
Shanda H. Blackmon, MD, MPH\textsuperscript{1}, David T. Cooke, MD\textsuperscript{2}, Richard Whyte, MD\textsuperscript{3}, Daniel Miller, MD\textsuperscript{4}, Robert Cerfolio, MD\textsuperscript{5}, Farhood Farjah, MD, MPH\textsuperscript{6}, Gaetano Rocco, MD\textsuperscript{7}, Matthew Blum, MD\textsuperscript{8}, Stephen Hazelrigg, MD\textsuperscript{9}, John Howington, MD\textsuperscript{10}, Donald Low, MD\textsuperscript{11}, Scott Swanson, MD\textsuperscript{12}, James I. Fann, MD\textsuperscript{13}, John S. Ikonomidis, MD, PhD\textsuperscript{14}, Cameron Wright\textsuperscript{15}, MD, Sean C. Grondin, MD, MPH\textsuperscript{16}

\textsuperscript{1}Thoracic Surgery Division, Department of Surgery, Mayo Clinic, Rochester, MN
\textsuperscript{2}Section of General Thoracic Surgery, University of California, Davis Medical Center, Sacramento, CA
\textsuperscript{3}Division of Thoracic Surgery, Beth Israel Deaconess Medical Center, Boston, MA
\textsuperscript{4}WellStar Healthcare, Marietta, GA
\textsuperscript{5}Department of Cardiothoracic Surgery, University of Alabama at Birmingham, Birmingham, AL
\textsuperscript{6}Division of Cardiothoracic Surgery, University of Washington, Seattle, WA
\textsuperscript{7}National Cancer Institute, Pascale Foundation, Naples, Italy
\textsuperscript{8}Memorial Hospital-University of Colorado Health, Colorado Springs, CO
\textsuperscript{9}Department of Surgery, Southern Illinois University, Springfield, IL
\textsuperscript{10}NorthShore University Health System, Evanston, IL
\textsuperscript{11}Esophageal Center of Excellence, Virginia Mason Medical Center, Seattle, WA
\textsuperscript{12}Brigham and Women’s Hospital/Dana-Faber Cancer Institute, Boston, MA
\textsuperscript{13}Department of Cardiothoracic Surgery, Stanford University, Stanford, CA
\textsuperscript{14}Division of Cardiothoracic Surgery, Medical University of South Carolina, Charleston, SC
\textsuperscript{15}Department of Thoracic Surgery, Massachusetts General Hospital, Boston, MA
\textsuperscript{16}University of Calgary, Foothills Medical Centre, Calgary, AB

Correspondence:
Sean C. Grondin, MD, MPH, FRCSC
University of Calgary, Foothills Medical Centre
1403 - 29th Street NW, Room G33D
Calgary, AB T2N 2T9
Canada
1 403 944-8798
1 403 270-8431 (fax)
sean.grondin@albertahealthservices.ca

Word Count: 3279 (text)
Key Words: Credentialing, New Technology, Thoracic Surgery
Background

The purpose of credentialing is to help ensure that clinicians provide high-quality and high-value healthcare in accordance with accepted standards of care and legal requirements. Ensuring appropriate credentialing for new technology or advanced procedures may be challenging because historical data are often unavailable to evaluate the relationship between the credentialing process and the safety and quality of the healthcare services or patient outcomes. The main objective of The Society of Thoracic Surgeons (STS) Task Force on General Thoracic Surgery Credentialing is to propose a consensus statement and, most importantly, a framework for thoracic surgery credentialing as it pertains to new technology and advanced procedures. It is not the purpose or intent of this Task Force to mandate specific criteria for credentialing or certifying surgeons.

Although the details for adopting new technologies may vary depending on practice location and environment, this practical framework may serve as a reference (and not a mandate) for surgeons and hospitals as they plan for the safe introduction and implementation of new technologies and advanced procedures. The framework is intended to be sufficiently broad so as to be relevant to a range of institutional settings and scopes of practice. Purposefully, the Task Force based its proposals on either published literature or expert consensus and avoided attaching a “mandatory number of cases performed” in the credentialing process. The Task Force concluded that, in most instances, little or no quality data are available for most new technology and advanced procedures to support assigning a specific number of cases for credentialing. Consequently, the Task Force determined that in this context, credentialing should be
based on evaluation and documentation of knowledge and skills, continuous clinical and quality outcomes assessment, use of optimal clinical and administrative care processes, and in the case of new privileges, a Focused Professional Practice evaluation. We reviewed the literature to explore a standard certification guide for the use of new technology and advanced procedures and identified four common goals of credentialing. These being to develop 1) clear lines of responsibility for the credentialing process, 2) supportive governance structures, 3) accepted standards for credentialing, and 4) a culture of continuous improvement and evaluation of credentialing process outcomes (1-4).

In this consensus statement, the Task Force clarifies some of the terminology associated with the credentialing process and provides a description of the proposed framework for new technology and advanced procedures. We also categorize a representative list of new technology and advanced procedures in general thoracic surgery to which the framework may be applied and present case studies to illustrate how the framework checklist can assist in credentialing a surgeon and/or surgical team.

**Terminology**

To develop an effective framework for credentialing, one must be familiar with the common language regarding several relevant processes including certification, credentialing and privileging.

**Certification**

In thoracic surgery, certification is under the auspices of the American Board of Thoracic Surgery (ABTS), whose primary purpose of is to protect the public by establishing and maintaining high standards of care in thoracic surgery. To achieve
these objectives, the ABTS has developed highly specific qualifications for examinations as well as procedures for certification and maintenance of certification (5). The ABTS board certification is a minimum requirement for all thoracic surgeons and does not currently include guidelines for credentialing board-certified surgeons in the utilization of new technology or acquisition of new and advanced skills.

**Credentialing and Privileging**

Credentialing and privileging are processes that culminate in the formal recognition and attestation that a thoracic surgeon is both qualified and competent. Credentialing verifies that the thoracic surgeon meets universally recognized standards by reviewing such items as the individual's license, experience, certification, education, training, malpractice history, adverse clinical occurrences, clinical judgment, and professionalism through investigation and observation.

Privileging defines the surgeon’s scope of practice and the clinical services he or she may provide. Privileging is based on competence and should be a data-driven process with a demonstrated commitment to continuous quality improvement. The Joint Commission requires that physicians seeking new privileges undergo a defined Focused Professional Practice Evaluation (FPPE) (6). The Joint Commission requirements for a FPPE are: clear criteria for conducting performance evaluations, defined methods for establishing a monitoring plan specific to the requested privilege and determining the duration of performance monitoring, and documenting the circumstances under which monitoring by external individuals is necessary (6). An example of a FPPE form is shown in Appendix 1. Historically, individual hospitals have determined the criteria for granting privileges within a specialty, an approach that may
result in wide variability in training and expertise. Furthermore, in most instances, the patient does not have access to institutional criteria necessary for granting privileges as they are not a matter of public record (7).

In order to be fair, credentialing and privileging must be products of qualified and objective physician-controlled peer review using criteria that have been established through common professional, administrative, and legal practices. These criteria should be endorsed by a formal consensus process and be publicly available. Importantly, these criteria should be directly related to the quality of patient care, documented physician performance, and outcomes that can be measured. Peer review decisions must be fair, performed in good faith (not unreasonable, capricious, or arbitrary), include detailed documentation, be justifiable, and be equally applied to all practitioners without bias in accordance with reasonable standards of care. Peer review decisions should be confidential and protected. In cases of adverse peer review decisions, avenues of appeals using due process and the inclusion of fair hearings must be available to the surgeon undergoing the evaluative process.

In most hospitals, credentialing and the procedural list of privileges do not account for the introduction of new technology and advanced procedures. The responsibility for ensuring that a surgeon has acquired the appropriate training and mentorship in their utilization of a new technology and acquisition of new skills lies with both the practitioner and the hospital where he or she practices. Credentialing and privileging to perform a new procedure or to use a new technology ideally should not be based solely on the numbers of procedures performed, but rather on evaluation of knowledge and skills and outcomes of surgical care. Often, training of the entire surgical
team is essential and should be considered as an important aspect of the credentialing process. The entire educational experience should be transparent and include verification of knowledge acquisition, skill assessment, preceptorship or proctoring, monitoring of outcomes, and participation in a continuous quality improvement activity. In ensuring the quality of a program, an institution should consider the resources available to the surgeon during the knowledge and skill acquisition period.

STS Task Force Credentialing Framework

The key components in the framework for credentialing new technology and advanced procedures in general thoracic surgery are described below.

Verification of Knowledge and Skills

There are currently few validated models that are available for the training of new technology or advanced procedures in general thoracic surgery. Surgeons wishing to learn a new technology or procedure often complete, at a minimum, a course or didactic session in the topic. Subsequently, the course instructor provides verification that the surgeon attended the course and is “endorsed” to introduce and implement the technology or procedure. It is challenging to determine the exact number of cases required to achieve competency in a new technology or procedure because the learning curve for each individual may be variable. Because the safe implementation of new technology by an independent surgeon or as part of a clinical team often requires a basic surgical skill set, the Task Force recommends that the surgeon be board eligible or certified in thoracic surgery and complete a course or didactic session in the new technology. The degree of training should be adjusted to the complexity of the
technology or procedure in reference to the surgeon’s training. For example, a thoracic surgeon learning to perform endobronchial ultrasound (EBUS) would require far less training and safety monitoring than if he were to begin to perform percutaneous lung ablation. Because of the varying complexity of new technology or procedures, it is prudent not to dictate a specific training pathway, but rather, to emphasize the importance of defining the preparation needed to align the complexity of the procedure with the surgeon’s existing skill set.

Based on the expert opinion of the Task Force, five levels of supervision for credentialing for new technology and advanced procedures are proposed (Table 1). Level 1, the lowest level, is certification that the learner attended a lecture or completed a lecture format course (no verification of skills). Level 5 is the highest level of validation of learning outside of a formal training or mentorship program. Level 5 training, however, is not always practical or affordable and lower levels may be appropriate for some new technology and advanced procedures. These levels of verification serve as a guide for hospitals, trainees, and instructors by employing appropriate nomenclature when classifying the level of training for a particular skill. Such nomenclature should be incorporated into training certificates in a standard fashion to enhance accuracy of evaluation; for example, “the clinician learned the principles of VATS lobectomy at our course, completing an animal model skills assessment and achieving Level 3 skills verification.” Level 5 training, however, may be achieved during a “mini-fellowship” during which a surgeon travels to a high-volume center and acquires the skills under direct supervision.
Although it is acknowledged that industry (i.e. manufacturers of pharmaceuticals, medical devices and biologics) may provide valuable education opportunities, industry should not set credentialing standards for clinicians. In addition, the relationship of the clinician adopting the new technology or advanced procedure with industry should be transparent with the appropriate public disclosure.

**Team Management**

To effectively introduce new technology and advanced procedures, clear communication among colleagues, hospital administrative personnel, and allied health professionals is critical. The plan to implement new technology and advanced procedures should be designed with patient safety as the main priority. An implementation program should be drafted to include information on patient selection and consent, availability and cost of specialized equipment, education plan for team members, clinical outcome data gathering and reporting, and, if applicable, development of a perioperative crisis management plan.

**Institutional Collaboration**

Although the details for adopting new technology may vary depending on the local healthcare facility, approval from the institutional innovative care/new technology committee (or equivalent) is recommended. In some cases, accreditation by specialty committee may be necessary. For example, the introduction and use of laser bronchoscopy may require approval by the institution’s laser committee; such approval will likely require documentation of training and may require a period of proctorship. If the intent of the surgeon is to participate in research on the comparative-effectiveness of new technology and/or involves a technology granted an investigational device
exemption (IDE) by the Food and Drug Administration (FDA), appropriate Institution Review Board (IRB) approval must be obtained. In emergent situations, the use of a device/technology under an IDE is allowed under discreet specifications outlined by the FDA; in non-emergent situations, approval is required by the FDA for compassionate use (8). Off-label use of a FDA-approved device does not require IRB approval, although IRB involvement, informed consent, and disclosure to the patient of off-label use may be appropriate in certain circumstances—particularly when use of the device is novel and/or when risks are unknown. Technology that has been granted a humanitarian device exemption (HDE) by the FDA may be used only after the IRB has approved such use to treat a specific condition.

Monitoring of Outcomes

Credentialing surgeons for new technology and to ensure that clinicians provide high-quality healthcare services can be challenging. In most cases, no previous data are available to evaluate the relationship between the credentialing process and the safety and quality of healthcare delivery. Because capturing patient outcome data can be difficult and onerous, developing metrics of the effectiveness of credentialing processes represents an area for further research, particularly in the optimal design and use of databases (9). If an institution adopts a structured credentialing process or modifies an existing one, the date of adoption/modification should be recorded to facilitate future assessments of its utility and effectiveness.

Participation in the STS National Database or an equivalent regional, state-wide, or local clinical outcomes registry (e.g. American College of Surgeons-National Surgical Quality Improvement Program, Michigan Society of Thoracic and Cardiovascular
Surgeons Quality Collaborative or local hospital reviewable database) to allow for continuous assessment of outcomes and quality is recommended for credentialing new technology and advanced procedures. These databases provide important information that can be used to assess the acquisition of new technical skills and ongoing skills development. Individual outcomes can be benchmarked against other institutions for comparison. As an example, surgeons who demonstrate participation in the STS database as a reference, can thus track their outcomes in a comparative fashion and can provide necessary information for re-credentialing and privileging. Similarly, hospitals that follow the recommendations for credentialing may attest to participating in registry-based continuous quality improvement.

*Patient-centered Transparency*

The primary focus of the credentialing process of new technology and advanced procedures is to ensure patient advocacy, healthcare quality, and patient safety. This approach includes clear communication with full disclosure to the patient that a new technology or advanced procedure is being considered as a part of his or her clinical care. These discussions should include the known risks and benefits of the new technology or advanced procedure, as well as the costs and comparative-effectiveness of such approach relative to the existing treatment options. Consent forms should be carefully reviewed with the patient along with information, if requested, regarding the surgeon’s training and experience to date. Disclosure of current results with the technology or procedure including morbidity and mortality data is recommended. As noted, clinician relationships with industry sponsoring the new technology or advanced procedure should be disclosed.
New Technology and Advanced Procedures in General Thoracic Surgery

In developing the framework for credentialing, the Task Force first identified a representative list of new diagnostic and therapeutic procedures used in general thoracic surgery to treat disease processes such as benign and malignant airway as well as chest wall, mediastinal, and esophageal disorders. These new technologies and advanced procedures are often not delineated in the credentialing and privileging lists of most hospitals. A detailed review of the minimum requirements in methodology, logistics, and training was performed with a specific focus on new technology and advanced procedures beyond residency training. Next, the Task Force separated new technologies or advanced procedures into two broad categories based on the most appropriate pathway for: 1) credentialing and privileging for a thoracic surgeon expanding an existing skill set and 2) credentialing and privileging for a thoracic surgeon as part of a clinical team to perform a new procedure that is largely outside the traditional boundaries of thoracic surgery. “Credentialing and privileging for a thoracic surgeon expanding an existing skill set” refers to credentialing in a new technology or procedure to which the surgeon was not exposed during training but that logically can be considered an extrapolation or derivative of ABTS eligible or certified skill set. “Credentialing and privileging for a thoracic surgeon as part of a clinical team to perform a new procedure” refers to new technology or procedure that is not logically considered an extrapolation or derivative of ABTS eligible or certified skill set but for which a thoracic surgeon may play a clinical leadership role in its use. Examples of for both categories are listed in Table 2.
Credentialing Checklist

Regarding new technology or advanced procedures that the surgeon was not exposed to during residency training, a stepwise approach using a checklist based on the above framework can be used for the credentialing process (Table 3). The ABTS eligible or certified surgeon first completes a course preferably with instructional didactic and hands-on components. In adopting the technology or advanced procedure, the surgeon drafts an implementation plan that includes information on the risks and benefits of the new procedure, as well as the costs and comparative-effectiveness of the new technology. The implementation document includes details pertaining to the training of allied health professionals including practice cases and crisis management plan, if necessary. The proposed consent form and patient information packet are attached to the document, which is then submitted for approval by the institutional innovative care/new technology committee, or equivalent.

For the implementation of the new technology or advanced procedures, the degree of training is adjusted to the complexity of the technology or procedure in reference to the surgeon’s training. For instance, with VATS lobectomy, one can employ a stepwise approach with a systematic adoption of necessary techniques transitioning from a traditionally open to completely minimally invasive approach, augmented by an instructional course, and followed by committed proctorship. A detailed case log with operative details, complications, length of stay, and mortality rate should be kept by the surgeon and available for review. After being credentialed, the thoracic surgeon should demonstrate satisfactory independent performance of the new technology or advanced
procedure with participation in an outcomes database for continuous quality improvement.

Table 4 provides illustrative case studies of the credentialing pathway for 1) an advanced procedure that the Task Force considers an expansion of a thoracic surgeon’s expected skill set, e.g. per-oral endoluminal myotomy or POEM (Case Study 1); 2) a new technology or advanced procedure where the thoracic surgeon is part of a clinical team, but the procedure is not logically considered an extrapolation of ABTS eligible or certified skill set, e.g. percutaneous radiofrequency ablation (RFA) of a lung tumor for secondary metastasis (Case Study 2); and 3) a new procedure that can be considered “blended”, e.g. VATS Maze procedure by a primarily adult cardiac surgeon employing techniques grounded in general thoracic surgery (Case Study 3).

Future Directions in Credentialing

It has been proposed that the creation of an “Interstate Medical License” would be ideal in facilitating the education and skills training for credentialing (10). The interstate medical license would allow instructors to travel outside their immediate institution and their state to mentor and assist surgeons in the operating room. The learner or trainee would in turn be permitted to travel to other institutions for training in advanced procedures. The license potentially can be expanded to a “World Medical License” allowing international mentorship and training. These expanded licenses are not intended to allow routine clinical practice in a state where the instructor does not have a license or in a healthcare facility where he does not have privileges; instead, it would allow instructors to assist in the education of surgeons in advanced and
“emergency” procedures. In these situations, although it is still necessary for the hospital to grant clinical privileges, a standardized credentialing process can facilitate the education and acquisition of new technology and advanced procedures in a safe manner with more hands-on experience.

Conclusions

The credentialing and privileging process associated with new technology and advanced procedures in general thoracic surgery is an undefined path. To date, there is no standardized process for thoracic surgery credentialing with specific regard to implementation of new technology and advanced procedures (11). This manuscript proposes a framework that hospitals and surgeons can use as a guide in the credentialing process for current and future new technology. For the safe implementation of new technology, surgeons need to ensure that patients make informed decisions regarding their treatment and participate in their peri-operative care. Incorporation of outcomes into a quality-driven thoracic surgery database is important to facilitate ongoing monitoring of outcomes and continuous quality improvement as well as assessment of the new technology and advanced procedures.
Acknowledgement

The authors would like to thank Ms. Catherine MacPherson for her editorial assistance in the preparation of this article. The authors also would like to thank Dr. B. Zane Atkins of the University of California, Davis and Dr. Michael Lanuti of the Massachusetts General Hospital with assistance with Case Study content.

Abbreviations

ABTS = American Board of Thoracic Surgery; CT = Computed tomography; EBUS-TBNA = Endobronchial ultrasound-transbronchial needle aspiration; EMR = Endoscopic mucosal resection; EUS = Endoscopic ultrasound; FDA = Food and Drug Administration; HDE = Humanitarian device exemption; IDE = Investigational device exemption; IMRT = Intensity modulated radiation therapy; IRB = Institutional review board; MWA = Microwave ablation; NSQIP = National Surgical Quality Improvement Program; OR = Operating room; PCT = Percutaneous cryotherapy; POEM = Per-oral endoluminal myotomy; RATS = Robotic-assisted thoracic surgery; RFA = Radiofrequency ablation; SBRT = Stereotactic radiotherapy; STS = Society of Thoracic Surgeons; VATS = Video-assisted thoracic surgery
References


Table 1. Five levels of supervision when training for new technology and advanced procedures

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Certifies that the learner attended a lecture or completed a lecture format course (no verification of skills).</td>
</tr>
<tr>
<td>Level 2</td>
<td>Certifies the learner completed a course and was assessed via a test or other evaluation of training and was provided feedback regarding their assessment score (a better model incorporates a minimum pass rate).</td>
</tr>
<tr>
<td>Level 3</td>
<td>Certifies the instructor observed the learner perform a skill and verified completion of task. Alternatively, the learner completed a course and participated in a lecture and skills lab, allowing assessment of the skills on a synthetic or tissue-based model.</td>
</tr>
<tr>
<td>Level 4</td>
<td>Certifies the learner performed the procedure in a patient in a clinical setting with supervision (proctor or preceptor).</td>
</tr>
<tr>
<td>Level 5</td>
<td>Certifies the learner performed a series of clinical cases, the outcomes of which have been reviewed and verified. An example of Level 5 learning may be submitting a series of video-recorded cases with outcomes to a review committee for verification.</td>
</tr>
</tbody>
</table>
Table 2

Examples of new general thoracic technology or advanced procedures that are considered extensions of a thoracic surgeon’s skill set

- Advanced bronchoscopic procedures such as endobronchial ultrasound-transbronchial needle aspiration (EBUS-TBNA), navigational bronchoscopy, and ablation of tumors with laser, placement of airway valves and stents, treatment of the airway for asthma, argon plasma coagulation, cryotherapy, radiofrequency ablation of the airway, microwave ablation of tumors, and placement of brachytherapy catheter or seeds for radiation therapy.

- Advanced foregut interventional endoscopic procedures such as endoscopic ultrasound (EUS), endoscopic mucosal resection (EMR), radiofrequency ablation (RFA), and per-oral endoluminal myotomy (POEM).

- Minimally invasive esophagectomy and foregut surgery including LINX™ reflux management system.

- Video-Assisted Thoracic Surgery (VATS) (e.g. anatomic lung resections, mediastinal surgical procedures).

- Robotic-Assisted Thoracic Surgery (RATS) (e.g. anatomic lung resections, esophagectomy, mediastinal surgical procedures).

Examples of new general thoracic technology or advanced procedures where the thoracic surgeon may play a clinical leadership role as part of a team but is not logically considered an extrapolation of ABTS eligible or certified skill set

- Stereotactic radiotherapy (SBRT).

- CT-guided percutaneous radiofrequency ablation (RFA) and microwave ablation (MWA), and percutaneous cryotherapy (PCT) to the lung.

- Intensity modulated radiation therapy (IMRT) mapping of a tumor (such as mesothelioma) for radiation treatment.
Table 3. Checklist for credentialing

- **Verification of knowledge and skills assessment**
  - ABTS eligible or certified surgeon
  - Documented completion of a course or didactic session
  - For recent graduates of an accredited program, case-logs and a program director letter attesting to competence

- **Team Management**
  - Draft of implementation program complete
  - Education plan for team members complete
  - Crisis management plan complete

- **Institutional collaboration**
  - IRB and/or institutional innovative care/new technology committee approval

- **Monitoring of outcomes**
  - Participation in a continuous quality improvement committee and/or morbidity/mortality conference.
  - Participation in an auditable database (e.g., National Surgical Quality Improvement Program (NSQIP), STS National Database, Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative) or registry or shared database that is accessible by the host institution.
  - Demonstrate ability to present accurate and detailed morbidity and mortality rates to administration upon request.

- **Patient-centered transparency**
  - Provide appropriate consent forms for IRB and/or innovative committee approval
  - Provide the patient information on the risks and benefits of the new procedure, alternative treatments as well as the general costs (i.e. to the patient and/or
payer) and comparative effectiveness of the new technology versus existing
treatment options

- Provide the patient with information on the surgeons training and experience to
date.

ABTS = American Board of Thoracic Surgery; IRB = Institutional review board; STS =
Society of Thoracic Surgeons
Table 4. Case studies using the credentialing pathway

<table>
<thead>
<tr>
<th>Case Study 1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New technology or advanced procedure that is an extension of a thoracic surgeon’s ABTS eligible or certified skill set</strong></td>
</tr>
<tr>
<td>Per-oral endoluminal myotomy (POEM) is an advanced procedure to endoscopically treat achalasia via an endoluminal myotomy. Working together, the gastroenterologists and surgeons at the Mayo Clinic began a process to become credentialed. This credentialing process was initiated by several of the gastroenterologists and surgeons taking formal courses and completing mini-fellowships. After taking didactic courses and then practicing in the skills laboratory, consultants were prepared to present the new technology to the “Clinical Practice Committee”. This committee reviews preparedness and training, balanced with need and a desire to offer safe implementation of new technology, and regularly reviews privileging and credentialing within the main hospital and its affiliates. A database is established to prospectively follow patient outcomes. This technology is now offered to patients that are deemed acceptable candidates. Clinical trials, that require IRB approval, are being initiated to follow patients undergoing this procedure to allow the teams to compare the outcomes against other standard procedures.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New technology or advanced procedure where the thoracic surgeon may play a clinical leadership role as part of a team, but is not logically considered an extension of ABTS eligible or certified skill set</strong></td>
</tr>
<tr>
<td>Radiofrequency ablation is considered an advanced procedure. Using CT guidance, the clinician inserts a probe into a solid tumor, and heat is generated from high frequency alternating current to ablate or destroy the solid tumor tissue. The thoracic surgeons at the Massachusetts General Hospital collaborated with the thoracic radiologists to develop a multidisciplinary approach to the RFA treatment of primary and secondary lung tumors. An implementation plan was developed confirming equipment, number of</td>
</tr>
</tbody>
</table>

22
ablations, patient care and observation on the thoracic surgery service, and cancer surveillance. The thoracic surgeons were instructed on the steps of the procedure by thoracic radiologists. IRB was not necessary as the technology is FDA approved. All patients are presented in a thoracic surgery Morbidity and Mortality conference. A prospective database keeps track of all patients treated with RFA. Comparative modalities, such as SBRT, are discussed with the patient and the treatment team, and the specific case by case role of RFA is determined in a multidisciplinary manner.

Case Study 3

Blended example: A new technology or advanced procedure based on General Thoracic surgery techniques is adopted by an adult cardiac surgeon

Minimally invasive VATS Maze procedure is considered a new technology and advanced procedure. The adult cardiac surgeons at the University of California Davis developed a VATS Maze program by first determining the local need and level of interest with potential clinical collaborators including thoracic surgeons and cardiologists. Based on their clinical experience and ABTS board certification, the adult cardiac surgeons are experts in the "open" or "traditional" approach to the Maze procedure. The surgeons and their team visited other programs as a group to learn their clinical care processes and techniques as regards the VATS Maze. Through these site visits, the surgeons identified an external proctor to oversee the first five cases. The core operating room team, including nurses and anesthesiologists, was the same team for thoracic surgical cases, so they were familiar with VATS equipment. The surgeons informed the patients that the VATS Maze program was a new technology/procedure. The comparative effectiveness of the different approaches to the Maze procedure is discussed with the patients. All cases are discussed in the Cardiothoracic Surgery Division Continuous Quality Improvement meeting. Cases are
recorded as Maze procedures in the STS Adult Cardiac Surgery Database and are immediately available for quality review.

CT = Computed tomography; FDA = Food and Drug Administration; IRB = Institutional review board; RFA = Radiofrequency ablation; VATS = Video-assisted thoracic surgery; STS = Society of Thoracic Surgeons
Appendix I.

Focused Professional Performance Evaluation
For New Physicians and Newly Requested Privileges

Provider Name: ____________________________________________________________

I. Proctoring: by Division Chief (or Appointee) within First Month of Hire Date/New Privileges

<table>
<thead>
<tr>
<th>Major Operative Case (or clinic procedure if primarily clinic-based)</th>
<th>Meets Expectations?</th>
<th>Criteria</th>
<th>Meets Expectations?</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication for Procedure</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>Yes ☐ No ☐</td>
<td>Completion of Surgical Checklist</td>
</tr>
<tr>
<td>General Demeanor</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>Yes ☐ No ☐</td>
<td>Interactions with patients</td>
</tr>
<tr>
<td>Technical Skills</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>Yes ☐ No ☐</td>
<td>Interactions with staff</td>
</tr>
<tr>
<td>Level of Efficiency</td>
<td>Yes ☐ No ☐</td>
<td></td>
<td>Yes ☐ No ☐</td>
<td>Interactions with trainees</td>
</tr>
</tbody>
</table>

Comments:
__________________________________________________________________________
__________________________________________________________________________

Remediation plan (if any expectations above not met):
__________________________________________________________________________
__________________________________________________________________________

Division Chief (or Appointee) ___________________________ Date ____________

II. Case Review with Surgeon-in-Chief and Division Chief: 3-6 Months Post Hire Date/New Privileges

☐ Discussed overall experience to date, issues/concerns, additional support required (provide details)
__________________________________________________________________________
__________________________________________________________________________

☐ Reviewed case log and outcomes of procedures performed during first six months (attach documentation).
  ☐ No concerns to date.
  ☐ Intervention required (explain):
__________________________________________________________________________

Based upon his/her performance, I recommend:
☐ Re-credential for 2 years
☐ Re-credential for _________