

214.001 POLICY AND REGULATION.

Subdivision 1. Policy. The legislature finds that the interests of the people of the state are served by the regulation of certain occupations. The legislature further finds: (1) that it is desirable for boards composed primarily of members of the occupations so regulated to be charged with formulating the policies and standards governing the occupation; (2) that economical and efficient administration of the regulation activities can be achieved through the provision of administrative services by departments of state government; and (3) that procedural fairness in the disciplining of persons regulated by the boards requires a separation of the investigative and prosecutorial functions from the board's judicial responsibility.

Subd. 2. Criteria for regulation. The legislature declares that no regulation shall be imposed upon any occupation unless required for the safety and well being of the citizens of the state. In evaluating whether an occupation shall be regulated, the following factors shall be considered:

- (1) whether the unregulated practice of an occupation may harm or endanger the health, safety and welfare of citizens of the state and whether the potential for harm is recognizable and not remote;
- (2) whether the practice of an occupation requires specialized skill or training and whether the public needs and will benefit by assurances of initial and continuing occupational ability;
- (3) whether the citizens of this state are or may be effectively protected by other means; and
- (4) whether the overall cost effectiveness and economic impact would be positive for citizens of the state.

Subd. 3. Regulation of new occupations. If the legislature finds after evaluation of the factors identified in subdivision 2 that it is necessary to regulate an occupation not heretofore credentialed or regulated, then regulation should be implemented consistent with the policy of this section, in modes in the following order:

- (1) creation or extension of common law or statutory causes of civil action, and the creation or extension of criminal prohibitions;
- (2) imposition of inspection requirements and the ability to enforce violations by injunctive relief in the courts;
- (3) implementation of a system of registration whereby practitioners who will be the only persons permitted to use a designated title are listed on an official roster after having met predetermined qualifications; or
- (4) implementation of a system of licensing whereby a practitioner must receive recognition by the state of having met predetermined qualifications, and persons not so licensed are prohibited from practicing.

Two or more of these modes may be simultaneously implemented if necessary and appropriate.

Subd. 4. Information from Council of Health Boards. The chair of a standing committee in either house of the legislature may request information from the Council of Health Boards on proposals relating to the regulation of health occupations.

214.002 EVIDENCE IN SUPPORT OF REGULATION.

Subdivision 1. Written report. Within 15 days of the introduction of a bill proposing new or expanded regulation of an occupation, the proponents of the new or expanded regulation shall submit a written report to the chair of the standing committee in each house of the legislature to which the bill was referred and to the Council of Health Boards setting out the information required by this section. If a committee chair requests that the report be submitted earlier, but no fewer than five days from introduction of the bill, the proponents shall comply with the request.

Subd. 2. Contents of report. A report in support of the regulation of a health-related or non-health-related occupation must address the following issues as specifically as possible:

(1) the harm to the public that is or could be posed by the unregulated practice of the occupation or by continued practice at its current degree of regulation;

In 2010, surgeons performed more than 51 million inpatient procedures in the United States. Even more (nearly 57 million) were performed at ambulatory surgery centers. In Minnesota hospitals, approximately 2,200,000 invasive surgeries were performed in 2013. Procedures range from outpatient procedures, to complex and highly invasive surgeries such a coronary artery bypass surgery or neurosurgery. Surgical technologists are present for every invasive surgery.

The potential for harm to the public from the surgical technologist comes from two main sources: surgical site infections and foreign objects left in surgical patients. Tasks such as wrong-site surgery, falls, medication errors, positioning the patient and other perioperative tasks may also pose risks. The Institute of Medicine (IOM) report, “To Err is Human: Building a Safer Health System,” published in 1999 estimated that over 98,000 patients die from preventable medical error every year. Of the eight “never events” identified, 60 per cent of them occur in the operating room. Minnesota statutes have identified 27 preventable adverse events for the purpose of hospital reporting. Nearly 25 per cent of these events occur in the operating room. More recently, a 2013 *Journal of Patient Safety* study estimates that preventable adverse events at U.S. hospitals cause as many as 440,000 patient deaths a year—a statistic that would make medical errors the third-leading cause of death in the United States.

The surgical technologists act as the surgeon’s co-pilot. The surgical technologist sets-up and manages complex surgical equipment, instruments and supplies throughout the surgery; manages specimens such as cancer, skin grafts, and organs; and oversees the sterile integrity of the operating room, including the hundreds of instruments that are used in even the most basic surgery, preventing surgical site infections and adverse surgical events such as retained foreign objects.

Skillful pre-surgery technique protects patients from life-threatening surgical site infections, malfunctioning equipment and unneeded delays during the procedure. The surgical technologist must be able to anticipate the needs of the surgeon because every moment a patient is in surgery the risks related to anesthesia and bleeding increase. The surgical technologist is trained to handle and minimize exposure to hazardous materials, communicable diseases and bloodborne pathogens.

Surgical Site Infections

The surgical technologist is responsible for maintaining the integrity of the sterile field. The sterile field is a notional area surrounding invasive or surgical procedures. Rather than a dedicated area, the sterile field refers to surfaces that sterile objects, such as surgical instruments, may contact. Surfaces include the hands and chest area of sterile team members, the sterilized portion of the patient, the drapes that protect the surgical site, and the instrument tray. Instruments that touch any surface outside of the sterile field are automatically considered contaminated. Protecting the sterile field involves carrying out specific procedures known as aseptic technique.

Nosocomial or hospital-acquired infections (HAIs) are a growing concern in the healthcare field. A 2007 U.S. Public Health Service (PHS) study estimated that approximately 1.7 million patients developed HAIs in 2002, resulting in an estimated 98,987 deaths. The study estimated that 22 percent, or approximately 290,000, of the infections were surgical site infections.¹ An investigative report by the Chicago Tribune for the same year reported 2.1 million infections and 102,000 deaths. It also estimated that 6 percent of patients admitted to hospitals acquire infections while there.² For perspective, the PHS 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.³

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 spread 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, MRSA caused only 2 percent of Staph infections. By 2003, that number had jumped to 64 percent.⁴ The CDC estimates that there were 80,400 MRSA cases in 2011. Other drug resistant bacteria strains found in healthcare settings include Vancomycin-

¹ R. Monina Klevens, Jonathon R. Edwards, Chesley L. Richards, Teresa C. Horan, Robert P. Gaynes, Daniel A. Pollock and Denise M. Cardo. March-April 2007. "Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002." *Public Health Reports*. Vol. 122, pp 164.

² Michael J. Berens, "Unhealthy Hospitals: Infection Epidemic Carves Deadly Path: Poor Hygiene, overwhelmed workers contribute to thousands of deaths," Chicago Tribune, July 21, 2002.
<http://www.chicagotribune.com/news/chi-0207210272jul21,0,2177158.story>

³ Robert N. Anderson & Betty L. Smith. "Deaths: Leading Causes for 2002" National Vital Statistics Reports, Vol. 53, No. 17, March 7, 2005, p 7.

⁴ McCaughey, Betsy. *Unnecessary Deaths: The Human and Financial Costs of Hospital Infections*, 3rd edition. Committee to Reduce Infection Deaths. Available at www.hospitalinfection.org.

Intermediate/Resistant Staphylococcus aureus, Acinetobacter, S. pneumoniae, Drug-resistant TB and Vancomycin-resistant Enterococci.⁵

The rise in HAI rates grew slowly over several decades. High infection rates are often associated with sometimes flagrant disregard for infection risks by surgeons, nurses and other personnel. The introduction of stringent aseptic technique and other measures can reduce the risk of surgical site infections significantly. To accomplish this, hospitals implement cultural change at all personnel levels.⁶

Health regulatory and professional organizations have elevated infection control to a policy issue. The 2009 American Recovery and Reinvestment Act directed \$50 million in stimulus funding to state efforts to reduce HAIs. The Joint Commission has made reducing the risk of health care acquired infections one of its patient safety goals for hospitals and ambulatory surgery centers, specifically including reducing the risk of surgical site infections.

Regulatory and accreditation standards require all hospitals in Minnesota to maintain an Infection Control Program, charged with implementing prevention and surveillance measures throughout the facility and discovering the root cause of any infection outbreaks.

Foreign Objects

The surgical technologist is the professional near the patient responsible for keeping track of all objects used during the surgical procedure. This includes performing counts of objects, especially sponges, and ensuring that no pieces have broken off instruments. Retained foreign objects (RFO) can lead to multiple problems, including pain, infection, internal damage, additional surgeries or even death. Occasionally RFOs are asymptomatic for years, or create non-specific symptoms.

Analyst estimates of the incidence of retained foreign objects vary. Common estimates range from 1 in 8,000 to 1 in 18,000 inpatient operations. A notably thorough study of surgical cases performed at the Mayo Clinic, Rochester found that 1 in 5,500 inpatient operations resulted in foreign body retention. In abdominal cavity operations, incidence rate estimates rise to one in every 1,000 to 1,500 procedures.⁷ RFOs may be underreported, however, as malpractice settlements often include confidentiality agreements and some surgeons may persist in “defensive charting,” recording incidents on charts in a manner that reduces the risk of liability. According to the Minnesota Department of Health data show 30 RFOs were reported in 2012 in Minnesota hospitals.

Wrong site/wrong patient surgery

⁵ 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.

⁶Ibid. McCaughey, Betsy.

⁷ Cima, Kollengode, Garnatz, Storsveen, Weisbrod and Deschamps. 2008. “Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients.” *Journal of the American College of Surgeons*. Vol. 207. pg. 80.

All members of the surgical team, including the surgical technologist, are charged with the responsibility of assuring that the correct surgical procedure is performed on the correct patient. Team members all participate in the surgical pause, or “time out” to underscore the importance of correct site surgery. Wrong site surgery is the fourth leading sentinel event, according to the Joint Commission. Since the inception of the Joint Commission’s Sentinel Event program, the number of wrong site surgery cases has increased from 115 cases in 1998, to a total of 592 cases reported by June 30, 2007. Joint Commission statistics show that wrong site surgery occurs in 1 out of 27,686 cases, or 1 out of every 112,994 surgeries. Researchers have confirmed that the Joint Commission numbers may be low, because reporting of sentinel events is voluntary. Minnesota law (Ch. 144.7065) requires healthcare facilities to report the occurrence of any wrong site surgery. The Minnesota Department of Health data show that 50 wrong site, wrong patient or wrong surgeries were reported in 2012.

Minnesota Adverse Health Events Reporting Act Data Analysis

The Minnesota Adverse Health Events Reporting Act requires public dissemination by healthcare facilities of 28 adverse medical events. **Analysis of the data from 2009-2013, by facility, reveals that reported adverse surgical events (wrong body part, wrong procedure, wrong patient, foreign retained objects) occurred 40% less often in hospitals that require education and certification for surgical technologists compared to hospitals that do not require education or certification for surgical technologists.**

The surgical technologist is the professional near the patient responsible for counting supplies and instruments to prevent foreign retained objects. **Foreign retained objects analyzed separately occurred 55% less in hospitals that require surgical technologist education and certification compared to hospitals that do not.**

Data were calculated using relative increase. Because of the confidentiality of root cause analyses of these events, it is difficult to determine exact fault. Nevertheless, the data decisively show that healthcare facilities that value competency in their surgical staffs experienced better outcomes.

(2) any reason why existing civil or criminal laws or procedures are inadequate to prevent or remedy any harm to the public;

Currently, no law or regulation exists to assure objective evidence of even minimum competence of the person in the scrub role. Surgical technologists remain the only members of the surgical team who are not required to meet threshold educational and certification criteria in order to practice in their area of expertise.

(3) why the proposed level of regulation is being proposed and why, if there is a lesser degree of regulation, it was not selected;

The entry-to-practice model reflected in H.F. 1993 is in fact the least intrusive and invasive level of regulation and oversight. No lesser degree of regulation is available.

(4) any associations, organizations, or other groups representing the occupation seeking regulation and the approximate number of members in each in Minnesota;

The Minnesota State Assembly of the Association of Surgical Technologists (MN-AST) was incorporated in October, 2000, and is the sole professional organization for surgical technologists in Minnesota. MN-AST is a constituent and affiliated organization of the Association of Surgical Technologists (AST), the sole national professional association representing surgical technologists. The Association of Surgical Technologists (AST) was established in 1969 with the support of the American College of Surgeons, American Medical Association (AMA), American Hospital Association (AHA), and Association of periOperative Registered Nurses (AORN). AST currently has a membership of over 36,000 members, and represents the interests of over 95,000 surgical technologists nationwide. Currently, 1,162 AST members reside in Minnesota. The Bureau of Labor Statistics estimates that there are approximately 1,800 surgical technologists in Minnesota.

(5) the functions typically performed by members of this occupational group and whether they are identical or similar to those performed by another occupational group or groups;

Surgical technologists are allied health professionals, who are an integral part of the team of medical practitioners providing surgical care to patients. Surgical technologists work under the supervision of a surgeon to facilitate the safe and effective conduct of invasive surgical procedures, ensuring that the operating room environment is safe, that equipment functions properly, and that the operative procedure is conducted under conditions that maximize patient safety. Surgical technologists possess expertise in the theory and application of sterile and aseptic technique and combine the knowledge of human anatomy, surgical procedures, and implementation tools and technologies to facilitate a physician's performance of invasive therapeutic and diagnostic procedures.

The following description of the surgical technologist in the scrub role has been approved by the American College of Surgeons and the Association of Surgical Technologists:

Scrub Surgical Technologist

The scrub surgical technologist handles the instruments, supplies, and equipment necessary during the surgical procedure. He/she has an understanding of the procedure being performed and anticipates the needs of the surgeon. He/she has the necessary knowledge and ability to ensure quality patient care during the operative procedure and is constantly on vigil for maintenance of the sterile field.

Duties are as follows:

1. Checks supplies and equipment needed for surgical procedure
2. Scrubs, gowns, and gloves
3. Sets up sterile table with instruments, supplies, equipment, and medications/solutions needed for procedure
4. Performs appropriate counts with circulator prior to the operation and before incision is closed

5. Gowns and gloves surgeon and assistants
6. Helps in draping sterile field
7. Passes instruments, etc., to surgeon during procedure
8. Maintains highest standard of sterile technique during procedure
9. Prepares sterile dressings
10. Cleans and prepares instruments for terminal sterilization
11. Assists other members of team with terminal cleaning of room
12. Assists in prepping room for the next patient
13. Holds retractors or instruments as directed by the surgeon
14. Sponges or suctions the operative site
15. Applies electrocautery to clamps on bleeders
16. Cuts suture material as directed by the surgeon
17. Connects drains to suction apparatus
18. Applies dressings to closed wound.

(6) whether any specialized training, education, or experience is required to engage in the occupation and, if so, how current practitioners have acquired that training, education, or experience;

No specialized training, education or experience is currently required to perform surgical technology tasks and functions in a hospital or other healthcare facility in Minnesota. There are no regulations governing who may perform the surgical scrub role, or the minimum qualifications necessary for employment or assignment to the surgical suite.

(7) whether the proposed regulation would change the way practitioners of the occupation acquire any necessary specialized training, education, or experience and, if so, why;

H.F. 1993 does not change how surgical technologists are educated. Minnesota's surgical technologists are currently being well educated by our nine nationally accredited training programs. It would change how surgical technologists are utilized post-graduation by placing education, certification and continuing education requirements on surgical technologists if they are hired by a hospital. The Legislature is currently investing large sums each year at the six MnSCU training programs (Rochester, Anoka, Duluth, St. Cloud, East Grand Forks and Luverne), but then allows hospitals to not hire these trained personnel to provide patient care in the OR. The State should either promote patient safety in the OR by passage of H.F. 1993 or stop funding the training programs.

(8) whether any current practitioners of the occupation in Minnesota lack whatever specialized training, education, or experience might be required to engage in the occupation and, if so, how the proposed regulation would address that lack;

All currently practicing surgical technologists in Minnesota, and all graduates of Armed Forces surgical technologist education programs will be grandfathered into practice under the proposed bill.

(9) whether new entrants into the occupation would be required to provide evidence of any necessary training, education, or experience, or to pass an examination, or both;

The proposed bill is not a licensure bill. Nevertheless, all practicing surgical technologists must demonstrate continuing education either by maintenance of the CST credential (which requires 60 hours of continuing education over four years) or by submitting proof to the healthcare facility that the surgical technologist has completed 15 hours of continuing education annually. Records of either the credential, or the continuing education credits, will be maintained by the healthcare facility.

(10) whether current practitioners would be required to provide evidence of any necessary training, education, or experience, or to pass an examination, and, if not, why not; and

All currently practicing surgical technologists in Minnesota, and all graduates of Armed Forces surgical technologist education programs will be grandfathered into practice under the proposed bill.

(11) the expected impact of the proposed regulation on the supply of practitioners of the occupation and on the cost of services or goods provided by the occupation.

There will be no impact either on the currently employed surgical technologists or on future demands. A report issued in 2013 by the Board of Trustees of Minnesota State colleges and Universities (MnSCU) determined that “Minnesota is well-served by nine surgical technologist programs which are geographically distributed throughout the state. All programs are accredited by the commission on the Accreditation of Allied Health Programs or the Accrediting Bureau of health Education Schools. Six of the nine programs are offered by MnSCU institutions. Programs graduate approximately 140 students per year with MnSCU programs accounting for approximately 71% of total graduates. MnSCU programs report strong certification exam pass rates for students with three programs achieving 100% pass rates. These programs also report almost 90% employment rates for students seeking related employment within one year of completion.” Data from the Bureau of Labor Standards in the U.S. Department of Labor show that states that have enacted legislation comparable to H.F. 1993 have not experienced any change in the cost of surgical technologists in their states. Payers of surgical services, however, have experienced some savings as a result of reduced rates of infection, second-surgeries, longer hospital stays, etc. from better surgical outcomes and avoided surgical adverse events. The average cost of a surgical adverse event is estimated at \$35,000 per incident.

Subd. 3. Additional contents; health-related occupations. In addition to the contents listed in subdivision 2, a report submitted by supporters of regulation of a health-related occupation must address the following issues as specifically as possible:

(1) typical work settings and conditions for practitioners of the occupation; and

Surgical technologists work in hospital surgical suites and are present from before surgery begins through completion of the surgery. Prior to the surgery beginning the surgical technologist may prepare the suite for the surgeon by obtaining the appropriate equipment and supplies for the surgery and assuring that the surgical area is sterile.

(2) whether practitioners of the occupation work without supervision or are supervised and monitored by a regulated institution or by regulated health professionals.

To the extent surgical technologists are performing delegated medical or nursing functions, they are supervised and receive clinical guidance from these regulated health professionals. The proposed bill expressly provides that surgical technologists are to be supervised by a physician or registered nurse.

Further Questions From Chair Liebling

1. What other professions are likely to be impacted by the proposed regulatory changes?

The legislation does not modify any scope of practice for any other professions and does not impact any other profession.

- 2) What position, if any, have professional associations of the impacted professions taken with respect to your proposal?

Although it does not affect their members, the Minnesota Nurses Association asked for three additions to the bill. Two of their requests were accepted: 1) providing that the surgical technologist shall be supervised by a physician or registered nurse; and 2) providing that a hospital unable to find a qualified surgical technologist may hire a registered nurse or licensed practical nurse to perform these functions. The third request from the MNA was that language be added to the bill that provides for specific R.N. staffing ratios in hospital surgical units. This request was not granted because the bill does not deal with R.N. staffing ratios or staffing levels for any hospital personnel. It was suggested to the MNA that if they seek to enact a bill addressing their concerns about staffing ratios for R.N.s in hospitals, that they introduce a bill and seek a hearing. Because nurse staffing ratios are not being added to the bill, the MNA opposes its passage.

The Minnesota Hospital Association (MHA) has philosophical concerns with the bill. It opposes, on principle, any legislation that seeks to direct how hospitals are to employ health care professionals. It has been noted to the MHA that most of its members, including the Mayo Clinic, Allina Hospitals and Clinics, Avera Health, Catholic Health Initiatives, Children's Hospitals and Clinics, Fairview Health Services, HealthEast Care System, HealthPartners, North Memorial Health Care, Sanford Health and Winona Health, either already comply or are in the process of implementing the provisions of H.F. 1993. These health care systems account for the vast majority of all surgeries performed in Minnesota. As noted earlier, because of the commitment of these health care systems to quality and patient safety, their surgical adverse events rate is 40% below the rate of MHA members that do not comply with the requirements of H.F. 1993.

3. Please describe what efforts you have undertaken to minimize or resolve any conflict or disagreement described above.

Multiple meetings have been held over the interim with both the Minnesota Nurses Association and the Minnesota Hospital Association in an effort to better understand their concerns and to see if a compromise acceptable to all can be achieved. As noted above, two of the three concerns raised by the MNA have been addressed. Because of the MHA's philosophical opposition to the

bill, as opposed to opposition based on specific provisions, we are unable to eliminate their opposition.