THE VIRGINIA BOARD OF HEALTH PROFESSIONS
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

STUDY INTO THE NEED TO REGULATE CENTRAL SERVICES/STERILE PROCESSING TECHNICIANS IN VIRGINIA

December 17, 2008

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Executive Summary

Background & Authority

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board is beginning an ongoing review of emerging health professions. The study will highlight individual professions selected by the Board for review. The Board selected *Central Service/Sterile Processing Technicians* as one of the emerging professions for review in 2008.

The study is governed by the methodology described in the Board's *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998*. The following seven criteria (the Criteria) collectively serve as the benchmark for its decisions.

(1) Unregulated practice of the profession poses a recognizable harm or risk for harm to the consumer resulting from practices inherent in the occupation, the characteristics of the clients served, the setting or supervisory arrangements for the delivery of services, or any combination of these factors.
(2) Practice requires specialized education and training, and the public needs to be assured of initial and continuing occupational competence.
(3) Autonomous practice occurs so that the functions and responsibilities of the practitioner require independent judgment.
(4) The scope of practice is distinguishable from other licensed, certified or registered occupations.
(5) The economic impact due to restriction on the supply of practitioners and the cost of board operations is justified.
(6) Alternatives to regulation have been explored and none are found which would adequately protect the public.
(7) The least restrictive regulation that is consistent with public protection must be recommended.

The Board reviewed the relevant literature related to central services/sterile processing and related occupations, federal and state laws and regulations, information on educational accreditation and credentialing programs, licensing and disciplinary information, salary and compensation and media coverage. They held a public hearing on August 14, 2008 and solicited and received written comment.

Findings

Central Services departments provide material management and distribution services within medical facilities. Central to this role is the collection, processing and redistribution of reusable medical equipment and instruments. To ensure the safety and cleanliness of reusable equipment, Central Services technicians decontaminate, sterilize

and package instruments according to manufacturer and Food and Drug Administration specifications. This is referred to as sterile processing.

Maintenance of the sterile field surrounding invasive procedures is a collaborative effort between central services personnel, operating room staff and other practitioners. Sterility is affirmed by chemical and biological indicators on packaging (packaging is included in the sterilization process) and final inspections by OR staff. Most central services personnel work in larger facilities with centralized departments. In smaller offices and clinics, medical assistants generally handle sterilization.

The International Association of Healthcare Central Services and Material Management (IAHCSMM) represents the profession nationally. The IAHCSMM has a Virginia Chapter, the Virginia Association of Central Services (VACS). The IAHCSMM provides certifications for central services technicians, supervisors and managers. Additionally, the independent Certification Board for Sterile Processing and Distribution, Inc. (CBSPD) provides the only NCCA accredited certifications in the field.

Candidates may attain either certification through on-the-job training, but educational courses are available for those seeking training. Candidates may complete education online or through industry supplied, on-the-job training modules. Additionally, various community colleges and technical centers offer diplomas or certificates, some leading to associate's degrees. No specific CS programs are available in Virginia.

Central services provides an attractive career path for entry-level persons holding a high school diploma or GED. According to the Bureau of Labor Statistics, the average annual salary of persons working as Medical Equipment Preparers (the equivalent of Central Services Technicians) in Virginia was $26,790 as of May, 2007. Additionally, dedicated professionals can take advantage of diverse education and training opportunities to move into management positions. The cost of education and certification is reasonable for those seeking long-term employment in the field.

Central services/sterile processing activities are affected by a variety of laws, regulations, agencies and private accreditation organizations. The U.S. Food and Drug Administration (FDA) works with the Association for the Advancement of Medical Instrumentation (AAMI) and device manufacturers to elaborate sterilization procedures and standards. The U.S. Centers for Medicare & Medicaid Services (CMS) collaborates with states and private medical accreditation organizations to ensure that medical facilities receiving federal funding meet minimum safety standards and pursue best practices. Infection control is a major priority. Accredited hospitals must have infection-control committees to develop and maintain safe practices and to investigate any problems. The U.S. Centers for Disease Control and Prevention (CDC) provide comprehensive infection control guidelines for medical facilities.

New Jersey is the only state that currently regulates central services/sterile processing personnel. Their acute care facilities must employ a certified central services manager, including additional management certifications. Central services staff at acute

care facilities must be certified at the technician level within three years of employment. Staff at ambulatory care facilities must be certified within two years. New Jersey recognizes both IAHCSMM and CBSPD certifications.

The potential for harm comes from two sources: Improper cleaning of electronic medical equipment and contamination following mishandling of any reusable materials. Improper cleaning of electronic medical equipment can cause device failure, fires or burns. On October, 31st, 2007 the FDA issued a Public Health Notification warning of these outcomes and recommending that hospitals identify potential problems and institute preventative measures. The more significant risk of harm stems from the spread of infection. In addition to the direct risk to patients, infections can spread to healthcare workers and the public at large. This is of particular concern in healthcare settings where vulnerable patients and systematic antibiotic use can create an ideal environment for drug-resistant organisms. A CDC study uncovered 1.7 million hospital-acquired infections (HAIs) in 2002, resulting in 98,987 deaths. If formally tracked, HAIs would have been the sixth leading cause of death in 2002, above diabetes and influenza/pneumonia.

Discovering the source of HAIs is a difficult task. Infectious agents can attack patients from multiple vectors, including the air, hands, water and surfaces. Most of the infection control literature focuses on proper hygiene of practitioners, proper use of antibiotics and limiting the extent and duration of invasive procedures. However, proper sterilization of equipment is a fundamental prerequisite for preventing infections.

According to the Joint Commission, infection-related sentinel events are "seriously underreported." Official information on infections is difficult to come by. Nevertheless, breakdowns of sterile processing procedures occasionally make their way to the media. An internet search of media reports revealed fourteen incidents affecting 10,121 patients. Most of these were procedural problems that did not result in infection. Patients were often encouraged to attain free blood screenings as a precautionary matter.

However, two incidents resulted in 21 infections and 3 deaths. It is difficult to determine the exact vector of infection in any incident. In one incident, the hospital moved responsibility for disinfection of some equipment from the central sterilization department to other medical personnel. In the other, an ongoing controversy between the FDA, sterilization equipment manufacturers and hospitals has complicated the investigation into the causes of the infections.

Lee Germain of the Virginia Association of Central Services submitted written comment supporting regulation of central services. Her comments include first hand accounts of incidents reported by central services professionals.

Recommendation

At its December 17, 2008 meeting, the Regulatory Research Committee considered a motion that Central Services/Sterile Processing Technicians not be regulated at this time. The motion was not seconded and the Committee took no further action.

The full board also met on December 17, 2008 and reviewed recommendations from the Regulatory Research Committee. After careful consideration and deliberation, the Board voted, with two Members abstaining, to not recommend regulation of Central Services/Sterile Process Technicians through the Board of Health Professions at this time.

In keeping with the regulatory principles established by the Board, criterion three must be met to justify a recommendation of professional licensure and criterion six must be met to justify a recommendation of voluntary certification or registration. Following this criteria, the Board recommended no professional regulation by the Board of Health Professions at this time.

In considering Criterion Three: Autonomous Practice, the Board noted that the risks associated with sterile processing are often difficult to attribute to individual technicians, rendering discipline of individual technicians through professional regulation cumbersome. Furthermore, the Board noted that Sterile Processing technicians are employed by healthcare facilities and are usually organized within hierarchical oversight structures.

In considering Criterion Six: Alternatives to Regulation, the Board considered whether regulation through the Virginia Department of Health's facility licensing requirements or through private facility accreditation organizations was more appropriate. Additionally, the Board considered whether professional licensure through the Virginia Department of Professional and Occupational Regulation was more appropriate.

Central Services Technicians

Background

On November 29, 2007, at meeting of the Board of Health Professions' Executive Committee, Lee Germain, from the Virginia Association of Central Services (VACS), presented comment regarding the need for mandatory certification of central sterile technicians. Ms. Germain noted inconsistencies in the training and varied responsibilities of central sterile technicians among hospitals. Ms. Germain presented several examples of patient harm due to contaminated patient care instruments. On properly seconded motion by Pia Trigiani, the Committee voted unanimously to refer the matter to the Regulatory Research Committee for study. This report is the result of the Committees research efforts.

Authority

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board will conduct a study into the need to regulate central sterile technicians and provide recommendations through the Director and Secretary of Health and Human Resources accordingly (see §54.1-2510 of the Code of Virginia).

To govern evaluative reviews, the Board has developed formal criteria and policies referenced in its publication, *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998.* Among other things, the criteria assess the degree of risk from unregulated practice, the costs and benefits of the various levels of regulation, and the advantages and disadvantages of the various alternatives to regulation that might protect the public. By adopting these criteria and application policies, the Board has endorsed a consistent standard by which to judge the need to regulate any health profession. The aim of this standard is to lead decision-makers to consider the least governmental restriction possible that is consistent with the public's protection. This standard is in keeping with regulatory principles established in Virginia law and is accepted in the national community of regulators.

Study Scope & Methodology

The general scope of this study is to review the competencies and standards of practice for central sterile technicians in the Commonwealth and other jurisdictions. The Regulatory Research Committee will focus their efforts in determining the answers to the following key questions:

- What is the potential risk for harm to the consumer?
- What specialized skills and training do practitioners possess?
- To what degree is independent judgment required in their practices?

- Is their scope of practice distinguishable from other regulated occupations or professions?
- What would be the economic impact to the public if this group were regulated?
- Are there alternatives other than state regulation of this occupation which would adequately protect the public?
- If the Committee determines that this occupation requires state regulation, what is the least restrictive level that is consistent with the protection of the public's health, safety and welfare?

To answer the key questions, the following steps are recommended:

1. Conduct a review of the general policy literature, if any, related to the regulation of the respective group.
2. Conduct a review of the current relevant states laws and regulations.
3. Review malpractice insurance coverage data (if it is found to exist) in conjunction with other data to address Criterion One - Risk of Harm to the Public.
4. Review available reimbursement data to develop an estimate of how regulating this group may affect costs to address Criterion Five – Economic Impact
5. Prepare an initial draft report to the Board for public comment.
6. Conduct a hearing on the issue of the state regulation of this occupation, including any public health and safety issues germane to current practices as well as the potential fiscal impact which may result from such regulation.
7. Review all public comment, apply the Board's criteria and policies, and consider recommendations for changes in Virginia statute.
8. Prepare a draft with recommendations to the full Board.
9. Review the report and recommendations by the Board, and publish a draft report for consideration by the Department Director and Secretary.
10. If required based on recommendations by the Department Director and Secretary, amend the report and prepare a final report for their approval.

Overview of the Profession

Central Service/Sterile Processing Technicians provide centralized inventory control and distribution for medical equipment in hospitals, clinics and other healthcare facilities. A significant part of this function is the processing and sterilization of reusable medical equipment, from basic surgical tools to advanced endoscopes that allow surgeons to look inside the body and perform minor procedures using fiber-optic technology.

The Bureau of Labor Statistics tracks central service/sterile processing technicians (Medical Equipment Preparers) in its Occupational and Employment Statistics (OES) database (OES Code 31-9093). Medical Equipment Preparers include persons who

> "Prepare, sterilize, install, or clean laboratory or healthcare equipment. May perform routine laboratory tasks and operate or inspect equipment."

The OES reports that in May of 2007, 43,790 persons worked as Medical Equipment Preparers nationally. Of these, 29,960 (64.5%) worked in hospitals, 5,020 (11.5%) worked in dentist and physician offices, 2,050 (4.7%) worked in outpatient clinics and 990 (2.3%) worked in medical laboratories. Other employers include equipment suppliers, manufacturers, and off-site (contracted) processors. Virginia businesses and institutions employed 1,280 Medical Equipment Preparers in May of 2007.

The International Association of Healthcare Central Services and Material Management (IAHCSMM) is, as of February, 2008, the sole professional organization representing Central Services and Sterile Processing Technicians. The IAHCSMM was founded in 1958. In February 2008, it merged with the American Society for Healthcare Central Service Professionals. The IAHCSMM, with offices in Chicago IL, has over 9,000 members, holds an annual conference and publishes a trade magazine. It provides training materials, educational opportunities and scholarships, and certifications (see page 6).

The Virginia Association of Central Services (VACS) is the Virginia branch of the IAHCSMM. VACS holds two conferences each year, one in the spring and one in the fall. In addition to networking with vendors and colleagues, these conferences provide continuing education opportunities. VACS also provides two awards for exceptional service to the field, the Central Services Team of the Year Award and the Charlotte Jenkins Educational Award. VACS operates from 7216 Woodside Street in Richmond, Virginia and maintains a website at www.vacsweb.com.

In addition to the IAHCSMM certifications, the Certification Board for Sterile Processing and Distribution, Inc, (CBSPD) with offices in Alpha, New Jersey, provides the only certifications for sterile processing professionals accredited by the National Commission for Certifying Agencies.

Sterile Processing[1]

The sterilization role of Central Service/Sterile Processing technicians relates most directly to patient care and safety. This process can be broken up into four basic functions: decontamination; assembly and packaging; sterilization; sterile storage and distribution.

Decontamination, which refers to the physical removal of blood and soil, begins immediately after instruments are used. Allied health practitioners provide initial cleaning and sorting of used instruments. Central Service personnel then pick up and securely transport the instruments to a centralized decontamination area. Once there, technicians further sort the items, disassemble them when appropriate, and put them through one of several decontamination processes, including heated disinfection washers,

[1]This section based on descriptions by the Sterile and Materials Processing Department of the University of Rochester Medical Center available at http://www.urmc.rochester.edu/Sterile/basics.html. Accessed 10/24/2008.

ultrasonic washers or detailed hand washing. Technicians then inspect the items for cleanliness and damage.

Following decontamination, items are further sorted, reassembled and packaged. Packaging includes textiles, pouches or rigid containers. Many non-invasive items are designated for various levels of disinfection, however surgical and other invasive items are fully sterilized. Technicians prepackage items destined for sterilization to prevent contamination once the sterilization process is complete.

Sterilization involves the killing of any potential pathogen on instruments. Sterilization can take a variety of forms, depending on the unique sensitivities of the instrument. The most common form is steam sterilization. However, other methods use chemicals, gases, radiation and heat. Many of these processes can pose occupational and environmental hazards. Each of these methods uses mechanical, chemical and biological indicators that sterile processing technicians interpret to ensure sterility. [2]

Once disinfected or sterilized to the appropriate level, items are sorted and placed in sterile storage. Technicians often create surgical kits, used in specific procedures. Sterile items and packaging have differing shelf lives, and must be distributed carefully. Sterile processing technicians ensure sterilized items remain sterile from the time they leave sterilization machines to the time they reach perioperative nurses or surgical technologists in the operating room.

Manufacturers of medical equipment and supplies provide detailed instructions for disinfection and sterilization of equipment. Additionally, the Food and Drug Administration monitors sterilization methods. Sterilization processes are often redundant, minimizing the potential risk to patients.

Central Services/Sterile Processing[3]

Most hospitals combine the functions of central services and sterile processing. However, some hospitals have begun to separate "Central Services" from "Sterile Processing," placing inventory control under material management divisions and sterile processing under Operating Room (OR) or Infection Control (IC) supervision. Three main reasons are cited for the change: 1) as medical equipment has become more complex and diverse, so have sterilization procedures, 2) the proliferation of techniques involving potentially dangerous chemicals and 3) the healthcare industry has become increasingly concerned with the hospital-related infections and drug resistant pathogens. (see page 21).

[2] For a summary sterilization monitoring processes see: Centers for Disease Control. "Infection Control in Dental Settings: Sterilization-Monitoring" http://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm

[3] See Seavey, Rose. 2007. "Raising the Bar: Increased Training and Compensation for Sterile Processing Professionals." *Managing Infection Control*. August, 2007. pp 69-72.

Overlapping Scopes of Practice

Several professions play an essential role in maintaining the sterile field around any invasive procedure. Persons working in these professions receive training and certifications that are applicable to both central services and sterile processing functions. Some of these professionals may work in central services and sterile processing departments.

Surgical Technologists[4]

Surgical Technologists perform many functions within the operating room as both sterile and non-sterile members of the surgical team. One of the key capabilities of surgical technologists is to prepare surgical instruments and equipment within the operating room before surgery. Surgical Technologists assemble surgical kits and ensure the sterility of anything entering the surgical field. Certified Surgical Technologists (CSTs) demonstrate knowledge of medical instruments, equipment and the sterile process. The Association of Surgical Technologists notes in their brochure "Surgical Technology: A Growing Field" that these skills lead some surgical technologists to pursue opportunities in central services departments.

Perioperative Nurses[5]

Perioperative Nurses are licensed nurses (RN or LPN) that specialize in the care of surgical patients. While perioperative nurses perform many of the same functions in the operating room as surgical technologists, they receive more formal education and training than CSTs. Their role is to manage patient care within the operating room.

Biomedical Equipment Technicians[6]

Biomedical Equipment Technicians (BMETs) are experts in the installation, care and maintenance of healthcare equipment, including proper sterilization techniques. BMETs tend to specialize in certain classes of equipment, such as surgical or sterilization equipment. Healthcare facilities often employ their own BMETs, however, many work for equipment suppliers and maintenance contractors. BMETs Central Services departments work closely with BMETs to ensure the proper care of medical equipment, including sterilization equipment within the CS department. The Association for the Advancement of Medical Instrumentation provides certification for Certified Biomedical Equipment Technicians (CBETs).

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[4] For information on Surgical Technologists see the Association of Surgical Technologists: www.ast.org. For Certification information see the National Board of Surgical Technology and Surgical Assisting: www.nbstsa.org.

[5] For information on Perioperative nursing see the Association of Operating Room Nurses: http://www.aorn.org.

[6] For information on Biomedical Equipment Technicians see the Association for the Advancement of Medical Instrumentation: www.aami.org.

Medical and Dental Assistants

In physicians' and dentists' offices, and in smaller clinics, medical and dental assistants handle the disinfection and sterilization process. Accredited medical assistant educational programs and certifications for medical and dental assistants require knowledge of sterilization and aseptic technique.

Certification

Two organizations provide certifications for central services/sterile processing professionals: The International Association of Healthcare Central Services and Material Management (IAHCSMM) and the Certification Board for Sterile Processing and Distribution, Inc. (CBSPD). Three of the CBSPD's six certifications are accredited by the National Commission for Certifying Agencies. None of IAHCSMM's certifications are independently accredited.

Both IAHCSMM and CBSPD offer entry-level, supervisory and management level certifications as well as specialist certifications. IAHCSMM offers the Certified Registered Central Service Technician (CRCST), Certified in Healthcare Leadership (CHL), Certified in Healthcare Materiel Management Concepts (CHMMC) and Certified Instrument Specialist (CIS) credentials. CBSPD offers the Certified SPD Technician (CSPDT), Surgical Instrument Processor, Ambulatory Surgery Technician, Flexible Endoscope Reprocessor, SPD Supervisor and SPD Manager credentials. The CBSPD is also accredited by the United States Department of Veterans Affairs.

Comparison of Entry Level Certifications

Certified Registered Central Services Technician

The IAHCSMM certification is not accredited by the National Commission for Certifying Agencies or any other national or regional credentialing body. The National Organization for Competency Assurance (NOCA) created the NCCA in 1989 to act as an independent accreditation commission. The NCCA assumed the role of the National Commission for Health Certifying Agencies, which worked closely with the Federal Government to develop standards in voluntary certification programs.[7]

To be eligible for the CRCST certification exam, candidates must complete an approved training course and complete 400 hours of hands on experience in ten practice areas (see Table 1) before or within six months of taking the certification exam. Currently employed candidates with the required 400 hours of experience can sit

Practice Area	Hrs
Patient Care Equipment	32
General Cleaning	32
Wrapping Packaging	36
Linen Folding	36
Assemble Instrument Tray	60
Sterilization	64
Storage Clean & Sterile	36
Case Carts	32
Distribution	32
Miscellaneous	40

Table 1: CRCST hands on experience.

[7] Browning, A.H., Bugbee, A.C., & Mullins, M.A. 1996 *Certification: A NOCA Handbook*. National Organization for Competency Assurance (NOCA). USA. pg. x.

for the exam and attempt to certify without completing a training course. The Prometric/Thomson Sylvan Learning Centers, private testing facilities, administer the exam at 300 locations throughout the United States.

Certification	Level	Accredited	Exam Content
IAHCSMM			
Registered Technician	Entry	No	Microbiology; Sterilization; Infection Control; Packaging and Storage; Inventory Management
Instrument Specialist	Special	No	Knowledge and Recognition of Medical Instruments; Instrumentation Practice Skills
Supervision Principles	Super	No	Management and supervisor responsibilities; Healthcare Leadership
Material Management	Manage	No	Strategic Budgeting; Purchasing; Supplier Certification; Waste Control; Training; Storage
CBSPD			
SPD Technician	Entry	NCCA	Roles and Responsibilities (18%); Life Sciences (9%); Decontamination (20%); Preparation and Handling (17%); Sterilization (22%); Sterile Storage, Inventory Management and Distribution (14%)
Surgical Instruments	Special	No	Decontamination of Surgical Instruments (30%); Preparation and Packaging of Surgical Instruments (35%); Sterilization of Surgical Instruments (25%); General Knowledge of Surgical Instruments (10%)
Ambulatory Surgery	Special	No	Roles and Responsibilities (15%); Life Sciences (10%); Decontamination (25%); Preparation and Handling (20%); Sterilization (25%); Sterile Storage and Distribution (5%)
Flexible Endoscope	Special	No	Infection Control(12%); Reprocessing Techniques (13%); Standard Equipment for Endoscopic Procedures (19%); Chemicals (11%); Rules and Regulations (10%); Safety (14%); Basic Medical Competencies and Performance Standards (7%); Recordkeeping (3%); Specimen Handling (4%); Ethical Standards(7%)
SPD Supervisor	Super	NCCA	Fiscal Management (2%); Human Resources Management (12%); Roles and Responsibilities (27%); Life Science (10%); Decontamination (9%); Preparation and Handling (14%); Sterilization (12%); Sterile Storage, Inventory Management and Distribution (14%)
SPD Manager	Manage	NCCA	Fiscal Management (8%); Human Resources Management (12%); Roles and Responsibilities (28%); Life Science (9%); Decontamination (10%); Preparation and Handling (11%); Sterilization (9%); Sterile Storage, Inventory Management and Distribution (13%)

Table 2: Certifications offered by the IAHCSMM and CBSPD and exam content. Only three of the CBSPD certifications are NCCA accredited.

CRCSTs must complete 12 continuing education contact hours, or CRCST points, annually. CRCSTs may attain points by attending workshops, educational seminars, hospital oriented in-service training or by completing approved self-study lessons.

The fee to take the CRCST exam is $105. CRCSTs must renew their certifications annually by completing continuing education requirements and submitting a $40 renewal fee. The renewal fee includes IAHCSMM membership dues.

Additionally, IAHCSMM recognizes certifications from other certifying boards. Candidates wishing to receive certification in this manner must have completed the 400 hours of hands-on experience, completed 12 hours of continuing education within the previous year and submited proof of alternate certification.

SPD Technician

The CBSPD's CSPDT certification is accredited by the NCCA. The CBSPD itself is accredited by the United States Department of Veteran's Affairs.

To be eligible for the certification exam, candidates must have completed one of the following:

- 12 months of full-time employment or equivalent part-time hours
- Successful completion of a related allied health program and 6 months employment practicing SPD.
- Completion of 1 year of healthcare product sales or service related to the SPD profession.
- Completion of a Central Service/SPD Training Course with a passing grade of 70 or higher.[8]

The CSPDT exam consists of 125 multiple-choice questions. Lasergrade, a private testing company with sites throughout the United States, administers CBSPD certification exams.

Certifications last for five years. Within that period, CSPDTs must complete 100 hours of continuing education. However, employment counts towards continuing education requirements, resulting in a reduced requirement for employed CSPDTs. Full-time employment provides 10 hours per year while part-time employment provides up to 5 hours. CSPDTs can also receive continuing education hours for adult education courses, college courses, committee or officer service in government or national organizations, approved in-services, submitting approved test questions, publishing articles, or presenting educational programs. The fee to take the CSPDT exam is $115. CSPDTs must renew their certification every five years by submitting continuing education hours and a $100 renewal fee.

	Education	Experience	Annual CE hrs*	Fee	Renewal Fee	Renewal Period	Annualized Renewal Cost
CRCST	Approved Course	***And*** 400 hrs	12	$105	$40**	1 yr	$40
SPD Tech	Training Course	***Or*** 12 months	10	$115	$100	5 yr	$20

Table 3: Summary of Entry Level Central Services Certifications
*Continuing Education Hours per year
**The CRCST renewal fee includes IAHCSMM membership dues.

[8] See CBSPD website: http://www.sterileprocessing.org/cert-levels.htm accessed 10/16/2008.

Education

Training courses are optional parts of both entry-level certifications. Candidates that have the requisite 400 hours of on the job experience can skip the education requirement for CRCST certification. Candidates wishing to sit for the SPD Technician certification may substitute training for experience.

Each certifying association has its own criteria for acceptable training courses. The IAHCSMM requires approved IAHCSMM courses. The CBSPD requires that course instructors be certified or have extensive experience in the field.

IAHCSMM Educational Offerings

The training portion of the CRCST certification eligibility criteria requires candidates to complete either an IAHCSMM sponsored Purdue University Correspondence course or an approved IAHCSMM course. As of this writing, IAHCSMM has not responded to a request for information on its approved courses. In addition to the Purdue University Correspondence Course, IAHCSMM provides a textbook and group training kits and it approves instructors.

Purdue University, in cooperation with IAHCSMM, offers an online Principles of Central Service correspondence course. The course is based on the *IAHCSMM Central Service Technical Manual, 7th Edition* and is designed to teach students the knowledge and skills needed to act as CRCSTs, including passing the exam. The course covers the following topics:

- Medical Terminology
- Anatomy and Physiology
- Microbiology for Central Service
- Regulations and Standards
- Infection Prevention and Control
- Decontamination
- Disinfection
- Surgical Instrumentation
- Sterile Packaging
- High Temperature Sterilization
- Low Temperature Sterilization
- Inventory Management
- Management of Patient Care Equipment
- Quality Assurance
- Safety
- Communication and Human Relations Skills

The course takes approximately 80 to 100 hours to complete. Once completed, students must pass a 175 multiple-choice question exam with at least a 70 percent grade. The cost of the two-credit course is $555.10, including all course materials. Students who do not wish to receive college credit may enroll as non-credit seeking students for $420.00.

The Purdue University course is based on the IAHCSMM produced textbook, *Central Service Technical Manual, 7th Edition*. The text consists of 23 chapters surveying all aspects of Central Services and Sterile Processing. Students may purchase

the textbook alone for $80 or with an accompanying workbook for $125. The textbook and workbook may be used as a self-study program.

IAHCSMM also offers a complete group-training package, Exx Cel 2000 Plus, to central services administrators or trainers. This training package provides instruction for both entry level and experienced central services personnel. Exx Cel 2000 consists of eight stand-alone training kits:

Training Kit 1: Benchmarking As Part of the Total Quality Management (TQM) Process

Training Kit 2: Low Temperature Sterilization: A Primer on Alternative Products and Processes

Training Kit 3: Ethylene Oxide: A Close Look at the Low-Temperature Sterilant of Choice

Training Kit 4: Sterilization Principles for Medical Devices: Flat and Pouch Packing Materials

Training Kit 5: Sterilization Principles for Medical Devices: Rigid Container Systems

Training Kit 6: Managing Safety Hazards in Central Service

Training Kit 7: Effective Use of Low- and Intermediate-Level Disinfectants in Central Service Departments

Training Kit 8: Proper Use of Chemical Cleaners in Central Service Operation

Administrators and trainers may purchase these kits individually for $125 each or as a complete package for $875.

IAHCSMM also approves instructors. To become an IAHCSMM Approved Instructor for IAHCSMM Central Service Technician Courses instructors must be CRCSTs or academic instructors that have passed the CRCST exam. Instructors must attend one "Instructor's Update" and one "Instructor's Meeting" every two years. Additionally, they must agree to teach *only* the IAHCSMM provided curriculum and use the latest IAHCSMM instructor guide. Instructors must require students to use the IAHCSMM text and workbook, or provide these books as part of the course fee.

In addition to these educational offerings, a search of central services training programs revealed many that claimed to prepare students for the IAHCSMM CRCST certification exam (see page 12). Although it could not be determined that these were IAHCSMM approved courses, they provide another educational pathway for students wishing to gain the CRCST credential. Since formal education is not required to take the exam, a combination of job experience, training, self-study, online, seminar or classroom education can be pursued by CRCST candidates.

CBSPD Educational Offerings

Candidates wishing to sit for the CSPDT certification exam either must have 12 months of full time experience or have completed a relevant training course, or a combination of allied health education and experience. The only specific requirement

that CBSPD has for training courses is that instructors possess CRCST or CSPDT credentials or have extensive experience in the field. The CBSPD keeps a list of Central Services/Sterile Processing courses on its website, publishes study guides and workbooks and endorses a textbook.

CBSPD invites trainers and institutions to list Central Services/Sterile Processing courses on its website. The list is not an endorsement, nor does it signify approval of course content, but the courses listed can be used to meet CSPDT eligibility requirements if the instructor is properly qualified. The CBSPD website counsels potential students to examine these and other courses and instructors on their own for suitability. Currently, there are 18 programs listed on the website (see Table 4). Community Colleges offer nine of the programs, medical centers offer five, and independent instructors or contractors offer three listed courses. Courses for college credit range from six credit programs ($378) to 36 credit programs ($6480). Non-college credit courses range from 24-hour, multi-day seminars ($250) to a 500-hour course at a public technical training facility ($2,035). Virginia does not host any of the listed courses. The listing does not illustrate the availability of courses in Virginia or elsewhere.[9]

Institution	Location	Hours*	Fee
Baker College of Flint	Flint, MI	36 credits	$6480
Parkland Health & Hospital System	Dallas, TX	24	$250
Bayshore Community Hospital	Holmdel, NJ	66.5	$475
North Cypress Medical Center	Houston, TX	40	$300
Prairie State College	Chicago Heights, IL	48	$450
Atlantic Technical Center	Coconut Creek, FL	500	$2,035
Mid-State Technical College	Marshfield, WI	16 credits	NA
Al Ritchon, CST Tech, Surg Tech	Hayward, CA	40	$575
Aiken Technical College	Graniteville, SC	100	$790
Juan Miguel Ramos, CRCST	Tyler, TX	40	$650
Banner Desert Medical Center	Mesa, AZ	12 weeks	$750
Advantage Support Services	Nashville, TN	Online	$250
Bridgeport Hospital School of Nursing	Bridgeport, CT	80	$450
Lansing Community College	Lansing, MI	240	NA
Bunker Hill Community College	Chelsea, MA	10 credits	$1,510
Mt. Hood Community College	Gresham, OR	6 credits	$378
St. Vincent's College	Bridgeport, CT	36	$500

Table 4: Programs listed on the CBSPD Website: Eighteen programs have listed courses on the CBSPD website. The CBSPD does not endorse or investigate these programs.
*In total hours unless otherwise stated.

[9] See "CBSPD List of Central Service/SPD Courses" http://www.sterileprocessing.org/courses/courses1.htm, accessed 10/17/2008

The CBSPD produces a study guide and workbook to help students prepare for the CSPDT certification exam. The study guide is an outline of course content. The workbook complements *The Basics of Sterile Processing, 2nd Edition,* published by Sterile Processing University. *The Basics of Sterile Processing* provides a survey of Central Services/Sterile Processing functions including:

- Roles and Responsibilities
- Anatomy and Physiology
- Microbiology
- Infection Control
- Decontamination
- Patient Care Equipment
- Preparation/Packaging/Surgical Instruments
- Sterilization
- Sterile Storage
- Inventory Control and Distribution
- Medical Terminology

Students may purchase the study guide, workbook and textbook separately for $20, $30 or $100, respectively, or they can purchase all three for $120 from the CBSPD website. Much like the CRCST certification, there are multiple educational and training pathways for candidates pursuing the CSPDT credential.

Other Educational Offerings

An internet search revealed twelve additional Central Services/Sterile Processing related programs (see Table 5). Community colleges offer eleven programs, while the twelfth is offered by a private trainer. The community college programs ranged from three to 43 credit programs.

Institution	ST	Cred	Certif.
Community College of Allegheny County	PA	16	
Atlantic Cape Community College	NJ	3	IAHCSMM
Mid-State Technical College	WI	20	CBSPD
Waukesha County Technical College	WI	5	
Northeast Wisconsin Technical College	WI	10	CBSPD
Renton Technical College	WA	11	
Skyline College	CA	7	
Ivy Tech Community College	IL	36	IAHCSMM
Columbus Technical College	GA	15	CBSPD
Watson Enterprises (sterileprocess.com)	TX		CBSPD
GateWay Community College	AZ	18	
Clover Park Technical College	WA	43	IAHCSMM

Table 5: Other Educational Offerings. Some of these programs advertise that they prepare for certifications.

The Virginia Community College System does not offer specific central services programs. However, Piedmont Virginia Community College, with a campus in Charlottesville, and Lord Fairfax Community College, with campuses in Warrenton, Luray and Middletown, both offer Surgical Technologist certificates. These programs provide training on medical instrumentation and sterile technique. Additionally, the Chester campus of John Tyler Community College is offering the five-credit class: SUR 145-Fundamentals of Surgical Care. This course focuses on the preparation and care of surgical instruments and supplies, including sterile technique and packaging, within the operating room.

Economic Impact

Salary Information

The US Bureau of Labor Statistics (BLS) tracks Central Service/Sterile Processing personnel as Medical Equipment Preparers (OES Code 31-9093). The BLS provides detailed workforce and salary information on all employed (excluding unemployed and self-employed) workers in states and metropolitan areas. The latest OES information for Medical Equipment Preparers currently available is from May of 2007. Table 6 provides a snapshot of OES data from Virginia, Virginia's border states, Virginia's metropolitan areas and national data.

Area name	Work force	Hourly mean wage	Annual mean wage	10th Percentile	90th Percentile
Virginia	1,280	$12.88	$26,790	$8.83	$17.37
National	43,790	$13.43	$27,940	$9.37	$18.43
Kentucky	870	$12.32	$25,620	$8.82	$15.58
West Virginia	160	$12.34	$25,670	$8.38	$17.41
Tennessee	390	$12.79	$26,600	$8.94	$17.30
North Carolina	1,540	$12.88	$26,790	$9.74	$17.08
Maryland	560	$13.60	$28,280	$10.09	$17.98
Dist of Columbia	130	$15.39	$32,020	$11.38	$18.99
VA Beach, Norfolk*	480	$11.48	$23,870	$8.05	$14.79
Richmond*	140	$12.09	$25,150	$8.63	$16.55
DC, NoVa*	640	$15.03	$31,260	$11.60	$18.25

Table 6: BLS Employment and Wage Data for Medical Equipment Preparers. Listed from lowest to highest paid.
*Refers to the following Metropolitan Areas: Richmond, VA; Virginia Beach-Norfolk-Newport News, VA-NC; Washington-Arlington-Alexandria, DC-VA-MD-WV Metropolitan Division

Both the IAHCSMM and CBSPD conduct periodic salary surveys. Both organizations included surveys with their mailed newsletters and invited website visitors to fill out an online survey form. The CBSPD conducted a salary survey over the summer (2008) and is currently analyzing the results. The results of the 2004 survey are the latest available. The IAHCSMM last conducted a survey in 2002. Neither used scientific sampling methods or reported sample sizes. Considering the nature of the surveys, it is probable that the samples are biased towards certified technicians actively participating in continuing education or professional organizations, and those seeking certification, including specialist or supervisory certifications. New employees, or those less committed to the profession, may be underrepresented, affecting the results.

The CBSPD survey found that all technicians, both certified and non-certified, earned $13.41 per hour on average, with a range of $7.00 to over $20.00. Certified technicians earned, on average, $14.27 per hour. Wages for non-certified technicians were not reported separately, but these figures imply that certified technicians do receive a wage premium. Only 37 percent of certified technicians, however, indicated they had received a wage increase with their certification. Higher wages may be associated with high performance and dedication to the profession rather than the value of certification itself. Paradoxically, forty-seven percent of respondents indicated that their employer required certification. It is unknown how many facilities this represents, but the sampling method may have resulted in overrepresentation of technicians from these facilities.[10]

[10] See Certification Board for Sterile Processing and Distribution, Inc. 2004. "September 2004 CBSPD Salary Survey Results." http://www.sterileprocessing.org/survey_results_04.htm accessed 10/20/2008.

By contrast, the IAHCSMM survey found no significant difference between the pay of technicians with CRCST credentials and those without. More technicians earned between $10.50 and $12.99 (≈35 percent) than other income brackets, though reported earnings were as low as $6.50 per hour. IAHCSMM reported results as ranges rather than exact amounts, rendering the results less precise than the CBSPD survey.[11]

Both surveys also reported on the salaries of lead technicians, managers and other supervisory personnel. Lead technicians, the lowest supervisory level, reported earning on average $5.51 more per hour than SPD technicians in the CBSPD survey. The IAHCSMM survey results were less clear, with most lead technicians reporting hourly wage ranges similar to technicians. However, some gains for lead technicians were evident. Managers earned $24.84 per hour on average in the CBSPD survey, while almost 95 percent of managers responding to the IAHCSMM survey reported earning over $40,000, with almost 50 percent earning between $40,000 and $60,000.

Though these surveys were not performed using scientific sampling methods, their results dovetail with the BLS data. Some entry-level Central Services/Sterile Processing technicians earn little over the minimum wage. However, the median incomes for the profession, which are slightly lower than the mean incomes reported in Table 6, fall between the 25th percentile ($10.06) and 50th percentile ($15.10) of all wage and salary earners (OES code 00-0000 "All Occupations"). Moreover, 57 percent of management and director level respondents to the IAHCSMM survey indicated they possessed less than baccalaureate level education, indicating high earnings potential for career technicians with high school diplomas or associates degrees.

Economic Impact of Certification

The economic value of the certifications is difficult to measure. The IAHSCMM survey reported no significant differences in pay levels between CRCSTs and other technicians. The CBSPD data indicated that certified technicians earned higher wages, though it is difficult to link higher wages directly to certification. Likewise, hard data on the certifications of professionals in supervisory or specialist positions are not known. A survey of job openings in Virginia revealed that only a few technician level positions required certification within one year of hire. However, all of the lead, supervisor or manager level positions required certification. Thus certification is linked to career development, even if the benefits to frontline workers are not as direct.[12]

Certification costs are relatively low. Both certifications allow candidates to take the exam without formal training. A Virginia Central Services/Sterile Supply technician earning 10th percentile wages ($8.83 per hour, May 2007) can pay for either exam with

[11] See IAHCSMM. 2002. "2002 IAHCSMM Salary Survey." http://www.iahcsmm.org/special_feature_0502.htm accessed 10/20/2008.

[12] An internet search of job openings conducted on 10/20/2008 revealed 19 openings. Thirteen were for technician level positions, one team lead, one supervisor and two each for assistant manager and managers. Some of the technician level positions were ongoing advertisements for large health care organizations.

13 hours of labor. Students seeking training for certification have several options, many of them affordable. Table 7 provides an overview of certification and education options and costs in hours worked for 10th percentile and mean wage earners in Virginia ($8.83 & $12.88 respectively). Additionally, in-service training modules, such as the EXX CEL 2000 module, are available to employers to facilitate training. Since hospital accreditation agencies require training plans (see page 19), on-the-job training provided to employees can meet the educational needs of certification candidates.

Training Program	Cost	10th %-ile wage $8.83	Mean wage $12.88
CRCST	$105	12.00	8.25
CSPDT	$115	13.00	9.00
Purdue University Correspondence Course	$420	47.50	32.75
Bayshore Community Hospital Course, NJ	$475	53.75	36.75
Aiken Technical College Course, SC	$790	89.50	61.50
Sterile Processing University Online Course	$435	49.25	33.75
The Basics of Sterile Processing, w/ workbook & Study Guide.	$120	13.50	9.25
Central Service Technical Manual, 7th Edition w/ workbook	$125	14.25	9.75

Table 7: The cost of certification in hours worked. Includes various training options. Costs calculated in hours worked for Virginia workers earning 2007 10th percentile and mean wages, rounded to the nearest quarter hour.
*Many educational programs provide these books. They are also a self-study option.

In addition to initial training and certification costs, certified technicians face yearly renewal and continuing education costs. CRCSTs must pay a $40 renewal fee that includes membership in the IAHCSMM. They also must complete the equivalent of 12 continuing education hours annually. On-the-job "in-services," often provided by sales representatives or by trade magazines, provide the lowest cost continuing education option for employees. Additionally, the IAHCSMM, in cooperation with Purdue University, provides self-study modules, at two CEUs each, for $15. CSPDTs must renew every five years at a cost of $100. CSPDTs employed full time must complete an additional ten continuing education hours annually, using many of the same options as CRCSTs, including the option to use the Purdue Self Study Courses.

Existing Regulation

A variety of federal and state agencies and private organizations affect Virginia's Central Supply/Sterile Processing units and procedures. At the federal level, guidelines for infection control and medical equipment are promulgated by the Centers for Disease Control and the Food and Drug Administration (FDA). Additionally, the Centers for Medicare and Medicaid Services (CMS) demand minimum standards for the receipt of federal funds and encourage best practices. At the state level, the Virginia Department of Health licenses hospitals and, with the Department of Medical Services, administers CMS programs. Government agencies depend on accreditation recommendations and standards set by private organizations.

Federal

Centers for Disease Control: Infection Control Guidelines

The Division of Healthcare Quality Promotion of the Centers for Disease Control and Prevention promulgate guidelines for infection control in healthcare settings, including sterilization and disinfection guidelines.

Food and Drug Administration

The Food and Drug Administration is responsible for regulating all medical devices, including sterilization machines, sterile packaging and chemical sterilants. Medical devices designed for reuse must include appropriate sterilization and other safety instructions.

Reusing devices labeled as single use devices (SUDs) by healthcare facilities has become a common method of cutting costs. The FDA considers reprocessing SUDs as remanufacturing these devices and reprocessors of SUDs as remanufacturers. Reprocessors of SUDs, including hospitals, must register with the FDA and list the SUDs that they reprocess.

Currently ten third party sterile processing facilities and one hospital have registered as reprocessors of SUDs. These institutions are subject to FDA process regulation and periodic inspection.

The Centers for Medicare & Medicaid Services, HHS

CMS creates "conditions of participation" for providers that receive reimbursement for services through the Medicare and Medicaid programs. These conditions are in the *Code of Federal Regulations*. Section 482.42, "Condition of Participation: Infection Control" requires that hospitals designate an infection control officer or officers responsible for preventing, documenting and investigating hospital acquired infections. Additionally, Part c.1 of §482.41 "Condition of Participation: Physical Environment" directs participating hospitals to ensure equipment is safe and of acceptable quality.

The CMS delegates most of the work of monitoring healthcare facilities to states or to private accreditation bodies. The process of state approval of healthcare facilities is referred to as "certification." Accreditation bodies granted the authority to approve facilities for reimbursement are referred to as "deeming authorities." Additionally, on behalf of CMS, states perform surveys of about one percent of privately accredited hospitals each year.

Section 32.1-137 of the *Code of Virginia* designates the Board of Health as the sole agency of the Commonwealth for certification of medical care facilities under Title XVIII of the *Social Security Act* (Medicare). It also designates the Board of Health *with*

the Virginia Department of Medical Assistance Services to provide certification under Title XIX (Medicaid).

There are currently only two deeming authorities recognized for hospitals. Section 1865 of Title XVIII recognizes hospitals accredited by the Joint Commission on Accreditation of Hospitals and the American Osteopathic Association as (with exceptions and subject to discretion) meeting the standards for Medicare Reimbursement.

Virginia

Section 32.1-125 of the *Code of Virginia* requires that all inpatient and outpatient hospitals operating in Virginia be licensed or certified. The Virginia Department of Health licenses over 100 inpatient and outpatient hospitals throughout Virginia. Additionally, the Virginia Department of Health has certified all licensed hospitals for Medicare and Medicaid Reimbursement.

Virginia Department of Health
Office of Licensure and Certification

The Office of Licensure and Certification licenses and certifies Hospitals in Virginia. It performs biennial inspections and promulgates rules for licensure. The following rules apply to Central Services/Sterile Processing.

State Board of Health
Section 12 VAC 5-410 "Rules and Regulations for the Licensure of Hospitals in Virginia."

Part II. Organization and Operation of General and Special Hospitals.
Article 2. Patient Care Services.
Section 12 VAC 5-410-250. Sterile Supply Service.

A. Each hospital shall operate a sterile supply service or provide for the processing, sterilizing, storing, and dispensing of clean and sterile supplies and equipment.

B. Facilities shall be provided for the cleaning, preparation, sterilizing, aeration, storage and dispensing of supplies and equipment for patient care.

C. Areas for the processing of clean and soiled supplies and equipment shall be separated by physical barriers.

D. Written procedures shall be established subject to the approval of the Infection Control Committee for all sterile supply service functions including:

1. Procedures for all sterilizing and for the disposal of wastes and contaminated supplies; and
2. Procedures for the safety of personnel and patients.

. . . . . .

Article 4. Environmental and Maintenance Services.
Section 12 VAC 5-410-490. Infection Control (relevant sections)

A. Each hospital shall have an infection control committee to perform at least the following functions:

1. Establish a hospital-wide infection surveillance program and designate an infection control officer to conduct all infection surveillance activities and to maintain appropriate records to include infection rates by body site and clinical service and all hospital acquired blood stream pathogens.
2. Establish written policies governing the admission and isolation, including protective isolation, of patients with known or suspected infectious diseases.
3. Develop, periodically evaluate, and revise as needed, infection control policies, procedures and techniques for all appropriate phases of hospital operation and service in order to protect patients, employees, and visitors. These policies shall include, but are not limited to, appropriate employee health screening and immunization and acceptable techniques and practices for high risk procedures such as parenteral hyperalimentation, urinary tract catheterization, dialysis, and intravenous therapy.

Part IV. Outpatient Surgical Hospitals: Organization, Operations, and Design Standards for Existing and New Facilities.
Article 4: Patient Care Services.
Section 12 VAC 5-410-1210. Sterile Supply Services.

A. Adequate provisions shall be maintained for the processing, sterilizing, storing, and dispensing of clean and sterile supplies and equipment.

B. Written procedures shall be established for the appropriate disposal of pathological and other potentially infectious waste and contaminated supplies.

Virginia Department of Medical Services

The Virginia Department of Medical Services recognizes hospitals that are certified by the VDH for Medicare participation, or hospitals that are accredited by the Joint Commission on Accreditation for Hospitals that do not treat age groups eligible for Medicare. These facilities are eligible for Medicaid reimbursement.

Private Organizations

The American Osteopathic Association

The American Osteopathic Association's Healthcare Facilities Accreditation Program (HFAP) accredits two hospitals in Virginia: The Dickenson Community Hospital of Clintwood and the Norton Community Hospital of Norton. The HFAP, begun in 1945, has been accrediting hospitals under Medicare for over thirty years. The HFAP *Accreditation Requirements for Healthcare Facilities, February 2005 Edition* includes sections on infection control, central supply, decontamination and sterilization, packing and storage and other Central Services/Sterile Processing services. This includes an infection control committee.

Joint Commission on Accreditation of Healthcare Organizations

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits 113 hospitals in Virginia. The JCAHO has been accrediting hospitals for Medicare since 1965. It began accrediting hospitals in 1953. Its accreditation manual includes standards on infection control and care of medical equipment, including a requirement that sterilizers be routinely tested and maintained.[13] Additionally, the JCAHO regards hospital-acquired infections resulting in death or serious injury as "Sentinel Events." Investigations into sentinel events require a tracer method to determine the root cause of infections. These investigations encourage extensive record-keeping of sterilization processes.[14] Infection Control is also a 2009 "National Patient Safety Goal."

The Association for the Advancement of Medical Instrumentation

Association for the Advancement of Medical Instrumentation (AAMI) standards are often considered when determining best practices. The AAMI provides a three-volume book set dedicated to sterilization of Medical Instruments:

- Part 1: Sterilization in Health Care Facilities, 2009 edition
- Part 2: Sterilization Equipment, 2006-2007 edition
- Part 3: Industrial Process Control, 2006-2007 edition

The AAMI also provides a subscription service, providing two CD-sets annually and continuous web updates, that provides up-to-date, comprehensive standards for medical equipment, including sterilization practices.

[13] Hospital accreditation standards are currently being updated. JCAHO has pre-published many of the new standards on their Standards Improvement Initiative for Hospital Accreditation Program. These revised standards become effective on Jan. 1st, 2009. http://www.jointcommission.org/Standards/SII/sii_hap.htm

[14] Cantrell, Susan. 2007. "ICPs: Assuring sterilization means acquiring education." HealthCare Purchasing News. Dec. 2007. http://www.hpnonline.com/inside/2007-12/0712-ic-sterileassurance.html. Accessed 10/22/2008.

Other States

New York

As of October 24, 2008, New York was considering two bills, A3220 and S3737, which would provide for mandatory certification for sterile processing technicians. Both bills were referred to the Higher Education Committee of their respective houses on January 9, 2008. The identical bills set requirements for licensure, impose mandatory continuing education requirements and delineate the profession.

New Jersey

The Health Care Facilities Planning Act (N.J.S.A 26.2H-1 et seq.) authorizes the Department of Health and Senior Services (DHSS) to promulgate rules for the licensing of health care facilities. These rules are listed in Section 8:43G of the New Jersey Administrative Code. N.J.A.C. provides extensive rules pertaining to the maintenance and processes of Central Services departments. Among these are rules pertaining to the qualifications of management and staff.

Acute care facilities must employ a full-time central services director or supervisor. This person must be certified by a recognized national sterile program and have a minimum of two years supervisory experience. DHSS currently recognizes the CBSPD Certified SPD Manager (CSPDM) credential and the IAHCSMM Certification in Health Care Leadership (CHCL) credential for this position.

Acute care facilities must develop an education plan for each department, including Central Services (NJAC §8:43G-5.9). New Central Services staff must receive on the job training on practices and equipment used in the hospital. The competency of CS staff members must be documented annually by the director (NJAC §8:43G-83). All Central Services staff must be certified through a recognized national sterile processing program within three years of employment. Additionally, staff using ethylene oxide, a common disinfectant chemical, must be licensed by the Department of Environmental Protection (NJAC §8:43G-8.2). Lastly, the infection control provisions at Ambulatory Care Facilities require that any individual that reprocesses reusable medical instruments must be certified within two years of employment. (NJAC 8:43A-14.5). The DHSS currently recognizes the CBSPD technician (CSPDT) and the IAHCSMM technician (CRCST) credentials.[15]

A review of penalty letters revealed one enforcement action regarding improper certification of Central Services personnel. A 2006 inspection discovered two nurse aides whom had not received training in central services processing surgical instruments

in central services. Additionally, the supervisor of central services was not certified. Several other violations were also discovered at the facility.[16]

Potential for Harm

The Board of Health Professions views risk of harm as the gateway criteria for regulation. The 1998 report "Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions" requires the following elements to establish a risk of harm:

Risk for Harm to the Consumer

The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.

Improper Central Service or Sterile Processing techniques have the potential to harm the public through two main routes: nosocomial infections and malfunctioning equipment.

Nosocomial Infections

Nosocomial infections, also known as health care acquired infections, health care associated infections or hospital acquired infections are, generally, infections caught by patients in a health care setting.

The U.S. Centers for Disease Control and Prevention, in their 2002 report "Estimating Health Care Associated Infections and Deaths in U.S. Hospitals, 2002" define Health Care Associated Infections as:

> . . . a localized or systemic condition that (1) results from an adverse reaction to the presence of an infectious agent(s) or its toxin(s), (2) that occurs during a hospital admission, (3) for which there is no evidence the infection was present or incubating at admission, and (4) meets body site-specific criteria. [17]

[16] A list of enforcement actions is available at: http://www.state.nj.us/health/healthfacilities/hospfines/summaries.shtml#bar043007. The action mentioned above occurred on April 30th, 2007 in response to Survey Event #RMP711. Accessed 10/24/2008

[17] R. Monina Klevens, et al. "Estimating Health Care-Assosiated Infections and Deaths in U.S. Hospitals, 2002," *Public Health Reports* U.S. Center for Disease Control and Prevention, March-April 2007, V.122: p161.

SafeCareCampaign.org[18] defines nosocomial infections as:

> An infection acquired in hospital by a patient who was admitted for a reason other than that infection. An infection occurring in a patient in a hospital or other health care facility in whom the infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility.

Cause of Death	2002 Deaths
Heart Disease	696,947
Cancer	557,271
Stroke	162,672
Lower Respiratory	124,816
Accidents	106,742
HAIs	**98,987**
Diabetes	73,249
Influenza/ pneumonia	65,681

Table 8: 2002 Cause of Death including HAIs. The National Center for Vital Statistics does not track Hospital Acquired Infections. If counted, HAIs would have been the sixth leading cause of death in the US in 2002.

Nosocomial infections are widespread and numerous. The CDC found that in 2002 there were 1.7 million nosocomial infections resulting in 98,987 deaths in U.S. hospitals alone. A 2002 investigative report by the Chicago Tribune estimated hospital acquired infections (HAIs) contributed to 103,000 deaths in 2000. The report noted that 2.1 million, or 6 percent of hospital patients, contract nosocomial infections each year.[19] For perspective, the CDC estimate of 98,987 hospital acquired infections resulting in death in 2002 would place nosocomial infections as the 6th leading cause of death in 2002, behind unintentional injuries and above diabetes (see Table 8).[20]

In addition to the direct risk of harm to patients, health care workers and the public at large are also at risk from nosocomial diseases. Hospitals use antibiotics to treat infections and to prevent infections in vulnerable patients. The use of antibiotics encourages bacteria to develop resistance. They also kill less harmful bacteria, providing a non-competitive environment where resistant bacteria can flourish. These resistant strains can be transmitted to health care workers and to the public.

Methicillin-resistant Staphylococcus (MRSA) is the most common drug resistant bacteria associated with nosocomial infections. The incidence of MRSA has grown rapidly over the past few decades. In 1974, only 2 percent of Staph infections were caused by MRSA. By 2003, that number had jumped to 64 percent.[21] The CDC estimates that there were 94,360 MRSA cases in 2005 (85 percent were healthcare related) resulting 18,650 deaths. Other drug resistant bacteria strains found in healthcare

[18] The Safe Care Campaign, spearheaded by Victoria and Armando Nahum, is a public and provider education campaign supported by a consortium of industry and government organizations. See www.safecarecampaign.org

[19] Michael J. Berens, "Unhealthy Hospitals: Infection Epidemic Carves Deadly Path: Poor Hygiene, overwhelmed workers contribute to thousands of deaths," Chicagoe Tribune, July 21, 2002. http://www.chicagotribune.com/news/chi-0207210272jul21,0,2177158.story

[20] Robert N. Anderson & Betty L. Smith. "Deaths: Leading Causes for 2002" National Vital Statistics Reports, vol 53, No 17, March 7, 2005, p 7.

[21] McCaughey, Betsy. *Unnecessary Deaths: The Human and Financial Costs of Hospital Infections*, *3rd edition*. Committee to Reduce Infection Deaths. Available at www.hospitalinfection.org.

settings include Vancomycin-Intermediate/Resistant Staphylococcus aureus, Acinetobacter, S. pneumoniae, Drug-resistant TB and Vancomycin-resistant Enterococci.[22]

Discovering the source of nosocomial infections is a difficult task. Infectious agents contaminate equipment or enter patients from a variety of vectors. Some patients may be carrying infections when they enter healthcare facilities. Some infections are not discovered until after patients are discharged. Efforts to reduce healthcare associated infections emphasize hand-washing, protective attire, housekeeping and maintenance, proper medication use, limiting the duration of invasive procedures, isolating of infectious patients, culturing and surveillance, using clippers instead of razors and good recordkeeping.

The Virginia Department of Health, CMS, the Joint Commission and the AOA all require hospitals to maintain infection control officers or committees responsible for preventing and investigating infections. The Joint Commission requires root-cause or tracer analysis of all infections that fit the definition of "sentinel events." Sentinel events are events that result in death or loss of limb or function. Hospitals voluntarily report sentinel events to the Joint Commission. As of September 30th, 2008, the Joint Commission had received reports of 109 infection-related events since January, 1995. According to its January 22nd, 2003 Sentinel Event Alert "Infection Control Related Sentinel Events," the Joint Commission believes infection-related events are "seriously underreported." The alert identified several remedial steps taken by healthcare facilities in response to infection-related sentinel events, including revising equipment cleaning procedures, staff training and competency assessments and revising hand-washing procedures. The full text of the alert is included in Appendix A.

Additionally, the US Food and Drug Administration maintains a database of adverse events involving Medical Devices. This database, known as the Manufacturer and User Facility Device Experience Database (MAUDE), consists of voluntary reports (since 1993), distributor reports (since 1993) and facility reports (since 1991). It is not a database of all adverse events involving medical devices, but does include events related to bacterial contamination. As of Sept. 30th 2008, no bacterial contamination related events were in the database for 2008. Eleven reports were made in 2007, referring to six separate incidents. Of these, two incidents, made in five reports, were linked to improper disinfection.[23] One resulted in two patient infections, one of which required hospitalization. The other was a follow up report from a 2003 incident relating to discovery of bacteria in equipment before use on patients. Both of these reports stemmed from hemodialysis equipment. See Appendix B for text of these reports.

[22] See "Center for Disease Control and Prevention: Antimicrobial Resistance in Healthcare Settings" at http://www.cdc.gov/ncidod/dhqp/ar.html. Accessed 8/29/2008.

[23] Other events related to non-processed implanted equipment or to equipment failure that did or could have resulted bacterial contamination.

Media Reports

Following breakdowns in sterile processing technique, many hospitals and health care facilities will provide free testing to potentially exposed patients. This often involves notifying hundreds or thousands of patients and often results in media coverage. Officials often describe the risk to patients as "theoretical" as opposed to actual. Thus, many hospitals will not notify patients, to avoid exposing patients to unnecessary anxiety. Table 9 lists incidents occurring since 2000 discovered during the course of the research, including an internet search for incidents, and submissions by Ms. Lee Germain of the Virginia Association of Central Services. This is not an exhaustive list of media-reported incidents, and includes only incidents found occurring in the United States directly linked to improperly sterilized medical instruments or devices.

Most of these incidents involved precautionary letters sent to patients with no evidence that medical instruments or devices were actually contaminated. However, in two separate incidents 21 persons were infected, resulting in three deaths. Additionally, one incident exposed 3,800 patients to used hydraulic fluid. More information on these incidents is provided below. It is important to note that infections and deaths can be linked to medical equipment and instruments but that a definite causal chain for contamination vectors is difficult to establish.

In 2002 at Alleghany General Hospital in Pittsburgh, PA, 16 patients became infected with the pneumonia causing bacteria Pseudomonas aeruginosa. Alleghany General Hospital used the Steris System I endoscope to sterilize endoscopes used on these patients. The Steris System I, specifically designed for difficult to clean endoscopes, has been the subject of much controversy. This incident resulted in FDA and US Justice Department investigations into the sterilizer. They are particularly concerned with one of rinse-water filters.

The manufacturer of the product, Steris Corp, claims that problems associated with the device are due to improper use of attachments. Steris Corp has since modified the Steris System I. However these and other changes have resulted in a warning letter from the FDA, sent on May 15th, 2008, that could return the system to pre-market testing status. Mr. Earl Foster, 58, died as a result of this outbreak.[24]

Early in 2006, White Memorial Medical Center in Los Angeles, California, transferred disinfecting duties for laryngoscopes from its central sterilization department to respiratory therapy staff. In late November and early December of that year, Pseudomonas aeruginosa infected five infants in the neonatal unit. An investigation by the Los Angeles County Department of Public Health linked the outbreak to contaminated laryngoscopes. Disinfection of the laryngoscopes has since been

[24] See: Davies, Paul. 2004. "Germ Watch: Clinic Infections Put a Sterilizer of Lab Devices Under Microscope, Maker of Widely Used System Defends its Effectiveness after Bacterial Outbreaks, Word of a Probe by the FDA," The Wall Street Journal. Dec. 24, 2004.; and FDA Warning Letter CIN-08-5964-15 available at http://www.fda.gov/foi/warning_letters/s6781c.htm, accessed 10/27/2008.

transferred back to the central sterilization department. The infections killed two of the infants.

Year	St	Facility	Device	Patients	Infect-ions	Deaths	Agent	Nature of Mistake
1999-2005	PA	Dental Clinic at the Veterans Affairs Medical Center		2000	0	0	NA	Procedure not followed
2002	PA	Alleghany General Hospital	Bronchoscope	500	16	1	P. aeruginosa	Improper Sterilization--water filters
2003	PA	Grand View Hospital	colonoscope	86	0	0		Inappropriate disinfecting solution.
2003	WA	University of Washington Medical Center		600	0	0	NA	Soaked for 2 minutes instead of 20 minutes--Programming/software error
2004	CA	Scripps Memorial Hospital	gastroscope	299	0	0	NA	Nurse knowingly disregarded OR procedures when cleaning equipment
2004	CA	Stanford Hospital	Endoscopes	92	0	0	NA	Machine broke down, not fixed.
2004	NC	Duke University Health Systems	Surgical Instruments	3,800	NA	0	Hydraulic Fluid	Hydraulic fluid used as disinfectant
2004	NY	Manhasset-North Shore University Hospital	Endoscope	177	0	0	NA	Filters changed every 3 months instead of six to eight weeks.
2005	PA	Forbes Regional Hospital	Olympus Colonoscope	200	0	0	NA	Improper cleaning of new equipment
2005	VA	Inova Loundoun Hospital	Endoscope	144	0	0	NA	Improper programming of sterilization equipment
2006	CA	White Memorial Medical Center	Laryngoscope	NA	5	2	P. aeruginosa	Sterilization moved from Central Services Unit
2006	MO	Truman Veterans Hospital	B-K biopsy transducer	263	0	0	NA	Soaked in improper solution. Cleaning instructions not clear
2008	TX	United Regional Health Care System	Surgical Tools	1800	0	0	NA	Malfunctioning Detergent Dispenser
2008	NC	Cape Fear Valley Medical Center	Surgical Instruments	160	0	0	NA	Instruments disinfected, but Steam Sterilization skipped.
			Totals	10121	21	3		

Table 9: Media Reported Infection Incidents linked to medical devices. A non-exhaustive list of incidents discovered during the course of the research.

An odd incident occurred at the Duke University Health System in North Carolina in 2004. Maintenance contractors servicing an elevator emptied hydraulic fluid into empty disinfectant buckets from the central services department. The disinfectant supplier later picked up the buckets. While at the supplier, workers resealed these buckets with the hydraulic fluid still in them and delivered them to two Duke University Health System hospitals. Sterile processing personnel then used the hydraulic fluid, instead of disinfectant, in disinfecting machines.

The machines covered instruments with a light coating of hydraulic fluid. Some staff noted the slick instruments, but the hospitals did not discover the mix up until practitioners had used fluid-coated instruments on about 3,800 patients. Though the hospitals did not report any infections, dozens of patients have complained of various ailments, including fatigue and joint pain.[25]

These incidents highlight how even a seemingly trivial oversight by sterile processing technicians can affect the lives of many patients. However, the role of central

[25] Dr. Lawrence Muscarella maintains a list of news articles pertaining to infection control issues. That list is available at: http://www.myendosite.com/infection_control_media.htm

services/sterile processing technicians in incidents resulting in injury or death are less clear. A legal controversy regarding the Steris System I has prevented definitive conclusions as to the cause of the infections. In the California incident, harm occurred when hospital administrators removed responsibility for disinfecting some instruments from central services/sterile processing. The North Carolina incident resulted from a series of errors. Observant sterile processing personnel could have prevented this incident.

Equipment Failure

The Center for Devices and Radiological Health of the US Food and Drug Administration issued the Public Health Notification "Avoiding Hazards with Using Cleaners and Disinfectants on Electronic Medical Equipment" on October 31, 2007 to address problems associated with malfunctioning equipment due to improper cleaning. Overuse or improper use of cleaning chemicals can corrode electric circuits.

The notification identified "equipment fires and other damage, equipment malfunctions, and healthcare worker burns" as the main problems resulting from improper cleaning. Furthermore, it identified "over-infusion of medications, loss of life-supporting drug therapy, and loss of patient ventilation" as potential life-threatening results of improper cleaning techniques.

Public Comment

Lee Germain of the Virginia Association of Central Services provided written comment supporting additional regulation of Central Services. In addition to her own supporting comments, Ms. Germain provided accounts of her experiences as a Central Services professional and accounts collected from other professionals. She also provided an article written by Kristina Pirrollo, CRCST, CHL, of New York City-based Nexera Consulting Inc on certification of central services personnel. These comments were provided to the Board and are included here in Appendix C. The Board has received no additional comment at the time of this writing.

Policy Considerations

When examining other health professions regulated within the Department of Health Professions' health regulatory boards, the key factors that are associated with each form of professional regulation are: educational requirements, examination requirements, scope of practice, discipline, and continuing education. To assist the Committee in its review, Table 4, next page, provides an essential overview of each factor in relation to the form of traditional state regulation. It indicates whether the factor in necessarily required or associated with the form of regulation (Y), is optional (O), or is not required (N).

Form of Regulation	Educational Requirement	Examination Requirement	Discipline	Standards of Practice	Continuing Education
Licensure	O	O	Y	Y	O
Voluntary Certification	O	Y	Y	Y	O
Registration	N	N	Y	Y	O

Option 1-Licensure

Licensure is the most restrictive level of state regulation and largely confers a monopoly to the group in question. Licensure ensures that the scope-of-practice and the professional title are reserved to individuals who meet certain minimal competencies to safely practice. To select this option for Central Services/Sterile Processing Technicians, all six Criteria must be met.

(1) There must be a high risk of harm to the consumer that results from the practices inherent in the profession, the characteristics of the clients served, and/or the setting or supervisory arrangements for health service delivery.
(2) The profession must be viewed as requiring special skills and training.
(3) Practitioners must generally practice autonomously.
(4) The scope of practice is distinguishable from other health professions and occupations.
(5) The economic costs to the public of regulation and the potential reduction of supply are justified.
(6) Alternatives such as strengthening inspections and injunctions, disclosure requirements and consumer protection laws and regulations are insufficient to address the risk of harm to the public from the unregulated practice of the profession.

Option 2 – Voluntary Certification

This is the second most restrictive level of regulation. It presumes a moderate potential for risk of harm to the public that is attributable to the nature of the practice, client vulnerability, or practice setting and level of supervision. It requires that all of the Criteria listed above be met, except #3 (Autonomous Practice). Voluntary certification provides assurances for the public that the individual practitioner who obtains certification has at least a minimal level of competency to safely practice. It affords discipline of the certificate holder. The scope-of-practice is not restricted, but the use of the professional titles or credentials would be reserved to those meeting the certification requirements. This method affords consumers and employers with a means of identifying competent practitioners but does not restrict the performance of their duties only to those certified.

Option 3 – Registration

Registration simply requires that all practitioners be registered as individual practitioners. Discipline could be taken against the registrant and not simply the facility. There is no test of minimal competency. This option provides accountability of the individual without the potential economic impact of restricting the supply of practitioners. Clients, supervisors, and others would be able to track disciplinary history of the individual which should preclude incompetent or unscrupulous practitioners from leaving one area in Virginia only to go to another. Criteria #1, #4, #5 and #6 must be met.

For Options #1, #2 or #3, the regulation of practitioners should be housed within a recognized board which can assure competency, set appropriate standards of care, and take disciplinary action when necessary.

Option 4 – No Professional Regulation

To select this option, the work of practitioners must be considered safe, ordinary work, with no special, distinguishable knowledge or skill required to adequately protect the public's health, safety and welfare.

Note: In addition to the regulation options of licensure, voluntary certification and registration, the Central Services/Sterile Processing profession lends itself to regulation at different levels. The board could regulate central service/sterile processing managers, supervisors or technicians. Additionally, the board may consider a broad scope of practice that encompasses central services and material management or consider a regulatory scope limited to sterile processing functions.

Recommendation

At its December 17, 2008 meeting, the Regulatory Research Committee received comment from Mr. Ray Taurasi of the IAHCSMM supporting regulation of Central Services/Sterile Processing Technicians and viewed a video provided by the Virginia Association of Central Services. The committee considered a motion that Central Services/Sterile Processing Technicians not be regulated at this time. The motion was not seconded and the Committee took no further action.

The full board also met on December 17, 2008 and received comment from Mr. Ray Taurasi. After careful consideration and deliberation, the Board voted, with two Members abstaining, to not recommend regulation of Central Services/Sterile Process Technicians through the Board of Health Professions at this time.

The Board considered Criterion One: Risk for Harm to the Consumer, and noted that Sterile Processing Technicians are vital members of hospital and, in particular, operating room staff. Additionally, Sterile Processing Technicians are essential for the prevention of the spread of infections within healthcare settings, a growing concern within the healthcare field. The Board also noted the specialized skills and training

required to process increasingly complex medical instruments using new technology and techniques.

In considering Criterion Three: Autonomous Practice, the Board noted that the risks associated with sterile processing are often difficult to attribute to individual technicians, rendering discipline of individual technicians through professional regulation cumbersome. Furthermore, the Board noted that Sterile Processing technicians are employed by healthcare facilities and are usually organized within hierarchical oversight structures.

In considering Criterion Six: Alternatives to Regulation, the Board noted other avenues to regulation, such as Department of Health licensing requirements, exist for addressing risks associated with the practice of the profession. In particular, they noted the that each hospital must maintain an Infection Control Committee, and that the Infection Control Committee must approve written procedures for sterile processing departments. The Board also noted that private accreditation organizations, such as the Joint Commission on Accreditation of Healthcare Organizations, also provide rules for infection control, equipment care and sterile processing and other best practices. Members of the Board considered whether facility licensing or accreditation requirements are more appropriate than a professional regulatory board for determining the proper qualifications of Sterile Processing Technicians.

The Board further noted that Sterile Processing Technicians perform work on equipment and instruments and do not provide direct patient care. Members of the Board considered whether professional regulation by the Department of Occupational and Professional Regulation was more appropriate than professional regulation by the Board of Health Professions.

In keeping with the regulatory principles established by the Board, criterion three must be met to justify a recommendation of professional licensure and criterion six must be met to justify a recommendation of voluntary certification or registration. Following this criteria, the Board recommended no professional regulation by the Board of Health Professions at this time.

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Appendices

Appendix A

Available at:
http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_28.htm

Accessed 10/27/2008

Sentinel Event Alert

Issue 28 - January 22, 2003

Infection control related sentinel events
Despite the small number of infection-related sentinel event cases reported to the Joint Commission, the number of patients acquiring infections in the health care setting, as well as the number of patient deaths due to an acquired infection, remains high. According to estimates from the Centers for Disease Control and Prevention (CDC), each year nearly two million patients in the United States get an infection in hospitals, and about 90,000 of these patients die as a result of their infection. Infections are also a complication of care in other settings including long term care facilities, clinics and dialysis centers.

The CDC works in conjunction with approximately 315 hospitals throughout the United States to collect data for its National Nosocomial Infections Surveillance (NNIS) System. A cooperative effort begun in 1970, the system describes the epidemiology of nosocomial infections and antimicrobial resistance trends, and produces nosocomial infection rates to use for comparison purposes. The most recent NNIS report was published in the December 2002 issue of the American Journal of Infection Control and is available on the NNIS website.

According to the Joint Commission database, only 10 infection-related reports have been reviewed under the sentinel event policy since its implementation in 1996. Fifty-three patients were affected, of which 14 died. While the age of the patients afflicted varied, the vast majority were infants (29) and seniors (19), many of whom were immunosuppressed. Settings included the newborn and pediatric intensive care units, long term care facilities or units, general medical/surgical units, and endoscopy and obstetrics units. The infecting organisms included HIV, Pseudomonas aeruginosa, E. coli, MRSA (methicillin resistant Staphylococcus aureus), salmonella, and Clostridium sordellii. The number of reported infection-related sentinel event cases represents an insufficient sample from which to draw any generalizable conclusions and recommendations.

Numerous high profile media reports of incidences of patient death resulting from hospital-acquired infections indicate that such cases are seriously under-reported to Joint Commission. Joint Commission emphasizes that patient death or permanent injury/loss of

function as a result of a nosocomial infection does indeed meet the criteria for reviewable sentinel events. As such, each event should undergo a root cause analysis to identify risk reduction strategies, and should be considered for reporting to Joint Commission's Sentinel Event Database to expand the knowledge base about the scope and characteristics of serious nosocomial infections, the factors that lead to their occurrence, and effective strategies for prevention.

Multiple root causes and risk reduction strategies

As a result of the sentinel events arising from infections and in response to the identified root causes, health care organizations implemented various risk reduction strategies, including the implementation of relevant clinical pathways for MRSA, endometritis and urinary tract infection. These strategies include:

- Revising orientation and training processes and competency assessments.
- Revising equipment cleaning processes.
- Revising handwashing procedures.
- Switching to the use of single-use IV flush vials.
- Adding waterless handrubs.
- Defining supervisory expectations.
- Revising critical care privileging and ICU admission criteria.
- Conducting in-service and team trainings.
- Instituting tracking systems.

CDC issues new handwashing guidelines

On Oct. 25, 2002, the CDC released new guidelines that advise the use of alcohol-based handrubs in conjunction with traditional soap and water and sterile gloves to protect patients in health care settings. The recommendations come as part of the new Guidelines for Hand Hygiene in Healthcare Settings, and reflect the positions of the Healthcare Infection Control Practices Advisory Committee and the Hand Hygiene Task Force (comprising members of the Healthcare Infection Control Practices Advisory Committee, the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control and Epidemiology Inc., and the Infectious Diseases Society of America).

The hand hygiene guidelines are part of an overall CDC strategy to reduce infections in health care settings and to demonstrate that organizations can help prevent the spread of germs from one patient to another by improving hand hygiene. Information about the guidelines is available from the CDC, APIC, SHEA and IDSA, and promotional materials may be obtained from the CDC at www.cdc.gov. "Clean hands are the single most important factor in preventing the spread of dangerous germs and antibiotic resistance in health care settings," says Julie Gerberding, M.D., director, CDC. "More widespread use of these [alcohol-based handrub] products that improve adherence to recommended hand hygiene practices will promote patient safety and prevent infections."

Joint Commission plans to review its existing infection control standards and survey process with the help of a newly appointed infection control expert panel. One of the panel's goals is to support organizations' patient safety efforts by lowering nosocomial infection rates throughout the organization and in targeted specific vulnerable populations such as surgical, intensive care and immunosuppressed patients.

Joint Commission recommendations

Joint Commission recommends that health care organizations:

1. Comply with the CDC's new hand hygiene guidelines.
2. Manage as sentinel events all identified cases of death and major permanent loss of function attributed to a nosocomial infection (i.e. except for the infection, the patient would probably not have died or suffered loss of function). Note: This recommendation does not require any change in current surveillance methodology (see the "IC" standards in your Joint Commission accreditation manual).

Resources

1. Emerging Infectious Diseases, Vol. 7, No. 2, March-April 2001, Centers for Disease Control and Prevention, http://www.cdc.gov/ncidod/eid/vol7no2/wenzel.htm.

2. Centers for Disease Control and Prevention National Nosocomial Infections Surveillance System, http://www.cdc.gov/ncidod/dhqp/nnis_pubs.html.

3. NNIS definition of nosocomial infection—a localized or systemic condition 1) that results from adverse reaction to the presence of an infectious agent(s) or its toxin(s), and 2) that was not present or incubating at the time of admission to the hospital.

4. Guidelines for Hand Hygiene in Healthcare Settings – 2002, Centers for Disease Control and Prevention, http://www.cdc.gov/.

5. Association for Professionals in Infection Control and Epidemiology (APIC), http://www.apic.org/.

6. Society for Healthcare Epidemiology of America (SHEA), http://www.shea-online.org/.

7. Infectious Diseases Society of America (IDSA), http://www.idsociety.org/.

Appendix B

These five reports refer to two separate incidents discovered in the MAUDE database referring to bacterial contamination of equipment. These were the only incidents in the database related to improper processing from 2007 and 2008 discovered in a search of the MAUDE database made on 10/27/2008 using the search parameter: Device problem: Contamination Bacteria.

To search the MAUDE Database, visit:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

Text of the incident reports is unedited.

1st Incident

GAMBRO DASCO PHOENIX HEMODIALYSIS EQUIPMENT

Model Number PHOENIX
Device Problem Contamination, bacterial
Event Date 05/01/2007
Patient Outcome Hospitalization; Required Intervention
Event Description
The customer reported that, two pts experienced catheter infections at the same time on two different phoenix machines (please refer also to mdr 9616240-2007-00077). This report relates to the incident occurring on phoenix machine serial number ph7040. The organism was a very atypical salt-loving gram negative organism - halomonas, species unk. The two pts were dialyzed on different pt shifts, in different treatment areas. Both machines continued to be used after the two pts exhibited their catheter infections, and there is no evidence that any other pt treated on either of those machines was infected.

GAMBRO DASCO

Device Problem Contamination, bacterial
Event Type Injury
Manufacturer Narrative
This pt was dialyzed via a central venous catheter. The organism halomonas was isolated from his blood cultures. He received antibiotic therapy (ceftazadime) as an outpatient, and recovered. He remains on his regular outpaitent dialysis schedule. The phoenix machine ph7040 has been used on other pts since the incident, with no other pts developing an infection with this organism. There has been no change in the clinic's machine disinfection protocol. The hospital's infection control dept investigated these two unusual infections and found the presence of the halomonas organisms in cultures taken from the machine drains and the orifice of the who (waste handling option) on the machine. Dialysate and water treatment system cultures at the clinic have historically been negative or within the association for the advancement of medical instrumentation

(aami) limits. The infection control dept suspects that inadequate disinfection, especially of the who port, resulted in this extremophilic organism remaining in the machines.

GAMBRO DASCO PHOENIX HEMODIALYSIS EQUIPMENT
Model Number PHOENIX
Device Problem Contamination, bacterial
Event Date 05/05/2007
Patient Outcome Hospitalization; Required Intervention
Event Description
The customer reported that two pts experienced catheter infections at the same time on two different phoenix machines (please refer also to mdr 9616240-2007-00076). This report relates to the incident occurring on phoenix machine ph2843. The organism was a very atypical salt-loving gram negative organism - halomonas, species unk. The two pts were dialyzed on different pt shifts, in different treatment areas. Both machines continued to be used after the two pts exhibited their catheter infections, and there is no evidence that any other pt treated on either of those machines was infected.

GAMBRO DASCO

Device Problem Contamination, bacterial
Event Type Injury
Manufacturer Narrative
This pt was dialyzed via a central venous catheter. During treatment, he complained of chills. Blood cultures were drawn and were positive. The pt was hospitalized. The organism halomonas was isolated from his blood cultures. While hospitalized, he received antibiotic therapy (ceftazadime and cefazolin) and his catheter was changed as part of the intervention. He was discharged after three days and has resumed his regular outpatient dialysis schedule. The phoenix machine ph2843 has been used on other pts since the incident, with no other pts developing an infection with this organism. There has been no change in the clinic's machine disinfection protocol. The hospital's infection control dept investigated these two unusual infections and found the presence of the halomonas organisms in cultures taken from the machine drains and the orifice of the who (waste handling option) on the machine. Dialysate and water treatment system cultures at the clinic have historically been negative or within the association for the advancement of medical instrumentation (aami) limits. The infection control dept suspects that inadequate disinfection, especially of the who port, resulted in this extremophilic organism remaining in the machines.

2nd Incident

GAMBRO DASCO PHOENIX HEMODIALYSIS

Model Number PHOENIX
Device Problem Contamination, bacterial

Event Date 06/19/2003
Event Type Malfunction Patient Outcome Other;
Manufacturer Narrative
No pt injury was reported. Gambro us technical svc rep inspected the machine and found the bacterial colony counts had returned greater than action level after three consecutive draws and disinfections. He programmed the machine to perform an end-to-end heat disinfection along with cwp. Total number of events being summarized is 22. These reports are filed late as result of a retrospective review, as per our commitments in response to the gambro dasco warning letter of 1/5/06 and meeting with fda on 11/13/06.

Event Description
The customer reported an episode of bacterial contamination of the hydraulic circuit.

Appendix C

Public Comment

Lee Germain of the Virginia Association of Central Services forwarded the following comments:

Mandatory Certification for Central Sterile Services Employees

Lee Germain RN, CRCST

As a manager of Central Sterile Supply (CSS) I saw first hand how our department could jeopardize patient safety and well being. One sterilization error can affect many patients in a short period of time. One cracked or damaged instrument that goes unnoticed can severely injure a patient during surgery or inadvertently be left in the surgical site to cause problems at a later date. CSS is a department whose actions have far reaching effects in almost all areas of every hospital, affecting patient safety and infection control 24/7.

CSS employees have many job responsibilities and provide multiple services for every patient care area in the hospital including the disinfection of patient care equipment, decontamination and sterilization of surgical instruments, proper storage of sterile items, maintenance and stocking of code carts, isolation carts and much more. It's my opinion that infection control starts in CSS.

Sterile instrument trays are used in the OR, as well in the ER, Cath Lab, L&D, Radiology Endo Labs, etc. Instruments have to be manually cleaned, disassembled when appropriate, run through automated washer decontaminators, set up into trays for many different uses and instruments inspected for proper function and damage. Sterilization is achieved by use of several complicated types of equipment with new sterilizing methods emerging all the time. Employees must be able to run all of the equipment and monitor their cycles, making sure proper parameters are met. Storage of the sterilized trays and products require careful handling to maintain sterility and the area must be kept at a specific temperature with proper air exchange and cleaning protocols. Proper transporting of sterile items to the end user is another important aspect in maintaining sterility and a safe product for patient use.

There are code carts in every department of the hospital and many times there are several. In a Code Blue, are the supplies and medications all there and in date? Are sterile items and trays properly stored in the cart to prevent contamination? Is equipment, such as the defibrillator and suction machine, working properly and disinfected so as to prevent the spread of a hospital acquired infection? As CSS employees we are responsible.

Patient care equipment such as IV pumps, syringe pumps in NICU, suction pumps, warming units, sequential compression units, etc. are disinfected

between patients in Central Sterile and stored until needed again. Improper cleaning has the potential to spread disease to the next compromised patient.

CSS has too many responsibilities to cover in my comments today. I touch on only a few. But it suffices to say that as a department, proper education of each employee is a must to ensure safe products for patient care. This has to include hospitals and all the departments that perform disinfection and sterilization processes. In addition, Surgery centers and physician's offices that do procedures and perform these same functions that may put patients at risk must also employ technicians who are properly trained and can provide the same standard of care.

Too often hospitals only respond when an incident occurs in their facility. It's almost like Central Sterile doesn't exist until the unspeakable happens and a mistake is made that puts the hospital on the front page of the news paper. That's when they react, agreeing to pay for upgraded equipment, some education and certification fees, etc. But with time memories fade, administrators move on and Central Sterile again goes to the back of everyone's mind. Education moneys are withdrawn and heads of upper management go back in the sand.

Central Sterile is a department of many hardworking caring individuals that take their many responsibilities very seriously with little appreciation or understanding from other departments. This is a job that needs to become a Profession and a profession that needs to be recognized for the responsibility that's put on their shoulders day in and day out for caring for and protecting patients in our healthcare facilities here in Virginia. Mandatory certification will promote education and professionalism that will in turn provide hospitals and out patient facilities with the best possible chance at positive outcomes for the patients in their care.

As manager of a busy CSS I had the following experience:

It is unusual to sterilize an instrument using a gravity displacement cycle in Central Sterile but it's sometimes necessary. Pre-vacuum sterilization cycles are used 99% of the time because they are faster and more reliable. They use a vacuum to remove air, which is a must, to allow steam to penetrate all packages in the sterilizer chamber and touch all the surfaces of all the items. The temperature is higher in Prevac cycles therefore the cycle time is less.

Gravity cycles allow steam to enter at the top of the chamber and "push" the air out of the drain in the bottom of the sterilizer. This is a less effective method of air removal than the pre-vacuum sterilizer cycles. Manufacturers will put their reprocessing instructions on packages and those recommendations should always be followed closely.

One evening a Respiratory Therapist came to CS with a tracheotomy tube made of a hard plastic that they wanted sterilized for a patient. This

tracheotomy tube had to be sterilized at a lower temperature and that meant doing a gravity load per the manufacturer's instructions.

Parameters of a Gravity cycle:

Time	20 minutes	(must be at least 12 minutes)
Temp	250 degrees	
Pressure	15 psi of gauge pressure	
Drying time	i.e. 8 minutes (depends on the quality of steam at each institution)	

Parameters of a Prevac Cycle: (cycle normally used on a daily basis in CSS Dept.)

Time	5 minutes	(must be at least 2 minutes)
Temp	275 degrees	
Pressure	30 psi of gauge pressure	
Drying time	i.e. 8 minutes (depends on the quality of steam at each institution)	

The request was left to the two technicians on the 11p-7a shift. One of the employees was new to the department and just going on nights after training on the day and evening shifts. The other technician had been a CSS tech for many years and had been on our staff for perhaps 3 years. Neither one of these employees knew or remembered what the parameters were for a gravity cycle and how to set the sterilizer.

There were several choices they could have made at that point.

1. Leave the article for the next day, avoiding the chance of making a mistake.
2. Call someone in management for direction/help.
3. Look in the sterilizer user's manual for parameter settings for a gravity cycle as well as directions for setting the sterilizer.

They made another choice, however, and it was the beginning of a nightmare for 85+ patients, administration and many employees.

The techs set the cycle as follows:

Time	2 minutes	(must be at least 12 minutes)
Temp	250 degrees	
Pressure	15 psi of gauge pressure	
Drying time	20 minutes	

External indicator tape on the outside of the trays and packages had changed appropriately (strips appear on tape and a dot on container locks from exposure to heat) so the load was released for use. The CSS employee unloading the sterilizer did not check the sterilizer tape to see that the parameters were **not** correct on that cycle. That employee should have caught the error at that point.

Three days later an OR nurse came to CSS with an internal indicator that had not turned appropriately, indicating a sterilization issue. Three days had gone by and no other OR nurses reported a problem with the internal indicators.

Upon investigation, the sterilization error was found, a recall of items was done but most had been used in the 3 days since the load was "sterilized". At the time we had no tracking system in place to help us know which patients had been exposed to the un-sterile instruments except by including all patients on the schedule those three days that the instruments "could" have been use on.

The surgeons and patients we identified as *possibly* being exposed were contacted and a schedule of testing was set up to monitor each for Hepatitis, HIV, etc. over the next year. Any resulting infections and litigation were not shared with me. However, as a nurse from the open heart team in the past, I did know of a sternal infection in one of the Open Heart patients that were considered in the affected patient group.

As a result of these actions, patients were affected emotionally and/or physically, 2 employees were fired, and administration and management of CSS, OR and Material Management went through intense stress over the situation. Processes involving sterilization, patient safety, tracking and all departmental policies and procedures were examined and updated to avoid future errors of this kind. In addition, we made it mandatory in our hospital group that CSS employees become certified, ensuring a more complete education for each person working in the department and a better understanding of the importance of the job and responsibility of each technician.

Lee Germain

Situation #2 Endoscopy Lab

Preventive maintenance was done on the two scope washers in the Endoscopy Department by the manufacturer's representative. The settings on one of the two machines were not properly reset after this inspection and the cycle time was too short for proper disinfection. Therefore more than half of the scopes used in the department during that time were not properly disinfected.

The employee in the department that cleaned and ran scopes through the washers never checked the computer readout tapes to see that one of the machines was not set properly and never questioned why one unit ran shorter cycles that the other. The unit used these scopes on patients for approximately 3 months before the error was caught. Hundreds of patients were examined in this endoscopy lab during that time period and had to be notified and tested by the hospital.

Patient safety was jeopardized by uneducated staff and the lack of a policy that should make sterilization and disinfection the responsibility of the correct department, the one properly trained in these processes, Central Sterile Services.

From: mlgerm@aol.com [mailto:mlgerm@aol.com]
Sent: Friday, November 07, 2008 7:58 PM
To: Crow, Justin
Subject: Fwd: TWO Scenarios:

You can see who this if from!!!
Lee

-----Original Message-----
From: Jenkins, Charlotte H *HS <CHJ3W@hscmail.mcc.virginia.edu>
To: MLGERM@aol.com <MLGERM@aol.com>
Sent: Fri, 7 Nov 2008 1:41 pm
Subject: FW: TWO Scenarios:

Charlotte H. Jenkins
University of Virginia Health System
Supply Chain and Logistics
P.O. Box 800690
Charlottesville, VA 22908
Phone: 434-982-3361
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E-mail:chj3w@virginia.edu

From: Via, Donna S *HS
Sent: Friday, November 07, 2008 1:09 PM
To: Jenkins, Charlotte H *HS
Subject: TWO Scenarios:

1) OR Nurse Sue and Surg Tech Bill are setting up for a surgical procedure-a breast biopsy for a patient who has a wire in place to localize the site, having been placed earlier in the day in Radiology. The instrument set and disposable supplies were picked the day before and waiting on the supply cart. When opening supplies, the nurse and surg tech check all wrapped supplies for package integrity as well as expiration dates and any internally sterilized supplies for an outside chemical indicator that indicates exposure to sterilization. This is done prior to opening so that no

unsterile item is introduced to the sterile field. All supplies look acceptable. The instruments are contained within a rigid container system and the outside chemical indicator shows acceptable results. However, when the OR nurse removes the locks and lifts the top off of the rigid container system, she notes that no filter has been placed in to the rigid container system. The instruments are not sterile! The nurse immediately contacts SPD to check for the availability of another set. None are available. The anxious patient is delayed from being brought into the OR while the instrument set is flash sterilized and then must be cooled before the procedure can commence.

2) OR Nurses Sally (circ) and Bobby (scrub) are performing a knee arthroscopy with ACL repair. All supplies are opened, the patient is brought into the room and anesthesized, positioned, and draped. The MDs proceed with first scoping the knee. A hamstring graft is obtained and prepared. The surgeons prepare to drill the site for the graft to go through. They size and request the appropriate drill bit for the graft. As they begin to use the cannulated drill bit they immediately stop, as they see old crusty bioburden exuding from the drill bit. They are very unhappy with the scrub nurse and say so. More antibiotics are ordered for the patient. Antibiotic irrigation is used to cleanse the site. The contaminated drill bit is removed from the sterile field. Other drill bits in the set are checked and two more are found also with old bone inside. The entire set must be removed from the field, hand washed and brushed to remove the dried on bone. The set is then flash sterilized. A delay of about 20 minutes results where the surgical team can only wait for the returned drill bits as all other sets are being used. So as not to waste tourniquet time, the tourniquet is released.

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From: mlgerm@aol.com [mailto:mlgerm@aol.com]
Sent: Thursday, November 06, 2008 5:17 PM
To: Crow, Justin
Subject: Fwd: Board of Heath Professions & Regulatory Research Committee meetings

-----Original Message-----
From: Lorraine Jenkins <Lorraine.Jenkins@chesapeakeregional.com>
To: 'mlgerm@aol.com' <mlgerm@aol.com>
Sent: Thu, 6 Nov 2008 3:42 pm
Subject: RE: Board of Heath Professions & Regulatory Research Committee meetings

Lee,
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**Vendor brought in spine instruments and implants to be used on a scheduled procedure. Instruments received in decontamin area. Upon cleaning noted that a particular instrument came apart, instrument impacted with bone and old dried blood. Spine Rep notified. Rep stated he was not aware the instrument came apart and stated it had never been taken apart. Instruments had been used at multiple area hospitals on numerous patients, with out proper cleaning.

**Material Management called SPD manger and stated they had Dr's office on phone stating they needed to purchase a liquid to put in table top sterilizer to sterilize instruments. MM was calling for SPD input. After speaking with person on phone, found out they were the secretary at front desk and knew nothing about the equipment. SPD staff went to office to assist them. Found out they were trying to use an old table top sterilizer that had been in a back store room for about 10 years. The sterilizer had not been validated; they had no manual or staff who knew anything about sterilization protocol. The office had new Dr in practice who asked to use it. Help them research equipment; find a manual, education on AMMI validation process.

Does this help?? I will think of some incidents.
LJ

From: mlgerm@aol.com [mailto:mlgerm@aol.com]
Sent: Thursday, October 02, 2008 8:19 AM
To: Crow, Justin
Subject: here it is

CS Certification ... a Must for Everyone

Kristina Pirollo, CRCST, CHL
04/16/2008
Did you know that hairdressers must pass a state exam to become a certified beautician? What about respiratory therapists or dental hygienists? Aren't surgical techs in the operating room (OR) certified, as are some OR nurses? We feel more comfortable about purchasing a certified pre-owned car. We only want certified teachers working in our schools. If so, why is education and certification in the central service (CS) profession minimized? Every state should require any facility that employs CS personnel to achieve and maintain certification and/or licensure. There should be no debate about it. The bottom line is that CS personnel indirectly save lives everyday. CS staff must have

thorough knowledge of code carts, case carts, par levels, OR supplies, specialty items, thousands of different surgical instrumentation, disinfections, chemicals, gas plasma, ethylene oxide, pre-vacuum, gravity sterilization, infection control, human anatomy, microbiology, and the list goe s on and on.

Why is it taking so long for state assemblies and state departments of health to understand the importance of this issue? Shouldn't CS professionals be the first to promote and demand certification? I say shame on those who do not support these issues and continue to keep them on the back burner. Why does the Joint Commission, the Association of periOperative Registered Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI), and even the International Standards Organization (ISO) have so many standards and still it is so hard to mandate certification? Healthcare facilities that employ CS personnel should not wait for their states to pass laws requiring mandatory certification. It should be a facility requirement for employment, not a way to save money by paying non-certified CS personnel a lower salary. Certainly many hospitals have an education budget that would allow CS personnel to attend certification classes, or at least pay for the required textbooks. The precedent exists for nurses, phlebotomists, dietary personnel and hospital employees. These facilities should raise the bar, demand certification, hire and pay for the very best.

What about the managers and directors who oversee CS personnel? Too often people from nursing, pharmacy or purchasing are hired for the CS department, and these individuals have no concept of what CS actually does. How can someone who has no prior hands-on experience oversee this department? College degrees are great, however, the y do not replace CS certification. How can managers begin to understand the issues that take place within the CS department unless they have worked there as techs? How can this individual be an advocate for the CS staff? The bottom line is that mandatory certification and hands-on training in the CS department is an absolute must.

There are many professional organizations that offer continuing education. The International Association of Healthcare Central Service Materiel Management (IAHCSMM) partners with Purdue University in Indiana to offer online courses and self-study programs. These courses are extremely helpful in gathering the necessary information and knowledge to pass the certification exam. Many industry vendors offer scholarships for certification, and CS professionals should take advantage of these services.

While some healthcare facilities are educated about the importance of certification and understand the daily function of CS, these facilities will also offer a pay raise and possible career growth path upon certification. Who wouldn't like a promotion and more money? It is time for all CS staff to get certified. The fight for mandatory certification will only become a bigger challenge; eventually, CS professionals will be unable to find employment in certain states in which mandatory certification is already required, such as New Jersey.

That being said, some CS personnel insist that they don't need to be certified. They feel they should be grandfathered in for years of servic e rendered. They believe they won't get more money for their efforts or they fear that they will fail the exam. Many may feel that when they "have" to do it, they will. It's a matter of choice; if the choice is not obtaining certification, these individuals don't belong in CS. They shouldn't be cleaning, disinfecting and sterilizing the surgical instruments that may be used on someone's

family member. If the Food and Drug Administration (FDA) enforces reprocessing guidelines on manufacturers, then CS staff should be certified and knowledgeable in carrying out the recommended practices.
In the very near future, all states, healthcare facilities and CS employees will agree that certification is the way to go and will continue this journey toward excellence. We often do not get a second chance to do something right. Everyday we indirectly save a life. From the detergent that cleans the contaminated instrument, to the sterilizer that makes the surgical tray sterile-ready, to an instrument that is used to deliver that beautiful newborn, that's us... we are the CS professionals! ICT

Kristina Pirollo, CRCST, CHL, is a consultant with New York City-based Nexera Consulting Inc.
