initially have an internal discussion about how using this concept could further the healthcare facility's quality and productivity goals. Investigation of the various product options might be enhanced by inviting reprocessing equipment vendors to make presentations specifically addressing the integrated process flow features of their equipment. Inviting the feedback of an interdisciplinary group, including the architect, the infection preventionist, the IT representative, and the supply chain, finance, risk management, and perioperative managers, will enhance discussion with the vendors and support SPD in moving forward with product selection.

Device integration is a method of networking different types of reprocessing equipment that are all necessary to the successful completion of SPD work processes. Device integration helps simplify the steps of various tasks while accurately capturing the interrelated data. The experience of one hospital with identifying the need, selecting the appropriate product applications, and enjoying the benefits of device automation and integration of these devices is described in an AAMI Leading Practice, *Integrated Process Flow in the Modern Sterile Processing Department*.[82] Reported benefits include the following:

- Enhancing surgical equipment turnover
- Promoting efficiency
- Reducing waste
- Improving accuracy in selecting decontamination and sterilization cycle parameters
- Improving documentation
- Fostering safety through developing ergonomic design solutions

During this project, planners conducted an in-house equipment sizing study, although this type of study is a common offering of reprocessing equipment vendors. Because there is a heavy orthopedic-related surgery practice at this facility, a primary planning consideration was to correctly determine the volume of trays and instruments that would be reprocessed. The author noted that 70% of the inventory consisted of system trays that had one to three inserts per tray. This factor must be considered in washing-equipment sizing studies because each insert must be removed and will require its own space on the washer rack. Because reprocessing requirements for an instrument tray cannot be evaluated by simply measuring its exterior, it is important to understand the volume of individual inserts that make up a tray.

The vendor that was selected offered full automation for both washers and sterilizers and its design features stood out during site visits to view the equipment in operation. (It is important that the equipment vendor also have a vision for expanding features to address future needs.) Once the equipment features and product selection were made, the design planning was able to move more efficiently. Because the selected vendor had connectivity abilities, the infrastructure (IT drops) could be placed with confidence at all workstations and washer–disinfector, cart washer, and sterilizer locations.[82]

DECONTAMINATION EQUIPMENT PLANNING

Options for Cleaning and Disinfection

Selecting equipment for SPD's decontamination area is based on addressing the need to accomplish one or more of three functions—cleaning, disinfection, or high-level disinfection—in a cost-effective and efficient manner. Manual cleaning is accomplished by the use of cleaning tools such as soft-bristled brushes and chemical agents like enzymatic cleaning solutions. Automated cleaning is accomplished by the use of ultrasonic cleaners and various types of washers. Disinfection can be accomplished over a specified time period by either thermal (hot water or air) or chemical means.

Cleaning and/or disinfection are required before soiled devices are handled by personnel or are prepared for subsequent reprocessing steps, such as packaging and sterilization. Triage of soiled materials arriving in the SPD decontamination area is required so that the appropriate cleaning and disinfection process will be applied to each type of medical device in accordance with the manufacturer's IFU.

Spaulding Classification System

The classification system successfully applied for many years to planning the methods of disinfection or sterilization was devised by Earle H. Spaulding and is based upon the degree of risk of infection associated with using the device for patient care. The three categories of risk are termed critical, semicritical, and noncritical[3]:

- **Critical items** "confer a high risk for infection if they are contaminated with any microorganism." Examples include surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. Critical items require sterilization.
- **Semicritical items** "contact mucous membranes or nonintact skin." Examples include respiratory therapy and

anesthesia equipment, cystoscopes, laryngoscope blades, and some endoscopes. Semicritical items require high-level disinfection.

- **Noncritical items** "contact intact skin, but not mucous membranes." Examples include bedpans, blood pressure cuffs, and crutches. The generally accepted practice is to clean and disinfect these items in the patient care areas where they are used, and many healthcare facilities do not transport them to the SPD.

Manufacturers' IFU

ANSI/AAMI ST79 notes that SPD should select the appropriate cleaning, disinfecting, and sterilizing methods on the basis of the characteristics of the device and the process specified by the device manufacturer's written IFU.[4] The device manufacturer is required to specify use of a particular type of cleaning equipment and cleaning agent. From both practical and liability viewpoints, SPD should consult the device manufacturer if it elects to use an alternative decontamination method or equipment.[4] It follows, then, that to properly determine the decontamination area equipment mix, there must first be knowledge of the medical device manufacturers' IFU for all medical devices to be reprocessed in SPD.

Maintaining up-to-date IFU is time-consuming. Using an on-line subscription service that is a clearinghouse for many medical device manufacturers' IFU (such as onesourcedocs.com) helps SPDs access current information. Additionally, medical device manufacturers' websites are sources of IFU. Cleaning instructions and other reprocessing information could also be manually entered into the database available to SPD technicians using instrument-tracking software-based systems.

Ultrasonic Cleaning

Importance of Ultrasonic Cleaning

Ultrasonic cleaners have become increasingly necessary to successful cleaning outcomes as medical device design has created more complex instrumentation. Because this pre-disinfection process is a required element of many instrument manufacturers' IFU, equipment redundancy is highly recommended. The entire workflow process slows down when this equipment is not available, and productivity might be severely affected if there is inadequate ultrasonic cleaning capacity. Furthermore, cleaning (and the ensuing sterilization) might be ineffective if an ultrasonic cycle is not used for devices with cannulations, crevices, and articulations. It is important for equipment planners and the SPD team to research the need for and application of this technology. Hopefully, the data collection process conducted with SPD customers, described in Section 3 in the text on "Functional Programming," will provide enough detailed data to enable planners to forecast volumes and to select the most appropriate sizes, models, and number of ultrasonic cleaners, as well as the necessary accessories.

Medical Device Factors in Equipment Selection

Equipment planners are cautioned that it is not uncommon for ultrasonic cleaning technology to be underused in the current location, in spite of access to device manufacturers' IFU. Many older SPDs operate with an equipment mix that is inadequate for handling today's cleaning needs and with too little space for adding additional equipment. As a result, it is not as simple as deciding that because the current SPD has two ultrasonic cleaners, three will be adequate in the future. It is important to acknowledge any current limitations, analyze the new workflow, and understand how the productivity of the next step in the decontamination process (thermal disinfection) is affected by the need for ultrasonic cleaning. The optimal ratio of ultrasonic cleaners to washer–disinfectors can be determined by reviewing these factors:

- The number of surgical procedures using instrumentation that requires an ultrasonic cleaning cycle to comply with the device manufacturers' IFU (e.g., robotic gynecologic or cardiothoracic procedures)
- The types and volume of soiled instruments requiring an ultrasonic cleaning cycle because of device construction that makes cleaning difficult without it (e.g., orthopedic instruments such as reamers)
- The types and volume of soiled devices requiring an ultrasonic cleaning cycle with internal port flushing (e.g., cannulated instruments that require lumen flushing)
- The length of the ultrasonic cleaner processing cycle recommended by the medical device manufacturer's IFU (e.g., at least 15 minutes)
- The volume capacity of the ultrasonic cleaner proposed for the project (e.g., 22 pounds of instruments in a 15-gallon ultrasonic cleaner tank with 20-inch by 13-inch by 3.5-inch trays)
- The automatic wash cycle minimum parameters noted in the device manufacturers' IFU (e.g., at least 13 minutes) as compared to the standard instrument processing cycle parameters set for the washer–disinfector (e.g., at least 18 minutes)