# Chapter 3

**Key Policies and Procedures**

## 3.0 KEY POLICIES AND PROCEDURES

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15 Chapter 3 was last reviewed and updated in February 2015.

16 Section 3.3 was drafted by Jeffrey Feldman, M.D., and represents the consensus of the Anesthesia Patient Safety Foundation Consensus Conference on this topic, held in September 2013.
3.0 KEY POLICIES AND PROCEDURES

Every Department of Anesthesiology should maintain a file of currently approved policies and procedures, ideally as an online resource on the department’s web page. Many of the included policies will be “inherited” from higher levels of the organization, including the healthcare system, the medical school or the central administration of the practice. Other policies will be unique to the department. Recommended practices for management of the Policy and Procedure Manual include the following:

- The Manual should be reviewed and updated on a scheduled basis, ideally at least once each year.
- The Manual should be organized in a consistent fashion and should include a Table of Contents and an index to facilitate its use as a reference by members of the department.
- All policies and procedures should be time-limited to 3-5 years, and should be reviewed by the department when outdated. Each document in the Manual should include the date on which it was last reviewed and approved.
- Policies and procedures that specify action by department members should be periodically reviewed by appropriate experts; e.g. the informed consent policy should be reviewed by the corporate or hospital attorney; the billing documentation policy should be reviewed by a trained compliance officer.
- Every member of the department should know where the Manual can be found and how to access material within it. This is a common question encountered during Joint Commission and other external surveys.

MADOM is not intended to provide an exhaustive list of recommended policies and procedures. A few examples are included to cover common needs, and more will be added over time. We have also included the Table of Contents of the Policy and Procedure Manual of one large private practice, as an illustration of what the contents of a manual may include.

Resources
The ASA has produced dozens of Standards, Guidelines, Statements and Other Documents and Sample Policies and Procedures that may be helpful in developing policies and procedures. Several of these valuable documents are listed below:

- Guidelines for Ambulatory Anesthesia and Surgery (2013)
- American Society of Anesthesiologists® Quality Checklist
- Anesthesia Machine Preoperative Checkout – Sample Procedures
- Anesthesia Machine Obsolescence
- Standards for Basic Anesthetic Monitoring (2011)
- Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (2014)
- Statement on Documentation of Anesthesia Care (2013)
- Guidelines for Office-Based Anesthesia (2014)
- Guidelines for Patient Care in Anesthesiology (2011)
- Standards for Postanesthesia Care (2014)
- Basic Standards for Preanesthesia Care (2010)
- Statement on Security of Medications in the Operating Room (2013)
3.0.1 POLICY AND PROCEDURE TABLE OF CONTENTS (SAMPLE)

Common Homepage Structure

Welcome to the online Department of Anesthesiology Policy and Procedure Manual. This resource provides nursing personnel with 24-hour access to current policies and procedures for St. John’s Mercy Medical Center. Hard copies of these materials are available in the Department of Anesthesiology Office.

Policies may be viewed alphabetically or by policy number. You may also run a keyword search on all policies and attachments by clicking on the word “Search” below. For questions or assistance with the online policies, please contact the Department of Anesthesiology Office.

View Policies Alphabetically

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3.1 DIRECTOR OF ANESTHESIA SERVICES (DAS) AND MANAGEMENT OF SEDATION SERVICES

Centers for Medicare and Medicaid Services (CMS) regulations call for every facility to designate a Director of Anesthesia Services (DAS) with responsibility for oversight of all anesthesia and sedation within the facility. In most facilities the DAS is the Chief or Chairman of the Anesthesia Department. The DAS is responsible for establishing policies for anesthesia and sedation in all locations in the facility, for credentialing providers to administer anesthesia and sedation, and for quality management of all sedation and anesthesia services.

Recognizing that sedation is a continuum, the DAS has the unique responsibility of allocating privileges for moderate and deep sedation. Privileges for mild and moderate sedation may be extended to non-physicians and non-anesthesiologist physicians with evidence of appropriate training and experience. Because deep sedation can easily become general anesthesia, privileges for intentional deep sedation should be restricted to anesthesia professionals and non-anesthesiologist physicians with substantial training in resuscitation and airway management such as emergency medicine physicians, intensivists and oral-maxillo-facial surgeons. Non-anesthesiologist physicians granted privileges for deep sedation should be restricted to practice only in their own specialty location and patient population (e.g. the emergency department; dental patients).

The criteria for granting sedation privileges for non-anesthesiologist providers should address the following:

1. Evidence of procedure specific training, which includes documentation of completed requirements through an ACGME-approved program (when appropriate)
2. A method of objective assessment of knowledge concepts (knowledge test)
3. ACLS and licensure requirements
4. Evidence of participation in a quality assurance process tracking adverse outcomes or unusual events with established oversight by the DAS. Quality metrics should be collected monthly and should address at a minimum core metrics (volume and outcome measures). Suggested quality metrics for sedation services have been provided as part of MADOM
5. Compliance with CMS Conditions of Participation (regulations and interpretative guidelines pertaining to deep sedation)
6. Oversight by the DAS of initial and ongoing performance (i.e. Joint Commission OPPE and FPPE) should have a clearly delineated process and include recommendation letters or data from department directors for the initial evaluation and a process for competency evaluation for ongoing privileging.
7. Oversight by the DAS of the performance improvement process (CME requirements) or participation in the Deep Sedation Education program.
8. Separate privileging may be necessary for pediatric deep sedation procedures.

More information on the role of the DAS, including ASA policy statements related to sedation services, may be found on the ASA Standards, Guidelines, Statements and Other Documents webpage.

Related ASA Resources
- Advisory on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners (2010)
- Position on Monitored Anesthesia Care (2013)

Section 3.1 was updated on December 23, 2014.
• *Distinguishing Monitored Anesthesia Care From Moderate Sedation/Analgesia (Conscious Sedation) (2013)*

• *Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists (2002)*

• *Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who Are Not Anesthesia Professionals (2011)*

• *Statement on Granting Privileges to Nonanesthesiologist Physicians for Personally Administering or Supervising Deep Sedation (2012)*
3.1.1. PROCEDURAL SEDATION METRICS (AQI)

Quality Metrics for Procedural Sedation
AQI consensus recommendations for the Director of Anesthesia Services charged with initiating a quality management program in procedural sedation. Data must be gathered each month from each unit where patients receive sedation. Data gathering should be modified as necessary to fit the information technology available and the patient population served.

Core Elements

Volume Metrics
- Type and number of procedures performed
- Number of patients receiving light or moderate sedation
  - Number receiving sedation via Computer-Assisted Personalized Sedation (CAPS)
- Number of patients receiving deep sedation
- Number of patients cared for by an anesthesia team

Outcomes
- Cases completed as planned, without complication, versus:
- Cases cancelled due to patient discomfort or anxiety
- Cases with unplanned escalation in the continuum of sedation
- Patients receiving rescue medication: flumazenil or naloxone
- Unplanned respiratory support required in light or moderate sedation cases
  - Placement of nasal trumpet or oral airway
  - Placement of supraglottic airway (e.g. LMA) or endotracheal tube
  - Assisted ventilation with bag-valve-mask
  - Oxygen saturation < 85% for greater than 3 minutes
- Patients experiencing a serious adverse event (e.g. perforation, anaphylaxis, cardiac arrest)
- Unplanned admission of an outpatient within 24 hours
- Unplanned patient transfer to an Emergency Department

Optional Elements
As the quality program matures and information technology capabilities advance, these data will enable further improvements in patient care:
- Patient demographics: age, sex, ASA Physical Status
- Procedure duration
- Medications used: doses and times
- PACU and facility length of stay
- Patient satisfaction: at PACU discharge and at 48 hours post-procedure
- Provider satisfaction: proceduralist and nursing staff
3.1.1.2 PROCTORING FORM (SAMPLE)

MEDICAL STAFF PROCTORING EVALUATION REPORT

For Department of Anesthesiology

Anesthesiologist ____________________________ Date: ____________

Patient Medical Record #: ____________________ Age: (circle) Adult _____

ASA Status: _____ Child >2____

Procedure ____________________________________________

Location: (circle) OR OSS MIS Other ________________ Child <2____

(specify)

Please comment on the nature and quality of the procedure/activity performed:

1) Pre-operative management:

___________________________________________________________

___________________________________________________________

2) Operative management:

___________________________________________________________

___________________________________________________________

3) Immediate post-operative management:

___________________________________________________________

___________________________________________________________

4) Other Remarks: (technique/judgment/knowledge)

___________________________________________________________

___________________________________________________________

Satisfactory / Unsatisfactory

Proctor: ____________________________ Date: ________________

(print name)

Signature: ____________________________

Note: Completed evaluation forms are to be immediately forwarded to Medical Staff Administration ______ where they will be placed in the physician’s or ______ Professional’s confidential credential file. They must not be left in the patient’s chart at any time.
3.2 INFORMED CONSENT

The doctrine of Informed Consent is based on the premise that a patient has the “right to determine what shall be done with his (or her) own body.” The doctrine of Informed Consent is based on the premise that a patient has the “right to determine what shall be done with his (or her) own body.” Under this doctrine, a physician may be held legally liable if he or she performs a procedure without authorization from the patient, even if the procedure benefits the patient.

The doctrine is also applied to cases in which a patient authorizes treatment, but does so without a full understanding of the risks associated with it. In this circumstance, the physician who fails to provide complete information may be held liable under a negligence theory for the breach of duty to fully inform the patient and obtain the patient’s informed consent. To succeed on such a theory, however, the patient must establish that had the risks been disclosed, a reasonable person in his or her position would not have consented to the treatment.

The actual legal requirements for informed consent are based on individual state law and will consequently vary depending on the state where the anesthesiologist practices. Additionally, many states have adopted statutes that require physicians to obtain informed consent and in some cases spell out the information that must be provided. It is imperative that anesthesiologists be aware of the current legal requirements in the state where they practice.

Most states now require the physician to disclose information that a reasonable patient under similar circumstances would want to know in order to make an informed decision. The “reasonable patient” standard has largely supplanted the old standard that was based on what a “reasonable physician” would disclose. Under this standard, a physician need not disclose every risk, but only those that are "material." A risk would be deemed “material” when "a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."

In procedures involving general anesthesia, for example, the possibility of death or paralysis would be considered material risks which must be disclosed, even though the incidence of risk is extremely low. Injuries to teeth are not uncommon and although not of life-threatening significance, are among the anesthesia risks that the informed consent process should discuss.

A genuine emergency will override the requirement to obtain consent. In addition, some courts have recognized a "therapeutic privilege" exception, under which a physician may withhold disclosure if he or she believes it will prevent the patient from making a rational decision or will cause psychological damage to the patient. Anesthesiologists should be wary of relying on the therapeutic privilege unless the patient is extremely agitated. Physicians proceeding without consent under either the emergency or therapeutic privilege exception should also thoroughly and contemporaneously document the facts supporting their reasoning. Additionally, if the patient states he or she does not want to receive the relevant information on risk, this fact should be documented.

Physicians, including anesthesiologists, should secure written informed consent from patients, or from their representatives if they are legally incompetent (e.g., minors), for the anesthesia procedure.

19 Some states apply a "subjective" standard and will impose liability if it is proven that the specific patient would not have undergone the procedure if he or she had known the risks involved. See, e.g., Scott v. Branford, 606 P. 2d 554 (Okla.1979).
20 Canterbury, supra, at 787.
Professional liability defense attorneys also recommend – and many malpractice carriers require – that the anesthesia consent form be separate from any other consent forms the patient may sign and that it contain the following information:

1. The nature of the anesthesia procedure and the method of administration;
2. The identity of the person who will administer the anesthesia, especially if the attending anesthesiologist is not the person obtaining the consent;
3. The risks, complications or dangers of anesthesia; and

Legal experts also agree that it is advisable for the anesthesiologist to thoroughly explain the information above to the patient to ensure that he or she understands the nature of the consent. The fact that the anesthesiologist has explained the necessary information should also be documented, as well as the fact that the patient has been given an opportunity to ask questions to his or her satisfaction. Obviously, the information must be provided before the patient signs the consent form.

Hospitals are required, as a condition of their participation in the Medicare program, to make sure that the anesthesia service has a written policy addressing patient consent. The anesthesia section of the Medicare surveyors’ instructions does not elaborate on consent, but the surgery section provides, by analogy, a valuable guide to the views of the Centers for Medicare & Medicaid Services (CMS) and its hospital survey agent, The Joint Commission.

Many physicians view the informed consent requirement as another burden complicating the rendering of medical service. A better view would be to regard it as the best opportunity to involve the patient in the decision-making process. The true objective is to allow patients to make an informed decision about the choice of treatment. To fulfill this objective, the patient must receive appropriate information that will allow him or her to make an educated and objective evaluation of the risks and benefits associated with the procedure in question. Patients who have given properly informed consent are fully aware of the potential risks of a procedure and are less likely to bring legal action even if the results are not what they desired.

MADOM includes two copies of anesthesia informed consent statements in use in large urban hospitals in two different states. These forms differ in their approach and specificity; in any event, readers are cautioned that the legal requirements may vary from state to state, and counsel should be consulted before a particular form is put to use.

Anesthesiologists should consider who is present before beginning a discussion for consent for a planned anesthetic. Such a discussion necessarily includes personal health information, and the patient has the general right to limit distribution of that information.

Additional Resources:


3.2.1 INFORMED CONSENT FORM (SAMPLE A)

INFORMED CONSENT AND AUTHORIZATION FOR ANESTHESIA

1. I, ____________________________ for ______________________________ as Parent = Guardian = Representative (acting on his/her behalf), am asking to receive anesthesia during my pending procedure/operation/treatment. I want to have anesthesia in order to lessen the pain I would otherwise experience.

2. I understand that regardless of the type of anesthesia used there are a number of common foreseeable risks and consequences which may occur. The following are some but not all of the common foreseeable risks and consequences which I have been told can occur: sore throat and hoarseness, nausea and vomiting, muscle stiffness, injury to the eyes. Further, I understand instrumentation in the mouth to maintain an open airway during anesthesia might irreversibly result in dental damage including fracture or loss of teeth, bridge work, dentures, crowns and fillings, deformation of the gums and lips.

3. I understand the medications that I am taking may cause complications with anesthesia or surgery. I understand that it is in my best interest to inform any doctors about the nature of any medications I am taking, including, but not limited to: aspirin, cold remedies, narcotics, PCP, marijuana, and cocaine.

4. I understand that the more severe the potential risks and consequences of anesthesia include, but are not limited to: changes in blood pressure, drug reaction, cardiac arrest, brain damage, paralysis, or death.

5. I acknowledge that Dr. ____________________________ has told me that in his/her judgment the type(s) of anesthesia I could receive is/are (check all that apply):
   - General Anesthesia
   - Spinal Anesthesia
   - MAC (Monitored Anesthesia Care)
   - Epidural Anesthesia
   - Other Regional Anesthesia

6. I understand that during my procedure/operation/treatment invasive monitoring may be necessary. I understand the risks and benefits associated with this type of monitoring which have been fully explained to me.

7. I understand that while I am receiving anesthesia, conditions may develop which require modifying or extending the consent. I therefore authorize modifications or extensions of this consent that professional judgment indicates to be necessary under the circumstances.

8. Should the need arise during my operation or immediate postoperative period, I also consent to the administration of blood and/or blood products. Further, I understand that despite careful handling and screening of blood and blood products by collecting agencies, I may still be subject to ill effects as a result of receiving a blood transfusion and/or blood products. The following are some, but not all, of the potential risks that I am told can occur: fever and allergic, hemolytic reactions, transmission of disease such as hepatitis, AIDS, and cytomegalovirus (CMV), and fluid overload.

9. I understand that I must not eat or drink anything, not even water after 12 midnight the day prior to surgery unless directly permitted by the anesthesia staff.

10. I consent to appropriate tests and treatments which may better evaluate my risk and prepare me for surgery as part of my medical care associated with this procedure/operation/treatment.

11. I understand that any anesthetic care will be given to me by or under the supervision of a Medical Center attending anesthesiologist. Knowing that Medical Center is a teaching institution. I understand that along with my attending anesthesiologist and his/her assistants and designees, other medical care personnel such as certified registered nurse anesthetists, technicians, interns, residents and medical students may be involved in any anesthetic care.

12. I understand the University's teaching mission and agree to the presence of appropriate observers during my procedure/operation/treatment for the advancement of medical education and care.

PATIENT INFORMATION

By signing this request form, I am indicating that I understand the contents of this document, agree to its provisions, and consent to the administration of anesthesia, during my procedure/operation/treatment. I know that I have consented or would like more detailed information. I can ask more questions and get more information from my attending physician. I also acknowledge that the practice of anesthesiology, medicine and surgery is an art and science that no one has given me any promises or guarantees about the administration of anesthesia to its results.

I fully understand what I am now signing of my own free will.

Witness to
Affirmation
and Signature

<table>
<thead>
<tr>
<th>DATE</th>
<th>TIME</th>
<th>Patient Signature</th>
<th>DATE</th>
</tr>
</thead>
</table>

PHYSICIAN ATTESTATION

I, Dr. ____________________________, attest that this patient or the representative named above has been informed about the common foreseeable risks and benefits of undergoing operation/treatment as well as its reasonable alternatives[, if any. Further questions with regard to this procedure have been answered by his/her apparent satisfaction.

Physician Signature

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3.2.2 INFORMED CONSENT FORM (SAMPLE B)

CONSENT FOR SURGERY, ANESTHESIA AND OTHER MEDICAL SERVICES

DATE __________ TIME __________ AM/PM

1. I consent to the performance upon __________________________________________
   (Myself or Name of Patient)
   the following surgery or other medical procedure __________________________________
   (State Nature and Extent of Operation)
   I understand that this surgery procedure is to be performed under the direction of Dr. __________

2. I understand that during the course of the surgery or other procedure the doctor named in paragraph 1) or his associates may consider it necessary or advisable to perform procedures or to render medical treatment in addition to that named in paragraph 1) because of conditions which may not be presently foreseeable. Therefore consent to the performance of such additional surgery or treatment and procedures as are deemed necessary or advisable.

3. I consent to the administration of such anesthetics as may be considered necessary or advisable by the person authorized to administer anesthesia. (Cross out if no anesthesia to be used).

4. I consent that tissues or parts of my body removed at surgery, body fluids, x-ray films, and other materials, as well medical information concerning me, may be used in research studies, in publications of results, and in teaching.

5. The nature and purpose of the surgery, treatment or procedure and the reasonable (1) alternate methods of treatment, (2) risks, and (3) possibility of complications have been fully explained to me. No guarantee or assurance has been given by anyone as to the results that may be obtained.

6. I have read and understand the above authorization and the reasons why the surgery, treatment or procedure is necessary.

(Signed) ___________________________ (Patient or Person authorized to consent for patient)

(Witness for) ___________________________ (Relationship to Patient)

(Witness) ___________________________

(If consent received by telephone, signature of monitoring Switchboard Officer)

(If consent received by telephone, signature of Staff Member, his Authorized Representative or other Official)

AFFIRMATION OF INFORMED CONSENT BY ATTENDING PHYSICIAN

I, ___________________________, have informed the above named patient or the person authorized to extend consent on the patient’s behalf, of the medical conditions requiring surgical treatment or the further diagnostic procedures referred to above. I have explained, consistent with accepted medical judgment, the nature and purpose of the treatment or procedures, the reasonable (1) possible alternatives, (2) risks, and (3) complications, as in the treatment or procedure consented to.

_________________________ M.D.

DATE __________

AFFIRMATION BY ATTENDING ANESTHESIOLOGIST
(CROSS OUT IF NO ANESTHESIA REQUIRED)

I, ___________________________, have informed the above patient or the person authorized to extend the patient’s consent of the methods of anesthesia proposed for the procedure referred to above. I have explained consistent with accepted medical judgment the nature and purposes of the anesthesia, the reasonable (1) alternative anesthesia methods, (2) risks involved and (3) possibility of complications. In addition I have explained that the anesthetic but that an alternative form of anesthesia may be used if required by unexpected conditions arising before or during the procedure.

_________________________ M.D.

DATE __________

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3.3 ENDOTRACHEAL TUBE STORAGE (SAMPLE POLICY)

[ NAME OF PRATICE / MEDICAL FACILITY ]

[ OFFICIAL NAME OF ANESTHESIOLOGY DEPARTMENT ]

Policy and Procedures Manual

Endotracheal Tube Storage

Devices such as endotracheal tubes (ETT’s) may be exposed to potentially infectious material during indicated use, and can become contaminated through direct contact with the patient's skin, mucous membranes, secretions and blood. An ETT interferes with normal patient defenses allowing pathogens direct access to the lung.

To reduce the risk of infection, the importance of standardizing the process of reprocessing as indicated, with a minimum high level disinfection or sterilization (if a single use device is not used and manufacturer’s instructions for use is adhered to), and storage is emphasized.

**Single Use Device**

ETT’s are commonly obtained as sterile single use devices. As defined, single use devices are intended for one time use, on a single patient, during a single procedure.

**Storage**

- ETT’s should be kept free from contamination until the time of use. Once opened, there is potential for microorganisms to settle on the device the longer it remains open and unused. Increased handling of the opened unused device increases the chances of contamination. Ensure that the storage area provides protection from dust, moisture, temperature and humidity extremes. Refer to the CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) document entitled Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008.

**Pre-opening of Endotracheal tubes (ETT)**

- The physician anesthesiologist or nurse anesthetist may (with proper hand hygiene):
  - Open the packaging and conduct a risk assessment of the ETT; checking ETT and balloon
  - They may stylet the ETT with a clean stylet
  - Following inspection and/or stylet placement, the ETT will be returned to the packaging and placed in a clean storage location until use.

* The anesthesia tech’s will remove any opened/styleted ETT’s weekly (usually on Mondays). In this way, no ETT will be open for more than 7 days. Therefore there is no need for dating any opened ETT package.

**[DATE ENACTED]**

Approved by:

[ Name of Department Chair / Leader ], [Credentials], [Department Title]
REFERENCES

_The Standards FAQs for Endotracheal Tubes – How to clean, disinfect and store this device:_

**Posted:** Oct 11, 2013 - CAMAC – [Ambulatory Health TJC – Endotracheal Tubes](#) - How to clean, disinfect and store this device.

**Posted:** Oct 11, 2013 - CAMH – [Hospitals – Endotracheal Tubes](#) – How to clean, disinfect and store this device.

**Posted:** Oct 11, 2013 - CAMOBS – [Office Based Surgery – Endotracheal Tubes](#) – How to clean, disinfect and store this device.

_The Standards FAQs for Laryngoscopes – Blades and Handles – How to clean, disinfect and store these devices:_

**Posted:** Oct 11, 2013 - CAMAC – [Ambulatory Health Care – Laryngoscopes](#) – Blades and Handles – How to clean, disinfect and store these devices

**Posted:** Oct 11, 2013 - CAMH – [Hospitals – Laryngoscopes](#) – Blades and Handles – How to clean, disinfect and store these devices

**Posted:** Oct 11, 2013 - CAMOBS – [Office Based Surgery – Laryngoscopes](#) – Blades and Handles – How to clean, disinfect, and store these devices
3.4 TRAINING ANESTHESIA PROFESSIONALS TO USE ADVANCED MEDICAL TECHNOLOGY

Advanced Medical Technology (AMT) includes all of the devices required to care for anesthetized patients safely. Anesthesia delivery systems, infusion pumps, airway management devices, ultrasound machines, cardiopulmonary bypass pumps and even information management systems need to be used properly to avoid patient injury. Although designs have become increasingly user friendly, and safety is an underlying priority in the design process, it is still not possible to use advanced medical technology safely without training.

The Anesthesia Patient Safety Foundation (APSF) recommends that anesthesia professionals receive training to use AMT safely and effectively before using the technology to care for patients. Implementation of an effective training program requires cooperation between anesthesia professionals, healthcare organizations and technology manufacturers. The specific considerations below were developed by APSF and are intended to guide development of educational programs that insure that anesthesia professionals are competent to use AMT.

Considerations for Anesthesia Professionals

- Understand the setup, function, operation, and information necessary to provide safe and effective patient care when using the device.
- Consistently use the device safely and effectively.
- Consistently use a device’s safety features and take appropriate measures to avoid known potential for patient harm.
- Identify when each device is not functioning as intended and be able to perform basic troubleshooting and respond appropriately to maintain the highest level of patient safety.
- Have competence assessed by various mechanisms, including but not limited to, written or oral examinations, demonstrating safe use to a skilled observer, and using the device in simulations of relevant clinical situations.

Considerations for Health Care Organizations

- Require appropriate advanced medical technology training and demonstrated competence before an anesthesia professional is permitted to use a (new or existing) device to care for patients unless a person with demonstrated competence is present throughout the procedure.
- Provide formal advanced medical technology training programs for every anesthesia professional including a mechanism to ensure that anesthesia professionals who are new to the institution receive this training before they begin delivering patient care.
- Document an individual’s participation in technology training, education, and assessment.
- Create a mechanism to ensure that the advanced medical technology training program is meeting its goals.
- Establish a schedule for periodic reassessment of anesthesia professionals’ continued competence. Allocate time for training and assessment within the regular workday.

Considerations for the Technology Manufacturer

- Utilize a rigorous, user-centered, human factors design process to create devices that are easy to learn to use, easy to use, easy to remember how to use, and that fail safely and gracefully.
- Develop effective training materials and instructions for use (IFU) using the same rigorous engineering processes applied to other aspects of the device.
• Create standardized user training and recommended competency assessment materials, based on user-centered design and validation methods, which can be used by institutions to comply with these recommendations.
• Assist customers in the implementation of user training and competency assessment materials and procedures.

Technology manufacturers are best positioned to develop training programs, but these programs will only be effective if training is considered a priority and time allotted during the workday for professionals to develop competence.

It is important to note that APSF does not intend for these recommendations to be standards, guidelines, practice parameters, or clinical requirements, nor does application of these recommendations guarantee any specific outcome. Furthermore, these recommendations may be adopted, modified, or rejected according to clinical needs and restraints. APSF recognizes that these recommendations are subject to revision as warranted by the evolution of medical knowledge, technology, and practice.