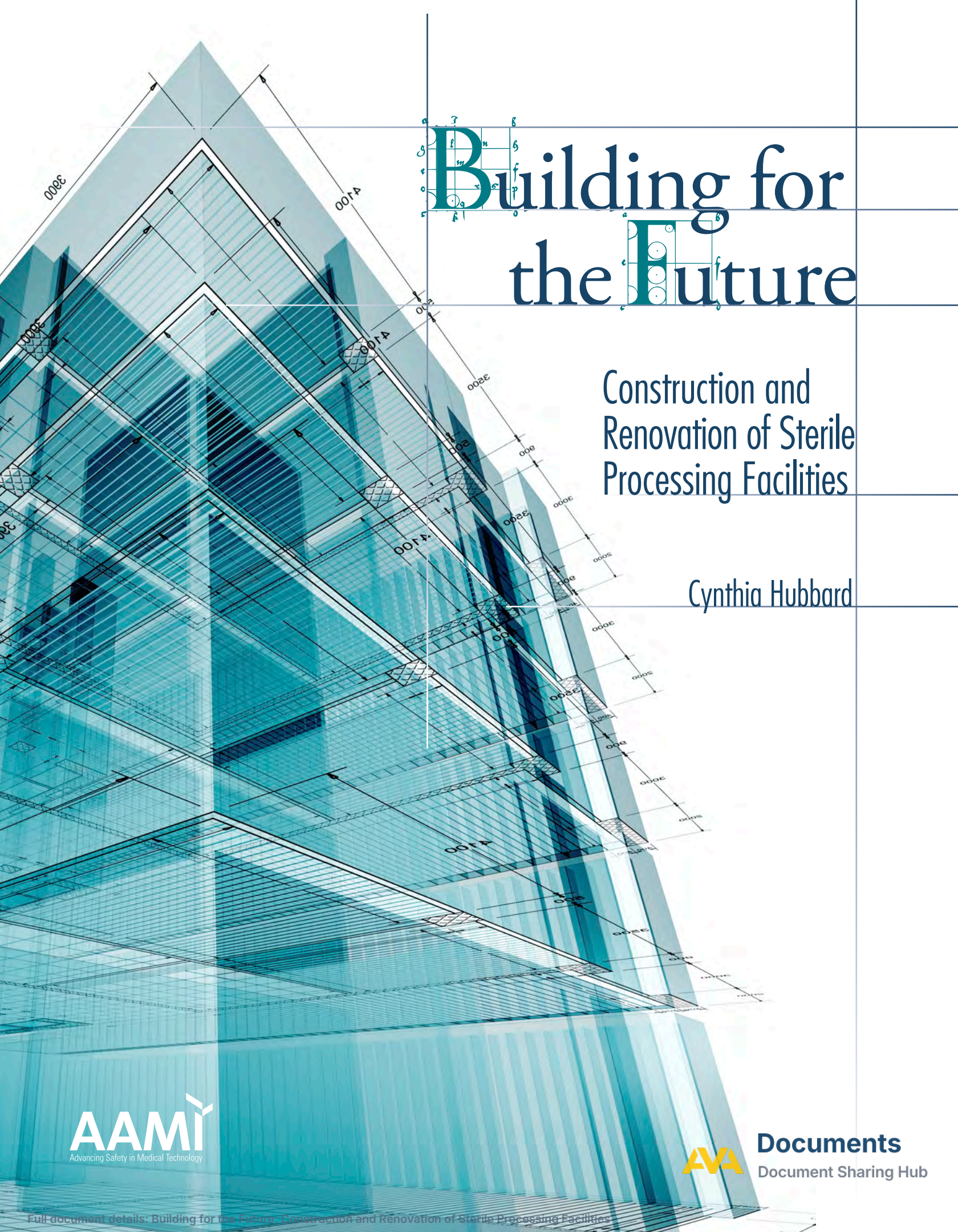




Building for the Future

Construction and
Renovation of Sterile
Processing Facilities

Cynthia Hubbard

Building for the Future Construction and Renovation of Sterile Processing Facilities

Cynthia A. Hubbard, RN

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Published by
Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

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Printed in the United States of America

ISBN 1-57020-463-2

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Dedication:

I would like to especially thank my husband, Michael E. Hubbard, for his patience with my immersion in the creation of this book and for his ongoing support of my efforts to advance the sterile processing specialty and improve patient care outcomes.

Acknowledgments:

During the writing of these guidelines, I was very fortunate to have the assistance of several creative and forward-thinking minds. Judy Veale, as copy editor and researcher, is exceptional and brought a long and productive writing career with AAMI and other organizations to bear in creating a cohesive first-of-its kind document. Mark Duro, a dedicated sterile processing manager with first-hand renovation and construction planning experience, provided the most practical of suggestions and additions. Darren Henkel's experience as a materials manager, equipment consultant, space planner, and project manager on many SPD construction projects ensured that the discussions related to the design process were current and relevant to today's issues. The clinical expertise of consultants Rose Seavey and Cynthia Spry, as well as their willingness to share their practical knowledge, ensured that the most current infection prevention concepts were consistently applied to sterile processing issues and to meeting the needs of perioperative patient-care practitioners. Martha Young's enthusiastic support for this project and her attention to detail in ensuring that sterilization practice and equipment planning were presented in a comprehensive manner are greatly appreciated. Veteran perioperative manager Karen Stewart's assistance in reviewing these guidelines reflects a collaborative working relationship forged while we navigated the often murky planning waters encountered when developing a successful SPD/OR interface in a new construction project. Thanks to Cindy Molko, Damien Berg, Sue Klacik, and those persons and organizations that provided materials that are included in the Annexes as practical examples of planning documents. And, thanks are also due to the reviewers and guiding forces at AAMI: Steve Campbell, Erika Hatva, and their team. I thank you all for your support and professionalism.



Foreword

In 2010, AAMI members expressed interest in a comprehensive construction planning guideline for sterile processing departments (SPDs), because resources and references on this topic had not previously been organized and developed. During the writing of *Building for the Future: Construction and Renovation of Sterile Processing Facilities*, extensive research was undertaken to document principles and requirements related to the many issues. Relevant articles detailing experience with the design process and its application to construction and renovation work in sterile processing were found to be lacking in the literature searches. Consequently, recommendations on the practical application of many aspects of the planning process and ideas to enhance effective design in sterile processing have been based on the sterile processing-related work experience of the author.

Creating these guidelines has been a privilege and a pleasure and has allowed me to apply my experience both as a sterile processing manager and a consultant for SPD construction planning into a document that explores the many issues and provides planners with tools that can be used to achieve successful outcomes. During the writing process, I was reminded of the many learning opportunities I have had over the years and how these varied experiences prepared me now to analyze retrospectively what worked well and where we struggled. I am grateful for my many mentors, teachers, and colleagues who provided guidance along the way and for their special skills in contributing to the project outcomes.

From this perspective, I can emphatically state that collaborative planning, accurate data, having an eye toward the future, and ongoing, respectful communication are the keys to successful project management. Participation in planning and implementing new construction and/or SPD renovation is not commonly found in the resumes of sterile processing managers and architects. Consequently, new SPD planners and designers, although initially excited by the possibilities of a new construction project, frequently become overwhelmed by the many details and stresses of the process. In this situation, designers might lose perspective of the key operational and space needs in SPD as they interface with a lengthy process that requires flexibility, negotiation skills, and compromise.

Building for the Future: Construction and Renovation of Sterile Processing Facilities is the first comprehensive document to explore the many interrelated issues associated with construction planning, which include the following:

- The roles of team members
- The identification and quantification of the current sterile processing workload
- The identification and quantification of the projected future sterile processing workload
- The identification of future technology enhancements or applications
- The integration of functionality with space planning and design
- The options for reprocessing equipment
- The importance of incorporating infection prevention and control into design
- The space planning components specific to the SPD
- The tools for collaborative planning

These issues are discussed within the framework of both SPD new construction and renovation projects. The tools and concepts are collected and presented here to assist planners of both small and large projects in anticipating the requirements of the project phases. By working through the data requirements that drive the space program and understanding the operational needs, planners can develop a better comfort level for what is required for an efficient sterile processing area. And, because planning for the future is an often nebulous task, planners using these guidelines should be able to ensure both dynamic and flexible results for their specific circumstances. When the tough decisions present themselves during the planning process, planners will have the confidence to insist on what is needed rather than compromise outcomes.

In the future, the sterile processing community can benefit from further development of the topics surrounding new construction and renovation planning. Both operational and architectural perspectives are needed in the healthcare literature. By sharing our collective experience in managing the process we can facilitate collaborative communication approaches that are effective in bringing about a better understanding of SPD's needs. And, by incorporating both current workload projections and anticipated future requirements into the design planning, we can build in longer-term functionality, efficiency, and infection prevention into each and every SPD construction and renovation project.

1. Introduction

The healthcare delivery system in the United States is in transition again because of technology advances, the impact of healthcare reform on the growth of outpatient care, and the push toward more cost-effective inpatient care. In response to public awareness and a growing concern for patient safety, organizations are looking for ways to reduce waste and improve efficiency by streamlining processes and operations. Additionally, there is a need to ensure a consistently high level of quality in activities that put patients at risk for healthcare-associated infections (HAIs). Because medical device reprocessing activities, especially those concerning decontamination and sterilization in hospitals, are vital infection prevention components, they are subject to continual scrutiny.

In cases of a system failure or a patient incident, the first step taken to prevent a recurrence and improve sterile processing consistency is generally to focus on procedures and processes. By reviewing current practice and comparing it with the recommendations of groups such as The Joint Commission (TJC), the Centers for Disease Control and Prevention (CDC), state health departments, the Centers for Medicare and Medicaid Services (CMS), and professional organizations such as the Association of periOperative Registered Nurses (AORN), the International Association of Healthcare Central Service Materiel Management (IAHCSCMM), the Association for Professionals in Infection Control and Epidemiology (APIC), and the Association for the Advancement of Medical Instrumentation (AAMI), managers can learn what constitutes best practices. By implementing procedural and process improvements based on best practices, much can be done to create both a climate and activities that foster consistent quality.

In many circumstances, however, the approach needed to create an environment supportive of improved quality involves not only cultural or procedural changes, but also some level of physical remodeling or even new construction. Historically, sterile processing areas have been designed and constructed for long-term use, and renovation or new construction occurs only when there is obsolete equipment to be replaced or the healthcare facility itself is planning new construction related to the support of surgical patients. As a result, sterile processing, perioperative services, and facility managers—and even hospital administrators—seldom have experience in planning and managing construction-related projects in reprocessing areas and feel unprepared for the process.

The purpose of this manual is to assist everyone concerned with the quality of design in healthcare sterile processing departments (SPDs) by providing guidelines for planning and managing construction. Project managers, sterile processing professionals, perioperative services managers, facility managers, hospital administrators, and new members of the healthcare design community will find useful information here. The manual covers three main topics: new construction, renovation, and equipment planning.



2. Definitions and Abbreviations

DEFINITIONS OF TERMS

Alcohol-based hand rub (ABHR)¹

60–95 percent ethanol- or isopropyl-containing preparation base designed for application to the hands to reduce the number of viable microorganisms.

Anion Negatively charged atom or molecule.

Aspergillosis² Fungal disease caused by molds belonging to the genus *Aspergillus*. *Aspergillus* spp. are prototype healthcare-acquired pathogens associated with dusty or moist environmental conditions.

Automated endoscope reprocessor (AER)³ Device that automates and standardizes several important reprocessing steps and provides high-level disinfection of flexible endoscopes.

Biofilm⁴ An accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily.^{5 *†}

Biological indicators (BIs)⁴ Test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.

Bowie-Dick test⁴ Diagnostic test of a dynamic-air-removal steam sterilizer's ability to remove air from the chamber and prevent air re-entrainment.

Building information modeling (BIM)⁶ Representation of the building process used to facilitate the exchange and interoperability of information in digital format.

Case cart system Inventory management and distribution system using a dedicated cart to hold supplies and instruments required for either one large surgical procedure or multiple smaller cases. Standardized pick lists generate the work order; required items are picked from the inventory; the completed enclosed cart is transported to the surgical suite; and soiled instruments are returned in the cart to the decontamination area of SPD.

Cation Positively charged atom or molecule.

* The biomass may consist of multiple bacterial species, yeast species, or both.

† Some microscopic organisms have the ability, when growing in water or water solutions or in vivo (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as glycocalyx) and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

Charrette Collaborative session in which designers, users, and other stakeholders discuss solutions to design issues in an unrestricted but structured medium to facilitate creativity and problem solving.

Chemical indicators (CIs)⁴ Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment. ANSI/AAMI/ISO 11140-1:2005, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*⁷, defines six classes of CIs and specifies performance requirements for them:

Class 1 (process indicators) Chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

Class 2 (Bowie-Dick test indicators) Chemical indicators intended for use in a specific test procedure (e.g., the Bowie-Dick test used to determine if air removal has been adequate in a steam sterilization process).

Class 3 (single-variable indicators) Chemical indicators designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

Class 4 (multi-variable indicators) Chemical indicators designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.

Class 5 (integrating indicators) Chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

Class 6 (emulating indicators) Chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators.^{*†}

Decontamination⁴ According to the Occupational Safety and Health Administration (OSHA), “the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.”^{10 §}

Decontamination area⁴ Area of a healthcare facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

Decibel (dB) Logarithmic unit that measures the intensity of sound.

Deionization (DI)¹¹ Water treatment process that uses specially manufactured ion-exchange resin to remove ionized salts from the water.[¶]

Distillation¹¹ Water treatment process that uses phase change to purify water.^{**}

Emotional intelligence A set of skills involving abilities to recognize and monitor one’s own emotions and the emotions and feelings of others.

Endotoxin⁹ High-molecular-weight complex that is associated with the cell wall of Gram-negative bacteria, is pyrogenic in humans and specifically interacts with *Limulus* amoebocyte lysate (LAL).

^{*} FDA recognition of chemical indicators is limited to Class 1 process indicators, Class 2 indicators for use with special tests, and chemical integrators, which have resistance characteristics consistent with the “Guidance for Industry and FDA Staff: Premarket Notification [510(k) Submissions for Chemical Indicators,” issued 12/19/2003.⁸

[†] See ANSI/AAMI/ISO 15882:2008⁹ for information on the selection, use, and interpretation of chemical indicators.

[§] The term is generally used in healthcare facilities to refer to all pathogenic organisms, not just those transmitted by blood.

[¶] DI typically does not remove organics, viruses, or bacteria, except through “accidental” trapping in the resin. When DI is used, it is advisable to follow the deionizer with a bacterial filter to ensure that the treated water does not contain high levels of bacteria.

^{**} For purposes of this book, distilled water is considered to be water generated from a properly maintained still on-site, not bottled water labeled as distilled.

Gravity-displacement steam sterilization cycle⁴ Type of sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the sterilizer chamber.*

Greenfield Project lacking any constraints imposed by previous work (e.g., the need to remodel or demolish an existing structure); brand new.

Hand hygiene¹ General term that applies to washing hands with water and either plain soap or soap/detergent containing an antiseptic agent; or thoroughly applying an alcohol-based hand rub (ABHR).

Handwashing^{1,12} Process of washing hands with plain (i.e., nonantimicrobial) soap and water.

Hardness, water¹¹ Concentration of calcium and magnesium ions in water, expressed as parts per million (ppm) or milligrams per liter (mg/L) of calcium carbonate (CaCO₃) equivalents.[†]

Healthcare-associated infection (HAI)¹³ Infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care.

Immediate-use steam sterilization (IUSS)⁴ Process designed for the steam sterilization of patient care items for immediate use.[§]

Immunocompromised patients² Those patients whose immune mechanisms are deficient because of immunologic disorders (e.g., human immunodeficiency virus [HIV] infection, congenital immune deficiency syndrome, chronic diseases [such as diabetes, cancer, emphysema, and cardiac failure]) or immunosuppressive therapy (e.g., radiation, cytotoxic chemotherapy, anti-rejection medication, and steroids).

Infection control risk assessment (ICRA)¹⁴ Multidisciplinary organizational process that focuses on reducing risk from infection throughout facility planning, design and construction (including renovation) activities. The environment, infectious agents, and human factors

and the impact of the proposed project are considered by a multidisciplinary team that includes, at minimum, those with expertise in infectious disease, infection control, patient care, epidemiology, facility design, engineering, construction, and safety, as circumstances dictate.

Infection control risk mitigation recommendations (ICRMRs)¹⁴ Written plans that describe specific methods to avoid the transmission of air- and waterborne biologic contaminants during construction and when the HVAC and plumbing systems and critical equipment such as the steam sterilizers are commissioned.

Lean design A management strategy revolving around continuously reviewing processes and improving them by identifying unnecessary steps, encouraging standardization, and avoiding duplicate spaces for the same function.

LEED (Leadership in Energy and Environmental Design) Ecology-oriented building certification program and rating system sponsored by the U.S. Green Building Council and intended to improve energy efficiency, indoor environmental quality, materials selection, sustainable site development and water savings.

Low-emission glass Glass that reflects heat, but lets in light.

Pasteurization 1) Disinfection process that uses hot water at temperatures of 65 °C to 77 °C (150 °F to 170 °F) for a contact time of at least 30 minutes.^{4,11 ¶}

2) Process developed by Louis Pasteur of heating milk, wine, or other liquids to 65 °C to 77 °C (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.³

Personal protective equipment (PPE)⁴ According to OSHA, “specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.”¹⁰

* Typical operating temperatures are 121 °C to 123 °C (250 °F to 254 °F) and 132 °C to 135 °C (270 °F to 275 °F).

† Soft water is 0 to 60 ppm CaCO₃, moderately hard water is 60 to 120 ppm, hard water is 120 to 180 ppm, and very hard water is more than 180 ppm.

§ Immediate-use steam sterilization was formerly known as flash sterilization.

¶ Although not clearly defined, this process is essentially equivalent to high-level disinfection; as a result of heat transfer through water, all forms of microorganisms (including *Mycobacterium tuberculosis*), but not necessarily large numbers of bacterial spores, are killed.

pH level¹¹ Number denoting alkalinity or acidity.*

Potable water¹¹ Water that has been treated and delivered in a manner so that it meets EPA guidelines as suitable for drinking.†

Prevacuum steam sterilization cycle⁴ One of the two types of dynamic-air-removal sterilization cycles. Air is removed from the chamber and the load by means of a series of pressure and vacuum excursions.§¶

Process challenge device⁴ Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

Qualification test¹⁵ Challenge test of the sterilizer performed by the sterilizer manufacturer or other service provider, in cooperation with healthcare personnel, after (a) installation, relocation, and any major redesign of the sterilizer, and (b) sterilizer malfunctions and major repairs.

Reprocessing¹⁶ All the steps performed to make a contaminated reusable or single-use device patient-ready. The steps may include cleaning, functional testing, repackaging, relabeling, disinfection, or sterilization.

Reverse osmosis (RO)¹¹ Membrane separation process for purifying water that is based on molecular sieving and ionic rejection and that is effective in removing ions as well as dissolved organic contaminants with molecular weights above 100.

Single-use device (SUD)¹⁶ [Device] intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. The labeling may or may not identify

the device as single-use or disposable and does not include instructions for reprocessing.

Standard threshold shift¹⁷ Change in hearing threshold (relative to the baseline audiogram) of an average of 10 dB or more at 2000, 3000, and 4000 Hz in either ear.

STAT Immediately.

Steam-flush pressure-pulse (SFPP) steam sterilization cycle⁴ One of the two types of dynamic-air-removal sterilization cycles. Air is removed from the chamber and the load by means of a series of steam flushes and pressure pulses above atmospheric pressure.** ††

Sterile processing department⁴ Department within a healthcare facility that processes, issues, and controls medical supplies, devices, and equipment, both sterile and nonsterile, for some or all patient care areas of the facility.

Sterilization⁴ Validated process used to render a product free from viable microorganisms.§§

Sterilizer access area Area immediately adjacent to the sterilizer that allows access for maintenance.

Thermal disinfection¹¹ Disinfection process that uses hot water at adequate temperatures (higher than 60 °C) to kill residual microorganisms.

Ultrasonic cleaner Device that uses high-energy, high-frequency sound waves transmitted into a cleaning solution for removal of soil from joints, crevices, lumens, and other difficult-to-clean parts of instruments.

* The pH scale is logarithmic and runs from 0 to 14; the neutral point is 7. Numbers below 7.0 indicate acidity, and those above 7.0 indicate alkalinity.

† If the potable water does not have the characteristics described in Table 1 of [TIR 34], it may require treatment before being used in the reprocessing of medical devices.

§ The dynamic-air-removal cycle is generally preferred to a gravity-displacement cycle because of more efficient air removal, a shorter exposure time at higher temperatures, and a shorter drying phase, resulting in an overall reduction in cycle time.

¶ Typical operating temperatures are 132 °C to 135 °C (270 °F to 275 °F).

** The dynamic-air-removal cycle is generally preferred to a gravity-displacement cycle because of more efficient air removal, a shorter exposure time at higher temperatures, and a shorter drying phase, resulting in an overall reduction in cycle time.

†† Typical operating temperatures are 132 °C to 135 °C (270 °F to 275 °F).

§§ In a sterilization process, the nature of microbiological inactivation is described by an exponential function. Therefore, the presence of a viable microorganism on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

Validation⁴ Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.*

Vegetative bacteria³ Bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

Verification of cleaning¹⁸ Defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and through observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and providing process controls along with validation and verification methodologies that ensure adequate, consistent cleaning levels.

Washer–disinfector¹⁹ Machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

Water purity¹¹ Indication of the extent to which impurities (e.g., dissolved organic and inorganic solids and microbial contaminants, ionic, and chemical) have been removed.

Water quality¹¹ Descriptor of the levels of various impurities present in water.†

Water treatment system¹¹ Collection of water purification devices and associated piping, pumps, valves, and gauges that together produce purified water of a specified quality and deliver it to the point of use.

ABBREVIATIONS

AAMI Association for the Advancement of Medical Instrumentation

ABAAG Architectural barriers act accessibility guidelines

ABHR alcohol-based hand rub

ACGIH American Conference of Governmental Industrial Hygienists

ADA Americans with Disabilities Act

AER automated endoscope reprocessor

AHA American Hospital Association

AIA American Institute of Architects

ANSI American National Standards Institute

AORN Association of periOperative Registered Nurses

APIC Association for Professionals in Infection Control and Epidemiology

ASC ambulatory surgery center

ASGE American Society for Gastrointestinal Endoscopy

ASHE American Society for Healthcare Engineering

BI biological indicator

BIM building information modeling

CD construction document

CDC Centers for Disease Control and Prevention

CFR Code of Federal Regulations

CI chemical indicator

CIP capital improvement plan

CMS Centers for Medicare and Medicaid Services

CQI continuous quality improvement

dB decibel

DI deionization

EBD evidence-based design

ED emergency department

EI emotional intelligence

EO ethylene oxide

EPA U.S. Environmental Protection Agency

FDA U.S. Food and Drug Administration

* Validation covers three activities: installation qualification, operational qualification, and performance qualification.

† For example, potable water must meet defined water quality standards that ensure that the levels of inorganic chemicals, microorganisms, and radionuclides are within levels that do not pose a risk to the public when ingested.²⁰ For medical device reprocessing, the water quality needed at various stages in the process varies; for example, initial rinsing with potable water is appropriate, but final rinsing of cleaned medical devices may require treated water that meets more stringent criteria for ions, microorganisms, organics, and dissolved solutes.

GSA U.S. General Services Administration	OSCQ Office of Clinical Standards and Quality Control
HAI healthcare-associated infection	OSHA Occupational Safety and Health Administration
HEPA high-efficiency particulate air	PCD process challenge device
HHS U.S. Department of Health and Human Services	PEL permissible exposure limit
HIPAA Health Insurance Portability and Accountability Act	PPE personal protective equipment
HLD high-level disinfection	PQ performance qualification
HP hydrogen peroxide	PTS pneumatic tube system
HVAC heating, ventilation, and air conditioning	RO reverse osmosis
IAHCSMM International Association of Healthcare Central Service Materiel Management	ROI return on investment
IBC International Building Code	SFPP steam-flush-pressure-pulse
ICRA infection control risk assessment	SPD sterile processing department
ICRMRs infection control risk mitigation recommendations	STEL short-term exposure limit
IDP integrated design process	SUD single-use device
IEQ indoor environmental quality	TEE transesophageal echocardiography
IES Illuminating Engineers Society	TJC The Joint Commission
IFU instructions for use	TLV threshold limit value
IP infection preventionists	TWA time-weighted average
IQ installation qualification	USP United States Pharmacopoeia
ISO International Standards Organization	VA U.S. Department of Veterans Affairs
IT information technology	VOC volatile organic compounds
IUSS immediate-use steam sterilization	
LCG liquid chemical germicide	
LEED Leadership in Energy and Environmental Design	
MSDS Materials Safety Data Sheet	
NCG noncondensable gas	
NFPA National Fire Protection Association	
NIOSH National Institute for Occupational Safety and Health	
OQ operational qualification	
OR operating room	

3. New Construction

NEW CONSTRUCTION VERSUS RENOVATION

The decision whether to remodel or to build is influenced by factors such as project assumptions, intentions and goals, cost comparisons, space constraints, changes in the organization's mission or client base, available land, and community and philanthropic support. New construction projects are typically three- to four-year processes. Today, healthcare facilities are renovating spaces that can be less than five years old as service lines and programs change and/or there is a need to integrate new technology and new diagnostics. Weighing the options occurs through an interactive planning process of reviewing these and other influences specific to the facility's current situation.²¹

It is in the physiology of the building, not the bones, where the money is spent; therefore, master planning, identifying clear, definable goals, and prioritizing them with a programmatic team approach are essential elements. A good team that includes managers and clinicians, as well as architects, consultants, and engineers, can successfully renovate even critical, acute spaces and is the blueprint for success. An understanding of Occupational Safety and Health Administration (OSHA) requirements and AAMI standards for sterile processing is the key to building a good planning foundation. The following are among the key factors to consider when deciding between a renovation project and building a new structure:²¹

- Recognize that time and escalation are the enemy and need to be weighed against both approaches.
- Avoid overestimating renovation costs and underestimating new construction costs.
- Quantify the reasons for decisions; identify and challenge assumptions.
- Outline the project phasing and document upheaval.
- Include operational planning and its costs in the calculations.
- Consult the engineers early on and have energy cost data in hand for options.

The boom in hospital construction seen before 2008 was driven by the need to upgrade older facilities to create the physical environment for best practices, to create infrastructure for technology advances, and to handle the needs of an older population. Although hospitals are still assessing recent healthcare legislation, planners continue to study and assess the potential impact of bundled payments, lower reimbursement, incentive-based pay, and increased patient volumes. Forecasts are still cautious for new healthcare construction projects, especially for mid-sized or smaller hospitals, because of limited funding availability. Larger hospitals and

health systems appear to have an easier time garnering financing in an uncertain economy. Projects that were still in the pipeline in 2009 or that started in 2010 provided stability in the healthcare construction market, because construction typically lags behind the rest of the economy by 12 to 18 months.²²

However, the construction trend of building smaller specialty healthcare facilities continues and is focused on cancer treatment, orthopedics, and cardiac disease, mirroring preparations for the anticipated medical and surgical care of the baby boomer generation. Many of the modernization and addition projects are emergency departments (EDs), imaging and surgery centers, and replacement children's facilities. An emphasis on improving information technology (IT) infrastructure and air-handling/ventilation systems received more attention than in the past, according to a 2011 survey conducted by *Health Facilities Management Magazine* and the American Society for Healthcare Engineering (ASHE).²³ This trend reflects the opinion that hospitals must continue to value the needs of patients in a time of scarce capital. Renovations accounted for 73% of construction projects at healthcare facilities responding to the survey, indicating widespread efforts to avoid the higher debt of new construction but still address the needs.²³

The 2012 survey conducted by *Health Facilities Management Magazine* and ASHE reports that for a second year in a row, organizations anticipate greater expenditures on renovation than on new healthcare facility construction. Increasing priorities are ambulatory or outpatient facilities, medical office buildings, data centers, and specialty facilities for cancer treatment, children, rehabilitation, cardiology, and women's care. New construction projects are expected to be relatively flat for the next two years, and construction will be for lower-cost community projects rather than for big on-campus projects.²⁴

Improving infrastructure continues to be considered very critical for hospitals with aging air handling and boiler systems. And, in particular, there is intent for the next three years to invest in information technology in hospital building projects scheduled for surgery, emergency, and imaging areas. Many survey responders noted that they spent more on capital budgets for IT than on facility issues.²⁴

TRENDS AFFECTING DESIGN

Evidence-based Design

Evidence-based design (EBD) is a research-based approach to healthcare design that emphasizes features shown to promote

or improve patient health, well-being and safety, and staff efficiency.²⁵ Creating patient rooms for comfort also appeals to patient, family, and visitor satisfaction. Views of nature and designs that use natural light are also desirable. Features to increase patient safety and quality of care, such as multiple locations for handwashing facilities and decentralized nurses' stations, are incorporated into EBD schemes. Installation of wireless technology infrastructure is in keeping with the shift to electronic records and creates flexibility for patients and families to access the Internet and view educational and entertainment programs. Clinical staff use mobile devices for Internet access, patient charting, bar coding for supply charging, and bar coding for medication administration.

Sustainable Design

One of the goals of green architecture and sustainable design is to minimize any negative environmental impact of buildings by enhancing efficiency and encouraging moderation in the use of energy, materials, and space.²⁶ Sustainable design features, such as high-efficiency heating, ventilation, and air conditioning (HVAC); low-flow water fixtures; sustainable wall coverings, paints, and finishes; and low-emission glass for windows are being embraced in new construction and renovation projects in hospitals²² and will have an impact on SPD design. In 2011, there was an upswing in interest in and use of environmentally friendly materials and green construction methods in the belief that this approach will be more cost-effective in the long run. Sixty-eight percent of respondents to the 2011 *Health Facilities Management Magazine* survey said that they were acting on this belief.²³ Energy cost savings are expected to be the biggest mover for this trend as better products and methods of applying them to healthcare projects are being implemented.²³ Because healthcare facilities are typically built to be used for more than 30 years, mechanical units are evaluated not only by the initial cost, but also by assessment of the long-term cost benefit and return on investment (ROI). A ROI of five to ten years is a reasonable goal.²⁶

Lean Design

Lean design is a management strategy revolving around continuously reviewing processes and improving them by identifying unnecessary steps, encouraging standardization, and avoiding duplicate spaces for the same function. It is an interactive process involving an interdisciplinary team.²⁶

Today, administrators must explore ways to streamline work processes and reduce unnecessary square footage before beginning the design of any new construction project.²⁵ Input from employees at all levels of responsibility is critical to the

success of this pre-design approach. Such input is especially important to the design of a sterile processing department or a new surgical suite.

Surgery, sterile processing, and infection prevention personnel participating together in a Lean process review in the current environment might facilitate the analysis of ways to improve operations and patient safety outcomes. In addition to co-creating systems that will improve the current process, Lean analysis before design is critical to learning the issues that really affect success, rather than assuming that a particular approach will provide the desired outcome and answer all the issues and problems of the current building. Key issues affecting the design approach for a new building can be identified in advance by analyzing the outcome of the Lean process in the current environment. The following key issues or topics influencing the new design can be evaluated through a Lean operations assessment of current sterile processing and surgery spaces and processes:

- Adjacencies of sterile processing and surgical receiving areas
- Transport systems for movement of soiled instruments
- Transport systems for movement of sterilized instruments
- Transport systems for movement of equipment
- Holding spaces for loaned instruments at key points in the process
- Holding spaces for consignment supplies (devices such as implants and sutures)
- Use of a case cart system
- Waste stream components, including recycling and biomedical waste
- Traffic patterns for waste removal and holding
- Storage of sterile inventory within SPD and surgery areas
- A fast-track or quick-turn-around system for instrument reprocessing
- Equipment testing locations in the decontamination and assembly areas
- Instrument container cleaning, handling, and storage
- Instrument tracking, computer locations, and data integration
- Sterilization systems for steam and low-temperature processes

- Decontamination reprocessing philosophies
- Cleaning/decontamination and disinfection processes
- Equipment planning issues

See “A Practical Guide to Applying Lean Tools and Management Principles to Health Care Improvement Projects” for a detailed discussion of Lean design.²⁷

Integrated Design Process

An integrated design process (IDP) that brings all disciplines together and involves all of the healthcare facility’s stakeholders from the beginning of decision making can result in a more holistic approach. In an IDP, an architectural design firm brings together healthcare facility planners and managers from a wide range of disciplines to participate in group visioning exercises that are designed to bring out these stakeholders’ ideas very early in the planning process. This approach assists the architects by eliminating options that would not be valued or supported by the healthcare facility’s culture, and it reduces planning time and costs. SPD managers fortunate enough to be involved in this interactive group planning process will have easy access to the ideas of colleagues and customers; improve their understanding of the overall goals and needs of the organization and those affected by the new construction; and be able to share their ideas about sterile processing needs.

Not all projects and architects currently use an IDP format, but one such example of inclusive group planning was reported in *Healthcare Design Magazine*.²⁸ Participants included in the visioning exercise represented patients, physicians, administrators, nurses, clinical and support leaders, and facility staff. The healthcare design team offered preliminary design concepts and, during a three-day, facilitated charrette process, listened to the discussion, the issues raised and resolved, and the decisions reached. Ultimately, the architects received a clear direction for a range of key design elements of the new construction, including the arrangement of buildings on the site, the exterior look of the new facility, the horizontal and vertical department arrangements, the circulation of people and materials, the design of operating rooms (ORs) and patient rooms, and the desired access to nurses’ stations. From the healthcare facility’s point of view, this visioning process created consensus among a diverse group of participants and stakeholders, who became excited about the new vision and project direction. Participants carried back this positive message to others and also were able to enhance their area planning with a better overall knowledge of their role and the needs of others.²⁸

OVERVIEW OF THE PLANNING PROCESS

Strategic Planning

Strategic planning is the use of a process to develop clear goals for the organization as it defines its role in the healthcare community and to create a strategic direction in line with its mission and vision. Comprehensive data are collected with the assistance of outside professional planning consultants who facilitate planning sessions throughout the organization. After input from the various stakeholders (e.g., the board of trustees, administration, service-line representatives, physicians, financial planners, community members), data analysis provides a snapshot of current finances, goals, programs, constraints, competitors, technology assessment, planning assumptions, and needs, which will be compared with possibilities, financial projections, and options for the future. From this information, an overall strategic direction and business plan is created that can become actionable over time. Master plans are as individual as each institution and vary greatly as to mission, programs, cost, scope, time frame, and physical area. The goals and needs derived from the healthcare facility's service-line managers and the overall strategic planning process is then used to develop a facility master plan.

Facility Master Planning

Facility master planning is the mechanism for and process of planning the future physical development of a healthcare facility and/or its campus. The plan outlines how the philosophy, programmatic goals, mission, and needs developed through the strategic planning process will be translated into the reality of physical spaces within existing buildings and/or through development of new buildings. The facility master plan is typically created by the facility's planning team (administration, facility architect/engineer, and key campus constituents) with the assistance of an outside professional planning consultant. A comprehensive maintenance plan and a capital improvement plan (CIP), with phases and schedules, are incorporated with narratives about the philosophy, needs, and institutional goals into the facility master plan. Site plans and/or models illustrating the future look of the overall campus are created to provide a visual reference. This final facility master plan document now becomes the single focus and blueprint for many future decisions.

A facility master plan requires periodic review in order to be responsive to changes in the marketplace and to the dynamic nature of the organization's programs and services. Typically, master planning for SPD is tied into the planning for the

surgical patient support space and little is written about it. For three years in a row (2010 to 2012), there has been consistent interest shown in the development of facility master planning. In 2012, 60% of the more than 500 responders to the *Health Facilities Management Magazine* survey said that they have updated their master facility plans within the last two years. Long-term planning on a healthcare facility campus eliminates short-term, suboptimal space assignments.²⁴

Facility Assessment

In a facility assessment, the infrastructure and current condition of existing buildings (e.g., adjacencies, HVAC capability, elevator capacity and locations, and adaptability for new technology) are reviewed to determine their suitability for use in or retrofit to any program selected for future development. If individual building projects selected from the master plan do not fit into the current hospital footprint or the current buildings have infrastructure limitations that preclude their use (e.g., floor-to-ceiling heights), it will be necessary to consider other options.

Site Development

The planning for individual buildings is included in the facility development process and is the mechanism for incorporating principles of the master plan into a building project. An architectural firm studies possible site locations for the proposed expansion or new buildings. Factors considered in this phase are access routes, parking requirements, the relationship between existing structures, the topography, and the climate. The overall concept is further developed through more detailed planning and analysis, including financing projections and options for implementing programming.

Functional Programming

Planners and designers must capture the uniqueness of each organization and its activities to prevent generalized or incomplete assumptions. Discussions and data collection related to the current activities and work volume are the basis for documenting functions in any existing area. Creation of these data is best facilitated by an experienced functional programming consultant who discusses the current operations with area personnel and then spends additional time touring the current area to ensure complete understanding of functions. A tour of SPD is a step that cannot be overlooked. It is most beneficial to schedule the SPD tour during times when the highest volume of the various key activities must be managed and with a guide who can answer all of the questions that will come up.

Inadequacies and constraints in the current environment can be assessed by discussion of what doesn't work now. The programming team can then investigate options to prevent similar situations in the new area, as well as understand the basis for some of the biases, frustrations, and wasted efforts that exist in many SPDs.

Following the data collection, the focus shifts to a discussion of the new vision or mission and the goals for the area. In situations where new concepts are being proposed, such as a new case cart system or centralized reprocessing, accurate assumptions and work-volume projection data must be gathered, reviewed and, perhaps, tested. The needs of customers for the receipt of SPD work products must also be factored into the data collection. The bottom line for any SPD is that customer support is a major priority. To support a new surgical program, for example, information on the start times and length of procedures, the types of surgery, the number of available ORs, and the projected turnover time for completed cases is needed to determine the start time for decontamination activities and the projected peak volume of soiled instruments that must be managed. Tracing these activities throughout the 24 hours of the day will provide data that can be analyzed to program other critical factors, including equipment selection, waste holding, staffing, space requirements, and the relationship and adjacencies of the decontamination area to clean sterile processing areas and other departments. A typical list of data requirements for functional planning of SPDs is provided in Annex A.

Space Programming

Determining accurate space requirements is a critical step because the space programming documents form the basis for determining the square footage assigned to all project components. Space programming documents are organized to describe room-by-room functions and to tabulate the space needs for those functions. Several factors influence the success of a space programming document:

- The accuracy of workload projections
- The intended use of the space, the functional relationships, workflows, and traffic patterns
- The number of staff members who will occupy the space (and their needs for support spaces, such as locker rooms, conference areas, a break room, and offices)
- Any space allocation for future growth in work volume or new technology application

When all of the functions are identified and translated into the space program summary, the architect or space planner will add “grossing factors” to account for wall thicknesses, building and fixed equipment components (e.g., building columns), circulation around large pieces of equipment, and the movement of personnel, materials, and carts.

Having a clear understanding of all SPD functions, based on the functional planning document, is invaluable to space planners. However, space planners who have not worked in SPDs or who have limited experience in healthcare design frequently are challenged by some of the special—and critical—considerations associated with the area, including the following:

- How every process is interrelated and must flow within the total space
- Infection prevention issues and necessary traffic control requirements
- How to calculate the number of reprocessing units required to handle the workload volumes in the decontamination area
- How to calculate the number of sterilizers required to handle the projected workload volumes
- The need for redundancy of critical mechanical equipment, such as washers, ultrasonic cleaners, and sterilizers
- The necessary circulation space to accommodate equipment use and personnel movement
- The necessary circulation space to accommodate washer and sterilizer loading and unloading equipment
- The need for holding space for carts of freshly sterilized medical devices before they are unloaded
- How to translate the concepts of case cart systems into space requirements
- How to translate the use of rigid container systems and other instrument containment devices (e.g., containers of loaned instruments) into workload volumes for the decontamination area and the required holding and staging spaces in the decontamination, preparation, and sterile storage areas
- How to translate the use of loaned instruments into holding spaces in the decontamination, assembly, sterilization, staging/distribution and OR staging areas for clean and soiled carts

- The need for holding space for segregation of waste types and volumes in the decontamination area
- The need for holding space for items reprocessed by a U.S. Food and Drug Administration (FDA)-registered third-party reprocessor of single-use devices (SUDs)

Additionally, because the large reprocessing equipment (washers and sterilizers) might not have been specified and selected at this point, it is also challenging to plan the associated circulation space and service areas, which vary by manufacturer. The selection of cart styles also affects the space program. For example, when planning a new case cart system, it is not enough to project “about 40 carts” because some styles are taller, with a smaller footprint, than other models, which are shorter but wider.

Consequently, it is critical that there be thorough discussions, reviews, and a shared understanding of the proposed space program by the SPD team. Discussions and concerns need to be accurately documented, because ultimately there will be a sign-off from the SPD representative that establishes agreement with the architect’s space planning totals. It is also helpful to realize, at the beginning of the planning, that SPDs are not revenue-generating, but are support spaces. There will be pressure throughout the design process to reduce space in the project, which might affect the total usable space ultimately assigned to SPD. Flexibility will be needed. If SPD representatives participated in a Lean process review, the retooled operating concepts and workflows should be in their minds during functional programming. This background knowledge will be very helpful during times of negotiation and decision making as the project progresses and space allocation issues emerge.

See Annex B for examples of space program summaries for the decontamination, preparation and packaging, and sterilization areas in an SPD.

Conceptual Design

Included in the conceptual drawings are descriptions of the adjacencies and general space allocations for the various elements of the project brought together in an entire building (or several buildings). There might be options presented to show various arrangements of the now consolidated functions translated into space programs and building concepts. Space planning stacking documents, including cross-sections of the entire building, show all levels, along with the functions and adjacencies on each level, to help hospital staff and planners identify concerns with material and waste flow and with traffic patterns for patients, visitors, staff, and physicians. A review of

the desirable features and potential issues associated with each option, as well as the cost analysis of the alternate proposals, results in a decision on the preferred option. Cost projections and available funding ultimately will determine if the new construction project moves ahead at this point.

A recent article in *Healthcare Design Magazine* discusses how technology applications are assisting architects and planners in determining all aspects of a design, including dimensions and movement within the building.²⁹ Building information modeling (BIM) offers a three-dimensional approach to understanding the relationships between height, width, space, light, and other elements of the environment, thus enabling planners to see at an early stage how the building fits together. The software coordination features of BIM also detect potential snags that can be addressed in pre-schematic design, thereby reducing costly redesign at a later stage.²⁹ Additionally, simulation software using AutoCAD or other drawing formats is available to actually model movement within the designed space. Planners might consider using this approach to study transport routes, track materials movement, and identify bottlenecks in the flow. One resource that provides additional information about the various products and simulation software applications available today can be found at the Open Directory Project.³⁰

Sterile processing conceptual design is generally linked closely with that of the surgery planning. Building options might be created for vertical or horizontal adjacencies in the stacking documents. Other departments frequently reviewed for an efficient adjacency with SPD are the emergency department and the birth center. The concept design drawings allow SPD workflow and staff traffic patterns to be traced within the space; the overall room sizes, adjacencies, and equipment location and arrangement can now be visualized and staff support spaces identified and reviewed.

Schematic Design

Building on the agreements made in conceptual design, schematic design creates preliminary layouts and design schemes to bring a greater level of detail into the drawings that now represent the functional needs and spaces previously identified. Placing the agreed-upon adjacencies into the plan; addressing the sizes and sites of the main elevator banks; tracing flows of people and materials (both incoming and outgoing); and establishing security are some of the key issues that have an impact on the new construction. Fairly uncomplicated floor plans, created to a scale (e.g., 1/2 inch = 1 foot, or 1/24 of full size), begin this phase, and the continued reviews with each functional area refine and continue the development of the overall plans. During schematics, design

schemes will undergo several revisions, and it is still possible to accommodate certain changes. Consequently, it is vital that input is sought from all the stakeholders and that they keep abreast of changes.

As is true for other departments, SPD schematic design is a critical phase because space is now fixed and reprocessing equipment (which occupies much of the space and determines workflow) is drawn in place. The building support columns now are fully defined and often play havoc with the materials flow and equipment placement in a space such as SPD. The transport infrastructure, including any elevators between SPD and materials holding spaces in surgery, and the building's mechanical support spaces for HVAC now take up their required spaces. The location of floor drains, electrical outlets, lighting grids, and other such elements is determined now, so it is critical that SPD managers understand their requirements for activities such as equipment testing and battery charging. Comments from discussions with SPD, infection prevention, and surgery representatives are noted by the project planners and architects and incorporated as much as possible into revised drawings.

Design Development

After the major design ideas have been approved in schematics, the project moves into the design development phase. Planning drawings are developed in greater and greater detail in this phase, which typically progresses through a 50%, 90%, and final set. New equipment is fully detailed in its location. Floor plans and traffic patterns are now fixed and if inefficiencies have not been addressed previously, they become more difficult to remedy going forward. Requests for major design changes will result in delays and additional costs and typically are not approved (unless they are code or structural necessities). Elevation drawings (including front, rear, and side views) give new visual perspectives on rooms and space and provide details of everything, including the size and placement of equipment, windows, doors, electrical outlet locations, and floor drains. Ultimately, detailed sets of drawings will be created to enable construction of the new building.

Construction Documentation

Construction documents include the building plans, specifications, and supporting documents needed to complete the construction project. The needs of the hospital and all of its various and diverse users have been translated throughout the previous project phases into a format universally understood by the construction industry. Included in construction documents are comprehensive instructions for the contractor on how the project should be built.

Created in this work phase are all of the architectural drawings and building elevations, as well as structural, mechanical, and electrical drawings and the “spec book.” The spec book covers the materials to be used and any specific methods required (such as compliance with sustainable building principles and practices). The final complete set of plans is commonly referred to as the “100% construction documents” or simply the “CDs.” The project can now be put to bid (the drawings are submitted to interested contractors who will estimate the cost to construct and complete the job), and final permits will be obtained. As construction progresses, any required changes are documented as change bulletins or supplemental instructions, which also become an official part of the construction documents. Because change orders are expensive and cause delays, there will come a time when they cannot be accommodated.³¹

Equipment Specifications

Equipment specifications are necessary to establish the intended use of equipment, the features required to achieve the desired outcomes, and the quality level to which it must perform. Functional, or performance, specifications describe the performance characteristics of the equipment and will include reference to ease of operation, compatibility with other equipment or software, capabilities for multiple use, and the significant features required to achieve the results.

The University of North Carolina's Material and Disbursement Services Procedure 3 provides a lengthy discussion of important aspects of equipment specifications.³² It is common to rely on vendor-supplied technical specifications as a starting point to create specifications for some types of hospital equipment, but care must be taken not to unduly restrict competition or create unnecessary costs. Equipment specifications for the many hundreds of items required for a construction project will be written by several different groups, because general-purpose items require a different expertise than does specialty equipment. Equipment specifications will also include installation requirements, such as delivery method and timing; coordination with other contractors; electrical setup and power requirements; and accessories required for installation. Typically, final payment for large equipment that requires installation is withheld until after successful testing, operation, and acceptance by the owner's representative.³² This scheduled-payment approach is especially important to ensuring coordination and timely planning of electrical, drainage, steam, ventilation, and other systems required to support the technical specifications of the reprocessing parameters for SPD equipment such as washers and sterilizers.



The training requirements for new equipment are also included in the specifications to alert the manufacturer to the need for manuals and in-house education that must be conducted by the manufacturer's representative or provided at the manufacturer's location if hospital staff will be responsible for maintaining the new equipment after expiration of the initial warranty.³²

Service and warranty requirements must be included in the specifications; this is especially important for essential equipment that cannot be out of service awaiting repairs (e.g., low-temperature and steam sterilizers). Also required are specifications for response time by service technicians; warranty coverage for parts, labor, and technician travel time; and hourly rates for services after initial warranties expire. Extended service contract costs can also be included in the vendor's bid, if desired.³²

See Section 5 for additional discussion of new equipment planning for sterile processing projects.

Value Analysis

Along the way, planners will be looking at how to eliminate errors and waste, reduce delays, and determine the processes and materials most feasible for accomplishing the goals of the project without exceeding the budget. The formal process of value analysis and value engineering involves reviewing key user-requested functions of the new building(s) and investigating alternative methods (than those proposed) that will still provide the function but at the lowest cost. The goals are to identify equivalent methods and materials that will be less costly and to eliminate unintended redundancy or equipment that might have been overlooked because of changes in concept. Some aspects of user-proposed functions that are subject to value engineering include quality, appearance, life expectancy, reliability, and product features. Value engineers, working with hospital managers, can effectively lower the organization's costs (while maintaining the required quality, safety, and customer features) by thoroughly reviewing the functions and asking the proper questions to establish both the objective and subjective value, especially for costly items such as infrastructure and systems.³³

PLANNING NEW CONSTRUCTION FOR STERILE PROCESSING

Understanding the Organization's Vision

The healthcare facility's board of directors and administrators will set the overall project parameters and engage the design team to meet the needs that have brought forward the

construction project at this time. This means that the vision has been defined in general terms before involvement at the community level, department management level, or service-line management level. However, collaboration at all levels of the organization and construction community will be needed to refine and implement the vision.

Every organization has a team of in-house experts who understand what they need in a physical space to provide the most efficient and high-quality product or service. Creating a new physical facility takes thousands of collective hours by many disciplines over several years to manage the complexities that are involved and to make the vision come to life in an efficient and beautiful building. It also involves a structured process and project managers who can listen, facilitate, pay attention to the details, be disciplined about the time constraints of the process and deadlines, and lead without being overbearing. Many healthcare facilities and architects work closely with specialist project managers to obtain the information necessary to capture the data and direction that results in great design.³⁴

Planning for a new facility is generally discussed for many months at the highest levels of the organization before sterile processing managers become active participants. But, the day will come when the SPD manager is invited to join the planning team. Understanding the overall goals of the new building program, especially the surgery-related goals, helps focus SPD planning efforts. SPD managers should request any information available about the project and should ramp up their own data-collection efforts about a subject in which they are already experts: the sterile processing area.

Creating the Sterile Processing Vision Opportunity

The more inclusive the planning data, the more likely a new department can be created that functions in a manner very close to the SPD manager's vision. But, how does one create a vision for a new sterile processing area? Although the majority of sterile processing managers never have the opportunity to create a new department, every manager has lived with existing problems and understands what isn't working efficiently. The SPD manager might have even said: "If only _____." Or, perhaps he or she worked in another facility that was able to accomplish its goals because SPD was designed for greater efficiency or ease. Or, perhaps the reprocessing equipment layout was designed to reduce cross-traffic and wasted steps, enabling greater efficiency. Or, perhaps the reprocessing equipment layout produced a higher quality product with less downtime. Or, perhaps the SPD manager has read articles about SPDs that reportedly worked

well for everyone. A new construction project provides the opportunity to use these experiences and observations as the reference point for creating a sterile processing vision that can later be incorporated into the planning and design work of the project.

The Sterile Processing Team

Sometimes creating a vision for sterile processing is not an easy task. It must be a shared experience and must be more than just the manager's vision. SPD communication efforts should be focused on capturing technician and support-staff concerns, issues, and ideas. This information is important both prior to the manager's involvement in the official planning process and throughout the design and implementation phases. The manager might be skeptical, or even concerned, about the process or might learn that his or her positive enthusiasm for the journey ahead is not a shared enthusiasm. In the beginning, the buy-in from the team might be slow to develop because of the many unknowns and lack of concrete planning details. It is important to keep the communication channels open through a wide variety of means, including meetings, guest speakers, posters, newsletters, e-mail messages, in-services, opinion polls, and so on. It is also important to anticipate staff needs and concerns so as to avoid the many distractions caused by inaccurate information in the rumor mill.

The lengthy process of planning a new sterile processing area will bring up many unexpected issues and fears that need to be addressed, including the following:

- **Concerns about managing change.** Such concerns might be a big issue for some departments, especially if the majority of staff members have worked in the area for many years and the current situation is all that they have experienced. There is a feeling of comfort in daily routines, even if they are frustrating and even if the staff vocalize negative feelings about them. Some people believe that if they ignore the issue (or potential change) it will just go away, and they are reluctant—or refuse—to share their ideas.
- **Concerns about the effect of change on personal lives.** Work schedules affect everyone's personal life, but it is important to anticipate potential issues for technicians who carpool with friends, have young children, are used to certain days off, are attending classes, and so on. In an uncertain financial climate, many even fear that they might lose their jobs or have their hours reduced, with all the talk about how the new sterile processing area will increase efficiency.

- **Concerns that staff might not be able to meet new expectations.** New procedures, changes in workflow, and the need to learn how to operate new equipment are to be expected following the move to a new SPD. Some technicians might be intimidated or lack confidence that they can meet the new expectations. Early on, no one really knows what will be expected, but everyone understands at an emotional level that there will be new relationships, new customers, and new performance expectations and asks themselves if they will be up for the challenge. And, in truth, some people might choose this time to exercise more control of the situation by making their own changes in employment. Others will struggle to adapt to the change demanded by the new department.

Managers who have an accurate awareness of their feelings and those of others can more effectively promote open and honest communication in the workplace. During this time, the manager must communicate the same information multiple times and in multiple ways to the team to obtain all the necessary feedback.

Emotional Intelligence in the Workplace

Huge change, such as planning for a new SPD, brings many emotions to the surface. An understanding of emotional responses (to people and situations) provides information for managers that might help them assess their own behavior and that of their co-workers. In 1990, the concept of emotional intelligence (EI) was introduced by behaviorists. EI is defined as a set of skills involving abilities to recognize and monitor one's own emotions and the emotions and feelings of others. EI includes the ability to discriminate among various emotions and use this information to guide actions and thinking. Not everyone functions at the same EI level; people have different personalities, backgrounds, and experiences. Men and women also react differently and express emotions differently. In the workplace, there are a variety of human beings; some are less skilled at identifying, understanding, using, and managing their own emotional states and those of others. Managing negative behaviors during times of change can pose a huge challenge to the SPD manager.

Efforts to hide or ignore emotions do not work; ultimately, they surface in one form or another. The effects of negative emotions can be observed in verbal outbursts, inappropriate workplace behaviors, efforts to sabotage results, and dysfunctional behaviors in teams. Understanding the impact of emotions can assist managers in good decision making. Equally important, if managers can regulate their own behavior during times of stress (such as when challenged by new ideas, change in routines, and the negative emotions of

others), they will be better able to navigate the emotional stress of the planning project. Because one of the goals moving through the process of creating a new SPD is ultimately to unite the SPD team as they go forward, it is helpful to periodically check in with everyone about how they are feeling about the process³⁵

The Current Work Environment

Doing a job every day is the best way to really know and understand how it feels mentally, emotionally, and physically. Managers who take the time to work alongside technicians will benefit from learning how it feels to follow the procedures and complete the expected work in the expected time frame. Some of the observations that have practical application to process improvement and can assist in planning a better design include the following:

- Interruptions to the productive routines by people, phones, and conflicting information
- Inconveniences to efficiency created by current environmental conditions, including low lighting levels or lighting that is not located properly to illuminate the work, loud noise levels, ventilation issues, and areas (especially decontamination) that are too hot to work in comfortably
- An insufficient number of elevators for the volume of items transported, mixed use of elevators (patients with visitors and/or materials) that creates inefficiencies for moving supplies and instruments, and elevators that are too small or inconveniently placed, causing long travel distances and worker fatigue
- Equipment that breaks down frequently, is difficult to operate, is insufficient to handle the work volume in the expected time, or is difficult or time-consuming to clean and maintain
- Lack of available testing equipment, tools, work tables, sinks, computers, or printers
- Procedures that have confusing, unclear, or unnecessary steps
- Client expectations and the communication channels they use to indicate their needs
- Complaints from co-workers, colleagues, and customers
- Ergonomic issues, such as repeated bending, stooping, and lifting
- Infection prevention and control challenges

- Safety issues, such as water on the floor
- Limited technology applications that force time-consuming manual processes

Of equal importance is the identification of any systems, procedures, processes, and equipment that are working well and should be retained or duplicated in the new facility. It is helpful if any of these existing factors provide positive results that can be applied to the new environment, as this increases the comfort level of the team when they can use systems and equipment with which they are familiar.

Consultation with Colleagues within the Organization

It is always important to know and understand the needs of SPD's many customers. Hopefully, open communication that is respectful—and successful in resolving issues—is already in place. Before planning a new SPD, input from current customers might be sought to assess satisfaction with the services provided and gather information about future service expectations. If regular customer satisfaction surveys are conducted, the questions might be focused towards soliciting ideas and suggestions that will provide helpful communications about the project.

If the construction project involves new service lines or will expand SPD's customer base, information should be sought from colleagues planning these areas to determine their needs and expectations. This information might be difficult to collect, and certain assumptions might be required to move the planning along. If this approach is necessary, the assumptions should be shared with the new customers to verify, to the extent possible, the impact on SPD's workload and the expected service requirements.

In the absence of concrete data, SPD managers might ultimately need to use their intuition and gut instincts, because they understand their business better than anyone. As the project progresses, it is helpful to periodically consult colleagues for current updates on issues that affect SPD planning.

Networking

It is rare for there to be only one sterile processing facility in a particular geographic area, so many SPD managers are aware of and frequently interact with colleagues from other healthcare facilities in neighboring communities. Now is the time to contact local colleagues and, if practical, those in other cities to schedule a tour and time for a discussion about the pluses and minuses of their physical facility and its impact on operations. Good ideas come from many sources and can help

SPD managers form and solidify their vision. Observation at other facilities often starts the flow of ideas as one sees how one's peers have either solved their problems with good design or are using work-around procedures to compensate for building limitations. Other sources of information include the following:

- Social and business media, which provide access to professional chat sites
- Internet searches to access the experience of others
- National and local chapters of professional organizations

Sometimes the most important thing to be learned is what not to repeat!

Success Stories

Sources of design-related information include AAMI and publications such as *Healthcare Design Magazine (HDM)*, *Healthcare Purchasing News (HPN)*, and the *AORN Journal*. Although *HDM* and the *AORN Journal* do not typically focus on sterile processing topics, articles in these publications might provide helpful background information. Recently, *Healthcare Purchasing News* published an informative feature on the hospital selected for recognition as their 2012 "SPD Department of the Year."³⁶ At this facility, SPD functions had been performed in a space built in the early 1970s; it was outdated and too small, and the workflow was poorly designed to handle the needs of the 341 hospital beds. During planning of new construction, the facility administration, surgical department, and SPD wanted to be proactive to prevent complaints resulting from poor service and recognized the new construction project as an opportunity to make change work for the SPD team. The story illustrates how their planning for a new department also created a highly efficient and cohesive SPD team. The healthcare facility resolved design issues in a way that also met future needs. This article offers a look at the type of opportunities possible when an enthusiastic team, supported by administration, is actively involved with the planning process.

Assessing the Sterile Processing Workload

Data Collection

Resources are available from equipment planners and manufacturers to help identify the information that drives design decisions, but everything starts with accurate workload projections. It is critical that these data be complete and accurately interpreted, and it requires research and time to develop all the data components and have confidence in the results. The SPD manager might be assisted by the finance

department. Ultimately, the data will be shared with, and used by, the architectural planning team. Enough statistically significant data should be gathered to identify volumes, history and trends, and to help forecast future requirements. It might be useful to gather and analyze workload statistics covering the past five operational years to understand the overall impact of any volume fluctuations. Special care should be taken in the analysis if the method of gathering or reporting statistics has changed during this time frame (as is common in developing SPDs) or if there have been changes in management or in reporting relationships.

The Current Environment

Understanding the significant operational challenges facing SPD on a daily basis helps to generate the best planning information and makes it understandable to the other team members, including the architects.

It does help to fully appreciate any limiting factors in the current environment and use this information to create the best new designs possible. It is important to solicit feedback from the entire SPD team and its key customers about current operations, using the following questions (and others pertinent to the specific situation); to assess performance in this environment; and to identify potential future issues and discussion points.

Location of the SPD. Is the department conveniently located to serve current customers, especially surgery? Are there opportunities for improvement with the new construction?

Hours of operation. Is service available continuously (24/7), on weekdays only (24/5), or during business hours only (8–10/5)? Are there frequent (or infrequent) complaints or issues raised because of limited coverage? Will any changes be needed to address the facility's or SPD's new vision?

Staffing patterns for SPD and coverage if SPD is unstaffed. Is the staffing mix appropriate for the type and volume of work done throughout 24 hours? Are there any areas of SPD typically short-changed in coverage by qualified, experienced SPD technicians? Do others have access to SPD when qualified technicians are not available? Are there security issues? Will staffing numbers or scheduling need to be changed to implement the programs planned for the new construction?

Supervision. Are key shifts covered by some form of supervision? If there is not an official SPD supervisor, is there a supervisor from another, related area or a lead worker who handles issues or complaints? Are there communications gaps, quality concerns, or errors that have occurred when the

SPD is unsupervised? Will any changes in supervision be needed to implement new programs associated with the new construction?

Size of the current SPD. Has the workload volume increased beyond the ability of the current equipment to efficiently process the required throughput? Is space available to hold instruments, instrument containers, loaned instruments, and the volume of waste? Are staff support spaces adequate for employee needs? Which areas of SPD will require a larger space allocation to process the anticipated workload in the new facility?

Department adjacency to materials handling distribution system elements (e.g., elevators, pneumatic tube systems, dumbwaiters, cart lifts). Are any elements missing for bulk distribution or distribution of units (single or small items needed by particular users)? How long does it take to deliver a STAT item? Is it convenient to receive or retrieve bulk items from general stores? Must staff transporting items travel through unintended clinical areas to get to intended destinations? Are there elevation changes between buildings along the route that hinder cart transport? What improvements to the materials handling system would improve efficiency and services in the new facility?

Anticipated changes in concepts that will influence policies, procedures, and staffing. Are there opportunities to improve operational concepts with the new construction? What is the philosophy, for example, on using ethylene oxide (EO) sterilization or glutaraldehyde high-level disinfection (HLD)? Might there be a change in a component of the distribution system (e.g., an SPD-prepared case cart system vs. a supply-chain or outside-vendor-prepared system)?

Types and volumes of reprocessing equipment. Is there insufficient backup capacity for key equipment, such as sterilizers or washers? Is a different size or more than one size of a specific type of equipment needed (e.g., a smaller steam sterilizer to process a single instrument set with a non-typical or special cycle)? Is there an enhancement desired in the type of equipment used (e.g., automatic-loading washer-disinfectors vs. manually loaded machines or computer software applications that link monitoring, tracking, and productivity of individual sterilizers)? What will be the best equipment mix based on anticipated changes in type or volume of work or new programs expected in the future? Is there enough space to queue carts of materials awaiting reprocessing? How will queuing ability be affected by the space and new equipment?

Turnaround time. What is the current turnaround time (from receipt in decontamination through terminal sterilization and delivery of a high-quality product) under normal circumstances? Is it reasonable, or is it at variance with customers' expectations? Is there a fast-track system that conforms to best practices and manufacturers' instructions for use (IFU)? How are STAT requests handled, and can the new facility design improve the process and lessen the stress? If the physical environment is a factor in limiting turnaround time, can any specific designs improve this response in the new facility?

Infection prevention and control issues. Are there issues in the physical environment (e.g., type of surface [wood vs. washable materials] or deteriorating condition of floors) that make infection prevention and control a challenge or that are at variance with best practices? Are there traffic or workflow issues that enable opportunities for contamination? Is the ventilation system capable of meeting recommended temperature and humidity ranges in all areas of the SPD, especially in the decontamination area? Are cleaning and housekeeping procedures effective? Is there a need for a janitor closet, or do the housekeeping staff bring their supplies and equipment with them? Are hand hygiene facilities convenient to SPD's individual functional areas? What changes are needed with the new construction? Is there an application for equipment finishes that could be antimicrobial (e.g., copper)?

Safety and ergonomics. Are there current issues that present safety concerns, such as leaking equipment that frequently results in a wet floor in the preparation and packaging area? Are work tables adjustable in height to accommodate the variety of people using them? Are the sinks too deep or are the counters too low or too high? Do the storage conventions require that shorter workers lift heavy containers above their heads? Is the lighting adequate for technicians to read labels in sterile storage? Can technicians effectively see the intricacies (e.g., crevices, lumens) of devices during manual cleaning? Would computer enhancements for workstations, such as interfaces with magnification, be helpful in device inspection? Are emergency eyewash/shower stations available? How can the design of the new SPD improve the current situation and provide ergonomically-improved solutions?

Disposable or reusable products. Will the use of either product category change significantly with the new program? Will items currently picked as individual packages be bundled together from the manufacturer (e.g., specialty surgical packs)? Are any significant program changes anticipated, such

as a new facility-wide recycling program, a new laundry, or a mandate to implement designs with sustainable materials? Will the type and volume of SUD reprocessing change in the new facility? Will additional instrument containers be purchased to reduce the use of disposable wraps?

One-of-a-kind items. Are there opportunities to purchase additional instruments that are commonly used but in short supply because they are “doctor-owned” or “one-of-a-kind” items? How can SPD obtain support for increasing instrument inventory before moving to the new SPD?

Instrument reprocessing requirements. Is it possible to implement manufacturers’ IFU for all equipment and instruments currently used at the facility? If there are devices for which the manufacturers’ IFU are not available because of age, can replacements be planned? With the new equipment mix, will it be possible to reprocess instruments according to all of the required IFU? Can new product specifications be obtained in advance from customers so that SPD can be proactive in anticipating the reprocessing needs in the new facility? Will HLD with liquid chemical agents for items such as transesophageal echocardiography (TEE) probes be required in SPD? Is there appropriate space to complete the testing required for instruments such as scopes? Where should outlets for medical-grade air or other gases be located?

Patient care equipment requirements. Some SPDs receive a variety of patient care equipment items that must be cleaned and decontaminated. Items such as feeding pumps, IV poles, IV controllers, and other specialty equipment might be transported to SPD for reprocessing rather than be cleaned in the clinical units. If processing of patient care equipment is programmed for the new SPD, the required space elements must be included in the planning for the decontamination and clean storage areas. What is the type and volume of patient care equipment that SPD must handle in the new facility and is counter, cart, or floor space required for holding this equipment prior to the cleaning process? Is functional testing of the equipment required and, if so, where will testing tools and outlets be placed? How will SPD interface with the system for patient equipment repair? Will patient care equipment be included in an automated tracking/asset management system?

Technology applications. Many SPDs were designed before the widespread application of computer technology. Are there opportunities to incorporate new software applications into the planning? Technology is available that provides greater accuracy in data collection, trending and report compilation, inventory tracking, integration with washers and sterilizers, asset management, training aids, and interfaces with OR scheduling. What will be needed to ensure that the necessary

infrastructure and equipment (e.g., data drops, computers, scanners, printers) are in place to enable the use of these tools in the new SPD?

Soiled holding spaces in clinical areas. Are there any issues associated with the capacity of nursing units, the ED, and other clinical areas to hold soiled instruments and equipment until the transport system returns them to SPD? How will the current situation be improved in the new facility?

Inventory and supply chain management. How will supplies be removed from shipping cartons? Is a breakout area needed in the new SPD? Are new computer interfaces needed for inventory management? Is this the time to plan for implementation of an instrument tracking and inventory management system? Will a just-in-time application be used for any product category that affects SPD systems or products?

Other issues. Are there other specific concerns that have been identified in customer or employee satisfaction surveys, union grievances, employee meetings, incident reports, or accreditation surveys that can be addressed with new construction?

Asking the team these questions helps everyone share ideas and bring issues forward. And, practically speaking, the new area will create its own set of factors that influence (either promote or hinder) productivity, quality, service, and employee satisfaction. Sometimes things just do not translate as intended into new construction, because it is difficult to fully appreciate spaces and their functionality from drawings. Unfortunately, SPD managers rarely have access to drawings that are created for the entire facility throughout the process. Requesting such access periodically for key customer departments might enable them to see the broad view of department relationships and adjacencies, elevators, clean and soiled holding spaces, and traffic flows. SPD managers can only do their best to anticipate all of the issues and create the best designs possible as all of the opportunities are weighed and solutions formulated.

Analysis of the Current Workload

Once the planning exercise previously described is underway, all components of the current SPD workload that are routinely captured and reported to the finance department should be identified, including volumes of the following major categories for the current customer base:

- Patient care equipment
- Loaned instruments
- Specialty devices such as robotic instruments

- Endoscopes
- Powered equipment
- General-purpose instruments
- Implants
- STAT requests

These data can be analyzed to determine any upward or downward trends for a specified number of years. If there are trends indicating decreased use of a particular sterilized device, the reasons for the decrease should be investigated with the customer. For example, there might be a communications issue and SPD is not aware that a new model replaced the one currently sitting unrequested on the shelf. Or perhaps a reusable product has been replaced with a disposable product. Items that will not be needed in the future should be removed from inventory and not brought to the new facility.

The reports available from an instrument/equipment tracking system will greatly simplify the data collection and workload analysis. Using spreadsheets to capture and display all of the workload data and trends will help managers explain SPD needs during the planning process. It is also important to acknowledge that both typical and peak volumes play a factor in the stress level of the daily operation so that they can be considered in future planning.

Reports from a benchmarking system capture and compare SPD's productivity with that of similar facilities; analysis of the results can assist in identifying issues that affect the future design or staffing of SPD. One such benchmarking system is available from AAMI.³⁷

Estimating Future Needs

Services and Patient Volumes

The facility master planning that culminated in the new construction project is based on certain service and patient volume assumptions. This information provides a general idea of the healthcare facility's vision and a starting point for discussing needs with current and future customers. Other departments and service lines are also developing functional programs and space needs. Knowledge of customer planning enables the SPD manager to project the impact of new programs and potential service needs on future SPD workloads.

Analysis of the trends over the past few years provides growth information that can be factored into the SPD workload.

For example, if reprocessing volume for the cardiac surgery service line increased an average of 15% over the past five years, these data provide a starting point for discussion. If the cardiac surgery program projects a 5% growth, this number can be used (or adjusted, as needed for technology advances) to estimate future instrument volumes in SPD's reprocessing areas, as well as storage requirements for additional sets.

Collaborative planning will be needed throughout the entire project as customers develop, refine, enhance, adjust, or eliminate program components. Beginning the communication process early enables the SPD manager to understand patient support elements that are critical to workload planning.

Perioperative services. Because the surgery program drives the SPD program in most facilities and surgery staff and patients are generally the primary customers, the many service lines and needs of perioperative services must be understood as much as possible throughout the project phases. Basic data needed to estimate future SPD needs include the following:

- The number of operating rooms
- The outpatient versus inpatient programs
- The case mix and surgery schedule blocks projected for both inpatient and outpatient surgery
- The complexity and length of surgical procedures
- The new specialist surgeons that will join (or leave) the program
- The anticipated changes in the use or type of loaned instruments
- The type of storage and distribution support needed from SPD
- The relationship of the new surgical space to current facilities and buildings
- The surgery room and center core design
- The planning for hybrid surgical suites
- The extent to which immediate-use steam sterilization (IUSS) or other OR sterilization or HLD equipment is used

Emergency department. Understanding the needs of the ED, as well as any anticipated changes in its service or patient volume, ensures that this vital component receives uninterrupted support from SPD. Is the ED already designated a trauma center? Will there be significant changes in the

service level or in the type of patients who visit it? If SPD currently reprocesses medical devices or critical items for the ED, what changes will be needed to support the future ED program? What will be the impact on SPD distribution schedules for the ED if routes will change as a result of the construction or if the adjacency of the ED to SPD changes?

Birth center. Understanding the needs of this program is critical if SPD provides instrument reprocessing and/or a materials distribution system to the birth center. Current support and customer satisfaction should be reviewed. Vertical stacking of the birth center, perioperative services, and SPD is frequently planned in new construction to enable these departments to use the same dedicated clean and soiled elevators. It is important to assess the impact of the birth center's patient care projections, changes in its services, or use of new conventions on the SPD workload. For example, SPD planners should know if new construction for the birth center is designed around a case cart system for instruments and supplies, so that the number and contents of carts will be included in the SPD cart and supply staging space.

Endoscopy. Stand-alone endoscopy suites typically include their own dedicated reprocessing areas and separate cleaned and disinfected equipment storage. Personnel in these areas must follow best practices for cleaning, disinfection, and reprocessing according to device manufacturers' IFU. Many surgical procedures using endoscopic equipment are included in the general surgery and other service lines. Because the equipment is expensive, fragile, might require low-temperature sterilization or high-level disinfection, and is subject to breakage and inventory shortages, SPD must understand all of the interrelated components of endoscopy reprocessing planned for the various service lines occupying the new construction. From an infection prevention and control perspective, it is important for cleaning and sterilizing procedures to be consistent throughout the facility.³ Because of ventilation concerns, equipment testing requirements, and the variety of scopes that might be required, new SPDs might consider designing a separate alcove or space for the reprocessing of endoscopes.

Other clinical areas. Typically, only a low volume of reusable instruments is used by clinical units, intensive care units, imaging departments, and sites outside the healthcare facility (e.g., medical offices and clinics). However, their needs for reprocessing services from SPD must also be considered, especially if there is to be a significant program expansion. Some types of reusable patient care equipment might be cleaned and decontaminated in SPD. New adjacencies might necessitate review of, and possibly changes in, this concept,

especially if the new SPD location increases travel distances and times. Because patient equipment staging (in the decontamination and clean equipment stores areas) requires both floor and shelf space, it is important to understand this program element. To properly identify the impact of providing good customer service, it is helpful to understand the transportation, tracking, charging, and instrument maintenance needs, as well as the storage and handling requirements.

Medical Equipment Planners and Program Consultants

Independent healthcare facility medical equipment planners and programming consultants associated with the architectural design firms generally have a wide grasp of the many types of equipment options available from all manufacturers, as well as knowledge of the advantages and constraints of various manufacturers' products. They are hired to analyze SPD's future workload on the basis of data collected during interviews with SPD representatives. These data will be used to forecast the throughput requirements and to determine the type and number of units comprising the reprocessing equipment mix. Certain assumptions will be made regarding the hours of use of the equipment, the efficiency of the equipment, and staffing requirements. The results of this planning are then incorporated into the space and functional programming documents provided to the architectural team. Sterile processing professionals must assess the accuracy of the equipment planning done by others; understand the assumptions made; compare projections to the current volume and equipment mix; pay attention to their own gut reactions to the data; and check assumptions against the actual experience of other colleagues in the profession, as needed.

Manufacturer-associated, product-brand-specific equipment planners understand the capacities and features of the various equipment models available and use software designed to translate SPD's data into an equipment mix of their specific products. If this approach is used, the results should be carefully analyzed to ensure "apples to apples" comparisons and to determine if the equipment will meet SPD's stated quality and concept requirements. It is important to use one's gut instinct as well, based on the data that have been gathered and all of the planning factors previously mentioned, to validate the results of the data collection.

The starting point for equipment planning is accurate data collection and assumptions for future service requirements and workload projects. For more detailed information on equipment planning for sterile processing, see Section 5.

Long-Range Equipment Planning

Applications of technology will always change, and many SPDs currently suffer from previous planners' inability to predict future needs and changes in services or to provide any capacity for growth (especially in the space program for future washers and sterilizers). Sometimes operational components of program efficiency (e.g., staffing allocation, available hours for work, streamlining processes and procedures) can be adjusted in the future to address increased workloads.

However, if there is inadequate redundancy planned for critical equipment or space provided to add additional equipment in the future, no amount of process improvement will overcome this equipment capacity deficit. The workload calculations for reprocessing equipment must be analyzed to determine the number of machines needed and the available, *unused* machine hours during a 24-hour period. Projections based on medical device manufacturers' IFU are required, especially if the IFU are not being followed currently because of equipment limitations. Generally speaking, the equipment mix in hospital SPDs has historically been programmed to complete the required work in approximately 16 hours of actual reprocessing time each day. This time might not take into account all of the factors associated with loading, unloading, cleaning, and testing.

Perhaps a planning model that projects completion of the current workload volume in fewer hours would be more successful in creating viable long-range options to handle growth or unexpected workload peaks. Managers should visualize and estimate the impact on quality, operational efficiency, and space use if any one key element of the equipment mix is out of service for 8 hours, 16 hours, 24 hours, or longer. For example, if there is one cart washer and it is out of service, what is the backup plan and where will cart cleaning be performed? If one of the production sterilizers is out of service, how long will it take to complete the workload using the remaining sterilizers? Will this reduced SPD sterilizer capacity result in delays in completing the case carts and/or increased IUSS use in surgery? What would be the impact of this situation on workload projections 10 or 20 years into the future?

Additionally, it might be helpful to consciously create sterilizing equipment redundancy within the healthcare facility. For example, perhaps OR planning might include selection of sterilizers that can be programmed to run typical SPD cycle parameters for terminal sterilization in the event of equipment malfunction in SPD. Or, the sterilizers in the healthcare facility's outpatient surgery center can be planned with additional capacity so that they are able to provide

equipment redundancy to address future sterilization needs in a manner that supports SPD.

Developing Supportive Relationships With Customers

New construction is exciting but also causes stress on relationships with customers who already might be struggling to maintain positive communications. Sometimes it is easier to blame people than to understand the difficulty of accomplishing SPD's work in poorly designed systems. Going forward, it might help everyone to acknowledge current difficulties; SPD might choose to share the results of the planning exercises noted previously so that customers can understand its vision for future service. Sharing this information often creates a springboard that strengthens good relationships and repairs those that are problematic. If customers understand the limitations of the current environment and if they have the opportunity to affirm and support SPD's vision, they can participate in joint planning that often helps improve outcomes in the new facility. Maintaining positive attitudes helps both SPD planners and their customers take the high road in strengthening communications during the lengthy planning period for new construction.

Typically, a minimum of two years of joint planning with OR is needed to fully develop all of the details for the new systems and procedures that will be used in a newly constructed SPD and surgery construction project. This time can be viewed as an opportunity to improve communication and encourage individuals to develop new skills around their interests and expertise. One successful planning approach uses special-focus teams to review and create new systems for all of the major SPD functions impacting OR (i.e., decontamination, preparation and packaging, sterilization, inventory management, distribution).

It is helpful if the composition of the planning team represents the needs of the various surgical specialties, SPD's vision, infection prevention, and supply-chain management expertise, as appropriate for the functional area and planning topics. The selection of team members is critical, as both expertise and attitude play a part in successful planning. SPD and perioperative surgery managers must work together to empower the team and diligently create an environment that reinforces productive outcomes; a positive process will both educate all the disciplines and strengthen relationships.

The following list is a starting point for topics that typically will need to be addressed and developed during the planning process. Some issues might benefit from an internal SPD planning focus prior to discussion with customers, and

others are better planned by interdepartmental teams. The operational topics requiring careful consideration by planners include the following:

- **Decontamination.** Return of soiled instruments, case carts, and patient care equipment; computer-assisted tracking of equipment, instruments, and case carts; a fast-track system for instrument reprocessing; implementing manufacturers' IFU; receiving loaned instruments; waste holding and removal; sharps handling; manual cleaning sink design and locations, forced-air and faucet design; chemical HLD and thermal disinfection; personal protective equipment (PPE) selection and storage; handling contaminated items; instrument loading into the reprocessing equipment; cart cleaning; patient care equipment decontamination; use of ultrasonic cleaners; types and location of endoscope cleaning and testing equipment; traffic control; infection prevention and control; lighting and magnification; safety and emergency eyewash/shower equipment.
- **Preparation and packaging.** Ergonomically designed assembly workstations; instrument inspection after decontamination; instrument testing; packaging systems design for any new instruments; following manufacturers' IFU; rigid sterilization container use versus wrappers; reducing set weight to the recommended maximum of 25 pounds or less;⁴ standardization of set contents; use of chemical indicators (CIs); preparing devices with lumens; instrument backup; inventory of single instruments; instrument maintenance; instrument repair system; instrument tracking; backup supply and instrument storage; wrapping table; wrapper holding and storage; unloading carts from the cart washer; instrument container handling and staging; backup instrument storage; infection prevention and control.
- **Sterilization.** Monitoring sterilization cycles; use of BI monitoring for routine non-implant loads; sterilizer maintenance; BI monitoring of implant loads; incubator placement and storage of testing materials; cycle parameters (based on manufacturers' IFU); staging for sterilizer carts; cooling and handling of freshly sterilized packages; IUSS policy; use of low-temperature and HLD/liquid chemical sterilization equipment; management of loaned instruments; integrated recordkeeping and workflow design; infection prevention and control.
- **Case cart system.** Surgeons' preference cards for case picking; arrangement of cart contents; backup storage system; missing-item(s) notification; inventory management for bulk storage; case cart design; instrument and cart tracking; staging of loaned instruments; backup supply

distribution; add-on and emergency case picking and integrating case carts into the tracking system.

- **Communications systems.** STAT notification; add-on notification; cancelled cases; emergency planning; surgery schedule; out-of-stock notification; loan-borrow system; maintaining manufacturers' IFU; internal tracking of loaned instrument sets; recordkeeping, data management, and data integration and tracking systems.
- **Quality assurance.** QA system development; monitoring all reprocessing elements for continuous quality improvement; using incident reports to prevent recurrence of process failures; identification and resolution of system issues; use of process challenge devices (PCDs); managing positive BIs and nonresponsive CIs; load recall; verification of the cleaning process; release criteria for implants; qualification testing of the new cleaning equipment and new sterilizers; documentation of cleaning and sterilization processes; traceability of sterilized implants to patients.
- **Staff support.** Identifying staffing needs to complete reprocessing of new workloads; developing schedules based upon customer service; updating job descriptions; planning education needs; developing new competencies for equipment and new functions; dress code and traffic pattern issues.

The interdepartmental planning approach can be used to identify the needs of all of SPD's existing customers, including perioperative services, endoscopy, the ED, outpatient clinics, and the birth center, as well as new programs that SPD will be called upon to support.

Infection Prevention and Control

Understanding the Issues

The impact of HAIs is widely discussed in terms of costs and the effect on patients (including death or disability). There is no reported percentage of HAIs directly related to construction, but, in general, organisms of concern include those transmitted through air and water, such as *Aspergillus* spp., *Bacillus* spp., *Legionellae*, fungi like *Scedosporium*, *Histoplasma*, *Mucorales*, and molds like *Pusarium* spp. and *Penicillium* spp.³⁸

In 2011, researchers investigating an outbreak of *Bacillus cereus* complex in 230 patients in a Singapore hospital reported that environmental contamination from an adjacent construction site caused heavy air contamination that was transmitted through the air conditioning system. Even when laundered, towels were heavily contaminated with spores, and the growth of the organisms was increased by the linen storage system.³⁹

The cause of an *Aspergillus* outbreak that colonized dozens of patients was traced to the ventilation system that had been in use during the last stages of the construction activity. Construction dust and other particulates introduced into the return air duct contaminated the entire ventilation system. Wet construction materials had become a fungal reservoir within the structure. Use of a filtration unit could have prevented this situation, the associated costly mitigation efforts, and the negative impact on patients, on staff, and on community confidence. The lesson learned from these reports is that ongoing monitoring by the infection preventionist and the project planning team, as well as the use of infection control rounds, is needed for new construction.⁴⁰

Infection control risk mitigation recommendations (ICRMRs) are written plans describing specific methods of avoiding the transmission of air- and waterborne biologic contaminants during construction and when the HVAC and plumbing systems and critical equipment such as steam sterilizers are commissioned. Examples include the following:

- Using a dedicated ventilation/exhaust system for the construction area
- Installing and maintaining barriers for projects in high-risk areas
- Thorough cleaning of the ventilation system prior to occupancy of the construction area

Prepared by the infection prevention planning team, ICRMRs are important in providing a record of the issues identified during the project and of the specific methods set in place to mitigate risk.¹⁴

Infection Prevention and Control Planning

Typically, SPD and infection preventionists (IPs) work hand-in-hand to maintain the necessary approach to infection control required in the SPD environment. Periodic walk-through visits by the IPs have made them and the reprocessing staff aware of the key infection prevention issues. The participation of SPD managers in the infection prevention and control, quality assurance, or risk management committees has also strengthened communication and awareness of the many related factors in infection prevention.

New construction is a wonderful opportunity to create a physical environment that designs out some of the problems that might hinder current SPD operations. The *Guidelines for Design and Construction of Health Care Facilities*, compiled by the American Society of Healthcare Engineering, contains information for architects, IPs, and planners from all

disciplines regarding infection prevention issues. Infection prevention participation is encouraged at early stages in the process of new construction planning. And, use of the infection control risk assessment (ICRA) tool ensures a broad awareness of the issues by a multi-disciplinary team of specialists, including IP, engineering, construction, and safety representatives.¹⁴

Use of the ICRA tool enables the planning team to determine the levels of infection prevention needed at the construction site and during active construction activities. Some of the issues that must be reviewed include the following:

- Impact of disruption on patients and staff
- Potential patient relocation
- Use of barriers to protect patients (especially those who are immunocompromised) from airborne pathogens (e.g., *Aspergillus* sp.)
- Air handling and ventilation issues
- The need for and number of isolation rooms
- Control of waterborne pathogens (e.g., *Legionella* sp.) that can occur when the water system is disrupted

Oversight related to infection prevention is needed in “greenfield” (brand new) healthcare construction to address the many problems that can actually be built into construction.

The APIC and AIA guidelines concur with the Joint Commission standards incorporating the use of a preconstruction risk assessment for infection control. Standard EC.02.06.05, “Elements of Performance for the Environment of Care,” outlines the requirements.⁴¹ Budgets must now be provided to monitor construction activities. Healthcare facilities are encouraged to scrutinize architects’ error and omission insurance coverage to ensure that infectious diseases are covered. Additionally, healthcare facilities are advised to include agreements related to infection prevention (with penalties for noncompliance) in construction contracts.⁴⁰

Some of the many planning and design issues related to infection prevention that must be considered for construction include the following:¹⁴

- Ventilation requirements
- HVAC systems
- Plumbing and electrical systems
- Traffic patterns and workflow

- Handwashing sink design and locations
- Support for use of PPE
- Segregation, holding, and removal of waste, soiled linen, and SUDs that can be reprocessed
- Sterilization systems design
- Sterile storage systems
- Surfaces and materials composition of floors, walls, vents, ceilings, and furniture
- Types of finishes, moisture and mold resistance, cleanability

MANAGING THE DESIGN PROCESS

Interface with Architects and Consultants

Healthcare architecture has evolved over the years as a specialty in response to the increased complexity of regulations and standards, and several national architectural firms are noted primarily for healthcare facility design. The increased demand for new hospital construction prior to 2008 provided widespread experience as well as a business incentive for some architectural firms to form healthcare divisions within their organizations. Board certification for architects who practice in the healthcare specialty differentiates them from those who practice in other architectural specialties.

The architect's primary role is to orchestrate all aspects of the design project, while maintaining the schedule and managing the budget. National firms frequently form joint ventures with regional or local architectural firms for large healthcare projects to facilitate an experienced approach toward design and to ensure that successful innovations implemented elsewhere are considered in relation to local conditions and community values. Architectural joint venturing frequently strengthens the team because it assigns responsibilities to capitalize on both national and local expertise. Architects are experts in building codes, materials, site planning, and costs. Their job is to coordinate all of these factors and to hire and manage a team that can gather the data needed to plan and successfully build the new facility. In some cases, the owner contracts directly with the civil engineer, subconsultants, and construction firms that have previously completed projects on the campus.

Included on the project design team are programming and landscaping architects; engineers to advise on structural, electrical and mechanical systems; consultants on specialties (e.g., sustainability, materials management, waste management, materials handling, sterile processing, surgery,

food service, laboratory, interior design, medical equipment planning, information technology, parking); cost estimators; and construction professionals. The scope and complexity of the project, the expertise of the architectural firm, and the desires of the healthcare organization's planners frequently dictate use of specialty consultants. Physicians, healthcare personnel, managers, and internal hospital planners will be called upon to interface with these many groups over the course of the project.

Using an experienced consultant for surgery and sterile processing data collection, planning, and design work frequently benefits both the architect's team and the healthcare organization. These professionals understand the surgical and sterile processing environment, the key issues affecting quality outcomes for patient care, and how to address concerns that are important to the staff. Specialty consultants can critique and improve the architectural design approach, reinforce the application of integrated solutions, and bridge communications gaps, because they also speak the architect's language. The planning team might wish to develop practical criteria (e.g., experience, education, communication style, references) for selection of these professionals.

Keys to successful interface with architects and consultants are effective communication, clarification, and responsiveness to their requests. The internal SPD planners must present clear, organized, and well-documented data to support their vision and establish the functional and space program previously discussed. To ensure that the SPD reprocessing system is understood, they might wish to use several approaches to convey needs and data. It is very difficult to describe specific issues in the current environment and to explain reprocessing concepts in words and data alone. Touring SPD with the area's managers, as previously recommended, provides architects and specialty consultants with an opportunity for visual clarity and for appreciation of the issues under discussion. Touring other facilities that are examples of good design or that successfully apply new concepts under consideration is highly recommended for planning groups. Using photographs or other visual media to convey additional details of proposed new concepts or equipment also clarifies their application and is recommended to ensure understanding of how they will enable the SPD to meet its goals.

Healthcare architecture is an analytical, creative, and systematic process; and each step builds on the previous ones. As planning progresses, the SPD manager must continue to participate in each session, review the work completed by the architect's team, and provide constructive suggestions and feedback. It is desirable to document any concerns as they arise, so that they are clearly understood and conveyed to



the appropriate planners. The architectural design team and its consultants invest many hours and much creative energy throughout the process. As each step is completed, it becomes progressively more difficult to request changes, because what might seem to be a small change sometimes has a significant impact on other details that are already fixed in the plan.

General Design Resources

AAMI

www.aami.org; ANSI/AAMI ST79

American Hospital Association

www.aha.org

American Institute of Architects

<http://network.aia.org/academyofarchitectureforhealth/home/>

American Society for Healthcare Engineering

www.ashe.org

Architectural Record

<http://archrecord.construction.com>

The Center for Health Design

www.healthdesign.org

Healthcare Design Magazine

www.healthcaredesignmagazine.com

U.S. Green Building Council

www.usgbc.org

Whole Building Design Guide

www.wbdg.org

Design Considerations for Sterile Processing Areas Codes, Standards, and Regulations

The design of SPD areas is subject to many building codes and regulations. Key relevant codes and standards are summarized here. See Section 7 and the side bar for links to these organizations and standards.

Hospitals are among the most regulated of all building types and must follow federal, state, and local or general building codes. Federal facilities on federal property generally follow federal regulations rather than state and local codes. Because healthcare facilities treat Medicare patients, they must also meet federal standards and, to be accredited, they must meet the standards of an accrediting organization such as TJC. The federal government and TJC reference the National Fire Protection Association (NFPA) model fire codes, including

Health Care Facilities Code (NFPA 99)⁴² and the *Life Safety Code* (NFPA 101).⁴³

The 1990 Americans with Disabilities Act (ADA) greatly influences building design with specific accessibility requirements; its standards for accessible design were updated and published in 2010.⁴⁴ The *Architectural Barriers Act Accessibility Guidelines* (ABAAG)⁴⁵ and the General Services Administration's (GSA's) *ABA Accessibility Standard for Federal Facilities*⁴⁶ apply to federal and federally funded facilities, and their technical requirements are similar to ADA requirements.

OSHA regulations also affect the design of many hospital departments. Federal agencies that build and operate healthcare facilities (e.g., the Department of Veterans Affairs) have developed detailed programming, design, and construction standards for their facilities; many of them are also applicable to the design of nongovernmental facilities.

For a healthcare facility to be licensed by the state, its design must comply with individual state licensing regulations. Many states adopt the previously mentioned Facility Guidelines Institute's *Guidelines for Design and Construction of Hospitals and Health Care Facilities* as a resource,¹⁴ so those guidelines often have regulatory status. Additionally, state and local building codes are based on the model International Building Code (IBC).⁴⁷ Federal agencies are usually in compliance with the IBC except when NFPA 101,⁴³ NFPA 70 (*National Electric Code*),⁴⁸ ABAAG,⁴⁵ or the GSA's ABA Accessibility Standards⁴⁶ take precedence.⁴⁹

Resources for Building Codes and Regulations

Americans with Disabilities Act

www.ada.gov

Joint Commission

www.jointcommision.org

Facility Guidelines Institute

www.fgiguideines.org

International Code Council

www.iccsafe.or/Pages/default.aspx

National Fire Protection Association

www.nfpa.org

Occupational Safety and Health Administration

www.osha.gov

U.S. Department of Veterans Affairs

www.cfm.va.gov/TIL/

Staff Support Spaces

Healthcare is a labor-intensive industry. Creating aesthetically pleasing work environments and efficient spaces aids in staff retention, promotes quality outcomes, and reduces worker fatigue. When possible, staff input should be obtained so that there is broad participation in planning and the ideas of persons using and working in these spaces can be incorporated. Participation in more than just the color selection for walls and floors should be sought, and is highly desirable. Encouraging widespread participation by SPD personnel creates more enthusiasm for change and demonstrates respect for individuals.

Locker rooms and toilets. One of the primary reasons for creating SPD locker rooms is to facilitate changing from outside street clothes to facility-provided scrub attire. The projected number of staff members and guests who will use the SPD locker rooms in the new facility is included in the functional program.

Additional planning concepts incorporated into good design include dedicated male and female lockers and changing rooms located off the general corridor. Ideally, direct access through the locker rooms into a clean area, such as the preparation and packaging area, is provided. Staff members working in any of the clean areas of SPD should not have to travel through the decontamination area, soiled holding areas, or over long distances to get to their work environment.

Typically, many persons use these rooms at the same time (e.g., during shift changes), and enough circulation space is needed to allow access to individual lockers, toilets, mirrors, and sinks. In climates where coats are required, it is very helpful to have a separate section of wall hooks or hangers to hold these bulky items, because they are awkward to put into lockers. Separate shoe-holding space for street shoes and boots also helps staff keep the inside of their lockers clean. The number of toilets provided should take into account the projected number of users, especially if healthcare personnel from other departments (e.g., maintenance) are granted access. A single toilet in the locker room is not advisable. A shower within an SPD locker room might not be a desirable feature for personal safety reasons, especially if SPD is located in a remote area of the healthcare facility or lacks restricted, secure access.

In some of the most efficient designs, scrub attire is placed in a central area (in secured dispersers) for controlled access by many persons. This design saves space, improves control of resources, and eliminates the need to transport individual linen carts in and out of the locker rooms. If a central area for

holding and dispensing scrub attire is not part of the design, then space must be provided to stage clean scrub attire carts and maneuver them in and out of the locker rooms without damaging the door frames, doors, and walls. The size and design of any clean linen holding cart must be known in order to plan the space. For infection control reasons, the cart must accommodate within it the required volumes of clean scrub attire (clean scrubs should not be placed on the top of the cart).

Other highly desirable features of good design in the SPD locker rooms and toilets include the following:

- Individual lockers promote safety, security, and individual expression (staff frequently put photos of family inside their lockers).
- Lockers with slanted tops promote infection prevention by minimizing the collection of extraneous personal items and dust on top of lockers.
- Good lighting and mirrors help staff check their appearance and maintain the clean condition of their scrub attire and hair covering.
- A seating bench helps personnel change their attire and shoes.
- Separate containers for holding soiled scrubs and general trash promote infection prevention and control.

SPD break room. The proximity of SPD to the healthcare facility's cafeteria or surgery break room, as well as the general policy determining locations of break rooms, will dictate whether SPD staff will share a break room with other departments after the new construction. There are many space and facility advantages of shared break rooms (e.g., availability of food options, environmental control, cleaning efficiency, information sharing, opportunity for socialization) if appropriate space is designed for the number of persons using the facility at peak times and there is a culture of respect for every position. Most SPD staff members enjoy having their own break room, because it provides a space for visiting, team building, and discussions away from customers. Consequently, this arrangement is the preferred model for SPD.

Offices. Depending on the size of the SPD and its reporting relationships, a manager's office is required adjacent to the work areas in order to facilitate close contact with operations and team members. The office might be internally located (without direct access to the corridor) in some situations. However, an office accessed from the general corridor is the most desirable and least cumbersome for most SPD

managers, because it permits visitors to meet with the manager without having to comply with additional dress code requirements. The SPD manager's office must include space to meet with staff individually. If a separate conference room or meeting room for SPD is not included in the functional program, space for a table that accommodates a small group discussion is desirable within the office.

If the SPD manager's office is located on an outside corridor, finishes for walls and floors will be standardized with the general office design approved for the new facility. If the office is located within the SPD environment, it is designed as a clean area with floor and wall finishes like those of the preparation and packaging area.

Training and education spaces. Planners are advised to consider the requirements for new orientation and training for SPD team members. Use of technology and high-tech media applications can be combined with an understanding of adult learning principles to enhance learning opportunities and create a culture that facilitates learning in the new SPD. Planners can seek input from the SPD team to design a physical environment that optimizes the time spent in attending in-service programs or providing one-on-one assistance. Future accountability for reprocessing requires that technicians have tools to handle the pace of changing technical information. Education that also reinforces critical thinking will assist in good decision making when decontamination and sterilization issues arise. The ability to access data, digital images, and other tools of formal presentation, as well as provide hands-on equipment training, can be achieved by a variety of means, but requires dedicated space and a supportive learning environment (the SPD is a noisy environment that can interfere with learning). Designs that help create an effective learning environment within the SPD functional areas or in a separate area might be considered, depending on the space and on available technology support.

Processing Areas

Elements common to all SPD functional areas. In line with best practices in infection prevention and control, washable and durable surfaces, preferably created from sustainable materials, are required for everything in the SPD environment. Ceilings must have a flush surface and enclosed fixtures and should be constructed of non-particulate/non-fibrous materials. Walls that are smooth and painted are preferable to textured vinyl products that, although durable, have tiny crevices that are more difficult to clean.⁵⁰ Flooring materials should be selected with input from environmental services personnel, but, in general, floors should not require

waxing to maintain an attractive appearance. Floors should be installed with very few seams and an integral cove base that extends up the wall and does not provide crevices that support the growth of microorganisms.

Other highly desirable features of good design in all SPD areas include the following:

- To eliminate infection risks, facilitate cleaning, and encourage sustainability, it is helpful to design communications systems that are clutter-free and reduce paper usage. The communication system might involve white board, magnetic board, telephones, intercoms, pagers, computer-based data transmission, hard-copy data, other technologies, or a combination of applications. Its design must be thoroughly discussed with representatives of all areas of SPD and surgery so that their input can be reflected in the design. A well-planned communications system promotes efficiency, accuracy, and responsiveness to patient needs, but may require appropriate building infrastructure to support the voice and data network design.
- Handwashing facilities, which must be readily accessible in areas of SPD where employees might come in contact with blood or other potentially infectious materials, offer infection prevention and control and safety compliance (29 CFR 1910.1030(d)(2)(iii)).¹⁰
- Sinks should be trimmed with valves that can be operated without hands; this type of sink promotes infection prevention and control and sustainability.¹⁴
- Hand-hygiene solution dispensers promote infection prevention and control. Their placement must comply with fire regulations.
- Wall-mounted hand dryers or disposable-paper-towel dispensers located near handwashing sinks promote infection prevention and sustainability.
- Wall-mounted sharps containers promote safety and infection prevention and control.
- Wall-mounted clocks promote punctuality for start times and break times, assessment of workflow, monitoring work activities, and meeting attendance.
- Wall-mounted or facility-integrated, wired thermometers and hygrometers for measuring temperature and relative humidity promote infection prevention and control; temperature and humidity monitoring is recommended to comply with AAMI and AORN best practices.^{4,51}

- Signage that clearly identifies the SPD work areas (e.g., decontamination, case cart staging) and describes special considerations, such as access restrictions or the presence of hazardous materials, will assist customers and reduce accidental traffic.
- Audio signals and/or task lighting, such as might be associated with the arrival of an elevator or completion of a sterilizer cycle, provide audible and visual indications to SPD technicians that action on their part can now be taken (e.g., to unload the equipment) and promote productivity.

Decontamination area. The space allocation and design of the decontamination area is critical. Poor workflow design, inadequate lighting, ineffective ventilation, inadequate numbers of washers, ultrasonic cleaners and other reprocessing equipment, and lack of circulation space will only recreate over time many of the current issues. These factors must be carefully considered to reduce bottlenecks to staging; expedite sorting of soiled instruments; prioritize reprocessing of STAT items; and enable efficient and accurate cleaning and decontaminating of the wide array of complex medical devices and patient equipment. The reality for most decontamination areas constructed years ago is that designers failed to anticipate future needs and technology applications. Some of the drivers for space needs in the decontamination area are the use of rigid sterilization containers, the increasing number of specialty surgeries (including laparoscopic procedures), the need for reprocessing of endoscope and robotic instruments, and the proliferation of a wide variety of loaned instruments that frequently require multiple ultrasonic cleaning cycles.

If these space drivers were absorbed into the existing SPD over the years, hospital planners can benefit from that experience. Employee complaints about working in an undersized, hot, inefficient, and extremely physically challenging environment can be used to create a better space plan in the new SPD. The experiences of technicians and surgery colleagues can be applied in the critique of the space use and materials flow of the new design. If some programs are new, experienced colleagues, specialty managers, and proposed instrument and equipment vendors can be consulted for a better understanding of the impact of those programs on decontamination space and equipment selection.

The new decontamination area might be required to function for the next 30 to 40 years. The design process will provide an opportunity to ensure that current needs will be accommodated and that there will be the flexibility to handle both expected and unexpected future workloads. The infrastructure and space for current, developing, and projected technology systems and software interfaces should be created

now, even if they are planned for future application. For example, most new SPDs can be designed to use integrated technology for the major decontamination equipment, such as washers, to facilitate efficiency, accuracy, and recordkeeping and to accommodate seasonal variations in demand and corresponding changes in volume. The experience of a major East Coast medical center in planning, adapting, and using this technology might be helpful in the evaluation of equipment options and the application of integrated technology for the new SPD.⁵²

Personnel safety, ergonomic principles, and automation are key concepts to keep in mind when creating efficient decontamination area designs. Consideration of ergonomics encourages a review of the work activities to avoid excessive pushing, pulling, bending, lifting or reaching. Occupations that are physically demanding and require repetitive lifting (as occurs in all areas of SPD) create the greatest risk of both non-accidental and accidental back and shoulder injuries. Instrument sets are heavy and, although best practices recommend that they weigh less than 25 pounds to ensure proper sterilization,⁴ heavier sets (especially loaned orthopedic and neurosurgical instruments) are routinely encountered.

For the new SPD, planners are encouraged to seriously review currently available materials-handling options and consider automated loading and unloading of washer–decontaminators. Large departments will especially benefit from using conveyor feeds and rack-return conveyors to handle the high volume of racks exchanged between the decontamination and preparation and packaging areas. Overhead designs should be avoided because they put repeated stress on the neck and shoulders of workers and are difficult for women and other shorter workers to manage. The consensus is that people will be working longer and that the environment must accommodate the physical needs of older workers and be designed to avoid costly injuries.

The positioning of floor drains is critical and must be reviewed to ensure proper placement in relation to all decontamination equipment and workstations using water. It is helpful if floor drains are designed for easy, periodic cleaning.

The most efficient decontamination area designs create multiple workstations with flexibility to accommodate several functions, depending on need. For mechanical cleaning and disinfecting equipment, like washer–disinfectors, pass-through designs are best for efficiency and infection prevention. See Section 5 for additional information on decontamination equipment selection, design, and installation testing.



The decontamination area entry generally should consist of one entrance with doors large enough to prevent damage from bulky items, such as carts. Access to the area may be controlled by such means as an employee badge key card. If programmed, an elevator may also be used to bring carts of soiled items directly into the decontamination area. This dedicated soiled elevator should not access general areas, and its use should be limited to customers such as surgery and the birth center for return of soiled reusable medical devices and equipment that are to be reprocessed in the decontamination area. It should not be used by surgery staff or maintenance personnel as a shortcut to enter the decontamination area and then walk through to any clean areas of SPD. It is a critical infection prevention strategy to maintain control of traffic patterns, and the design of the decontamination area should prevent unauthorized access.

Other highly desirable features of good design in the SPD decontamination area include the following:

- Lighting that is bright enough to enable workers of all ages to properly view contamination on instruments is required; lighting must be positioned over each work area so that the work is illuminated, not in shadow. Appropriate lighting promotes thorough cleaning, infection prevention, better quality outcomes, and greater efficiency (especially in manual cleaning functions), with less frustration on the part of reprocessing personnel. Table 1 (excerpted from ANSI/AAMI ST79⁴) summarizes illuminance levels recommended by the Illuminating Engineers Society of North America (IES) for work environments.⁵³
- A dedicated elevator or other vertical materials-handling conveyance must be sized appropriately for the volume, maintained regularly, and cleaned daily to promote infection prevention, safety, and efficiency.
- Wall-mounted computer terminals and scanners promote the ergonomic use of instrument tracking systems and accuracy in documenting work types and volumes.
- Workstations designed with counter space on either side of the sinks reduce clutter and help prevent instrument damage and personnel injury.
- Counter space and holding space for cleaning patient care equipment (e.g., infusion pumps) segregate this activity from the flow of instrument reprocessing in the decontamination area.
- A dedicated fast-track workstation promotes responsiveness to surgery needs and allows visualization that priority work is in process.
- Multiple-compartment sinks (two- and three-sink models), with basins deep enough (8 to 10 inches) to allow manual cleaning and rinsing and sized for large containers and instruments, facilitate proper cleaning under water, help prevent instrument damage, and encourage rinsing with water of the required quality.
- Areas for cart holding and queuing that are adequately sized for peak volumes will promote efficient receiving, sorting, staging, and identification of priority processing.
- Washer–disinfectors with equipment loading conveyors and rack transfer carts facilitate efficient movement of fully loaded, heavy instrument and equipment racks and promote good ergonomics and personnel safety.

Table 1—IES-Recommended Illuminance Levels for Work Environments^{4,53}

Work Area/Function	Least Illuminance	Average Illuminance	Highest Illuminance
General inspection	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
Detailed inspection	1,000 lux (100 foot-candles)	1,500 lux (150 foot-candles)	2,000 lux (200 foot-candles)
Sink areas	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
General work areas	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)
Processed storage	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)

- Cleaning products should not be stored on the floor or under sinks. The space needed will be determined by the inventory and the sizes of the containers. Proper storage of cleaning products promotes effective environmental cleaning, facilitates infection prevention, and reduces waste.
- Using electronic chemical proportioners promotes infection prevention, proper dilution of chemicals for effective cleaning and disinfection, error reduction, and cost savings.
- If rigid sterilization containers are used, cleaning and decontamination will be required. Accurate information on container sizes and estimation of the necessary holding space aid in efficiency and equipment selection.
- Using cart washers for cart cleaning (with a backup system) requires cart staging and equipment that can handle the volumes efficiently, thus promoting infection prevention, good ergonomics, and worker safety.
- Endoscope cleaning and disinfection might be programmed for SPD. The use of automated machines, known as automated endoscope reprocessors (AERs), is recommended for this process. Such equipment is not pass-through, so it should be located within the SPD space so as to minimize transport of the endoscopes, which are fragile, and prevent recontamination of reprocessed devices after completion of the HLD cycle. This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements. The exact location of the AER (and the workflow and ventilation that this placement dictates) should be determined in consultation with the infection preventionist. Locating the equipment in the preparation and packaging (clean area) space is preferred by some authorities.
- Pasteurizing equipment, used for anesthesia and respiratory therapy equipment, might be programmed for the decontamination area and should be located so as to minimize handling and recontamination of reprocessed devices after cycle completion (pasteurizing equipment is not pass-through). This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements.
- Ultrasonic cleaners should be sized to handle the processing needs for specific instruments and may be either counter or console models, as appropriate for the volume and design of instrumentation.*
- A covered receptacle for soiled linen is required to handle any reusable linen, including towels, cloth cart covers, and other such items. This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements.
- A receptacle for general waste is required to contain disposables, such as used masks, shoe covers, plastic cover gowns, gloves, used CIs, and other such items. This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements.
- A receptacle (generally provided by the device reprocessing center) is required to contain SUDs (e.g., compression sleeves, catheters) that will be reprocessed under contract with an FDA-regulated third-party vendor.
- Personal protective equipment such as masks, gloves, cover gowns, and shoe covers can be stored on a shelf or cart in an alcove at the entrance to the decontamination area. This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements.
- In compliance with 29 CFR 1910.151(c), eyewash facilities and an overhead drench shower are needed for handling personnel exposure to chemicals.⁵⁴ Additionally, OSHA's bloodborne pathogens standard, updated April 3, 2012, includes a requirement for "flushing mucous membranes with water immediately or as soon as feasible following contact with blood or other potentially infectious materials" (29 CFR 1910.1030(d)(2)(vi)).¹⁰ ANSI Z358.1 addresses emergency eyewash and shower equipment in situations where employees are exposed to hazardous materials and notes that appropriate flushing systems must be "installed within ten seconds or 55 feet from the hazard."⁵⁵
- A pass-through window, designed to remain closed when not in use, should be constructed of safety glass or non-scratching plastic. Communication between the decontamination area and the clean preparation and packaging area is required for the transfer of non-wheeled equipment and devices after manual cleaning and disinfection. This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements.

* The instrument manufacturers' IFU must be reviewed to plan the number of ultrasonic cleaners, because this is a batch process and cycles of 10 to 20 minutes are not uncommon. Because of the need for equipment redundancy, programming more than one unit is advisable for the decontamination area. Greater emphasis on the use of ultrasonic cleaners is anticipated to address reports of inadequate instrument cleaning.

- Counter space and mobile carts are required for holding and staging work in progress, promoting efficiency and allowing good ergonomics for personnel.
- A clinical flushing-rim sink for fluid disposal is required in a location compatible with the workflow and protected from damage by passing cart traffic. Returning containers of fluids to SPD is not encouraged, but contaminated liquids should be disposed of in this equipment rather than in the sinks used for cleaning instruments. This design promotes infection prevention, safety, and efficiency.
- A janitor's closet for use by environmental services personnel when cleaning the decontamination area promotes infection prevention.
- The recommended temperature range for the decontamination area is 60 °F to 65 °F (16 °C to 18 °C) and the recommended relative humidity range is 30% to 60%; compliance with these temperature and humidity recommendations helps reduce the bioburden and provides for staff comfort.⁴ Area personnel are responsible for monitoring and documenting temperature and humidity daily and reporting significant variations. Other considerations of importance include ventilation specifications. The decontamination area should be maintained under negative air pressure; that is, when the doors open, the air outside the area should enter the decontamination space. A wall-

mounted visualization device for monitoring negative room pressure will be of assistance when the SPD is operational. Table 2 (excerpted from ANSI/AAMI ST79⁴) summarizes AAMI and Facility Guidelines Institute ventilation requirements for functional areas of SPD.

Preparation and packaging area. The functions and space requirements for this area were developed in previous planning phases. This is an opportunity to ensure that current needs will be accommodated and that flexibility will be built in to handle the expected—and unexpected—in the future. As described previously for the decontamination area, the infrastructure created should accommodate current, developing, and projected integrated technology systems and software interfaces. At the design stage, the layout of workstations and the projected traffic patterns and workflow should be reviewed to eliminate unnecessary steps, handle the throughput at every entry point from the decontamination area, and provide adequate circulation of people and carts.

As discussed in the previous section, infection prevention and control, safety, ergonomic considerations, and efficiency are key planning concepts to keep in mind when creating efficient designs. The most efficient schemes for the preparation and packaging area locate multiple workstations with flexibility to accommodate several assembly functions, depending on need. A large lighted table or flat-wrapping table is helpful and efficient if the functional program requires basin wrapping,

Table 2—Ventilation Requirements for Functional Areas⁴

Functional Area	Air Flow	Minimum Number of Air Exchanges Per Hour (ANSI/AAMI ST79 ⁴)	Minimum Number of Air Exchanges Per Hour (Facility Guidelines Institute) ¹⁴	All Air Exhausted Directly to the Outdoors?
Soiled/decontamination	Negative (in)	10	6	Yes
Sterilizer equipment access	Negative (in)	10	10	Yes
Sterilizer loading/unloading	Positive (out)	10	—	Yes
Restrooms/ housekeeping	Negative (in)	10	10	Yes
Preparation and packaging	Positive (out)	10, down-draft type	4	No
Textile pack room	Positive (out)	10, down-draft type	—	No
Clean/sterile storage	Positive (out)	4, down-draft type	4	No

for example. Such a table can also be used to inspect and reassemble small equipment. Instrument assembly workstations should be designed with the following important features:

- Eye-level bin storage for the many small items required for assembly
- Adjustable height capability
- Locking caster-design wheels
- Efficiency
- Ease of floor cleaning
- Adjustable overhead lighting
- Computer keyboard and CPU interface
- Washable, smooth surfaces

Especially critical in the preparation and packaging area is the design of the pattern grid for lighting. Lighting that is bright enough (but non-glaring) to enable workers of all ages to properly view articulations, crevices, and complexities of instruments is required so that they can verify cleanliness and identify damage. Lighting must be positioned over each work area so that the work is illuminated, not in shadow. Unless instruments are thoroughly cleaned, they cannot be effectively sterilized. See also Table 1.

A spaghetti diagram (one of the tools of Lean engineering) can be used to determine all of the “touch points” of the work-in-progress as the materials handling flow is traced throughout the department. The spaghetti diagram is an effective visual planning tool for checking efficiency in all areas of SPD, but especially helpful for determining the best design layout for the preparation and packaging area. See Figure 1 for an example from a major East Coast medical center of the materials-handling touch points identified in the reprocessing environment.

Other highly desirable features of good design in the preparation and packaging area include the following:

- A pass-through window, designed to remain closed when not in use, should be constructed of safety glass or non-scratching plastic. Communication between the preparation and packaging clean area and the decontamination area is required for the transfer of non-wheeled equipment and devices that have been manually cleaned and disinfected. This design promotes safety and infection prevention, in compliance with OSHA, CDC, TJC, and other agency requirements.

- Counter space and mobile carts are required for holding and staging work in progress, promoting efficiency and allowing good ergonomics for staff members.
- A dedicated fast-track workstation promotes responsiveness to surgery needs and allows visualization that priority work is in process.
- Integrating computer terminals and scanners into the workstations and providing access to a printer promote the use of an instrument tracking system, facilitate accurate documentation of work types and volumes, and allow printing of tray contents lists (if required).
- Areas for cart holding and queuing should be adequately sized for peak volumes to promote efficient receiving, sorting, staging, and identification of priority processing.
- A dedicated storage cabinet might be needed to prevent recontamination of HLD-reprocessed endoscopes if they are stored in the SPD for any length of time.
- Equipment loading conveyors and rack transfer carts facilitate efficient movement of heavy racks exiting from the washers and promote good ergonomics and personnel safety.
- Positioning a floor drain near where washer–disinfectors are unloaded is critical for handling any accumulating water, and the drain must be designed for easy periodic cleaning.
- Holding space for instrument containers facilitates cleanliness and ease of selecting the appropriate container size. Determining container sizes and the holding space needed for the peak volume aids in efficiency and workflow.
- Holding space for test equipment, scanners, timers, heat sealers, and other required tools promotes efficiency.
- A drying cabinet is desirable for use with the variety of endoscopes and other plastic medical devices that must be thoroughly dried after processing.
- Space for holding the various wrappers needed to accommodate the variety of instrument sets being prepared is required.
- The storage space for consumable materials used in preparing items for sterilization (e.g., labels, CIs, PCDs) should be readily accessible to workstations to promote efficiency and convenience.

- An enclosed pegboard cupboard or cabinet drawers for holding backup instruments facilitates security, efficiency in set completion, and infection prevention.
- A sufficient number of electrical outlets is required (especially if patient care equipment, such as IV controllers, is held in the area). Additional outlets should be located conveniently near equipment testing areas and on mobile workstations.
- Bulk materials should not be stored on the floor or under sinks. They must be held under the storage conditions recommended by the manufacturer of the product. (For example, CIs can be light-sensitive; BIs can be affected by

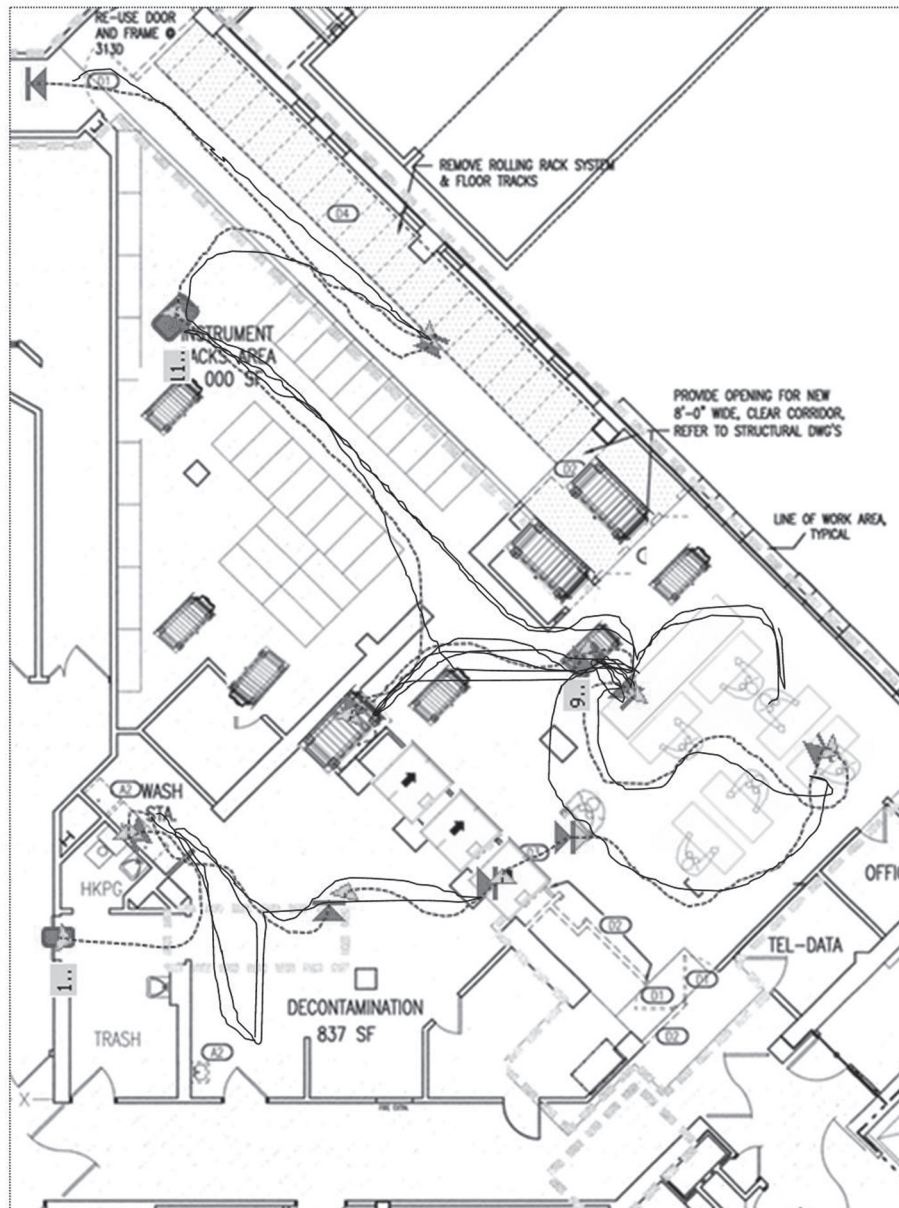


Figure 1—Example of a Spaghetti Diagram

(Figure provided courtesy of Mark Duro, New England Baptist Hospital)