NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the <u>submitting standards web page</u>.

NQF #: 0263 NQF Project: Patient Safety Measures-Complications Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Nov 15, 2007 Most Recent Endorsement Date: Nov 15, 2007

BRIEF MEASURE INFORMATION

De.1 Measure Title: Patient Burn

Co.1.1 Measure Steward: Ambulatory Surgical Center Quality Collaboration

De.2 Brief Description of Measure: Percentage of ASC admissions experiencing a burn prior to discharge

2a1.1 Numerator Statement: Ambulatory surgical center (ASC) admissions experiencing a burn prior to discharge.

2a1.4 Denominator Statement: All ASC admissions.

2a1.8 Denominator Exclusions: None

1.1 Measure Type: Outcome 2a1. 25-26 Data Source: Paper Records 2a1.33 Level of Analysis: Facility

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*): Not included in a composite

STAFF NOTES (issues or questions regarding any criteria)

Comments on Conditions for Consideration:

Is the measure untested?	Yes No	If untested, explain how it meets	criteria for consideration	ation for time-limited
endorsement:				

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check D)e.5):
5. Similar/related endorsed or submitted measures (check 5.1):	
Other Criteria:	

Other Chiteria.

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See <u>guidance on evidence</u>.

Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact:

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

De.4 Subject/Topic Areas (Check all the areas that apply): Surgery **De.5 Cross Cutting Areas** (Check all the areas that apply): Safety, Safety : Complications

1a.1 Demonstrated High Impact Aspect of Healthcare: Frequently performed procedure, Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):

As a result of advances in surgery and anesthesia, approximately 80 percent of surgeries in the United States are now performed on an outpatient basis. Ambulatory surgical centers perform approximately 40%, or more than 22 million, of those outpatient surgeries. 1

There are numerous case reports in the literature regarding patient burns in the surgical and procedural setting. The diversity of the causative agents underscores the multitude of potential risks that must be properly mitigated to avoid patient burns. Safety and health care organizations have published guidance and tools for management of these risks and emphasized the importance of reporting burns. 2-9

The literature on burns suggests that electrosurgical burns are most common. Joint Commission Sentinel Alert in 2000 showed in tracking sentinel events "burns from electrocautery uses with a flammable prep solution" as one of the seven most frequent operative and postoperative complications.10 A survey of members of the American College of Surgeons found that 18% of respondents had personally experienced an electrosurgical burn to their patient during laparoscopy.11 A publication from the ECRI highlights the increased risk of burns with newer surgical devices that apply higher currents at longer activation times.12

Although electrical burns are most prevalent, other mechanisms of burn injury are frequently reported in case studies and case series. For example, a case series of 19 patients with intraoperative burn accidents requiring subsequent surgical treatment found that although 13 were caused by electrical burns, 5 were caused by chemical burns and one had an unclear etiology.13 A closed claims analysis of 3000 claims found that of 54 burns, 28 were caused by patient warming devices.14

Surgical fires—fires that occur on or in a surgical patient happen rarely; however, their consequences can be grave, killing or seriously injuring patients and surgical staff and damaging surgical equipment. ECRI has stated, "[e]xtrapolating from data published by the Pennsylvania Patient Safety Authority in 2007, we estimate that 550 to 650 surgical fires occur nationally each year, making the frequency of their occurrence comparable to that of other surgical mishaps (e.g., wrong-site surgery or retained instruments)." In nearly all documented cases, the "classic triangle" of fuel, oxidizer, and ignition was identified retrospectively. ECRI concludes that the majority of patient fires could be prevented if the surgeon and anesthesiologist are aware of the nature of the hazard and how to minimize the risks. 6

1a.4 Citations for Evidence of High Impact cited in 1a.3: 1 U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. http://www.cms.gov/.

2 American National Standards Institute (ANSI). Safe Use of Lasers in Health Care Facilities. ANSI Z136.6. 2005.

3 American Society of Anesthesiologists Task Force on Operating Room Fires, Caplan RA, Barker SJ, et al. Practice advisory for the prevention and management of operating room fires. Anesthesiology 2008 May;108(5):786-801.

4 Anesthesia Patient Safety Foundation (APSF). Prevention and management of surgical fires [video]. February 2010. http://www.apsf.org/resources_video.php. Accessed August 16, 2011.

5 AORN. Fire safety Tool Kit. 2011. http://www.aorn.org/PracticeResources/ToolKits/FireSafetyToolKit/. Accessed August 16, 2011.

6 ECRI Institute. New clinical guide to surgical fire prevention. Health Devices 2009 Oct;38(10):314-32.

7 ECRI. Electrosurgery Checklist. http://www.mdsr.ecri.org/summary/detail.aspx?doc_id=8271. Accessed August 16, 2011.

8 National Fire Protection Association (NFPA). NFPA 99: standard for health care facilities. Quincy (MA): NFPA; 2005.

9 National Quality Forum. Serious Reportable Events in Healthcare 2006 Update. Washington, DC: NQF, 2007.

10 Joint Commission. Joint Commission Sentinel Event Alert. Issue 12 February 4, 2000: Operative and Postoperative Complications: Lessons for the Future. Chicago, IL

11 Tucker RD. Laparoscopic electrosurgical injuries: survey results and their implications.Surg Laparosc Endosc. 1995 Aug;5(4):311-7.

12 ECRI. Higher currents, greater risks: preventing patient burns at the return-electrode site during high-current electrosurgical procedures. Health Devices. 2005 Aug;34(8):273-9.

13 Demir E, O'Dey DM, Pallua N. Accidental burns during surgery. J Burn Care Res. 2006 Nov-Dec;27(6):895-900.

14 Cheney FW, Posner KL, Caplan RA, Gild WM. Burns from warming devices in anesthesia. A closed claims analysis. Anesthesiology 1994 Apr;80(4):806-10.

1b. Opportunity for Improvement: H M L I (There is a demonstrated performance gap - variability or overall less than optimal performance)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

This measure supports the quality improvement vision articulated by the NQF in its "Serious Reportable Events in Healthcare - 2006 Update: A Consensus Report" by giving ASCs a means to consistently measure and publicly report patient burns. As noted in the report, these occurrences are among those included in the list of serious reportable events, "a list of unambiguous, serious, preventable adverse events that concern both the public and healthcare providers and could form the basis for a national reporting system that would lead to substantial improvements in patient safety. The events on the list are identifiable and measurable, and the risk of occurrence of these events raises the awareness of all healthcare organizations regarding the potential for such occurrences and should stimulate the critical review of systems for their prevention."

While the NQF limits patient burns to those that result in patient death or serious disability, we believe there is value in reporting all burns, as any burn may serve as an indication that facility safeguards require review and possible revision.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers): [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

Although data for 1,139 ASCs are included in our public reporting of this indicator, many ASCs report their data to their corporate managing partner. This data is aggregated and reported in total rather than being reported individually by an ASC. As a result, although the ASC QC database includes data for 1,139 facilities for this measure, center-level rates are only available for 491 ASCs. The statistics reported below are based on the 491 individually-reporting ambulatory surgery centers, which are located throughout the US.

The rates for this measure were collected for 491 ambulatory surgery centers throughout the US for services provided during January to March 2011. The rate for patient burns ranged from a minimum of 0.0% to a maximum of 3.2%. The mean rate was 0.01% (SD: 0.01%), while the median rate was 0.00%. The maximum patient burn rate of 3.2% demonstrates that there is an opportunity for improvement in this measure.

This study sample was a convenience sample, which is drawn from ASCs that actively participate in the public quality reporting project sponsored by the ASC Quality Collaboration. Participation in the ASC QC's reporting project is voluntary. Given this, the sample is likely biased toward those ASCs that have taken an interest in the quality measurement and reporting activities of the ASC QC. In addition, those ASCs that volunteer may choose to collect and submit data on a measure-by-measure basis. For this

reason, it is possible that the sample may also be biased towards those with higher levels of performance for this measure.

1b.3 Citations for Data on Performance Gap: [*For <u>Maintenance</u> – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*] A convenience sample of 491 ambulatory surgery centers reporting individual data was selected to assess the opportunity for improvement for this measure. The centers were located throughout the US. Services from the first calendar quarter of 2011 were included in this portion of the study.

1b.4 Summary of Data on Disparities by Population Group: [For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> by population group]

The data the ASC Quality Collaboration currently receives for this measure is collected at the ASC-level or at the level of the corporate parent of the ASC. Corporate parent data submissions combine data from multiple ASCs. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. At this time, the ASC Quality Collaboration does not have access to any patient-level or individual population level data that would allow for analysis of subpopulation disparities based on race, sex and age. However, we understand the importance of subpopulation data and are taking steps that would allow us to collect the necessary data. We are actively pursuing the development of a registry that would allow us to develop subpopulation performance data for this measure and others. Potential registry development vendors have been identified and initial communications regarding the project have already taken place. We plan to select a vendor by third quarter of 2011, initiate the development of the registry database immediately upon contract acceptance, and have a functioning registry three months thereafter.

1b.5 Citations for Data on Disparities Cited in 1b.4: [For <u>Maintenance</u> – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]

Not available.

As stated in 1b4: The data the ASC Quality Collaboration currently receives for this measure is collected at the ASC-level or at the level of the corporate parent of the ASC. Corporate parent data submissions combine data from multiple ASCs. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. At this time, the ASC Quality Collaboration does not have access to any patient-level or individual population level data that would allow for analysis of subpopulation disparities based on race, sex and age. However, we understand the importance of subpopulation data and are taking steps that would allow us to collect the necessary data. We are actively pursuing the development of a registry that would allow us to develop subpopulation performance data for this measure and others. Potential registry development vendors have been identified and initial communications regarding the project have already taken place. We plan to select a vendor by fourth quarter of 2011, initiate the development of the registry database immediately upon contract acceptance, and have a functioning registry three months thereafter.

1c. Evidence (<i>Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.</i>)					
Is the measure focus a health outcome? Yes No If not a health outcome, rate the body of evidence.					

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?		
M-H	M-H	M-H	Yes		
L	M-H	М	Yes IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No		
M-H	L	M-H	Yes IF potential benefits to patients clearly outweigh potential harms: otherwise No		
L-M-H	L-M-H	L	No 🗌		
Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service			Does the measure pass subcriterion1c? Yes IF rationale supports relationship		

1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome):

This measure focuses on an intermediate clinical outcome. Managing burn risk helps ensure optimal patient safety and the desired health outcome from the surgical intervention.

1c.2-3 Type of Evidence (Check all that apply):

Clinical Practice Guideline, Other, Selected individual studies (rather than entire body of evidence) Expert opinion as reflected in publications such as position statements and consensus reports; State adverse event database reports

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population): The body of evidence addresses the frequency and harm associated with burns in the surgical setting, as well as the processes and effectiveness of those processes to assure patient safety from burns in the surgical setting.

This measure focuses on the frequency with which burns occur in ASCs.

1c.5 Quantity of Studies in the Body of Evidence (Total number of studies, not articles): Over 100

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): There is certainty that burns are harmful to patients. There is agreement that even when the event does not result in significant bodily harm, there is a loss of confidence that is harmful.

The evidence speaks directly to this measure, though it is not limited to ambulatory surgical centers.

Estimates of the frequency of burns vary in the body of evidence. These variations reflect the uncommon occurrence of these events.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Estimates of the frequency of the different types of iatrogenic burns vary in the body of evidence. These variations reflect the uncommon occurrence of these events.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

The literature suggests that efforts (such as improving equipment safety) to reduce these events are beneficial. The magnitude of the impact of these efforts has not been quantitated. There is no evidence to indicate that harm has resulted from efforts to reduce the incidence of patient burns.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: Body of evidence not graded.

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: Body of evidence not graded

1c.13 Grade Assigned to the Body of Evidence: Body of evidence not graded

1c.14 Summary of Controversy/Contradictory Evidence: No controversy or contradictory evidence reported.

1c.15 Citations for Evidence other than Guidelines *(Guidelines addressed below)*: Aly A, McIlwain M, Duncavage JA: Electrosurgery-induced endotracheal tube ignition during tracheotomy. Ann Otol Rhinol Laryngol 1991; 100:31–3

Airway fires during surgery. PA-PSRS Patient Safety Advisory 2007; 4:1-4

Anderson EF: A potential ignition source in the operating room. Anesth Analg 1976; 55:217-8

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Axelrod EH, Kusnetz AB, Rosenberg MK: Operating room fires initiated by hot wire cautery. ANESTHESIOLOGY 1993; 79:1123-6

Bailey MK, Bromley HR, Allison JG, Conroy JM, Krzyzaniak W: Electrocautery-induced airway fire during tracheostomy. Anesth Analg 1990; 71:702–4

Barker SJ, Polson JS: Fire in the operating room: A case report and laboratory study. Anesth Analg 2001; 93:960–5

Barnes AM, Frantz RA: Do oxygen-enriched atmospheres exist beneath surgical drapes and contribute to fire hazard potential in the operating room? AANA J 2000; 68:153–61

Baur DA, Butler RC: Electrocautery-ignited endotracheal tube fire: Case report. Br J Oral Maxillofac Surg 1999; 37:142–3

Bennett JA, Agree M: Fire in the chest. Anesth Analg 1994; 78:406

Boyd CH: A fire in the mouth: A hazard of the use of antistatic endotracheal tubes. Anaesthesia 1969; 24:441-6

Burgess GE III, LeJeune FE Jr: Endotracheal tube ignition during laser surgery of the larynx. Arch Otolaryngol 1979; 105:561–2

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Casey KR, Fairfax WR, Smith SJ, Dixon JA: Intratracheal fire ignited by the Nd-YAG laser during treatment of tracheal stenosis. Chest 1983; 84:295–6

Chang BW, Petty P, Manson PN: Patient fire safety in the operating room. Plast Reconstr Surg 1994; 93:519–21

Chee WK, Benumof JL: Airway fire during tracheostomy: Extubation may be contraindicated. ANESTHESIOLOGY 1998; 89:1576-8

Chiang YC, Lin TS, Yeh MC. Povidone-iodine-related burn under the tourniquet of a child--a case report and literature review. J Plast Reconstr Aesthet Surg. 2011 Mar;64(3):412-5.

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Datta TD: Flash fire hazard with eye ointment. Anesth Analg 1984; 63: 700-1

Dhar V, Young K, Nouraei SA, et al. Impact of oxygen concentration and laser power on occurrence of intraluminal fires during shared-airway surgery: an investigation. J Laryngol Otol 2008 Dec;122(12):1335-8.

Dini GM, Casagrande W: Misfortune during a blepharoplasty. Plast Recon- str Surg 2006; 117:325-6

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Eade GG: Hazard of nasal oxygen during aesthetic facial operations. Plast Reconstr Surg 1986; 78:539

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

ECRI Institute. New clinical guide to surgical fire prevention. Health Devices 2009 Oct;38(10):314-32.

Epstein RH, Brummett RR Jr, Lask GP: Incendiary potential of the flashlamp pumped 585-nm tunable dye laser. Anesth Analg 1990; 71:171–5.

Fire hazard created by the misuse of DuraPrep solution. Health Devices 1998;27:400–2

Galapo S, Wolf GL, Sidebotham GW, Cohen D: Laser ignition of surgical drapes in an oxygen enriched atmosphere (abstract). ANESTHESIOLOGY 1998; 89: A580

Greco RJ, Gonzalez R, Johnson P, Scolieri M, Rekhopf PG, Heckler F: Potential dangers of oxygen supplementation during facial surgery. Plast Recon- str Surg 1995; 95:978–84

Gunatilake DE: Case report: Fatal intraperitoneal explosion during elec- trocoagulation via laparoscopy. Int J Gynaecol Obstet 1978; 15:353–7

Gupte SR: Gauze fire in the oral cavity: A case report. Anesth Analg 1972; 51:645-6

Handa KK, Bhalla AP, Arora A: Fire during the use of Nd-Yag laser. Int J Pediatr Otorhinolaryngol 2001; 60:239–42

Healy GB, Strong MS, Shapshay S, Vaughan C, Jako G: Complications of CO2 laser surgery of the aerodigestive tract: Experience of 4416 cases. Otolaryngol Head Neck Surg 1984; 92:13–8

Herman MA, Laudanski K, Berger J. Surgical fire during organ procurement. Internet J Anesth 2009;19(1).

Hirshman CA, Smith J: Indirect ignition of the endotracheal tube during carbon dioxide laser surgery. Arch Otolaryngol 1980; 106:639–41

Howard BK, Leach JL: Prevention of flash fires during facial surgery performed under local anesthesia. Ann Otol Rhinol Laryngol 1997; 106:248–51

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Prasad R, Quezado Z, St. Andre A: Fires in the operating room and intensive care unit: Awareness is the key to prevention. Anesth Analg 2006; 102:172–4

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1c.16 Quote verbatim, <u>the specific guideline recommendation</u> (*Including guideline # and/or page #*): AORN has developed several standards and recommended practices pertinent to this measure:

Recommended Practices for Electrosurgery Recommendation II The ESU should be used in a manner that minimizes the potential for injuries.

Electrosurgical units are high-risk equipment.1 Potential complications of electrosurgery include patient injuries, user injuries, fires, and electromagnetic interference with other medical equipment and internal electronic devices.2 Electrosurgery safety is heightened by adhering to good practices.18 Adverse events (eg, patient burns and fires) may be reduced by adhering to basic principles of electrosurgery safety.15

Recommendation IV

The active electrode should be used in a manner that minimizes the potential for injuries.

IV.j. Fire safety measures should be followed when electrosurgery is in use according to local, state, and federal regulations.36,37

IV.j.1. Active electrodes should not be activated in the presence of flammable agents (eg, antimicrobial skin prep or hand antisepsis agents, tinctures, de-fatting agents, collodion, petroleum-based lubricants, phenol, aerosol adhesives, uncured methyl methacrylate) until the agents are dry and vapors have dissipated.2,38-42 Alcohol-based prep agents remain flammable until completely dry. Vapors occurring during evaporation also are flammable. Trapping of solution or vapors under incise or surgical drapes increases the risk of fire or burn injury. Alcohol-based skin prep agents are particularly hazardous because the surrounding hair or fabric can become saturated. Pooling can occur in body folds and crevices (eg, umbilicus, sternal notch). Ignition of flammable substances by active electrodes has caused fires and patient injuries. Flammable prep agents can be safely used by adhering to NFPA standards, local fire codes, and AORN recommendations and guidance statements. Use of nonflammable prep agents will minimize this risk.16,42-46

IV.j.2. Caution should be used during surgery on the head and neck when using an active electrode in the presence of combustible anesthetic gases.2,44,47

IV.m. Electrosurgery should not be used in the presence of gastrointestinal gases. Gastrointestinal gases contain hydrogen and methane, which are highly flammable. Fires and patient injuries have occurred.16,28,40,51,52

IV.n. Electrosurgery should not be used in an oxygen-enriched environment.28,32,53-55 An oxygen-enriched environment lowers the temperature and energy at which fuels will ignite.28,48 Fires, including airway fires, have resulted from the active electrode sparking in the presence of concentrated oxygen.2,16,53,54

IV.n.1. The lowest possible oxygen concentration that provides adequate patient oxygen saturation should be used.47,48 Mixing oxygen with nonflammable gases such as medical air reduces the risk of fire.16,47

IV.n.2. Surgical drapes should be arranged to minimize the buildup of oxidizers (eg, oxygen and nitrous oxide) under the drapes, to allow air circulation, and to dilute the additional oxygen.16,47,48

IV.n.3. The active electrode should be used as far from the oxygen source as possible.

IV.o. Personnel should be prepared to immediately extinguish flames should they occur.16,47

IV.j.3. Opened suture packets containing alcohol should be removed from the sterile field as soon as possible.16 Ignition of flammable substances by an active electrode has caused fires and patient injuries.16,43

IV.k. Sponges used near the active electrode tip should be moist to prevent unintentional ignition.32,47,48 Fires have resulted from ignition of dry sponges near the incision site.16,49,50

Recommended Practices for Laser Safety in Practice Settings

Recommendation VII

All people in the laser treatment area should be protected from flammable hazards associated with laser use.

VII.a. Fire safety measures should be followed when lasers are in use according to local, state, and federal regulations.36,37 Lasers are a potential ignition and fire source in the perioperative environment.11

VII.a.1. The laser should not be activated in the presence of flammable agents (eg, antimicrobial skin prep or hand antisepsis agents, tinctures, de-fatting agents, collodion, petroleum-based lubricants, phenol, aerosol adhesives, uncured methyl methacrylate) until the agents are dry and vapors have dissipated.11,33,38-41 Alcohol-based prep agents remain flammable until they are completely dry. Vapors occurring during evaporation also are flammable. Trapped solution or vapors under clear, adhesive, or surgical drapes increases the risk of fire or burn injury.40 Alcohol-based skin prep agents are particularly hazardous because the surrounding hair or fabric can become saturated. Pooling can occur in body folds and crevices (eg, umbilicus, sternal notch). Ignition of flammable substances by lasers has caused fires and patient injuries. Flammable prep agents can be safely used by adhering to National Fire Protection Agency standards, local fire codes, and AORN recommendations and guidance statements. Use of nonflammable prep agents will minimize this risk.20,37,38,41

VII.a.2. Caution should be used when using a laser in the presence of combustible anesthetic gases during surgery on the head, face, neck, and upper chest.11,34,39,42 The intense heat of laser beams can ignite combustible or flammable solids, liquids, and gases.34 The presence of increased oxygen concentrations enhances combustion and leads to the rapid spread of flames.42

VII.a.3. When using a laser, sponges and drapes near the surgical site should be kept moist.3,4,11,27,33,35,43,44 In an oxygenenriched environment, the high energy delivery of a laser will burn anything combustible or flammable. 11,44 The fire triangle requires an ignition source (eg, the laser); an oxidizer (eg, the oxygen enriched environment); and fuel (eg, surgical drapes). Moistening draping materials decreases the potential for fire.4

VII.a.4. During perineal surgery, moistened radiopaque sponges may be used for rectal packing or covering the anus.1,4,7 Moist packing prevents the release of methane gas from the rectum. Methane gas is highly flammable and potentially explosive.3,4,7

VII.b. Laser surgery should not be performed in an oxygen-enriched environment.11,34 An oxygen-enriched environment lowers the temperature and energy at which fuels will ignite.8,33,40,42 Fires, including airway fires, have resulted from the laser sparking in the presence of concentrated oxygen.8

VII.c. Personnel should be prepared to immediately extinguish flames should they occur.11

VII.c.1. Wet towels and saline should be available on the sterile field to extinguish a fire should one occur.4,6

VII.d. Fuel risks should be minimized.11 Many of the materials and solutions used in the perioperative setting are potential fuel sources (eg, prepping agents, linens, dressings, ointments, anesthesia components).11

VII.d.1. Flammable prep solution should have enough time to evaporate before drapes are applied.11,43 Prep solutions can be absorbed into linens and body fibers (eg, hair). Alcohol-based skin prep vapors can become trapped under drapes and coverings, and the volatility of these vapors can increase the risk of surgical drape fires.11 VII.d.2. Pooled solutions should be removed or patted dry.4,11 VII.e. The LSO should determine the type of extinguisher needed for each specific laser based on manufacturers' suggestions.44 VII.e.1. Fire extinguishers and saline should be immediately available where lasers are used.1,4,7 Immediate action can reduce the magnitude of injury.1 VII.f. Laser-resistant endotracheal tubes should be used to minimize the potential for fire during laser procedures involving the patient's airway or aerodigestive tract.1,7,8,10,11,34,35,42,43,49 Polyvinylchloride (PVC), silicone, and red rubber endotracheal tubes are combustible. 1,4,8,34,49 Burned PVC produces hydrochloric acid and harmful vapors.1,42 Burned red rubber tubes produce carbon monoxide.1 An airway fire may result in damage to the trachea and lungs, severe injury, and death.8,49 VII.g. The airway fire management procedure should be posted in laser treatment areas.49 VII.h. Surgical fires should be reported as a sentinel event to the appropriate agency (eq. FDA, state health department, certifying body, local fire department, ECRI).43,51 Reporting surgical fires raises awareness about hazards and adds to the body of prevention knowledge.52 Recommended Practices for Preoperative Patient Skin Antisepsis **Recommendation VI** Protective measures should be implemented to prevent skin and tissue injury due to prolonged contact with skin prep agents. (PNDS: 194, 198, 185, 1138, 175, 170) Chemical burns and skin irritations are more likely when antiseptic solutions are not allowed to dry and remain in contact with the skin for prolonged periods of time.22,3,56 The iodine in povidone-iodine prep solutions remains free until it has dried and can chemically irritate the skin. The use of forced-air warming under the surgical drapes adds heat to antiseptic solutions, which may increase the likelihood of a chemical or thermal injury. In a series of povidone iodine burns, authors reported burns resulting from soaked linen, soaked adhesive tape, drips on padding under tourniquet cuffs, solution running off surgical sites and onto the patients' backs. and a povidone-iodine-soaked gauze being used to cover an epidural site during surgery.56 VI.b. Electrodes, including the ESU dispersive electrode, should be protected from dripping or pooling of antiseptic agents. (PNDS: 1122, 175, 172) Antiseptic solutions contacting these electrical devices may cause chemical or thermal burns. VI.c. If a tourniquet is used, the cuff, padding, and skin under the cuff should be protected. Antiseptic solutions contacting tourniquet cuffs are compressed against and occlude the skin, increasing the likelihood of a chemical burn. **Recommendation VIII** If a flammable prep agent is used, additional precautions should be taken to minimize the risk of a surgical fire and patient burn injury. (PNDS: 176, 175, 1122) Using flammable skin prep agents in the operating room or procedural area poses a serious risk of fire because of the common use of ignition and heat sources (eg, electrosurgery, lasers, drills, fiberoptic cables). VIII.a. Perioperative personnel should be familiar with the flammability characteristics of all prep agents stored or used in the patient care area. (PNDS: 1122) Fires have resulted when personnel did not know or remember that a prep agent was flammable and used a heat source during the procedure.68

VIII.b. When flammable prep agents are used, they should be packaged in small quantities appropriate for a single application or be prepackaged in a unit dose.63,67 (PNDS: 1122) Packaging in small quantities may minimize the risk of soaking materials adjacent to the prepped area and limits the amount left over for disposal.

371

VIII.c. The prep agent should not contact fabric or be allowed to pool on or under body parts (eg, umbilicus, groin). (PNDS: 175, 176, 1122) Solution in contact with fabric may not dry adequately. Pooled prep agents require longer periods of time for evaporation.

VIII.d. If pooling occurs, the excess solution should be wicked away. Any solution-soaked materials should be removed from the procedure room before draping or using electrosurgery, laser, or other heat source.63,64,67 (PNDS: 175, 176, 1122) Wicking solution away from pooled areas allows the remaining solution to dry adequately.

Solution-soaked materials are easily ignitable, and removal from the operating room minimizes the risk of fire.

VIII.e. The prep agent should be allowed to dry and vapors to dissipate before application of an incise drape or surgical drape, or use of electrosurgery, laser, or other heat source.62-64 (PNDS: I75, I76, I122)

VIII.f. The use of a flammable prep agent should be discussed during the "time out" period used to verify the surgical procedure and site. (PNDS: 175, 176, 1122) Active communication about the use of flammable prep agents alerts all personnel to the inherent risks and verifies that appropriate precautions have been taken. At times, the person operating the heat (ie, ignition) source may be unaware that a flammable prep agent was used. Active communication prevents this misunderstanding.

VIII.g. Disposal of unused flammable prep agents must be handled in a manner to decrease the risk of fire and in accordance with federal, state, and local regulations. (PNDS: I138, I122)

VIII.h. Flammable skin preparation agents should not be heated. (PNDS: I122)

Recommended Practices for Safe Environment of Care

Recommendation IV

Potential hazards associated with the use of electrical equipment in the practice setting should be identified, and safe practices should be established. (PNDS: I138)

IV.c. Isolated power systems should be considered for operating rooms, which may be considered wet locations.16 (PNDS: I138) Adequate grounding provides protection from electric shock and fire hazards.16

IV.d. Line-isolation monitors should be provided for each isolated power system to indicate possible leakage or faulty currents.16,17 Line-isolation monitoring systems or ground-fault interrupting systems provide for continuous monitoring of current leakage. Systems that monitor current leakage and ground integrity reduce the hazards of shock, cardiac fibrillation, or burns produced by electrical current flowing through the patient's body to ground.16,17

Recommendation VIII

Blanket- and solution-warming cabinet temperatures should be controlled.

The danger of thermal burns from heated blankets or solutions is increased in the perioperative setting because patients are unconscious or sedated and cannot feel the increase in temperature or communicate their discomfort.

VIII.a. The warming cabinet temperature should be checked at regular intervals per the organization's policy and documented on a temperature log or recorded on a record provided by an electronic recording system.31-33 (PNDS: I122)

VIII.b. Solution-warming cabinet temperatures should be limited to the solution manufacturer's specifications for warming.32 The fluid manufacturer's recommendations should be obtained and followed for the maximum temperature and length of time fluids should remain in the warming cabinet. (PNDS: I122)

VIII.c. Intravenous (IV) fluid or irrigation fluid bags should not be used for patient warming devices. (PNDS: I122) Warmed IV bags used as warming devices have led to patient burns.36 In a closed claims study of intraoperative patient burns, the

most common device causing the burn was either heated IV bags or bottles of irrigation fluids.33

VIII.d. Fluids used for intracorporeal irrigation should not exceed 98.6° F (37° C) or approximate normal body temperature.35,37,38

VIII.e. Surgical skin prep solutions should not be warmed in warming cabinets unless stated as allowable in the manufacturer's directions. (PNDS: I122)

Recommendation IX

Potential hazards associated with fire safety in the practice setting should be identified, and safe practices should be established. Fire is always a risk to both patients and healthcare workers in the operating room.

IX.a. A written fire prevention and management plan should be developed by a multidisciplinary group and include all categories of perioperative personnel.

IX.b. Ignition sources should be controlled. (PNDS: I72, I73, I77)

IX.b.1. The active electrode tip of the ESU should be kept clean and in a holster when not in use.

IX.b.2. Electrosurgical units provide an ignition source when not used according to manufacturers' recommendations and when active electrodes are used in the presence of oxidizers, flammable solutions, and volatile or combustible chemicals or liquids.

IX.b.3. Lasers should be used with wet towels placed around the surgical site and after flammable prep solutions have dried.40

IX.b.4. The ends of an active fiber-optic light cable should not come in contact with surgical drapes. Fiber-optic light cables provide an ignition source if they are disconnected from the working element or light source and allowed to contact drapes, sponges, or other fuel sources.

IX.b.5. Light cables should be connected before activating the light source.

IX.b.6. The light source should be placed into a stand-by mode when not in use to prevent ignition. Backing into the light source or turning the fiber-optic light cable toward the body may cause surgical attire to ignite.41

IX.c. Personnel should move any equipment that emits smoke at any time, whether in use or not, to a safe area.42

IX.d. Fuel sources should be controlled. (PNDS: 172, 173)

IX.d.1 Waterless, brushless, surgical-scrub solutions should be allowed to dry completely to decrease the potential to produce ignition by static electricity or sparks.

IX.d.2. Local and state fire regulations regarding storage of alcohol-based, surgical scrub solutions and hand sanitizers should be followed.14

IX.d.3. Provide adequate time for the flammable surgical prep solution to dry completely and any fumes to dissipate before applying surgical drapes, using an active electrode or laser, or activating a fiber-optic light cable.43-45

IX.d.4. Prevent prep solutions from pooling, or soaking into the table linens or the patient's hair by

· using reusable or disposable sterile towels to absorb drips and excess solutions during the skin prep application,

· removing materials saturated with prep solution before draping the patient,14 and

wicking excess solution with a sterile towel to facilitate the surgical prep area drying completely.14,46,47

IX.d.5. Drapes should not be applied until prep solutions are dry, to prevent the accumulation of volatile fumes beneath them.

IX.d.7. Gowns and drapes should not be exposed to ignition sources.

IX.e. Oxidizers should be controlled. (PNDS: I72, I73)

IX.e.1. Oxygen and nitrous oxide should be used with caution in the presence of any ignition or fuel sources.

IX.e.2. Oxygen-enriched environments are created when the oxygen concentration is greater than 21%. This lowers the temperature and energy at which fuels will ignite.48,49

IX.e.3. Anesthesia circuits should be free of leaks.

IX.e.4. Electrosurgical units and lasers should be used with caution where oxygen is flowing.

223

IX.e.5. Suction should be used to evacuate anesthetic gas accumulation.

IX.e.6. When using a laser, only laser-resistant endotracheal tubes should be used for upper airway procedures or procedures near the trachea.40,48

IX.e.7. For surgeries involving the head and neck, water-soluble substances should be used to cover facial hair.50

IX.e.8. Oxygen concentration under drapes should be minimized by

· tenting of drapes, and

• using the lowest possible oxygen concentration that provides adequate patient oxygen saturation.14,40,48,51,52 Mixing oxygen with nonflammable gases such as medical air reduces the risk of fire.17,40,50

IX.e.9. Precautions should be taken when operating in the gastrointestinal tract because hydrogen and methane, which are flammable gases, may be present.50

IX.e.10. Nitrous oxide should be considered an oxidizer, and the same precautions that are used with oxygen should be observed.42

IX.f. Risk of airway fires should be minimized by

- using radiopaque wet sponges in the back of the throat to prevent or decrease oxygen leaks;
- inflating endotracheal tube cuffs with tinted solutions to improve visibility in the event of a cuff rupture;
- using suction to evacuate oxygen buildup;
- tenting drapes to prevent the accumulation of gases; and
- using pulse oximetry to evaluate the patient's optimal oxygen saturation level.17,40,50 (PNDS: 173)

IX.g. Processes should be in place to regularly inspect, test, and maintain fire extinguishing equipment and supplies.

1c.17 Clinical Practice Guideline Citation: Perioperative Standards and Recommended Practices, 2011 Edition. Association of periOperative Registered Nurses (AORN).

1c.18 National Guideline Clearinghouse or other URL: http://www.aorn.org/PracticeResources/AORNStandardsAndRecommendedPractices/

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: Guidelines not graded

1c.23 Grade Assigned to the Recommendation: Guidelines not graded

1c.24 Rationale for Using this Guideline Over Others: The AORN Perioperative Standards and Recommended Practices address a broad array of burn risks and their management. Other guidelines, such as the "Practice Advisory for the Prevention and Management of Operating Room Fires" by the American Society of Anesthesiologists Task Force on Operating Room Fires (Anesthesiology 2008; 108:786-801) and the European Society of Gastrointestinal Endoscopy guideline on the use of electrosurgical units (available at

http://www.esge.com/assets/downloads/pdfs/guidelines/2010_the_use_of_electorsurgical_units.pdf), are more limited in their scope and were therefore not selected.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: High 1c.26 Quality: Moderate1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met? (1a & 1b must be rated moderate or high and 1c yes) Yes No Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See <u>guidance on measure testing</u>.

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: http://ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)

2a1.1 Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome): Ambulatory surgical center (ASC) admissions experiencing a burn prior to discharge.

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*): In-facility, prior to discharge

2a1.3 Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses: DEFINITIONS:

Admission: Completion of registration upon entry into the facility.

Burn: Unintended tissue injury caused by any of the six recognized mechanisms: scalds, contact, fire, chemical, electrical, or radiation (e.g. warming devices, prep solutions, electrosurgical unit, or laser).

Discharge: Occurs when the patient leaves the confines of the ASC.

2a1.4 Denominator Statement (Brief, narrative description of the target population being measured):

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

All ASC admissions.

2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Adult/Elderly Care, Children's Health

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*): In-facility, prior to discharge

2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): DEFNITIONS:

Admission: Completion of registration upon entry into the facility.

2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population): None

2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): No denominator exclusions

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses): This measure is not stratified

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.): None.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): Better quality = Lower score

2a1.20 Calculation Algorithm/Measure Logic(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

The number of admissions experiencing a burn prior to discharge is divided by the number of ASC admissions during the reporting period, yielding the rate of burns prior to discharge for the reporting period.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): The measure is not based on a sample

2a1.25 Data Source (Check all the sources for which the measure is specified and tested). If other, please describe: Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): ASC medical records, as well as incident/occurrence reports, and variance reports may serve as data sources. No specific collection instrument is required although the ASC Quality Collaboration has developed a sample data collection instrument that may be used as desired. Facilities may use any collection instrument that allows tracking of all burns prior to discharge.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL http://ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf Not needed

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment: URL

http://ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf Not needed

2a1.33 Level of Analysis (Check the levels of analysis for which the measure is specified and tested): Facility

2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): Ambulatory Care : Ambulatory Surgery Center (ASC)

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

A convenience sample of 22 ambulatory surgery centers was selected for a retrospective chart audit comparing the reported values for the measure versus the values identified from the medical record. The centers were located in eight different states throughout the US. Services from April 1, 2010 to September 30, 2010 were reviewed in the course of the reliability testing.

2a2.2 Analytic Method (Describe method of reliability testing & rationale):

The numerator number of Ambulatory Surgery Center (ASC) admissions experiencing a burn prior to discharge and denominator (number of ASC admissions) values were compared for all 22 centers in the sample.

2a2.3 Testing Results (*Reliability statistics, assessment of adequacy in the context of norms for the test conducted*): The error rates at all 22 of the ASCs (100%) were zero for both the numerator and denominator. The results show an excellent level of reliability with an overall 100% accuracy rate.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence: In light of the evidence indicating the broad range of risks that must be managed in the ASC setting, the measure specifications include all burn injury mechanisms. The measure also evaluates all patients due to the relative infrequency of these events.

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Validity was measured via a formal consensus process. A questionnaire that included ratings of the various characteristics of the measure was distributed to 8 clinicians (RNs), who currently work in ambulatory surgery centers or have responsibility for multiple

surgery centers, two have credentials in quality and the others are involved in quality in their current positions. Responses were received from 7 of the panel members.

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment): Validity was measured via a formal consensus process. All seven respondents responded with a 5/5 rating for the question most related to content validity for this measure. Due to the high level of consensus on the primary validity question, multiple rounds of Delphi-type evaluations were not necessary. These results demonstrate a high level of agreement around the validity of the measure.

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):

Each attribute was measured on a 5 point Likert Scale. The attributes related to validity and average scores are listed below: 1. The measure appears to measure what it is intended to. (Median: 5.0/5.0; Mean: 5.0/5.0)

2. The measure is defined in a way that will allow for consistent interpretation of the inclusion and exclusion criteria from center to center. (Median: 5.0/5.0; Mean 4.9/5.0)

3. The data required for the measure are likely to be obtained with reasonable effort. (Median: 5.0/5.0; Mean: 5.0/5.0)

4. The data required for the measure are likely to be obtained with reasonable cost. (Median: 5.0/5.0; Mean: 5.0/5.0)

5. The data required for the measure can be generated during care delivery. (Median: 5.0/5.0; Mean: 5.0/5.0)

POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

2b3. Measure Exclusions. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)

2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): There are no measure exclusions

2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):

There are no measure exclusions

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*): Not applicable

2b4. Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)

2b4.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

The measure is not risk adjusted

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):

The measure is not risk adjusted

2b4.3 Testing Results (Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata): Not applicable

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: A burn should be a rare event if appropriate processes are in place. Risk adjustment for patient or procedure characteristics would mask any measurement of performance difference. Thus we believe this measure should not be risk adjusted.

2b5. Identification of Meaningful Differences in Performance. (The performance measure scores were appropriately analyzed

and discriminated meaningful differences in quality.)

2b5.1 Data/Sample (Describe the data or sample including number of measured entities: number of patients; dates of data; if a sample, characteristics of the entities included):

Although data for 1,139 ASCs are included in our public reporting of this indicator, many ASCs report at the corporate level and do not report data for their individual centers. The database includes center-level rates for this measure for 491 ASCs throughout the US. The statistics reported below include rates for this measure based on the 491 individually-reporting ambulatory surgery centers throughout the US.

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

Patient burns are a serious reportable event. As such, an individual ASC's rate for patient burns should be compared to a rate of zero. A statistically significant difference in performance may be detected by using a standard test of proportions as outlined in most standard statistical texts.

2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

The rate for patient burns ranged from a minimum of 0.0% to a maximum of 3.2%. The mean rate was 0.01% (SD: 0.01%), while the median rate was 0.00%. The maximum patient burn rate of 3.2% demonstrates that there is an opportunity for improvement in this measure.

2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

This measure is specified for a single data source (paper medical record/flow sheet)

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure): Not applicable

2b6.3 Testing Results (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

Not applicable

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): This measure is not stratified

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

The data the ASC Quality Collaboration currently receives for this measure is collected at the ASC-level or at the level of the corporate parent of the ASC. Corporate parent data submissions combine data from multiple ASCs. Disparity measures by population group require the collection of patient-level data or collection of the data for individual populations of patients. At this time, the ASC Quality Collaboration does not have access to any patient-level or individual population level data that would allow for analysis of subpopulation disparities based on race, sex and age. However, we understand the importance of subpopulation data and are taking steps that would allow us to collect the necessary data. We are actively pursuing the development of a registry that would allow us to develop subpopulation performance data for this measure and others. Potential registry development vendors have been identified and initial communications regarding the project have already taken place. We plan to select a vendor by the end of 2011, initiate the development of the registry database immediately upon contract acceptance, and have a functioning registry three to six months thereafter.

In addition, a federal quality reporting system has not yet been implemented for ambulatory surgical centers. Based on recent proposals from the CMS, we anticipate the agency will begin implementing an ASC quality reporting system in 2012 and that the

measure set for the quality reporting system might include this measure. When the system is implemented and if this measure is included in the measure set, patient level demographic data could be collected in association with ASC data on patient burns, allowing for the detection of any disparities.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (*Reliability and Validity must be rated moderate or high*) Yes No Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following *questions*): Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (*If used in a public reporting program, provide name of program(s), locations, Web page URL(s)*). <u>If not publicly reported in a national or community program</u>, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [For <u>Maintenance</u> – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

The ASC Quality Collaboration posts a public report of quality data on six ASC quality measures endorsed by the NQF on a quarterly basis. This quarterly report includes aggregated performance data on the Patient Burn measure. The report for the first quarter of 2011 is available at: http://www.ascquality.org/qualityreport.cfm. One thousand one hundred thirty-nine (1,139) ASCs submitted patient burn data for the first quarter 2011 report.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. <u>If usefulness was demonstrated</u> (e.g., focus group, cognitive testing), describe the data, method, and results: The patient burn rate is similar to measures reported by CMS on the Hospital Compare website. The concept of rates and percentages is commonly used in public reporting of health care and other quality indicators. This measure has an easy to understand numerator and denominator and is easily interpreted by healthcare professionals as well as lay-persons.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): The Centers for Medicare and Medicaid Services has proposed to include this measure in its ASC Quality Reporting Program. Please see CMS-1525-P, Section XIV.K.3.a.(1) at http://www.gpo.gov/fdsys/pkg/FR-2011-07-18/pdf/2011-16949.pdf.

3b. Usefulness for Quality Improvement: H M L I I (*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):

[For <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

This measure is in use in several other initiatives. For example, the ASC Association includes this metric in its Outcomes Monitoring Project, which is described at http://www.ascassociation.org/outcomes/.

It is also in use in various state association quality data collection and reporting projects, including the Texas Ambulatory Surgery Center Association, located at http://tascs.org/.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (e.g., *Ql initiative*), describe the data, method and results:

The patient burn rate is similar to measures reported by CMS on the Hospital Compare website. The concept of rates and percentages is commonly used in public reporting of health care. The definition of the indicator allows individual ASCs to calculate their rate and compare directly with the benchmark rates posted to the ASC Quality website.

Overall, to what extent was the criterion, *Usability*, met? H M L I Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (*Check all that apply*). Data used in the measure are:

generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H M L

4b.1 Are the data elements needed for the measure as specified available electronically (*Elements that are needed to compute measure scores are in defined, computer-readable fields*): No data elements are in electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources: Widespread adoption of electronic health records in ambulatory surgical centers would be needed to achieve electronic capture of data elements.

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results: Experience with this measure and feedback from users indicates that it is easy to use and has limited susceptibility to inaccuracies and errors. Reliability is very high. The ASC Quality Collaboration is not aware of any unintended consequences as a result of the use of this measure.

4d. Data Collection Strategy/Implementation: H M L I

A.2 Please check if either of the following apply (regarding proprietary measures): Proprietary measure

4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (e.g., fees for use of proprietary measures):

The ASC Quality Collaboration has included "Frequently Asked Questions" in the Implementation Guide for the measure to assist users in their implementation of data collection.

Overall, to what extent was the criterion, *Feasibility*, met? H M L I Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures (*either same measure focus or target population*) or competing measures (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as <u>NQF-endorsed measure(s)</u>: Are the measure specifications completely harmonized?

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (*Provide analyses when possible*):

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Ambulatory Surgical Center Quality Collaboration, 5686 Escondida Blvd S, St. Petersburg, Florida, 33715

Co.2 Point of Contact: Donna, Slosburg, BSN, LHRM, CASC, donnaslosburg@ascquality.org, 727-867-0072-

Co.3 Measure Developer if different from Measure Steward: Ambulatory Surgical Center Quality Collaboration, 5686 Escondida Blvd S, St. Petersburg, Florida, 33715

Co.4 Point of Contact: Donna, Slosburg, BSN, LHRM, CASC, donnaslosburg@ascquality.org, 727-867-0072-

Co.5 Submitter: Donna, Slosburg, donnaslosburg@ascquality.org, 727-867-0072-, Ambulatory Surgical Center Quality Collaboration

Co.6 Additional organizations that sponsored/participated in measure development: No additional organizations participated in measure development

Co.7 Public Contact: Donna, Slosburg, BSN, LHRM, CASC, donnaslosburg@ascquality.org, 727-867-0072-, Ambulatory Surgical Center Quality Collaboration

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. The ASC Quality Collaboration workgroup members meet via teleconference to develop, critique, and modify candidate measures; to maintain existing measures; and to offer sites willing to participate in testing. No contractors are used. The following is a list of the individuals (and their affiliation at the time of their participation) serving on the workgroup and contributing to this measure: AAAHC: Naomi Kuznets, PhD Ambulatory Surgery Foundation: Debra Stinchcomb, BSN, CASC, David Shapiro, MD, Sarah Martin, RN, BS, CASC and Marian Lowe AMSURG: Deby Samuels, Lorri Smith RN, BSN and Linda Brooks-Belli AOA/HFAP: Monda Shaver, RN, BSN, CPHIT and Susan Lautner, RN, BSN, MSHL AORN: Bev Kirchner BSN, CNOR, CASC and Bonnie Denholm, RN, MS, CNOR ASCOA: Ann Geier RN, MS, CNOR, CASC ASC Quality Collaboration: Donna Slosburg, BSN, LHRM, CASC HCA: Kathy Wilson The Joint Commission: Michael Kulczycki and Kathleen Domzalski NATIONAL: Rhonda Arnwine, MBA and Terry Hawes, RN, BHA Novamed: Cassandra Speier NUETERRA: Rachelle Babin RN, BSN Surgical Care Affiliates: Kim Wood, MD Symbion: Steve Whitmore and Gina Throneberry RN, MBA, CASC USPI: David Zarin, MD, Julie Gunderson RN, MM, CPHQ and Clint Chain, RN, BSN Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: Not adapted Measure Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the measure was first released: 2007 Ad.4 Month and Year of most recent revision: 12, 2010 Ad.5 What is your frequency for review/update of this measure? Annually, or more frequently if indicated Ad.6 When is the next scheduled review/update for this measure? 12, 2011 Ad.7 Copyright statement: None

Ad.8 Disclaimers: None

Ad.9 Additional Information/Comments: None

Date of Submission (MM/DD/YY): 09/13/2011