



Virginia Perfusion Society
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Elizabeth Carter, Ph.D.
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Virginia Department Of Health Professions
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Dear Dr. Carter:

The Virginia Perfusion Society (VPS) respectfully requests that the Department of Health Professions initiate a study that assesses the need for licensure of perfusionists. With filing of this Sunrise Proposal, we are aware of the criteria underlying this application and have included quantitative and qualitative evidence-based information to assist with the study and recommendation to the General Assembly of the Commonwealth.

The VPS and its elected and voluntary leadership, as governed by the members of the Society, and perfusionists who are not members, believe that licensure is the only level of regulation for adequately protecting the public. There are currently 90 practicing perfusionists in the Commonwealth. Between 2003 and 2010, approximately 48,000 residents of the state have received open heart surgeries or relevant organ transplants. Approximately 6,000 persons of all ages each year require the services of a perfusionist. Reliable statistical evidence supports the potential for 5 to 6 persons each year suffering a serious long-term adverse surgical outcome or possible death attributable to device malfunctions and incompetent practice.

Perfusionists are not now regulated by the State. There are no mandated educational or training standards, national professional certification standards for entry to practice, and no educational competency standards. For these and other reasons, the VPS believes that licensure will ensure the public health and safety for thousands of Virginians each year that require cardiovascular and cardiothoracic surgical procedures. Please refer to the attached documents that we believe provide support for our claim that perfusionists meet the Virginia Department Of Health Professions' criteria for regulation by licensure.

Sincerely,

Mike Brown, CCP
VPS Board Member
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Acronyms

AACP	American Academy of Cardiovascular Perfusion
ABCP	American Board of Cardiovascular Perfusion
AC-PE	Accreditation Committee – Perfusion Education
AMA	American Medical Association
AmSECT	American Society of Extracorporeal Technology
CAAHEP	Commission on Accreditation of Allied Health Education Programs
CPB	Cardiopulmonary Bypass/Open Heart Surgery
ECMO	Extra-Corporeal Membrane Oxygenation
FDA	Food and Drug Administration
IABP	Intra Aortic Balloon Pump
JCAHO	Joint Commission on Accredited Health Organization
OPTN	Organ Procurement Transplant Network, US Department of Health and Human Services, Health Resources and Services Administration,
VAD	Ventricular Assist Device
VSCQI	Virginia Cardiac Surgery Quality Initiative

Contact Information for Proposal Submitter

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Summary of Proposal Preparation

The Virginia Perfusion Society was formed in 2008. Information is available at www.virginiaperfusion.org

The Society is dedicated to serving our communities with quality patient care while promoting excellence in the field of Perfusion Technology. The Virginia Perfusion Society supports all perfusionists of the Commonwealth of Virginia by promoting educational opportunities, providing an open forum for communication, and shall present a platform for guidance in interactions with governmental and regulatory agencies.

Before incorporation, and after, the Society conducted surveys of perfusionists within the Commonwealth in regards to support for licensing of the profession. In the surveys conducted, an overwhelming majority of perfusionists supported state legal credentialing with licensure receiving the vast majority of support. Only five perfusionists at one hospital registered opposition to becoming a licensed profession.

The effort to submit a Sunrise Application/Proposal with the Virginia Department Of Health Professions has been an ongoing Society matter since 2008. With the renewed assistance of our national professional association, the Society has accomplished this goal and hopes that the Department will favorably recommend the licensing of perfusionists. Licensure will optimize public health and safety of thousands of residents of in the Commonwealth who now and in the future will suffer from heart disease and require open heart surgical procedures or organ transplant operations that will require the competent delivery of perfusion services.

The drafting of this proposal was reviewed by eight perfusionists prior to submission, as is being shared with all the perfusionists in the state willing to review, revise and submit additional commentary.

Profile of Perfusionists

1. What occupational or professional group is seeking regulation?

The name of the health profession seeking regulation is Perfusionist or Clinical Perfusionist.

2. What is the level or degree of regulation sought?

The level of regulation being sought is Licensure. The Virginia Perfusion Society is fully aware of the other categories of State regulation, and believes that licensure is best for the citizens of our State, and is best for maintaining high standards of entry to practice the profession of perfusion in the State. State certification does not prevent any person who is otherwise credentialed by the State in another medical profession, from practicing the perfusion profession, based solely on educational and experiential standards. State Registration is also too low of a consumer regulatory standard.

“Licensure” means a method of regulation by which the state grants permission to persons who meet predetermined qualifications to engage in an occupation or profession, and that to engage in such an occupation or profession without license is unlawful. Licensure is inclusive of language that defines an occupation or profession’s scope of practice, restricts the use of the occupation or profession’s title to those licensed, and restricts the use of the term to that specific occupation or profession. The Virginia State Credentialing Act § 54.1-2510 was established to protect public health, safety, and welfare from the unregulated application of identified providers of health care. Licensing Virginia’s perfusionists would place them on a peer level with perfusionists of other states, and put them on the credentialed level with many other licensed health care providers in Virginia that have equal or less responsibility, potential liability, and education. The credentialing level being sought would also serve to protect the consumer public from untrained and unqualified practitioners performing critical medical procedures and/or operating in a capacity beyond their area of expertise.

Since there is no current level of state regulation over the entry requirements for the profession, there are no minimum education and training standards for the profession. Additionally, there is no professional certification entry requirement to practice as a perfusionist at the current 19 open-heart hospitals. In the current non-regulated professional environment, medical centers may be capable of pursuing the hiring of unqualified ancillary medical professionals, or previously non-professionally certified perfusionists. These are perfusionists who graduated from an accredited training program, but who were unable to pass the professional certification examination.

3. Identify by title the association, organization, or other group representing Virginia based practitioners. (If more than one organization, provide the information requested below for each organization.)

The Virginia Perfusion Society is the only State organization that represents perfusion practitioners.

4. Estimate the number of practitioners (members and nonmembers) in the Commonwealth.

There are ninety practicing perfusionists in the Commonwealth who practice at the nineteen acute care hospitals with an open-heart program.

5. How many of these practitioners are members of the group preparing the proposal? (If several levels or types of membership are relevant to this proposal, explain these levels and provide the number of members, by type).

Fifty-two of the ninety perfusionists (57%) currently are members of Society.

6. Do other organizations also represent practitioners of this occupation/profession in Virginia? If yes, provide contact information for these organizations.

No

7. How was this organization and individual(s) selected to prepare this proposal?

The VPS is the only State organization in the State that represents the perfusion profession and a group of volunteers were asked to prepare this proposal with the assistance of the profession's national professional association.

8. Are there other occupations/professions within the broad occupational grouping? What organization(s) represent these entities? (List those in existence and any that are emerging).

None

9. For each association or organization listed above, provide the name and contact information of the national organizations with which the state associations are affiliated.

National Associations

American Society of Extracorporeal Technology (AmSECT) provides continuing education and representation to perfusionists. <http://www.amsect.org>

Criterion One: 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.

1. Provide a description of the typical functions performed and services provided by members of this occupational group.

Occupational description

Perfusionists have been recognized as a definable allied health profession by the American Medical Association since 1977. Working under the supervision of a physician (most commonly a surgeon), perfusionists are the only non-licensed health care professionals who routinely administer medications and blood products to patients, as well as analyze, interpret and treat abnormal blood gas and blood chemistry parameters. A perfusionist is the person responsible for the careful selection, set-up, and operation of the heart-lung machine. To maintain life during open-heart surgery, the patient's heart often must be stopped and the patient's blood is diverted outside the body, circulated through the heart-lung machine, and returned to the patient.

A perfusionist exercises a high degree of independent medical judgment when carrying out extracorporeal circulation and autotransfusion equipment during any major surgical situation where it is necessary to support or temporarily replace the patient's circulatory or respiratory functions. The perfusionist is knowledgeable concerning the variety of equipment available to perform extracorporeal circulation functions and is responsible, in consultation with the physician/surgeon/anesthesiologist, for selecting the appropriate equipment and techniques to be used.

Although practicing under the direction of an attending physician (a surgeon), a high degree of autonomy for decision-making is required of perfusionists, particularly in the intra-operative setting where split second decisions must be made and acted upon appropriately when a surgeon is focused on their medical responsibilities. In the vast majority of cardiac operating rooms, the perfusionist is the only clinician that is capable of diagnosing and ameliorating potentially lethal crisis events connected to cardiopulmonary bypass.

Job description

Perfusionists conduct extracorporeal circulation and ensure the safe management of physiologic functions by monitoring the necessary variables. Extracorporeal circulation procedures involve specialized instrumentation and/or advanced life-support techniques and may include a variety of related functions. During cardiopulmonary bypass, the perfusionist administers blood products, anesthetic agents, and medications through the extracorporeal device via physician prescription and appropriate treatment protocol. Perfusionists are responsible for the monitoring and delivery of patient blood oxygen content to preserve organ function, adequate anticoagulation of the circulating blood to prevent thrombus formation and subsequent stroke, induction of hypothermia, hemodilution, and other duties, when prescribed. In many centers, perfusionists are responsible for purchasing supplies and maintaining equipment, as well as for duties involving personnel and departmental management. Physician oversight for extracorporeal perfusion rests with the medical director of the respective cardiac surgical program.

A perfusionist sets up and operates the heart-lung machine to take over functions of patient's heart and lungs during surgery or respiratory failure. Perfusionists review patient medical records and documents, and consult with surgeons or physicians to obtain patient information needed to set up heart-lung

machine and associated equipment. The perfusionist monitors and observes the safe operation of the heart-lung machine and optimizes the patient's physiologic variables such as blood temperature, blood composition, and flow rate. Critical analysis is required to make continuous adjustments to the cardio-pulmonary bypass equipment to maintain normal body function.

Perfusionists practice under the supervision of cardiovascular and cardiothoracic surgeons both inside and outside of a hospital operating room. The majority of their medical functions are performed within the operating room. There are instances in which the perfusionist may report to other health care personnel within a facility-based reporting structure, but not for the purposes of clinical direction. Perfusionists are usually not delegated duties by other non-physician health care personnel.

Perfusionists do share similarities and overlaps in their scope of practice with other licensed health professions. In these instances, a perfusionist is performing a licensed function without a professional license. There also are functions of a perfusionist that are exclusive to perfusion professionals. This is done to help ensure continuity of care for the patient from hospital admission to discharge. Perfusionists are integral members of a multi-disciplinary team in various clinical settings across all open-heart hospitals in Virginia.

2. Has the public actually been harmed by unregulated providers or by providers who are regulated in other states? If so, how is the evidence of harm documented (i.e., court case or disciplinary or other administrative action)? Was this physical, emotional, mental, social, or financial?

Yes, there have been medical malpractice cases brought against perfusionists, in court cases and through disciplinary actions taken by perfusionist licensing boards and advisory committees in the currently licensed 17 States.

in 1989, Charles C. Reed and Trudi B. Stafford reported in the second edition of *Cardiopulmonary Bypass* that "The number of injuries or deaths from accidents during perfusion was one per 1,000 cases performed." One of the most catastrophic accidents is arterial air embolism. Air embolisms can be caused from inattention of the perfusionist to the level of the blood in the reservoir of the heart lung machine. Loss of blood flow to the heart lung machine can result in emptying of this reservoir and transmitting massive amounts of air into the patient's circulatory system. In certain circumstances, this scenario can occur in less than 15 seconds. Large amounts of air into the brain can result in a persistent vegetative state or death to the patient.

In January of 2002, an Alachua County jury handed down a \$10.8 million verdict against Shands Hospital in Gainesville, Florida because of a mishandled surgical procedure that led to permanent brain damage of a six-year-old boy. The parents of Gary Juliana took their then 2-month old baby to Shands Hospital in 1996 after the infant was diagnosed with respiratory distress and a heart murmur. During surgery, the perfusionist made critical mistakes while operating the heart-lung machine. As a result, the flow of oxygen to the brain was inadvertently stopped, leading to the child's injuries. Gary now suffers from cerebral palsy, clinical blindness, loss of speech, and mental retardation. Prior to the trial, the family settled with the perfusionist, who was an independent contractor, for \$2 million. (injuryboard.com)

A 78-year-old woman with diabetes, hypertension, and recent subendocardial MI underwent coronary arteriography demonstrating severe 3 vessel Coronary Artery Disease (CAD). She was scheduled for coronary artery bypass surgery. She was taken to the OR where the left internal thoracic artery was harvested and two segments of greater saphenous vein retrieved from the left thigh endoscopically. Preparations were made to initiate cardiopulmonary bypass with arterial blood inflow via the ascending aorta. A two stage venous cannula was placed in the right atrial appendage. Cardiopulmonary bypass was initiated to a target temperature of 32 degrees. The left internal thoracic artery was divided distally and demonstrated good flow. The target vessels on the heart were identified. At this point, an observer in the room noted that the arterial blood in the cardio-pulmonary bypass circuit was quite dark, indicating

possible low oxygen content. The mixed venous saturations were then noted to be in the low 40's. The arterial inflow saturation was noted to be in the 80's. The perfusionist immediately called for a back up, and a second perfusionist arrived in the room trouble shooting the machine. They identified that the oxygen inflow to the pump had not been appropriately turned on. Oxygen inflow was provided, and the arterial saturations immediately increased to normal values. The patient underwent the coronary bypass procedure uneventfully and awoke without neurologic deficit. It is important to recognize that having cooled the patient to 32 degrees provided the patient some additional protection despite the hypoxia and may well be responsible for her having awakened without neurologic deficit. An alternative course of action would have been for the surgeon to ask anesthesia to ventilate and immediately wean from bypass despite systemic hypothermia since the patient's heart was still beating. Importantly, this crisis event intervention is unavailable once the aortic cross-clamp is applied and the heart is arrested. As such, cross-clamp and initiation of cardiac arrest should be considered a critical and relatively irreversible step in the course of the procedure. This case demonstrates that it is critically important even on a routine case to assure that all is well with the bypass run before committing to cardiologic arrest.

Human Factors Analysis: The factors contributing to this accident included a relatively new perfusionist who had only recently passed his boards as well as a surgeon working with an unfamiliar team. In addition, the alarm for arterial blood saturations had been turned off as a matter of convenience in this perfusion program. Currently, there is no checklist for the perfusionist after initiating cardio-pulmonary bypass. There are at least 10 critical parameters/steps to perform at this critical time and there is no systematic method or steps to follow. It is also important to consider that new perfusionists have been trained on different bypass technologies; therefore the machine they use in this OR was different than the one utilized in their perfusion training program. There is limited mentoring for perfusionists at this institution, and this must be considered to guard against future errors. (from CTSNet)

The following case notes, lawsuits, financial awards, and judicial rulings are taken from the book, *Safety and Techniques in Perfusion*, by Charles C. Reed, Mark Kurusz, and A. Earl Lawrence, Jr.

...During cardiopulmonary bypass for aortocoronary bypass graft surgery the perfusionist allowed the arterial reservoir of the oxygenator to empty. An unknown amount of air was pumped into the patient and the anesthesiologist was the first to alert the team after hearing a strange noise which was air rushing through the coronary grafts which had been anastomosed distally. The patient never regained consciousness and was disconnected from life support on the second postoperative day and died immediately. Plaintiff filed suit against the surgeon, hospital, perfusionist, and anesthesiologist. During deposition it was established that the perfusionist used no checklist, and that the perfusionist had never turned on the low-level alarm sensor or the bubble detector. The case was settled out of court for an amount in excess of \$800,000.

...During cardiopulmonary bypass for aortocoronary bypass graft surgery, the perfusionist allowed the arterial reservoir to empty and air was pumped into the patient. An arterial line filter was being used in the arterial line, but the stopcock was closed. No other safety devices were in use. The patient died several days later. Suit was filed against the perfusionist, the hospital, the surgeons, and the anesthesiologist. The case was settled out of court for an amount in excess of \$225,000.

...During cardiopulmonary bypass, the perfusionist allowed the arterial reservoir to empty when the surgeon inadvertently, temporarily occluded the venous return line. Air was pumped into the patient, who subsequently died. An arterial line filter was part of the set-up; however the perfusionist was using the purge port to measure filter pressure and no purge line returned to the oxygenator or reservoir. A low level sensing device was in use but failed to function properly. Suit was filed against the perfusionist, hospital, and surgeon. The case settled out of court for an amount in excess of \$350,000.

...During mitral valve replacement, the surgeon inserted the vent into the left atrium via the left superior pulmonary vein. Blood initially began to travel down the vent tubing toward the heart-lung machine, but then reversed direction and blew a large amount of air into the heart. The cross-clamp had not been applied at the time. The patient suffered severe neurological damage. Suit was filed against the

perfusionist, the surgeon, and the hospital. The case was settled out of court for an amount in excess of \$1,250,000.

...During administration of cold cardioplegia at 4°C, an increased resistance was noted in the cardioplegia line. Cardioplegia was infused one time. When the coronary vessel was opened, the surgeon discovered gross clot formation. Further examination of the coronary vasculature revealed clot throughout the system. The patient was pronounced dead on the operating table. No one observed the positive cold agglutinin report.

...Patient with a documented history of hypertension and syncope suffered neurological damage during aortocoronary bypass graft surgery. Review of the perfusion record revealed that the first blood gas results drawn nine minutes after the start of bypass indicated an arterial pO2 of 65 mmHg and a perfusion pressure of 44 mmHg. The next blood gas sample was drawn 41 minutes later with no corrections noted in the gas flow rate, and the blood flow rate reduced by 10% in the interim. The perfusion pressure rose gradually to 78 mmHg during this period. A malpractice suit was filed against the surgeon and perfusionist. The case settled out of court for an amount in excess of \$475,000.

...During bypass the primary perfusionist was handed two units of blood to add to the perfusion circuit by a second perfusionist. Allegedly the circulating nurse and the second perfusionist had checked the blood. The primary perfusionist did not ask. A few minutes later the circulating nurse realized that the patient had been given another intended recipient's blood. The operation was completed and the patient underwent two complete blood exchanges while on bypass. The patient developed generalized DIC in the recovery room and died on the second postoperative day. A lawsuit was filed against the primary perfusionist, the hospital, and the surgeons. It was settled out of court for an amount in excess of \$1,000,000.

...During cardiopulmonary bypass the surgeon inserted the left heart vent via the superior pulmonary vein. He noted air entering the heart and removed the vent. The patient suffered severe brain damage. At deposition it was discovered that the perfusionist had inserted a cardiotomy reservoir between the vent and vent pump head, the purpose of which was not satisfactorily explained. The perfusionist also testified that the vent worked alright once he had been notified by the surgeon and had tightened the occlusion of the vent roller head. The case settled out of court for \$1,500,000.

Statistical Estimate of Perfusionist Related Surgical Case Injury or Deaths

2006 Cases	Perfusionist Caused # of Injuries/Death	2007 Cases	Perfusionist Caused # of Injuries/Death	2008 Cases	Perfusionist Caused # of Injuries/Death	2009 Cases	Perfusionist Caused # of Injuries/Death	2010 Cases	Perfusionist Caused # of Injuries/Death
6,025	6 Persons	5,940	6 Persons	5,436	5 Persons	5,435	5 Persons	5,227	5 Persons

Data Sources – VSCQI Virginia Cardiac Surgery Quality Initiative – Consortium of 16 hospitals and 10 cardiac surgical practices providing open-heart surgery in the Commonwealth of Virginia. Includes: Coronary Artery Bypass Only, MV Replacement + CAB, AV Replacement + CAB, MV Replacement only, MV Repair, AV Replacement, AV Replacement + MV Replacement, MV Repair + CAB.) **OPTN** – Organ Procurement Transplant Network, US Department of Health and Human Services, Health Resources and Services Administration, heart, heart/lung transplants in Virginia. **Reed and Stafford**, in the book, *Cardiopulmonary Bypass*, second edition, have reported that the number of injuries or deaths from accidents of a perfusionist was/is 1 per 1,000 surgical cases.

3. If no evidence of actual harm is available, what aspects of the provider group's practice constitute a potential for harm?

In addition to the aforementioned documented physical, emotional, mental, social, and financial harms, another way to answer this question is to provide examples on patient harm in performing perfusion services, including personal harm associated with the devices used by perfusionists.

Cardiopulmonary Bypass (CPB)

Because connection of the extracorporeal circuit to the patient requires cannula be placed within the arterial and venous systems, the perfusionist must monitor patient and circuit pressures to avoid vascular injury. Intra-circuit pressures must be maintained within acceptable limits to avoid circuit disruption. Inattention on the part of the perfusionist might allow the oxygenating device reservoir to be emptied and thereby introduce air into the cardiovascular system of the patient. The brain is particularly vulnerable to entrained air, which could cause severe brain damage or ultimately result in patient death. The heart-lung machine is comprised of individual consoles, sensors, and monitors. Every component must function properly, even in the event of power failure. The perfusionist is responsible to troubleshoot, diagnose and correct abnormal functioning of any portion of the cardiopulmonary bypass circuitry while a case is in process.

Medication Administration

Various medications must be administered through the extracorporeal circuit during cardiopulmonary bypass to ensure delivery to the patient. Medications to maintain anticoagulation, regulate blood pressure, diuretics, antibiotics, electrolyte solutions and insulin are often administered to the patient through the extracorporeal circuit. Medications often considered as "High-risk", such as heparin, potassium chloride, and various controlled narcotics and paralyzing agents are provided to the patient via the cardio-pulmonary bypass circuit. The cardioplegia referred to below under the heading *Myocardial Protection* are often two or more distinct solutions needing to be administered in precise amounts at specific times of the surgery. Interchanging the solutions could lead to perioperative myocardial infarction, heart failure or death. Medication errors, as reported by the FDA and the Institute for Safe Medication Practices are more common than desirable. The Institute of Medicine has previously issued reports on an unacceptably high incidence of patient injury or death associated with medication errors. The National Academies July 20, 2006 report states... "Medication Errors Injure 1.5 Million People and Cost Billions of Dollars Annually; Report Offers Comprehensive Strategies for Reducing Drug-Related Mistakes"

Blood and Blood Component Transfusion and Processing

It may become necessary to transfuse various blood product components (packed red blood cells, fresh frozen plasma or other blood components) through the extracorporeal circuit during cardiopulmonary bypass. Albumin, a specific blood protein, is often a constituent of the extracorporeal circuit priming protocol. There are several risks associated with blood transfusion including: if the blood is given very quickly such that the heart cannot pump the extra load, fluid may accumulate in the lungs; if the blood is incorrectly typed, or if there are components in the body that could not be detected during typing and 'cross matching', the transfused blood cells may be abruptly destroyed with consequent damage to the kidneys with severe illness in the recipient; white blood cells that may remain in the blood unit may clump together or release chemicals causing lung disease or severe fever; blood may be contaminated by bacteria during storage which will cause potentially fatal infections in the recipient; viruses and other parasites that were present in the donor may contaminate the blood and cause illness in the recipient (e.g. HIV, hepatitis, malaria, and many others). The perfusionist must be able to recognize and communicate to the surgical team abnormal reactions to blood transfusion.

Thermal (temperature) Regulation

The perfusionist is responsible for the proper temperature control of the blood and patient during cardiopulmonary bypass (CPB). Maintaining and preserving the patients' organs and tissues is the ultimate goal while on CPB. The patients' core temperature is often decreased during CPB in an effort to

reduce the oxygenation demand of the tissues thereby allowing for reduced blood flow and minimizing mechanical trauma to the blood elements. As a result of hypothermia, the patient must also be systemically warmed back to normal temperature prior to discontinuing CPB. Warming the blood too aggressively can cause multiple organ system injury, with the brain being the most vulnerable organ. The surgical procedure might require the perfusionist to apply regional (heart, brain, soft organs) temperature differences during the cooling, maintenance and rewarming phases.

Myocardial Protection

The perfusionist is responsible for delivering the cardioplegia (high dose potassium solution to achieve chemical arrest) solution through a series of pumps and heat exchangers directly into the heart at a precise flow rate, temperature, route, and pressure to safely arrest the heart. The goal is to protect and preserve the patient's myocardium (heart muscle) during CPB. Cardioplegia can be delivered antegrade, which means forward flow down the coronary arteries, returning through the heart's venous system, and eventually into the extracorporeal circuit, or it may be delivered retrograde (or reverse flow) through a cannula placed through the right atrium into the coronary sinus. Retrograde cardioplegia flows first through the heart's venous system, returning through the coronary arteries, through the two main coronary arteries at the root or base of the aorta and eventually returning via pumps to the extracorporeal circuit. At most centers, protocols to administer cardioplegia are customized based on the type of surgical procedure. Therefore, multiple cardioplegia strategies may exist in each surgical practice, with significant variances observed between open-heart surgery centers. Cardioplegia is commonly initiated using antegrade delivery until the heart is arrested, and then delivered retrograde to ensure protection of the entire heart. Delivering the cardioplegia cold serves to cool the myocardium and decreases the oxygen demand of the heart's tissues to a minimum. All nutritive blood flow to the heart is stopped for as long as 1 hour while surgical correction by the physician takes place. Intermittent doses of cardioplegia may be delivered every 15-20 minutes to maintain arrest and to protect/preserve the myocardium. A perfusionist must be very vigilant and attentive to the delivery of cardioplegia, particularly when delivered retrograde. The coronary sinus may rupture if the retrograde cardioplegia is delivered at too high a flow rate or pressure. The coronary sinus is on the underside of the heart and can be very difficult for a surgeon to repair. Improper delivery technique of cardioplegia can cause irreversible damage to the heart muscle preventing proper function potentially leading to death.

Blood Flow Rate

The perfusionist is responsible for maintaining adequate blood flow to all vital organs and tissues. The blood flow is individualized and is calculated from an algorithm based on patient height and weight. The perfusionist strives for a flow rate based on an appropriate cardiac index taking into consideration patient temperature, blood pressure, physician preference as well as the progress of the operation. Failure to optimize flow rate based on patient need could result in hypo-perfusion and its associated damage to vital organs and tissues from inadequate oxygen delivery and acidosis. Hyperperfusion could result in vascular damage, increased embolic burden to tissue beds, edema or other undesirable consequences.

Oxygenation and ventilation of the Blood

The perfusionist is responsible for monitoring the function of the device (blood oxygenator) used for oxygenating the blood and removing carbon dioxide (CO₂). Failure to properly oxygenate and ventilate could cause harm to vital organs and tissues. The brain is particularly vulnerable to hypoxia.

Acid/Base Balance and Electrolyte content of Blood

Inadequate pH balance of the blood can result in an acidotic or alkalotic state that can damage vital organs and tissues. Failure to correct pH imbalance can certainly lead to death. The brain is particularly vulnerable to acid-base imbalances. The routine use of hypothermia and rewarming imposes rapid and

dramatic shifts in acid-base physiology. Electrolyte imbalances are directly influenced by acid-base status.

Heparinization and ACT Control

The patient is fully anticoagulated with heparinized sodium prior to initiating CPB, so that blood does not clot in the CPB circuit. Blood clotting in the circuit reduces device functionality and consumes necessary blood components, but most importantly increases the likelihood of embolization of vital organs. The perfusionist is responsible for monitoring the Activated Clotting Time (ACT) and assuring adequate heparinization of the patient throughout the entire procedure. The goal is to maintain the patient's ACT at an appropriate level while on CPB. If the patient is not adequately heparinized, the patient's blood has the potential to clot, which would result in certain harm to the patient. Most often, the perfusionist is also responsible for operating the instrument used to analyze anticoagulation and its subsequent reversal post cardiopulmonary bypass.

Total Circulatory Arrest

During procedures involving the replacement or repair of the aortic arch or the arteries supplying blood to the brain, a period of circulatory arrest may be necessary. This involves what is referred to as "profound hypothermia". The patient is systemically cooled from the normal 37 degrees Celsius (98.6 degrees Fahrenheit) to 15-18 degrees Celsius (59-64 degrees Fahrenheit) allowing for CPB to be stopped. At this point, the patient has no blood flowing through their body, thereby reducing the blood pressure to essentially zero. This technique allows the surgeon to make the necessary repairs to the aortic arch and /or the cerebral blood vessels. Failure to understand and apply the principles of circulatory arrest by the perfusionist could potentially be very harmful to the patient. Blood flow, blood pressure, temperature regulation, acid-base and electrolyte balance must all be tightly controlled during the cooling, arrest and rewarming phases. All of the organs are vulnerable during this procedure, with the brain most vulnerable to the extremes of temperature, flow and blood pressure.

Cold Agglutinin

Cold agglutinins or cryoproteins are serum antibodies that work on the antigens found on the surface of red blood cells. This process may cause complement activation and red blood cells to clump at low temperatures and break down. The process does not occur if the patient is kept warm. The perfusionist must check to verify that the patient does not have a cold agglutinin problem. If the patient is found to have an unsuspected positive cold agglutinin antibody and the perfusionist cools the patient's blood to the point where the blood starts to clump and breakdown, the patient could suffer a perioperative myocardial infarction, renal failure, hemolytic anemia, and potential thrombosis.

It is important to recall that in conducting these responsibilities in the operating room, a perfusionist is keeping a surgeon and the OR team informed, but the surgeon is not directly involved with the monitoring of these responsibilities.

Examples of devices that can cause harm

Perfusionists function in supportive roles for other medical specialties in operating mechanical devices to assist in the conservation of blood/blood products during surgery, and for long-term support of a patient's circulation outside of the operating room environment. The exact duties and responsibilities are often dependent upon the protocols of a particular institution.

Autotransfusion Procedures (Cell Saver)

FDA classification II § 868.5830 - Autotransfusion apparatus

An autotransfusion device (Cell Saver) is mechanical device that can be utilized to salvage blood shed during or after a surgical procedure. The surgical shed blood is collected in a sterile reservoir, processed and concentrated by the autotransfusion device, and then washed and returned to the patient. The perfusionist must be vigilant to monitor that no clotting agents (Avitene, Helitene, Oxycel, Gelfoam Powder, and Instat MCH) or irrigating solutions (alcohol, antibiotics, betadine, chloropactin, hydrogen peroxide, and hypotonic solution) are collected with the patient's blood that would cause red blood cell destruction. There is also potential for bacterium if any bowel contents, urine, mucous membrane secretions, or infection at the site of aspiration is collected with the blood. All of which could potentially be very harmful to the patient if the blood was processed and returned to the patient.

Heater Cooler Unit

FDA classification II § 870.4250 - Cardiopulmonary bypass temperature controller

The perfusionist is responsible for controlling the cooling and warming of the patient's blood and therefore, the patient's body. This is accomplished by using a device called a heater cooler unit and a heat exchanger. The perfusionist controls and monitors the temperature of the water bath in the heater cooler unit. This water is circulated to the heat exchanger, which is a series of metal tubes that allows the water to circulate on one side while the patient's blood circulates on the other side. If the temperature gradient between the water and the blood becomes too great, while attempting to warm the patient, air bubbles may begin to appear in the patient's blood, leading to possible organ damage from air embolism.

Another dire consequence can occur if there is a leak in the metal tubing of the heat exchanger which would result in water to blood leak. The patient's red blood cells would suffer irreversible damage from this event, significant bacterial contamination of the bloodstream would also occur.

Intra Aortic Balloon Pump (IABP)

FDA classification III § 870.3535 - Intra-aortic balloon and control system

An IABP is an assist device that increases coronary artery perfusion, decreases the workload of the heart, and augments the cardiac output by 15-20%. The perfusionist is responsible for monitoring and operating the IABP during care of the patient. Indications for IABP are unstable angina, acute MI, cardiogenic shock, adjunct to PTCA, adjunct to cardiac catheterization, bridge to cardiac transplantation, and operative (pre, intra, and post) support. Complications associated with IABP that could cause possible harm to the patient are limb ischemia, thromboembolism, aortic dissection, vascular injury (laceration, false aneurysm, and hematoma), infection, balloon rupture, and thrombocytopenia.

Ventricular Assist Device (VAD)

FDA classification III § 870.3545 - Ventricular bypass (assist) device

Several ventricular assist devices are available for use when a patient is unable to be weaned from CPB, as a "bridge" to cardiac transplantation or for what IS TERMED "destination therapy". Catheters are inserted into the patient's heart, a blood pump is primed, the patient is connected to the blood pump, the blood pump is turned on, and the patient is weaned from CPB and supported by the VAD. The VAD takes over for the function of the ventricle and allows time for the heart to rest and hopefully recover. A patient can be placed on a single or bi-ventricular support to rest and support the right and left ventricles.

A patient can be supported by a VAD for several days or months outside the OR in the ICU. VADs can be utilized as a bridge to recovery, a bridge to a heart transplant, or in patients that do not meet the criteria for heart transplantation, referred to as Destination Therapy. Patients that require long-term or permanent VAD support may be discharged to home and continue receiving care through hospital heart-failure outpatient clinics. Morbidities commonly associated with VAD surgical insertions include hemorrhage, infection, thrombosis, and multi-organ system damage.

ECMO

Extra-Corporeal Membrane Oxygenation is another type of CPB technology that can be utilized by a perfusionist outside the operating room theater. An ECMO circuit can be used as a long term oxygenating device for a patient with reversible cardiac and/or respiratory failure who is no longer able to be supported conventional therapies. ECMO set-ups are designed as portable heart-lung machines. In

the adult critical care arena, the patient is commonly connected to the ECMO device using the femoral vein and artery, respectively. Blood is removed from the patient via the femoral vein, oxygenated, and then returned to the patient via the femoral artery. An ECMO circuit circulates oxygenated blood outside the body, allowing for the patient's native heart and lungs to rest and recover. Patients placed on ECMO are susceptible to bleeding, infection, thrombosis, and limb ischemia. ECMO therapy is also utilized in neonatal, infant and adolescent patient populations. Similar to adult ECMO, indications for pediatric ECMO include all cardiac and pulmonary complications that are believed to be reversible in nature. ECMO is an essential therapy to have in any pediatric or adult cardiac surgical practice. Moreover, ECMO has become increasingly common in critical care units that do not treat surgical patients. In pediatrics, indications for non-surgical ECMO therapy can include diaphragmatic hernia, aspirations, acute respiratory disease, cardiac arrest. In adults, expanded ECMO indications have included H1N1 and flu viruses, acute respiratory disease, cardiac arrest, pneumonia, and hemodynamic recovery. Having ECMO in pediatric cardiac surgical practices is not only essential to ensure safe patient outcome, it is a standard of care required by various pediatric medical societies and organizations.

Perfusionists participate in ECMO cases with licensed Respiratory Therapists (RTs). The VA RT licensing law stipulates (18 VAC85-40-70) that RT practice includes functions shared with other health licensed professionals including specific techniques required to diagnosis and treat patients, and invasive and noninvasive cardiopulmonary monitoring. Technically, an unlicensed perfusionist providing ECMO care, or other cases, alongside an RT could be interpreted as the perfusionist performing licensed medical functions without a license to do so. Licensing would correct this situation.

4. To what can the harm be attributed? Elaborate as necessary.

- **lack of skills**
- **lack of knowledge**
- **lack of ethics**
- **lack of supervision**
- **practices inherent in the occupation**
- **characteristics of the client/patients being served**
- **characteristics of the practice setting**

Patient harm can be attributed to any of these factors, as evidenced in actual harms described in Question #2. The potential for such harm falls into two major categories. First, perfusionists frequently work with patients that have life threatening conditions such as coronary artery disease, previous heart attacks, heart failure, heart valve disease, respiratory dysfunction, kidney failure, peripheral artery disease, cardiac arrhythmias, diabetes, and cerebrovascular diseases including stroke. The manner in which Virginia perfusionists work with these patients requires an observable degree of independent judgment for which they are liable (the amount and cost of required liability insurance similar to that of an emergency department physician), and the use of devices that are of a potentially life threatening and of a dangerous nature (each component of the extracorporeal circuit requires FDA approval assigned to devices regarded as the most dangerous to the public). Perfusionists in Virginia are not licensed. The duties performed and the levels of responsibility applied are parallel with licensed perfusionists from other states, as well as with other licensed caregivers in Virginia. This is inclusive of licensed professions that administer medications, blood products, and anesthetic agents to persons, which perfusionists do via the extracorporeal circuit, i.e. heart-lung-blood machine.

5. Does a potential for fraud exist because of the inability of the public to make an informed choice in selecting a competent practitioner?

No. A person needing a cardiovascular surgical procedure or organ transplant does not directly select a perfusionist. However, the lack of adequate hospital "credentialing" to assure continued professional competency does exist in the state. As a completely unregulated profession, the only institutional mechanism available to assure professional competency with continued voluntary professional certification to protect the cardiac patient from unqualified perfusionists is the Joint Commission on

Accredited Health Organization (JCAHO) requirement that hospitals “credential” all health care workers and physicians.

Credentialing is done through a random hospital inspection process by the JCAHO. The process consists of no more than the completion of an application form. The administration of a hospital that provides open-heart surgical services has a profession, perfusionists, that comprise very few workers, whose medical scope of practice is not legally defined. In most cases the hospital administration does not have access to criteria on which to judge performance, education or training. Most often they have to rely on the perfusionists themselves to determine their own criteria for employment, certification and training. Clearly, the range of documented record control, and therefore assurance of public safety is broad. The certification and re-certification processes for perfusionists are voluntary, and may not be a “credentialing” requirement and/or not well documented by hospitals.

Open heart hospitals in Virginia must also comply with Medicare Hospital Conditions of Participation to remain eligible for Medicare payments for persons over the age of sixty-five. Inspectors periodically review hospital compliance with these standards, which include standards for other medical service providers - physicians, physician specialists, nurses, laboratory professions, etc. For perfusion service providers in the operating room, the profession is NOT included as an identifiable profession requiring a minimum standard. Therefore, there is no federal hospital staff hiring or retention standard applying to perfusionists.

6. Does a potential for fraud exist because of the inability for third party payers to determine competency?

No. A third party payer does not select nor pay a perfusionist for services. Perfusion services are typically provided ancillary to those provided or required by a physician in a variety of hospital settings. As such, perfusionists do not order or prescribe the delivery of their professional services.

Perfusion services are compensated through the payments received by hospitals, and by physician group practices from private insurance plans or managed care plans, or by Medicare insurance payments to hospitals or physician surgical group practices. This service payment structure has historically been in place since the 1970s.

Under the federal Medicare program, perfusionists are not recognized medical service providers. Under Medicare and State Medicaid laws in perfusionist-licensed States, perfusionists are prevented from seeking separate reimbursement for their professional services. Under the Medicare Hospital DRG Prospective Payment System (42 CFR Parts 410,411,412,413,414,416,419, 482, and 485), hospitals are paid a set fee for a set number of cardiovascular surgical DRG coded services. Hospital-based perfusionist services are included and compensated for as a component of the hospital services provided to patients. Private insurance and private managed care programs use this Medicare payment system on a national basis for hospitals. The hospital surgical DRG reimbursement revenue is used for hospital overhead/capital expenses, and to compensate independently contracted for perfusion service provider companies, or sole proprietorships.

Under the Medicare Physician Fee Schedule (42 CFR Part 405, 410, 411, 413, 414, and 426), cardiovascular surgeons not employed by a hospital, and their practice groups, receive a "global" fee for a set group of cardiovascular procedures. Each CPT procedure has a set Medicare payment amount, and is based on a physician's work (Work RVU) component and a "Practice Expense (PE)" component. Perfusionist services are included and compensated from the "Practice Expense" component when employed by a surgical group practice, or provided by a contract perfusion service company perfusionist to a surgical group practice.

7. Is the public seeking regulation or greater accountability of this group?

No, the profession is seeking regulation given the dynamic nature of the profession. Current regulated cardiac team members are the surgeon, anesthesia caregivers and nurses. Perfusionists are not regulated in Virginia. Medical, perfusion and legal literature cite numerous instances of patient harm or death due to inadequate or substandard perfusion care

Patients (and their families) about to undergo open-heart surgery, coronary angioplasty, coronary stenting, or any of a variety of general surgeries require and deserve protection. These patients do not question the expertise of members of the surgical team, assuming that all are suitably qualified to perform their respective jobs. Consumer groups would greatly benefit from regulation and increased professional accountability, and it would be capricious to suggest that there is a part of the public population that would be less affected. Anyone who is about to undergo surgery should have the guarantee of the best quality care. If this regulation is enacted, all consumers will enjoy equal benefit knowing that all members of the surgical team are qualified when performing their respective medical services.

Criterion Two: Specialized Skills and Training.

The practice of the health occupation requires specialized education and training, and the public needs to have benefits by assurance of initial and continuing occupational competence.

1. What are the educational or training requirements for entry into this occupation? Are these programs accredited? By whom?

Yes. In the current states that license perfusionists, certification from the American Board of Cardiovascular Perfusion (ABCP) is required. Applicants for the board examination must first graduate from an accredited perfusion educational program to be eligible.

Since the 1950's, perfusion equipment and the technology related to it have progressed dramatically. Today it is possible to perform operations that were seemingly inconceivable just several years ago. Some of these include the repair of congenital heart defects in infants, and the transplantation of hearts, heart-lungs, and livers. In addition, equipment is available today to provide support for failing hearts until such time as surgery becomes feasible.

The fields of science and medicine continue to make great strides. There is every indication that in the coming years perfusion equipment and perfusion science will also continue to rapidly expand. This will provide not only new challenges and opportunities to serve patients, but also provide newer responsibilities for the perfusionist who are an integral part of this technology.

From the 1950's to the early 1970's, perfusionists were trained on the job. Formal schools for training perfusionists started in the mid 1970's. Currently there are 16 perfusion education programs in the United States that are accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). Upon successful completion of clinical and didactic course work the graduate will have a minimum of a certificate of completion or a baccalaureate degree with several programs now offering a masters degree. Formal training, and successful completion, at one of the accredited programs is now required of all persons wishing to enter the profession.

In general, the prerequisite science courses needed for entrance into a perfusionist education program include, but are not limited to anatomy, physiology, math, statistics, chemistry, physics, and biology. The courses required for the completion of perfusion education typically include further study in the science courses with emphasis on the relationship to cardiovascular systems, perfusion techniques and devices, pharmacology, research methodology, cardiac pathology, bio-statistics, and a research project in perfusion. The clinical practicum portion of perfusion education involves exposure to the various aspects of the scope of practice of the profession including all age groups.

Some perfusion programs require candidates to already have backgrounds in medical technology, respiratory therapy, nursing, physician's assistants, or some prior history of health care experience. A bachelor's degree is required for all programs that are not bachelor degree granting programs. Programs are generally up to two years in length.

The Commission on Accreditation of Allied Health Education Programs (CAAHEP) (<http://www.caahep.org/>) accredits Perfusion programs based upon the recommendation of the Accreditation Committee – Perfusion Education (AC-PE), (<http://www.ac-pe.org/index.html>). The accreditation standards that are set are the minimum requirements of quality used in accrediting programs that prepare individuals to enter the perfusion profession. The accreditation standards therefore constitute the minimum requirements to which an accredited program is held accountable to their constituents. To view the standards set forth by the Commission on Accreditation of Allied Health Education Programs, you may go to the web site: (http://www.caahep.org/documents/ForProgramDirectors/PERF_SG_Standards.pdf)

The AC-PE approved cardiovascular perfusion curriculum document is designed to serve as an aid to perfusion program directors, providing guidance and suggestion on the scope of the content areas that may be included in any educational curriculum designed to adequately prepare students for entry into the clinical field of cardiovascular perfusion. Its development was based upon the curricula of active accredited programs, the *Knowledge Base for Cardiovascular Perfusion* document prepared by the American Board of Cardiovascular Perfusion, and the curriculum portion of the Standards and Guidelines of the Accreditation Committee – Perfusion Education (AC-PE) and the Commission on Accreditation of Allied Health Education Programs (CAAHEP). The outlines provided herein (<http://www.ac-pe.org/documents/pdf/AC-PECurriculum.pdf>) cover 11 key content areas. Each outline includes a unit objective, which identifies the core theme of the topic, and learner objectives, which define the expected quantifiable outcome following concentrated study of the subject area.

- **Are sample curricula available?**

Some of the subject matter in several units of the curriculum may be covered through prerequisite course requirements for admission into cardiovascular perfusion education programs.

UNIT 1. BASIC SCIENCE

Cardiovascular Anatomy

1. Mediastinum Cardiovascular Anatomy
2. Heart
3. Cardiac Arteries, Veins, and Microcirculation
4. Conduction System
5. Major Arteries, Veins and Branches
6. Developmental and Cardiac Embryology
7. Vascular Embryology
8. Pathology and Surgical Repair
9. Adult Cardiac Valvular Pathology and Surgical Repair
10. Adult Coronary Artery Pathology
11. Perfusion Techniques for Aortic, Thoracic, and Thoracoabdominal Aneurysms and Dissections
12. Congestive Heart Failure
13. Congenital Heart Defects: Left to Right Shunts
14. Congenital Heart Defects: Cyanotic Anomalies
15. Congenital Heart Defects: Obstructive Anomalies
16. Congenital Heart Defects: Miscellaneous Anomalies

Physiology

1. Cardiovascular Physiology
2. Cardiovascular Hemodynamics
3. Renal Physiology
4. Ventilation, Oxygenation, Respiration
5. Myocardial Physiology
6. Hematology
7. Coagulation Management

Pharmacology

1. Pharmacodynamics and Pharmacokinetics
2. Pharmacology of Anesthetic Agents
3. Anti-arrhythmic Pharmacology
4. Inotropic and Vasopressor
5. Pharmacology Vasodilators
6. Pharmacological Treatment of Congestive Heart Failure (CHF)
7. Antimicrobial Agents/Antibiotics
8. Anticoagulants

9. Serine-Protease Inhibitors
10. Heparin Induced Thrombocytopenia (HIT)
11. Antithrombin III Deficiency, Chemotherapeutic, Immunosuppressive and Diabetic

Physics

Chemistry

Mathematics

Immunology

1. Immunology of Blood Contact with Artificial Materials
2. Immunology of Reperfusion Injury

UNIT 2. CARDIOPULMONARY BYPASS

Extracorporeal Circuit Components for Cardiopulmonary Bypass

1. Perfusion Circuits
2. Tubing
3. Pumps
4. Extracorporeal Filters
5. Oxygenators
6. Heat Exchangers
7. Reservoirs
8. Hemoconcentrators/Ultrafilters

Cardiopulmonary Bypass Techniques

1. Conduct of Cardiopulmonary Bypass
2. CPB Cannulation and Monitoring

Adequacy of Perfusion

Myocardial Preservation

1. Cardioplegia Administration Techniques
2. Cardioplegia Solutions
 - Systemic Hypothermia
 - Blood Conservation Techniques
1. Standards for Perioperative Autologous Blood Collection and Administration
2. Hemodilution
3. Intraoperative Autotransfusion
4. High Volume Autologous Platelet Concentration
5. Low Volume Autologous Platelet Concentration Systems
6. Hemoconcentration
7. Pharmacological Interventions

Special Considerations in Perfusion

1. Malignant Hyperthermia
2. Perfusion of the Pregnant Patient
3. Sickle Cell and Other Blood Disorders

Catastrophe

Adjunct Techniques

1. Assisted Venous Drainage
2. Selective Cerebral Perfusion

Patient Monitoring

Organ Transplantation

1. Heart Transplantation: Donor Recipient Considerations
2. Lung and Heart-Lung Transplantation
3. Liver Transplantation – Perfusion Support

UNIT 3. MECHANICAL ASSIST

Extracorporeal Life Support Techniques

1. ECMO
2. CPS
3. Intra-Aortic Balloon Pumping (IABP)

Ventricular Assist Devices

UNIT 4. PRINCIPLES OF LABORATORY ANALYSIS

Overview - Laboratory Analysis

Laboratory Analysis – Special Chemistry

Laboratory Analysis – Blood Chemistry

Laboratory Analysis – Coagulation

UNIT 5. BIOMEDICAL ENGINEERING

Biomedical Instrumentation

Biophysical Transport Phenomenon

Biomedical Electrical Safety

Medical and Diagnostic Imaging Technology

UNIT 6. SAFETY

Blood/Fluid Exposure

Patient Safety

UNIT 7. CONTINUOUS QUALITY ASSURANCE

Continuous Quality Improvement for the Perfusionist

UNIT 8. ETHICS

Medical Ethics

UNIT 9. HISTORY

Historical Development of Extracorporeal Technology

UNIT 10. RESEARCH

Introduction to Research Methods

UNIT 11. BUSINESS PRACTICES

Business Practice Regulatory Agencies

- **Are there training programs in Virginia?** No (See Attachment)

2. If no programs exist in Virginia, what information is available on programs elsewhere which prepare practitioners for practice in the Commonwealth? What are the minimum competencies (knowledge, skills, and abilities) required for entry into the profession? How were they derived?

The perfusion education and training programs outside of Virginia are all accredited and have the same curricula as given above. (See Appendix)

3. Are there national, regional, and/or state examinations available to assess entry-level competency?

- **Who develops and administers the examination?**
- **What content domains are tested?**
- **Are the examinations psychometrically sound -- in keeping with The Standards for Educational and Psychological Testing?**

A perfusionist must graduate from an accredited perfusion-training program to be eligible to take the professional certification examinations of the American Board of Cardiovascular Perfusion (ABCP). The ABCP constructs and administers the examination twice a year. The ABCP is the only certification body for the profession. The examination is composed of eleven major sections of the knowledge base to perform the profession. These are as follows:

1. Anatomy and Physiology
2. Pharmacology
3. Pathology
4. Laboratory Analysis
5. Quality Assurance
6. Clinical Management
7. Special Patient Groups
8. Special Procedures / Special Techniques
9. Catastrophic Events and Device Failure
10. Monitoring

The certification examination is composed of two parts. Part I, the Perfusion Basic Science Examination, is a 220 item, multiple-choice examination designed to cover perfusion basic sciences and cardiopulmonary bypass. Part II, the Clinical Applications in Perfusion Examination (CAPE), is also consists of a multiple-choice format where a series of clinical scenarios are presented, each with a series of questions. The number of questions on the Part 2 examination may vary from 200 to 220, depending on the scenarios used. Both the Perfusion Basic Science Examination and the Clinical Applications in Perfusion Examination are given only twice a year, in the spring and in the fall.

PERFUSION BASIC SCIENCE EXAMINATION

Eligibility Criteria

The criteria for application to take the Perfusion Basic Science Examination are as follows:

1. The applicant must fulfill one of the following criteria:

- a. The applicant must have graduated from, or be currently enrolled in, an accredited cardiovascular perfusion education program, and anticipating graduation prior to the date of the examination; or
- b. The applicant must have been admitted to the examination process before April 15, 1981 or have been previously certified by the ABCP.

2. Applicants for the examination must have the following on file in the National Office at least four weeks prior to the examination.

- a. A current official transcript of credits from the accredited school of cardiovascular perfusion, indicating date of graduation.
- b. A written statement of satisfactory clinical competency from the Clinical Competency Committee of the school.
- c. Documentation of a minimum of seventy-five (75) clinical perfusions performed during the education program. Credit will be considered for perfusion experience only when the following criteria are met:
 - 1. The student participated in the preoperative planning and selection of equipment used during the procedure.
 - 2. The student performed those technical manipulations that constituted the essential parts of the procedure itself.
 - 3. An instructor must be physically present during Perfusion procedures and that instructor should be a Certified Clinical Perfusionist.

The number of times that the Perfusion Basic Science Examination can be taken is not limited.

CLINICAL APPLICATIONS IN PERFUSION EXAMINATION

Eligibility Criteria

The criteria for application to take the Clinical Applications in Perfusion Examination are as follows:

1. The applicant must fulfill one of the following criteria:
 - a. The applicant must have graduated from, or be currently enrolled in, an accredited cardiovascular perfusion education program, and anticipating graduation prior to the date of the examination; or
 - b. The applicant must have been admitted to the examination process before April 15, 1981, or have been previously certified by the ABCP
2. Applicants for the examination must have the following on file in the National Office at least four weeks prior to the examination:
 - a. Documentation showing all requirements for the Perfusion Basic Science Examination have been met; and
 - b. A clinical record itemizing fifty (50) independent clinical perfusions after graduation from the accredited school of perfusion.

The number of times that the Clinical Applications in Perfusion Examination can be taken is not limited.

Scoring for each part of the examination is criterion referenced, with the cutoff scores determined by the summation of the Ebel weightings of each item selected for inclusion on the examination. Item Response Theory modeling is used to equate the scores of various forms of each examination. A criterion-referenced test is one that provides for translating test scores into a statement about the behavior to be expected of a person with that score or their relationship to a specified subject matter. Item response theory models the relationship between latent traits and responses to test items. Among other

advantages, IRT provides a basis for obtaining an estimate of the location of a test-taker on a given latent trait as well as the standard error of measurement of that location.

4. Are there requirements and mechanisms for ensuring continuing competence? For example, are there mandatory education requirements, re-examination, peer review, practice audits, institutional review, practice simulations, or self-assessment models?

There are mandatory education and clinical activity reporting to maintain professional certification. (From below) There are self-assessment tests online from AmSECT? There are no re-examination, peer reviewed practice audits, but there may be institutional review.

5. Why does the public require state assurance of initial and continuing competence? What assurances do the public have already through private credentialing or certification or institutional standards, etc.?

None

6. Are there currently recognized or emerging specialties (or levels or classifications) within the occupational grouping? If so,

- **What are these specialties? How are they recognized? (by whom and through what mechanisms – e.g., specialty certification by a national academy, society or other organization)?**
- **What are the various levels of specialties in terms of the functions or services performed by each?**
- **How can the public differentiate among these levels or specialties for classification of practitioners?**
- **Is a “generic” regulatory program appropriate, or should classifications (specialties/levels) be regulated separately (e.g., basic licensure with specialty certification)?**

There are none, so a generic regulatory structure would be the most appropriate.

Criterion Three: The functions and responsibilities of the practitioner require independent judgment

1. What is the nature of the judgments and decisions which the practitioner must make in practice?

- **Is the practitioner responsible for making diagnoses? - NO**
- **Does the practitioner design or approve treatment plans? – NO**
- **Does the practitioner direct or supervise patient care? – NO**
- **Does the practitioner use dangerous equipment or substance in performing his functions? - YES**
- **If the practitioner is not responsible for diagnosis, treatment design or approval, or directing patient care, who is responsible for these functions? - SUPERVISING PHYSICIAN**

2. Which functions typically performed by this practitioner group are unsupervised, i.e., neither directly monitored or routinely checked?

All of them.

- **What proportion of the practitioner's time is spent in unsupervised activity?**

While a perfusionist works in consultation with a surgeon, and under the general supervision of a surgeon and an anesthesiologist when administering medications, blood, and anesthetic agents during a cardiovascular surgical procedure, the time spent in operating the heart-lung machine is unsupervised and unmonitored by either physician and is nearly 100 percent of the time in the operating room..

- **Who is legally accountable/liable for acts performed with no supervision?**

The accountable/liable party is the perfusionist. But, in legal case history, the cardiovascular/ cardiothoracic surgeons can be involved, the anesthesiologist can be involved, as well as the hospital. Among the members of the operating room team, other than a surgeon, there is no one else who can seriously injure or cause the death of a patient, faster than a perfusionist.

3. Which functions are performed only under supervision?

- **Is the supervision direct (i.e., the supervisor is on the premises and responsible) or general (i.e., supervisor is responsible but not necessarily on the premises)?**
- **Who provides the supervision? How frequently? Where? For what purpose?**
- **Who is legally accountable/liable for acts performed under supervision?**
- **Is the supervisor a member of a regulated profession (please elaborate)?**
- **What is contained in a typical supervisory or collaborative arrangement protocol?**

All of medical functions performed by a perfusionist are completed under the supervision of a cardiovascular or cardiothoracic surgeon, who is present in the operating room and immediately available. However, the performance of the functions in the operation of the heart lung machine during cardiopulmonary bypass are being taken many feet away from the physician view and monitoring. Changes in patient status and the actions of the perfusionist are communicated verbally. In advance of a cardiopulmonary bypass case and open-heart surgery, the perfusionist and the surgeon will discuss the various patient factors and hemodynamics of what is wanted by the surgeon. The Commonwealth licenses cardiovascular and cardiothoracic surgeons.

4. Does the practitioner of this occupation supervise others? Describe the nature of this supervision (as in #3 above).

Perfusionists do not directly supervise other regulated professions. Departmental perfusion managers or Perfusion Chiefs do supervise other staff perfusionists and in some cases perfusion students in training.

5. What is a typical work setting like, including supervisory arrangements and interaction of the practitioner with other regulated/unregulated occupations and professions?

Perfusionists interact with licensed nurses, licensed Physician Assistants, licensed Respiratory Therapists (outside of the operating room) and surgical specialty physicians. Perfusionists only work in the hospital, and mostly in the operating room.

As previously explained regarding ECMO cases outside of the operating room and with the newer generation of mechanical circulatory devices used in other in-hospital settings, perfusionists participate in ECMO cases with licensed Respiratory Therapists (RTs). The VA RT licensing law stipulates (18 VAC85-40-70) that RT practice includes functions shared with other health licensed professionals including specific techniques required to diagnosis and treat patients, and invasive and noninvasive cardiopulmonary monitoring. Technically, an unlicensed perfusionist managing an ECMO case, or other cases, alongside an RT could be interpreted as the perfusionist performing licensed medical functions without a license to do so.

6. Does this occupational group treat or serve a specific consumer/client/patient population?

Yes. Perfusionists frequently and routinely work with patients that have life threatening conditions such as coronary artery disease, previous heart attacks, heart failure, heart valve disease, respiratory failure, kidney failure, peripheral artery disease, cardiac arrhythmias, diabetes, and cerebrovascular disease including stroke. The patient populations served range from babies, to teenagers, young adults, and older adults.

7. Are clients/consumers/patients referred to this occupational group for care or services? If so, by whom? Describe a typical referral mechanism.

There are none.

8. Are clients/consumers/patients referred from this occupational group for care or services? If so, to what practitioners are such referrals made? Describe a typical referral mechanism. How and on what basis are decisions to refer made?

Perfusionists cannot refer patients.

Criterion Four: The scope of practice is distinguishable from other licensed, certified and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities

1. Which functions of this occupation are similar to those performed by other health occupational groups?

- Which group(s)?
- Are the other groups regulated by the state?
- If so, why might the applicant group be considered different?

It is well established nationally that perfusionists are the only allied health professionals providing cardiopulmonary bypass for cardiac and thoracic surgical procedures. These procedures encompass all age groups, including neonatal, pediatric, adult and geriatric patients presenting with either congenital or acquired cardiovascular disorders. The perfusionist is specifically qualified to manage all aspects of cardiopulmonary bypass.

There are other allied health professions, as well as physicians that perform – as part of their licensed scope of practice - similar, but related functions in association with perfusionists. Many different patient care services must be provided in different settings within an acute care facility, i.e. hospital. Typically each department caring for the patient supplies personnel whose scope of practice and/or job description requires the provision of specific aspects of care. The professional society for perfusionists, the American Society of Extracorporeal Technology (AmSECT) has adopted model state licensing legislation that includes a professional medical scope of practice for the clinical perfusionist. This model has been used as the basis for individual state licensing laws.

For example, extracorporeal circulation for long-term support of failing respiratory and/or cardiac function typically referred to as ECMO (Extracorporeal Membrane Oxygenation), is generally provided by a specialized team. Long term cardio-respiratory support often requires extended (days to weeks) extracorporeal circulatory and/or respiratory assistance. The specialized teams managing the bypass include perfusionists, nurses, medical residents, and respiratory therapists. Perfusionists performing neonatal extracorporeal membrane oxygenation (ECMO) are often the primary non-physician consultant, and as such serve both a clinical and coordinating function. The other care providers on the team often report to the perfusionist.

Perfusionists, as well as nurses, nurse anesthetists, respiratory therapists, medical technologists, and other allied health professionals may perform “point of care” testing, including anticoagulation and hemostasis monitoring, blood gas and blood chemistry monitoring, and physiological monitoring. The interdependent relationships between the perfusionist and other health professionals vary in structure and function depending on the particular service being provided. For example, perfusionists performing “point of care” testing in the operating room often do so under the auspices of the laboratory department. The perfusion services department typically formulates policy and procedure in concert with the laboratory department, making certain to be in compliance with federal Medicare laboratory related regulations.

In general, the relationship between perfusionists and other health professionals is dictated by clinical expertise and institutional protocol. Given the complexity of modern patient care, health professions must share certain areas of their scope of practice in order to provide services that are both seamless and efficient.

The credentialing of perfusionists in Virginia would not be expected to have an adverse affect on other healthcare professions. Licensure of perfusionists would in no way effect the scope of practice of other health care professions. Perfusionists do not seek to limit other licensed practitioners from the

performance of their duties. Perfusionist members of operating room teams are the only ones that are not currently licensed by the State.

2. Which functions of this occupation are distinct from other similar health occupational groups?

- Which group(s)?
- Are the other groups regulated by the state?

All perfusion functions, with exception for advanced cardiopulmonary support, are distinct of other perfusion related allied health professions that are regulated and licensed in the Commonwealth.

3. How will the regulation of this occupational group affect the scope of practice, marketability, and economic and social status of the other, similar groups (whether regulated or unregulated)?

None

Criterion Five: The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioner, and the cost of operation of regulatory boards and agencies.

Peer reviewed third party studies have shown that the future available supply of perfusionists in 12 of the currently licensed 17 states has not been materially impacted with licensing of the profession. To cover the state revenue cost of existing perfusionist boards, and in most states, advisory committees to existing licensing boards, the licensing fees range from a low of \$150 to a high of \$350 on a biannual basis. This state revenue is exclusive of funds raised for the initial application fee for a state license, and fee for a criminal background check in some of the currently licensed perfusionist states. State budget neutrality is import for Virginia taxpayers, as is public health safety.

1. What are the range and average incomes of members of this occupational group in the Commonwealth? In adjoining states? Nationally?

A 2005 national Perfusion Benefits & Salary Survey considered throughout the profession to be the most accurate, unbiased information regarding salaries and benefits is included (in part) to address this matter. Included in the survey is demographic information regarding employment structure and salary levels as of 2005 on a national basis, and for a comparative state licensure basis (Huckaby, Perfusion Benefits & Salary Survey, 2005).

Employer	Caseload Range	Average Caseload	Salary Range	Average Salary
Hospital	30-400 / year	123 cases / year	\$36,000 - \$225,000	\$101,142
Private Perfusion Group	28-500 / year	149 cases / year	\$45,000 - \$250,000	\$91,187
Surgeon Employed	69-325 / year	169 cases / year	\$50,000 - \$155,000	\$90,025
Self Employed	40-360 / year	144 cases / year	\$60,000 - \$366,000	\$138,933

2. What are the typical current fees for services provided by this group in the Commonwealth? In adjoining states? Nationally?

3. Is there any evidence that cost for services provided by this occupational group will increase if the group becomes state regulated? In other states, have there been any effects on fees/salaries attributable to state regulation?

The following is from this same survey and compares Virginia's perfusionist's salaries to those in the other currently licensed perfusionist States.

State	Mean Income	Income Range	Median	Standard Deviation
Arkansas	\$121,210	\$56,900 - \$250,000	\$100,000	\$58,308
Connecticut	NA	NA	NA	NA
Georgia	\$88,623	\$52,000 - \$130,000	\$85,750	\$19,899
Illinois	\$98,231	\$55,000 - \$145,000	\$94,000	\$21,472
Kansas	\$91,236	\$62,000 - \$155,000	\$88,500	\$22,799
Louisiana	\$100,326	\$60,000 - \$144,000	\$95,276	\$12,510
Massachusetts	\$106,821	\$60,000 - \$150,000	\$104,000	\$24,903
Missouri	\$97,077	\$61,000 - \$175,000	\$94,500	\$23,762
Nebraska	\$91,529	\$72,400 - \$118,000	\$85,750	\$14,989
New Jersey	\$102,679	\$60,000 - \$170,000	\$95,000	\$30,235
North Carolina	\$88,928	\$55,000 - \$134,000	\$82,500	\$20,188
Oklahoma	\$73,200	\$58,000 - \$85,000	\$75,000	\$11,584
Pennsylvania	NA	NA	NA	NA
Tennessee	\$99,676	\$55,000 - \$250,000	\$94,500	\$37,360
Texas	\$98,067	\$47,000 - \$300,000	\$87,000	\$38,912
Wisconsin	\$104,995	\$76,000 - \$135,000	\$107,000	\$13,252
Nevada	NA	NA	NA	NA

Licensure would have no demonstrative impact on the salaries and/or income levels of Virginia perfusionists. Based on AMA allied health professional salary survey data from perfusionist's salaries and income are comparable with the other 17 states that currently license perfusionists, and are consistent with American Medical Association (AMA) allied health professional salary survey data as of 2006, the starting salary for a perfusionist, on a national basis, was in the range of \$60,000-\$75,000 dollars. The overall average was between \$70,000-\$90,000, with the upper range being \$100,000 dollars per year for perfusion managers. The AMA's data is valid for perfusionists employed full time for 5 years or less. This data is available at: <http://www.ama-assn.org/ama/pub/category/6038.html>

This survey data shows that perfusionists are already highly compensated for their professional services, regardless of their employment status, or whether they are licensed by a state. Perfusionists in 11 of the currently licensed 17 states were licensed before the 2005 survey. Based more on anecdotal than practical data, the licensure of perfusionists in these 17 states has not impacted the supply of perfusionists.

4. Would state regulation of this occupation restrict other groups from providing care given by this group?

- **Are any of the other groups able to provide similar care at lower costs?**
- **How is it that this lower cost is possible?**

State licensing of perfusionists would restrict hospitals from hiring cross-trained caregivers, or previously non-professionally certified perfusionists, to perform similar care, but only at open heart hospitals in the state. Establishing and maintaining high standards of entry to practice for the profession is necessary to prevent another medical profession, credentialed or non-credentialed by the state from practicing the profession, based solely on educational and experiential standards. There are a few hospitals in the state that hire out-of-state contract perfusion service companies to provide similar care, presumably at lower costs to employing staff perfusionists. In these few cases, it is believed that the lower cost of service may be associated with the hospital not having to provide state unemployment insurance, not having to pay the federal FICA per independent contracted person, and not having to provide medical malpractice coverage per independent contracted employee providing perfusion services.

5. Are there current shortages/oversupplies of practitioners in Virginia? In the region? Nationally?

Based on recent available graduation rates from accredited perfusion training programs, ongoing reductions in Medicare and private insurance payments for the range of perfusion related cardiovascular procedures, the consolidation or closing of hospital open-heart programs, there has, over the past several years been a convergent reduction in hospital perfusion staffing-ratios, on a national basis. The best estimate from the national professional association for perfusionists, the American Society of Extracorporeal Technology, is that there is and will continue to be an oversupply of perfusionists on a national basis. In Virginia, based on VSPS information/data, this same market availability situation applies.

A 2005 national Perfusion Benefits & Salary Survey considered throughout the profession to be the most accurate, unbiased information regarding salaries and benefits shows the following breakdown of employment settings for perfusionists on a national level.

EMPLOYER (as a percentage /national figures):

Individual Facility (Hospital)	Private Perfusion Group
1998: 50%	1998: 35%
2001: 52%	2001: 32%
2003: 55%	2003: 30%
2005: 49%	2005: 32%
Physician Employed	Self Employed
1998: 13%	1998: not surveyed
2001: 12%	2001: 4%
2003: 12%	2003: 3%
2005: 9%	2005: 5%
Staff Perfusionist	Chief Perfusionist
1998: 63%	1998: 31%
2001: 66%	2001: 26%
2003: 64%	2003: 28%
2005: 63%	2005: 24%

Instructor

1998: 0.9%
2001: 0.5%
2003: 1%
2005: 1%

Contract Owner

1998: 9%
2001: 7%
2003: 7%
2005: 11%

6. Are third-party payers in Virginia currently reimbursing services of the occupational group? By whom? For what?

- **If not in Virginia, elsewhere in the country?**
- **Are similar services provided by another occupational group reimbursed by third-party payers in Virginia? Elsewhere? Elaborate.**

As previously stated, there are no third-party payers in Virginia directly reimbursing for the services of perfusionists. This is also the case on a national basis.

7. If third-party payment does not currently exist, will the occupation seek it subsequent to state regulation?

No. Virginia perfusionists are seeking licensure to ensure public safety and not as a means to improve professional compensation for their services. Perfusionists are employed by hospitals, contracted for services by a hospital, or employed by a surgeon or surgical group practice.

Payment for service is an implicit agreement between the provider of perfusion services and the hospital. The patient often times has some type of insurance coverage either privately funded commercial insurance or publicly funded coverage by Medicare, Medicaid, or worker's compensation. Insurance payments are made to the hospital, or to a surgical group, and not directly to a provider of perfusion services.

Licensure will have no demonstrative impact on the salaries and/or income levels of Virginia's perfusionists or on the cost of cardiovascular care delivered to residents by Virginia open-heart hospitals. Perfusionist's salaries in Virginia and income are comparable with the other 17 states that currently license perfusionists, and are consistent with American Medical Association (AMA) allied health professional salary survey data.

Criterion Six: There are no alternatives to State regulation of the occupation which adequately protect the public

1. What laws or regulations currently exist to govern:

• **Facilities in which practitioners practice or are employed?**

Virginia State laws and regulations for hospitals.

Hospitals in Virginia are also licensed providers. There are neither statutory requirements nor regulations that specifically govern the perfusion profession, nor hospital hiring practices in this regard.

Perfusionists are and maintain national professional certification through the American Board of Cardiovascular Perfusion (ABCP). This is a certification body and has no enforcement authority over the potentially bad and dangerous practice of the profession. Hospital credentialing policies do require professional certification to continue to work at Virginia hospitals.

As previously noted in Question #B 5, open heart hospitals in Virginia must comply with Medicare Hospital Conditions of Participation to remain eligible for Medicare payments for persons over the age of sixty-five. Inspectors periodically review hospital compliance with these standards, which include standards for other medical service providers - physicians, physician specialists, nurses, laboratory professions, etc. For perfusion service providers in the operating room, the profession is NOT included as an identifiable profession requiring a minimum standard. Therefore, there is no federal hospital staff hiring or retention standard applying to perfusionists.

• **Devices and substances used in the practice?**

Heart-Lung Bypass machine and their components. As previously stated, new generation of mechanical circulatory devices are being marketed to hospitals, and are devices which for patient safety should be operated by perfusionists. The devices and the underlying technologies used in open-heart surgery are always evolving. As the unlicensed professionals best qualified by education and training to be responsible for these devices, and the safety of patients, there are no current state standards to ensure that these best practices will be followed in the future. Licensing of perfusionists in the Commonwealth correct this existing "double standard" for patient protection and safety.

The various individual non-disposable components of the heart-lung machine include consoles to drive blood pumps; transducers for measuring intra-circuit pressures and blood flows; sensors for fluid level and air bubble detection; and monitors to display pressures, temperatures, blood oxygen saturation; display modules with timers are also included. The FDA classifies medical devices according to strict criteria (as follows from the FDA website.) Of note is that the FDA lists the components of a typical cardiopulmonary bypass circuit individually for purposes of risk classification, all of which are listed as class II.

General Controls include:

1. Establishment Registration by manufacturers, distributors, repackages and re-labelers,
2. Medical Device Listing with FDA of devices to be marketed,
3. Manufacturing the devices in accordance with Good Manufacturing Practices,
4. Labeling medical devices in accordance with 21 CFR 801 or 21 CFR 809,
5. Medical Device Reporting of adverse events as identified by the user, manufacturer and/or distributor of the medical device.

Pre-marketing controls are device and device classification specific. Pre-marketing controls for a medical device may include: clearance to market by 510(k) or approval to market by Pre-Market Approval (PMA).

Post marketing controls include Device Listing, Medical Device Reporting (MDR), Establishment Registration and Quality System Compliance Inspection.”
Device Classification

There are 3 FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device. As the classification level increases, the risk to the patient and FDA regulatory control increases. Accessories to medical devices, devices used with a medical device to support use of the device, are considered the same classification as the medical device.

The FDA classification of medical devices is based upon classifications for devices currently legally marketed in the United States. The FDA determines the device classification by the device intended use and risk the device presents to the patient. New medical devices are compared to legally marketed medical device classifications with the same intended use and technological characteristics to determine the device classification.

Class I medical devices have the least amount of regulatory control. Class I devices present minimal potential harm to the user. Class I devices are typically simple in design, manufacture and have a history of safe use. Examples of Class I devices include tongue depressors, arm slings, and hand-held surgical instruments. Most Class I devices are exempt from the premarket notification and may be exempt from compliance with the good manufacturing practices regulation.

Class II medical devices are devices where General Controls are not sufficient to assure safety and effectiveness and existing methods/standards/guidance documents are available to provide assurances of safety and effectiveness. In addition to compliance with General Controls, Class II devices are required to comply with Special Controls. Special Controls include:

- * Special labeling requirements,
- * Mandatory performance standards, both International and United States
- * Post market surveillance
- * FDA medical device specific guidance

Class II devices typically require pre-market notification by submission and FDA review of a 510(k) clearance to market submission. A few Class II devices are exempt from the premarket notification. Information on Class II exempt devices is located within the device regulation, 21 CFR 862 through 892. Examples of Class II devices include physiologic monitors, x-ray systems, gas analyzers, pumps, and surgical drapes.

- § 870.4200 - Cardiopulmonary bypass accessory equipment.
- § 870.4205 - Cardiopulmonary bypass bubble detector.
- § 870.4210 - Cardiopulmonary bypass vascular catheter, cannula, or tubing.
- § 870.4220 - Cardiopulmonary bypass heart-lung machine console.
- § 870.4230 - Cardiopulmonary bypass defoamer.
- § 870.4240 - Cardiopulmonary bypass heat exchanger.
- § 870.4250 - Cardiopulmonary bypass temperature controller.
- § 870.4260 - Cardiopulmonary bypass arterial line blood filter.
- § 870.4270 - Cardiopulmonary bypass cardiotomy suction line blood filter.
- § 870.4280 - Cardiopulmonary prebypass filter.
- § 870.4290 - Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.
- § 870.4300 - Cardiopulmonary bypass gas control unit.
- § 870.4310 - Cardiopulmonary bypass coronary pressure gauge.
- § 870.4320 - Cardiopulmonary bypass pulsatile flow generator.
- § 870.4330 - Cardiopulmonary bypass on-line blood gas monitor.
- § 870.4340 - Cardiopulmonary bypass level sensing monitor and/or control.
- § 870.4350 - Cardiopulmonary bypass oxygenator.

- § 870.4360 - Nonroller-type cardiopulmonary bypass blood pump.
- § 870.4370 - Roller-type cardiopulmonary bypass blood pump.
- § 870.4380 - Cardiopulmonary bypass pump speed control.
- § 870.4390 - Cardiopulmonary bypass pump tubing.
- § 870.4400 - Cardiopulmonary bypass blood reservoir.
- § 870.4410 - Cardiopulmonary bypass in-line blood gas sensor.
- § 870.4420 - Cardiopulmonary bypass cardiotomy return sucker.
- § 870.4430 - Cardiopulmonary bypass intracardiac suction control.

Class III medical devices have the most stringent regulatory controls. For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. Typically a Pre-Market Approval (PMA) submission to the FDA is required to allow marketing of a Class III medical device. A few Class III medical devices are required to only have a 510(k) cleared by the FDA to be marketed. Examples of Class III devices that require a PMA are: replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

Heart/lung bypass machines are usually equipped with 4-5 occlusive, positive displacement roller-head pumps (§ 870.4370 - Roller-type cardiopulmonary bypass blood pump) one of which is often used for cardioplegia delivery and the remainder functioning as controlled suction for the return of shed blood to the extracorporeal circuit. The roller-head pump when utilized with sterile tubing can act as a collection device and bring blood from the sterile field back to the extracorporeal circuit. If the tubing is inadvertently reversed in the roller-head air can be pumped directly into the patient's cardiovascular system. The air can cause injury to several vital organs and possibly death to the patient. The brain is particularly vulnerable to air entrainment. In order for the roller-head pump to act as a suction device, an occlusion must be set between the roller-head raceway and the sterile tubing. The occlusion must be enough to provide a negative pressure inside the tubing, but not too much as to cause damage to the blood components which would harm the patient.

An unocclusive centrifugal type pump (§ 870.4360 - Nonroller-type cardiopulmonary bypass blood pump) is commonly used as the "artificial heart" to propel blood through the heat exchanger (§ 870.4240 - Cardiopulmonary bypass heat exchanger), oxygenation/ventilation device (§ 870.4350 - Cardiopulmonary bypass oxygenator), filtration system (§ 870.4260 - Cardiopulmonary bypass arterial line blood filter) and ultimately returning it to the patient as arterialized blood. This type of blood pump is "load sensitive" and therefore must be closely monitored to assure appropriate forward flow at all times.

Safety Devices

FDA classification II

- § 870.4200 - Cardiopulmonary bypass accessory equipment
- § 870.4205 - Cardiopulmonary bypass bubble detector
- § 870.4340 - Cardiopulmonary bypass level sensing monitor and/or control
- § 870.4300 - Cardiopulmonary bypass gas control unit.
- § 870.4310 - Cardiopulmonary bypass coronary pressure gauge
- § 870.4330 - Cardiopulmonary bypass on-line blood gas monitor
- § 870.4410 - Cardiopulmonary bypass in-line blood gas sensor

Heart/lung bypass machines are equipped with safety devices including level sensors, air/bubble detectors, and line pressure monitors, but if the perfusionist does not utilize them correctly the potential for harm to the patient greatly increases.

Blood/Blood Handling

The perfusionist for the benefit of the patient utilizes blood and blood products whenever the situation arises during a procedure. The perfusionist is frequently involved in the decision to transfuse blood to a patient during CPB procedures. The decision is always with the approval of a physician. The perfusionist does have the responsibility of making sure that the blood has been typed and crossed matched to the particular patient prior to administration through the CPB circuit. There have been mistakes in the administration of incompatible blood types, which have caused many catastrophic outcomes for patients including but not limited to renal failure, embolic episodes, and death.

Autotransfusion Procedures (Cell Saver)

FDA classification II - § 868.5830 - Autotransfusion apparatus

An autotransfusion device (Cell Saver) is mechanical device that can be utilized to salvage blood shed during or after a surgical procedure. The shed blood is collected in a sterile reservoir, processed and concentrated by the Cell Saver, and then washed and returned to the patient. The perfusionist must be vigilant to monitor that no clotting agents (Avitene, HeliTene, Oxycel, Gelfoam Powder, and Instat MCH) or irrigating solutions (alcohol, antibiotics, betadine, chloropactin, hydrogen peroxide, and hypotonic solution) are collected with the patient's blood which would cause red cell destruction. There is also potential for bacteremia if any bowel contents, urine, mucous membrane secretions, or infection at the site of aspiration is collected with the blood. All of which could potentially be very harmful to the patient if the blood was processed and returned to the patient.

Heater Cooler Unit - FDA classification II

§ 870.4250 - Cardiopulmonary bypass temperature controller

The perfusionist is responsible for controlling the cooling and warming of the patient's blood and therefore, the patient's body. This is accomplished by using a device called a heater cooler unit and a heat exchanger. The perfusionist controls and monitors the temperature of the water bath in the heater cooler unit. This water is circulated to the heat exchanger, which is a series of metal tubes that allows the water to circulate on one side while the patient's blood circulates on the other side. If the temperature gradient between the water and the blood becomes too great, while attempting to warm the patient, air bubbles may begin to appear in the patient's blood, leading to possible organ damage from air embolism.

Another dire consequence can occur if there is a leak in the metal tubing of the heat exchanger which would result in water to blood leak. The patient's red blood cells would suffer irreversible damage from this event, significant bacterial contamination of the bloodstream would also occur. It is the responsibility of the perfusionist to check the integrity of the heat exchanger prior to patient use.

- **Standards or practice?**

There are no current laws or regulations in Virginia governing the practice of perfusion. The purpose of licensing the profession is to establish a method of regulation by which the state grants permission to persons who meet predetermined qualifications to engage in an occupation or profession. There are voluntary Standards of Practice that have been developed by the profession's national association, the American Society of Extracorporeal Technology (AmSECT) to guide the clinical practice of the profession. These are not written into law in Virginia and are therefore only voluntary in day-to-day clinical practice of the perfusion profession.

AmSECT Guidelines for Perfusion Practice

ESSENTIAL I

An accurate perfusion record must be maintained according to an established protocol.

PRACTICE GUIDELINES

The perfusion record should include the following patient information:

1. Hospital ID
2. Age
3. Gender
4. Height
5. Weight
6. Body Surface Area (BSA)
7. Allergies
8. Blood Type
9. Pre-op Laboratory Data
10. Diagnosis/History
1. Additional procedure information should include:
 1. Date
 2. Procedure
 3. Perfusionist(s)
 4. Surgeon(s)
 5. Anesthesia Personnel
 6. Comments/Events
2. The following disposable supply lot numbers should be recorded:
 1. Oxygenator
 2. Cardiotomy reservoir
 3. Tubing pack/Arterial filter
 4. Cardioplegia set
 5. Ultrafiltration set
 6. Cell washing set
 7. Centrifugal pumphead and flow probe
3. The following patient parameters should be documented at a frequency determined by institutional perfusion protocol:
 1. Blood flow rates
 2. Arterial blood pressure
 3. Central venous/Pulmonary artery pressure
 4. Arterial/Venous Blood Gases
 5. Venous oxygen saturation
 6. Potassium concentration
 7. Ionized calcium concentration
 8. Sodium concentration
 9. Activated Clotting Times (ACT) and/or Heparin/Protamine assay results
 10. At least one of the following patient temperatures which may include:
 - * Bladder
 - * Esophageal
 - * Rectal
 - * Nasopharyngeal
 - * Tympanic
11. Additional temperatures may include:
 - * Venous blood
 - * Arterial blood
 - * Cardioplegic solution
 - * Myocardium
 - * Water bath(s)
12. Oxygenator gases including flow rate and concentration
13. Input fluid volumes including:
 - * Prime
 - * Blood products
 - * Asanguineous fluids
 - * Cardioplegic solution
 - * Autologous components
14. Output fluid volumes including:

- * Urine output
- * Ultrafiltrate

15. Medications and/or inhalational anesthetic agents administered via extracorporeal circuit

4. The perfusion record should be signed by the primary perfusionist and retained as part of the patient's medical record. Additional copies of the perfusion record may be retained in the perfusion department and/or patient database.

5. Patient parameters that are monitored / measured during the conduct of cardiopulmonary bypass should be documented.

ESSENTIAL II

The perfusionist shall employ a checklist(s) according to an established protocol.

PRACTICE GUIDELINES

1. The perfusion checklist(s) employed by the perfusionist during CPB should include a pre-bypass checklist.
2. Checklist(s) should be retained.

ESSENTIAL III

Extracorporeal circulation shall be conducted by a knowledgeable and competent perfusionist.

PRACTICE GUIDELINES

1. Extracorporeal circulation should be conducted by a certified or board eligible perfusionist. Certification by the American Board of Cardiovascular Perfusion or its equivalent meets this requirement.
2. A perfusionist should conduct cardiopulmonary bypass with perfusion assistance available.
3. For emergency situations, a perfusionist should be available within 30 minutes of the hospital.
4. Perfusion department/services should maintain a policy and procedures manual which includes:
 1. Routine and emergency procedures
 2. Departmental policies
 3. Continuing education policies
 4. Catastrophic perfusion event management
5. Policy and procedures should be reviewed and revised on a periodic basis.

ESSENTIAL IV

The perfusionist shall monitor the anti-coagulation status of the patient according to an established protocol.

PRACTICE GUIDELINES

1. Monitoring of the anticoagulation status of the patient intraoperatively should include the testing of activated clotting time (ACT). Other monitoring tests may include:
 1. Platelet count
 2. Heparin/Protamine assay
 3. Prothrombin Time (PT)
 4. Partial Thromboplastin Time (PTT)
 5. Thrombelastogram
2. Patient specific initial Heparin dose should be determined by one of the following methods:
 1. Weight
 2. Dose Response Curve, automated or manual
 3. Blood Volume
 4. Body Surface Area
3. Additional doses of Heparin during cardiopulmonary bypass should be determined by using an ACT and/or Heparin/Protamine assay.

4. The perfusionist may determine the Protamine dose.

ESSENTIAL V

Appropriate gas exchange shall be maintained during extracorporeal circulation according to an established protocol.

PRACTICE GUIDELINES

1. Appropriate oxygenator gas flow rate and concentration should be determined by using blood gas analysis which may include monitoring devices. Further determinations may be guided by oxygenator directions for use and perfusion parameters such as blood flow rate and temperature.
2. Blood gas analysis should be performed and recorded a minimum of every 30 minutes. Blood gas analysis may be performed at reasonable intervals as clinical conditions dictate.

ESSENTIAL VI

The perfusionist shall maintain an appropriate blood flow rate during extracorporeal circulation according to an established protocol.

PRACTICE GUIDELINES

1. Calculated blood flow rate should be determined prior to cardiopulmonary bypass using the patient's body surface area (BSA).
2. Appropriate blood flow rate should be determined by evaluation of a combination of:
 1. Venous oxygen saturation
 2. Body surface area
 3. Arterial blood pressure
 4. Temperature
3. Additional parameters that may guide blood flow rate include:
 1. Base excess
 2. Oxygen consumption
 3. Venous pO₂
 4. Arterial pO₂
 5. Circuit volume
 6. Physician request
 7. Body weight
 8. Anesthetic level
 9. Arterial oxygen saturation

ESSENTIAL VII

The perfusionist shall maintain an appropriate blood pressure during extracorporeal circulation according to an established protocol.

PRACTICE GUIDELINES

1. Arterial blood pressure should be monitored and recorded.
2. Maintenance of arterial blood pressure may be influenced by factors other than the conduct of cardiopulmonary bypass.

ESSENTIAL VIII

During extracorporeal circulation, the perfusionist must maintain a safe operational volume in the extracorporeal circuit according to an established protocol.

PRACTICE GUIDELINES

1. The perfusionist should pre-determine a safe operational level for each perfusion circuit used.
2. A method of safe level detection should be employed. Appropriate blood volume should be maintained to allow for sufficient reaction time in the event of a decrease or loss of circulating volume.

ESSENTIAL IX

Appropriate safety devices shall be employed.

PRACTICE GUIDELINES

1. The following devices should be employed during cardiopulmonary bypass:
 1. Arterial line filter in with a one-way valved purge line
 2. Bubble detector
 3. Level sensor
 4. Anesthetic gas scavenge line

2. Additional safety devices or techniques may include:
 1. One-way valve in the intracardiac vent/sump line
 2. Bubble trap
 3. Ventilating gas oxygen analyzer
 4. A method of preventing retrograde flow when using a centrifugal pump

ESSENTIAL X

Appropriate monitoring devices shall be employed.

PRACTICE GUIDELINES

1. These should include the following patient/circuit devices:
 1. Blood flow indicator
 2. Gas flow meter
 3. Physiologic monitor(s)
 4. Hematologic monitor(s)
 5. Temperature monitors
 6. Timers
2. These may also include:
 1. Blood gas analyzer
 2. Oxygen saturation monitor(s)
 3. Chemistry monitor(s)

ESSENTIAL XI

The perfusionist shall make a responsible effort at cost containment.

PRACTICE GUIDELINES

The perfusionist should actively participate in cost containment processes as they relate to the delivery of patient care. These activities may include a conscious effort at balancing user preference with patient care issues and cost containment in the selection of perfusion supplies and capital equipment. The perfusionist should be involved in quality management.

ESSENTIAL XII

The perfusionist must assure that properly maintained equipment is used in the conduct of extracorporeal circulation.

PRACTICE GUIDELINES

1. The perfusionist should check for the function of all pumps prior to each case. Roller pump occlusions should be verified and adjusted as necessary prior to each case. Blood flow sensor(s) should be checked for proper installation and calibration.
2. Preventive maintenance on perfusion equipment should be performed on a regularly scheduled basis. The interval of such maintenance may be determined any or all of the following:

1. Manufacturer recommendations
2. External accrediting agency guidelines
3. Institutional requirements

2. Does the institution or organization where the practitioners practice set and enforce standards of care? How?

For the most part, open-heart hospitals in Virginia have a hiring requirement that a perfusionist be certified by the American Board of Cardiovascular Perfusion (ABCP). Perfusionists maintain their voluntary professional certification through a two stage process. However, the lack of uniform hospital “credentialing” to assure continued professional competency does exist across the state. As a completely unregulated profession, the only institutional mechanism available to assure professional competency with continued voluntary professional certification to protect the cardiac patient from unqualified perfusionists is the Joint Commission on Accredited Health Organization (JCAHO) requirement that hospitals “credential” all health care workers and physicians.

Ongoing hospital credentialing is performed through a random hospital inspection process by the JCAHO. The process consists of no more than the completion of an application form. The administration of a hospital that provides open-heart surgical services has a profession, perfusionists, that comprises very few workers, whose medical scope of practice is not legally defined. In most cases the hospital administration does not have access to criteria on which to judge performance, education or training. Most often they have to rely on the perfusionists themselves to determine their own criteria for employment, certification and training. Clearly, the range of documented record control, and therefore assurance of public safety is broad. The certification and re-certification processes for perfusionists are voluntary, and may not be a “credentialing” requirement and/or not well documented by hospitals.

It is not known whether or how actively Virginia hospitals set or enforce these professional qualifications as a component of their institutional standards of care.

3. Does the occupational group participate in a nongovernmental credentialing program, either through a national certifying agency or professional association (e.g., National Organization for Competency Assurance)?

- **How are the standards set and enforced in the program?**
- **What is the extent of participation of practitioners in the program?**

Yes. Nationally, all perfusionists after passing the initial certification examination of the American Board of Cardiovascular Perfusion (ABCP), can maintain certification by recertifying annually, by filing a Clinical Activity Report. A perfusionist can be granted “Provisional Certification” for an additional year if not having performed 40 perfusion cases of various types in a one-year period, or 80 over a two-year period, and filing of a clinical activity report. A professional activity report is required to renew certification every three years, consisting of documentation showing attendance of at least 45 hours of Continuing Medical Education.

The ABCP recertification process includes the category of “Provisional Certification”. Certified clinical perfusionists who are unable to fulfill recertification requirements within the required three-year cycle may request a one-year extension of the filing deadlines. An extension will not be granted to an individual more than once during a three-year period or to an individual on probation.

The certification and recertification standards are determined by the ABCP. The clinical activity report for recertification consists of a document showing the dates and types of the 40-perfusion cases done, and their location(s). The report does not contain any reporting on the patient medical outcome of the 40 cases. Therefore, a perfusionist can perform cases, but does not have any direct peer evaluation of the competency of the service delivered to patients. There are random audits on case numbers and location

are done by the certifying body. Having filed the required reports on time, and paying a recertification fee, the voluntary certification title of CCP is automatically renewed.

The enforcement mechanism for a perfusionist that does not meet these recertification requirements is loss of the CCP designation, but no certifying body institutional/ hospital/employer reporting on loss of CCP status is performed.

Enforcement

Certification is enough to satisfy what is often considered to be the highest form of recognition within any profession, i.e. the voluntary participation in a process by which a non-governmental agency grants recognition to an individual. However, ABCP certification is voluntary and confers no legal standing in state matters. The ABCP mission statement reads

“...The American Board of Cardiovascular Perfusion will strive to develop and maintain quality standards in cardiovascular perfusion that promote safety and protection of the public. These standards will include the attainment and enhancement of knowledge, skills, and ethical professional conduct of certified clinical perfusionists by supporting pre-service and in-service education. This support will emanate from the design, implementation, and administration of the credentialing process. Additionally, this support will include stimulation of innovative educational activities and promotion of ethical professional development.”

Note the intentional use of the terms “...will strive...” and “...that promote...” The ABCP mission and priority is one of ensuring standards of knowledge and education - NOT public safety and welfare. The ABCP may deny, revoke, suspend or otherwise act upon certification or recertification where an individual is not in compliance with ABCP rules, regulations or standards.

A great and noble statement, but ABCP certification is voluntary, as is its recognition by perfusionists and employers. The American Board of Cardiovascular Perfusion will only “deny, revoke, suspend or otherwise act upon” what is considered to be an ethics violation, not a breach of a professional practice standard.

The American Board of Cardiovascular Perfusion is the sole judge of whether or not the information to require or permit revocation of any issued certificate. A perfusionist in danger of losing certification may make a formal written appeal to the ABCP.

As a general rule, for the medical, nursing and other allied health professions mandatory state credentialing precedes “board certification”. However, “board certification” provides no formal statutory recognition at the state level. Certification does NOT provide a legal process to address performance of perfusion by other licensed or unlicensed medical professionals.

Think of surgeons and anesthesia care providers. The attainment of “board certification” is a lofty and honorable voluntary achievement, but being licensed in the state is mandatory. Certification and state credentialing serve distinct and often separate purposes. They may be mutually exclusive or be symbiotic in form and function. They are not interchangeable, as one does not suffice for the other. Perfusion has now evolved as a profession to a point where governmental regulation is the next step both to protect the patient from unqualified practitioners, and to recognize the unique and high level of medical judgment and skill required in critical medicine.

4. Does a Code of Ethics exist for this profession?

- **What is it?**
- **Who established the Code**

- **How is it enforced?**
- **Is adherence mandatory?**

The American Society of Extra-Corporeal Technology (AmSECT), the American Academy of Cardiovascular Perfusion (AACCP) and the American Board of Cardiovascular Perfusion (ABCP) publish codes of ethics for perfusionists. (See Attached)

Enforcement/Adherence

There are no enforcement mechanisms for violation of, or adherence to any of these three organizational Codes of Ethics. Adherence is voluntary, not mandatory.

While these are useful as a construct and guidepost, membership in any of these groups is voluntary and censure from any of them is very unlikely to affect one's ability to practice. To protect against litigation, the very few instances of action against a perfusionist for unethical conduct by any of these organizations remain closely guarded secrets within the respective ethics committees. This certainly does little harm to the person charged and does not affect a perfusionist's ability to continue to deliver perfusion services. In any case, these associations have no means of statutory enforcement, since membership is voluntary. Their educational efforts serve to unify community care standards to a degree, but this does nothing to assure the public that the local perfusionist applies the recommended safeguards and techniques. There is also nothing to stop a perfusionist who has been released from employment due to continual mishaps to go elsewhere in the state to apply for employment. Due to the confidential information surrounding the dismissal of a perfusionist, one employer may not be permitted to divulge pertinent information regarding work performance or professional ethics. The extent of risks incurred in this area is not well understood. Adequate voluntary standards exist; however, the lack of statutory protection produces failure in the meaningful enforcement of these standards.

For example, the ABCP code of ethics states... "The ABCP may deny, revoke, suspend or otherwise act upon certification or recertification where an individual is not in compliance with ABCP rules, regulations or standards.

"II. The individual who willfully fails to promote the safety and welfare of the public, whether through negligent acts, acts of omission or through misrepresentation shall be considered to be not in compliance with these ethical standards."

The American Board of Cardiovascular Perfusion will only "deny, revoke, suspend or otherwise act upon" what is considered to be an ethics violation, not a breach of a professional practice standard. The ABCP is the sole judge of whether or not the information to require or permit revocation of any issued certificate. A perfusionist in danger of losing certification may make a formal written appeal to the ABCP and be granted a "Provisional" certification.

5. Does any peer group evaluation mechanism exist in Virginia or elsewhere? Elaborate.

There is no group evaluation mechanism specific to Virginia, since perfusionists are not regulated. Peer group evaluation does take place in the 16 licensed States for the profession.

6. How is a practitioner disciplined and for what causes? Violation of standards of care? Unprofessional conduct? Other causes?

There are no non-state sponsored mechanisms to discipline a perfusionist for a violation of professional standards of practice or professional code of ethics, i.e. unprofessional conduct. The only mechanisms that currently exist are in the other perfusionist-licensed states. The certification body, the American Board of Cardiovascular Perfusion, has no legal authority to discipline a perfusionist for any violation of

standards of care or unprofessional conduct. The ABCP can withdraw certification for not successfully meeting the requirements for reinstatement following a one year probationary period, for falsification of any portion of a recertification application, or for unethical conduct as described in the ethical standards of the American Board of Cardiovascular Perfusion. Revocation is not a required event to any other outside body. A perfusionist in danger of losing certification may make a formal written appeal.

7. Are there specific legal offenses which, upon conviction, preclude a practitioner from practice?

No, neither in Virginia, or nationally, except in the 16 States in which perfusionists are currently licensed.

8. Does any other means exist within the occupational group to protect the consumer from negligence or incompetence (e.g., malpractice insurance, review boards that handle complaints)? How are challenges to a practitioner's competency handled?

Perfusionists are generally covered by individual hospital-wide medical malpractice insurance, which helps protect patients against negligence or the incompetent practice of perfusion. It can be assumed that some open-heart hospitals have institutional review boards. There is no information on how challenges to a practitioner's competency is handled, other than a hospital firing a perfusionist. There are, of course, administrative review and legal processes to challenge a perfusionist's professional competency in the 16 states that currently license perfusionists.

9. What is the most appropriate level of regulation?

The Virginia Perfusion Society strongly believes that the appropriate level of regulation is licensure. Licensure is best for the citizens of our state, and is best for maintaining high standards of entry to practice the profession of perfusion in the state. State certification does not prevent any person who is otherwise credentialed by the state in another medical profession, from practicing the profession, based solely on educational and experiential standards. State registration is also too low of a consumer protection regulatory standard.

ACCREDITED SCHOOLS OF CARDIOVASCULAR PERFUSION – 2010

Midwestern University
Cardiovascular Science Program
19555 North 59th Avenue
Glendale, AZ 85308
888-247-9277
www.midwestern.edu/az-cardio/

University of Arizona
Circulatory Sciences Graduate Program
Cardiothoracic Surgery Services
P.O. Box 245071
Tucson, AZ 85724
520-626-6339
www.perfusion.arizona.edu/

Quinnipiac University
Cardiovascular Perfusion Program
P.O. Box 171
275 Mt. Carmel Avenue
Hamden, CT 06518
203-582-3427
www.quinnipiac.edu/x810.xml

Barry University
Cardiovascular Perfusion Program
11300 Northeast Second Avenue
Miami Shores, FL 33161-6695
800-756-6000 Ext 3214 or 305-899-3214
www.barry.edu/snhs/BSprograms/cardioPerfusion/

Rush University College of Health Science
Perfusion Technology Program
600 South Paulina, Suite 1021D
Chicago, IL 60612
312 942-2305
www.rushu.rush.edu/perfusion/

University of Iowa Health Care
Perfusion Technology Program
Cardiothoracic Surgery
200 Hawkins Drive, SE545GH
Iowa City, IA 52242-1062
319-356-8496
www.healthcare.uiowa.edu/programs/perfusion

University of Nebraska Medical Center
Clinical Perfusion Education
985155 Nebraska Medical Center
Omaha, NE 68198-5155
402-599-7227
www.unmc.edu/dept/alliedhealth/cpe

Cooper University Hospital/UMC
School of Cardiovascular Perfusion
One Cooper Plaza, 310 Sarah Cooper
Camden, NJ 08103
856 342-3277
www.cooperhealth.org/content/education_

North Shore University Hospital
School of Cardiovascular Perfusion
225 Community Drive, South Entrance
Great Neck, NY 11021
516-466-0215
www.cwpost.liunet.edu/cwis/cwp/hscience/medbio/cardio.html

SUNY Upstate Medical University
Department of Cardiovascular Perfusion
750 East Adams Street
Syracuse, NY 13210
315-464-6933/6932
<http://perfusion.upstate.edu>

Cleveland Clinic Foundation
Cleveland School of Perfusion Science
9500 Euclid Avenue, G33
Cleveland, OH 44195-5001
216-444-3895
ballc@ccf.org
or farrowr@ccf.org

University of Pittsburgh Medical Center (UMPC)
Shadyside School of Cardiovascular Perfusion
5230 Centre Avenue
Pittsburgh, PA 15232
412-623-2482
www.upmc.edu/shadyside/ResearchEd/SchoolCardioPerf.htm

Medical University of South Carolina
Extracorporeal Technology Program
P.O. Box 250964
151B Rutledge Avenue
Charleston, SC 29425
843-792-1795
www.musc.edu/cp/

Vanderbilt University Medical Center
1215 21st Avenue South
MCE 5th Floor, South Tower
Nashville, TN 37232-8802
615-322-6575
www.mc.vanderbilt.edu/cvpt

Texas Heart Institute
School of Perfusion Technology
P.O. Box 20345, MC-1-224
Houston, TX 77225
832-355-4026
www.texasheart.org/perfusion

Milwaukee School of Engineering
Cardiovascular Perfusion Program
1025 North Broadway
Milwaukee, WI 53202-3109
800-332-6763 or 414-277-7561
www.msoe.edu/grad/msp/

Walter Reed Army Medical Center
Cardiothoracic Perfusion Training Program
Building 2, Room 4C05
6900 Georgia Avenue NW
Washington, DC 20307-5001
202-782-3607
Active Duty PAs Only
www.wramc.aedd.army.mil

**PERFUSIONIST STATE PRACTICE ACTS 2011
LICENSING**

State	Statute Citation	Enacted Public Law	Year Enacted /Amended
Arkansas	Title 17, Subtitle 3, Chap 104	SB 499, PL 888	1999
Connecticut	Title 20, 381b Sec. 20-162	HB 5684	2005
Georgia	Chap 34 Title 43-34-170	HB 69	2002
Illinois	225 ILCS 125; 20 ILCS 2105/2105-15(7)	P.A. 91-580	2000
Louisiana	L.R.S. Ch 15, Title 37:1331 - 1344	SB 315, PL 811	2003
Maryland	Section 14-5E-01-26-5E-25	HB 287	2011
Massachusetts	Ch 112 MARS Sec 212-219	SB 2081	2000
Missouri	RSMO Ch 324 324.001-1148	SB 141, HB 567	1997 2001
Nebraska	Title 19, R.S.Supp. 38-2701- 2712	LB 236	2007
New Jersey	N.J.S.A. 45:9-37.94	AB 2114	1999
Nevada	Chap 630 NRS Sec. 3, Sec. 4-14	SB 269,	2009
North Carolina	NCGS-Chap 90 Art 40 § 90-682	SB 1059	2005
Oklahoma	59 OS SEC 2051-2071; OAC 527:1-1-1.	SB 788	1996 2002
Pennsylvania	63 P.S. § 422.1 et seq. 49 PA. CODE, Chap 16, 17, 18. and 63 P.S. §§ 271.1 - 271.18. 49 PA. CODE §§ 25.1-25.607	HB 500, 501	2008
Tennessee	Title 63 Chap 28 Sec 101-118	SB 310	1999
Texas	TX Occ Code, Chapter 603	Acts 1993, 73, Leg. Chap 545	1994 1999 2005
Wisconsin	Chap (1) (d): 448.03 (1)(c), 448.04 (1)(d)	PL 89	2002

TITLING LAWS

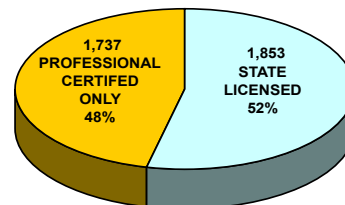
State	Statute Citation	Enacted Public Law	Year Enacted
California	Business & Professions Code Chapter 5.67	AB 566	1992

Figures ~ Comparison based on ABCP numbers, which is State residence, not State in which perfusionists are licensed.

Example ~ Missouri has 88 certified perfusionists, but has 125 currently licensed perfusionists.

Figures subject to change as more States become Licensed.

STATE REGULATION OF PERFUSIONISTS 2010



Perfusionist Licensing Committees

Arkansas

<http://www.arkansas.gov/directory/detail2.cgi?ID=1626>

Connecticut

http://www.ct.gov/dph/cwp/view.asp?a=3121&q=431044&dphNav_GID=1821

Georgia

<http://medicalboard.georgia.gov/portal/site/GCMB/menuitem.2f54fa407984c51e93f35eead03036a0/?vgnextoid=80131ec599906210VgnVCM100000bf01020aRCRD>

Illinois

<http://www.idfpr.com/dpr/WHO/pfusion.asp>

Louisiana

<http://www.lsbme.louisiana.gov/>

Massachusetts

<http://www.mass.gov/?pageID=eohhs2subtopic&L=6&L0=Home&L1=Government&L2=Departments+and+Divisions&L3=Department+of+Public+Health&L4=Programs+and+Services+A++J&L5=Division+of+Health+Professions+Licensure&sid=Eeohhs2>

Missouri

<http://pr.mo.gov/perfusionist-commission-members.asp>

Nebraska

<http://www.dhhs.ne.gov/crl/medical/Perf/perfPg2.htm>

New Jersey

<http://www.njconsumeraffairs.gov/perf/>

Nevada

<http://www.medboard.nv.gov>
Statute Link <http://www.leg.state.nv.us/NRS/NRS-630.html>

North Carolina

http://www.ncmedboard.org/licensing/license_application/category/perfusionists/

Oklahoma

http://www.okmedicalboard.org/display.php?content=lp_index:lp_index&group=lp&rmenu=1

Pennsylvania

http://www.dos.state.pa.us/portal/server.pt/community/state_board_of_osteopathic_medicine/12517

Tennessee

<http://health.state.tn.us/Boards/CP/>

Texas

<http://www.dshs.state.tx.us/perfusionist/default.shtm>

Wisconsin

<http://online.drl.wi.gov/boards/BoardMembers.aspx?aid=40>