NATIONAL QUALITY FORUM

Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: PSM-016-10 NQF Project: Patient Safety Measures				
MEASURE DESCRIPTIVE INFORMATION				
De.1 Measure Title: Colonoscope Processing Competency				
De.2 Brief description of measure: Percentage of all colonoscope reprocessing personnel at Ambulatory Surgery Centers and Office-Based Practices who are documented to be competent at reprocessing colonoscopes on initial assignment and at least annually thereafter, , as well as whenever any changes are made in colonoscope equipment or in manufacturers' recommendations.				
1.1-2 Type of Measure: Process De.3 If included in a composite or paired with another measure, please identify composite or paired measure This measure may be paired with PSM-014-10 Colonoscope processing personnel instruction and PSM-015-10 Colonoscope processing currency (or maintenance)				
De.4 National Priority Partners Priority Area: Safety De.5 IOM Quality Domain: Safety De.6 Consumer Care Need:				

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available. A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes A.2 Indicate if Proprietary Measure (as defined in measure steward agreement): A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission	A Y N

A.4 Measure Steward Agreement attached: Measure Steward Agreement AAAHC Inst -NQF - 634001877036870496.pdf	
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y□ N□
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ▶ Purpose: Public reporting, Internal quality improvement Other If AAAHC adopts these as standards, another intended use could be accreditation; and, if CMS were to adopt the measures to satisfy congressional mandate in TRHCA-MIEA 2006, yet another use could be payment incentive.	C Y□ N□
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1Testing: No, testing will be completed within 24 months D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. 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	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Patient/societal consequences of poor quality, Frequently performed procedure 1a.2	
1a.3 Summary of Evidence of High Impact: Colonoscopy is the most frequently performed procedure in the ambulatory care setting. In 2006, of the almost 6.25 million colonoscopy procedures performed in the ambulatory setting, approximately two thirds (almost 3.7 million) were performed in freestanding facilities. (1)	
The cost of failures associated with colonoscope reprocessing include: • mortality and morbidity (including pain and suffering) of patients who contract viral or bacterial diseases during colonoscopy with improperly processed endoscopes; • the associated health care expenses, shorter life spans, and decreased productivity; • uncertainty, fear, and suffering of those who were potentially exposed to the risk; • loss of faith in the safety of an examination having the potential to save many lives;	1a C P M N

- financial cost to health care organizations for tracking, informing, and testing patients who may have been exposed to identified threats;
- the cost of financial liability for negligence when reprocessing failures are identified and lead to litigation.

Published estimated direct costs of failed colonoscope processing are based on healthcare-acquired infections (HAIs), with surgical site infection (SSI) and CDI (clostridium difficile) being most appropriate for colonoscopy-associated infections. The Centers for Disease Control and Prevention reports low estimates of cost of SSIs of \$10, 433 per infection in 2005 dollars and high estimates at \$25,546 in 2002 dollars. For CDI the low estimate is \$5,042 and the high is \$7,179, in 2003 dollars. (2)

Please see the Agency for Healthcare Research and Quality (AHRQ) SEN (Special Emphasis Notice) which also indicates the opportunity for HAIs in ASCs. (3)

1a.4 Citations for Evidence of High Impact: (1) Centers for Disease Control and Prevention. National Survey of Ambulatory Surgery. 2006. Calculated from sums of weighted values of cases from Procedure Code 1 = 45.22, 45.23, 45.24, 45.25, 45.28, 45.42, or 45.43 for freestanding facilities versus freestanding and hospital-based facilities: ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Datasets/NSAS/. (2) Scott RD. The Direct Medical Costs of Healthcare-Associated in U.S. Hospitals and the Benefits of Prevention. Atlanta, GA: Centers for Disease Control and Prevention. 2009. http://www.cdc.gov/ncidod/dhqp/pdf/Scott_CostPaper.pdf (3) http://grants1.nih.gov/grants/guide/notice-files/NOT-HS-10-007.html

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: By systematically assuring the competence of ASC personnel who process colonoscopes, it is anticipated that patient safety will improve and there will be a decrease in possible patient exposure to HAIs.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

A recent CMS (Centers for Medicare and Medicaid Services) three-state pilot test, of a CDC-developed infection control assessment tool and direct surveyor observation of a single procedure from start to finish, has led to a US Government Accountability Office (GAO) recommendation "to collect nationally representative and standardized information on ASC [ambulatory surgery center] compliance with infection practices that reduce HAIs [healthcare acquired infections]."(1, 2, 3) This has been followed by a CMS requirement that its deemed ASC Accreditation Organizations (AOs) use the CDC-CMS developed tool to examine infection control policies and processes on-site. Additionally, ARRA (American Recovery and Reinvestment Act 2009) money (up to \$9 million) has been allotted to states to use this CDC-CMS tool on non-accredited ASCs. (4)

In 2004, Moses and Lee found wide variations in GI (gastrointestinal) endoscope disinfection practice and "while most [reprocessing] units claim to have ongoing QA programs, few use objective criteria to monitor effective disinfection or lapses in technique. latrogenic infection is uncommonly recognized following GI endoscope procedures." (5)

In 2005, Nelson emphasized the importance of compliance with guidelines in GI endoscope processing. (6) In 2006, Nelson and Muscarella reported that "in the absence of defective equipment, every reported case of nosocomial infection associated with a contaminated GI endoscope has been linked to a specific breech or violation of at least one of several requisite reprocessing steps." (7)

In their 2008 review of the literature, Seoane-Vazquez and Rodriguez-Monguio concluded that "although the risk of endoscopy-related infection is very low, continued efforts are needed to ensure that quality is maintained during endoscope reprocessing to reduce the incidence of endoscopy-related infections." (8)

In 2009, the Office of the Inspector General (OIG) of the Department of Veteran Affairs (VA), investigation of failures in endoscope processing at three facilities (2 involving colonoscope processing), uncovered several issues associated with endoscope processing. "Issue 1" was the "absence of colonoscope model-specific reprocessing SOPs (standard operating procedures) and/or competence records." Estimated VA

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colonoscope reprocessing compliance with competence was approximately 1 of 2 (50.2%) across VHA (Veterans Health Administration) colonoscope reprocessing units and compliance with SOPs was 77.9%; compliance with both was 47.4%. (9)	
Data from AAAHC Institute for Quality Improvement over the last 5 years (including more than 100 ambulatory organizations each year) also show opportunities to improve compliance with national recommendations regarding colonoscope processing each year. (10)	
1b.3 Citations for data on performance gap: (1) Surgistrategies 4-2-2009 (http://www.surgistrategies.com/hotnews/hhs-asc-infect-control-surveys.html) (2) Government Accountability Agency (GAO). Health-Care-Associated Infections: HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers. GAO-09-213 February 25, 2009 (http://www.gao.gov/products/GAO-09-213) (3) Becker's ASCReview, 4-2-2009 (http://www.beckersasc.com/news-analysis-asc/accreditation-patient-safety/hhs-plans-new-infection-control-surveys-for-surgery-centers.html) (4) The Medical News. \$9M ARRA funds to reduce healthcare-associated infections in ambulatory surgical centers. November 11, 2009. http://www.news-medical.net/news/20091111/249M-ARRA-funds-to-reduce-healthcare-associated-infections-in-ambulatory-surgical-centers.aspx (5) Moses FM, Lee JS. Current GI endoscope disinfection and QA practices. Dig Dis Sci. 2004.49:1791-1797. (6) Nelson DB. Recent advances in epidemiology and prevention of gastrointestinal endoscopy related infections. Curr Opin Infect Dis. 2005. 18:326-330. (7) Nelson DB, Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World J Gastroenterol. 2006. 12: 3953-3964. (8) Seoane-Vazquez E, Rodriguez-Monguio R. Endoscope-related infection: relic of the past? Curr Opin Infect Dis. 2008. 21:362-3666. (9) Department of Veteran Affairs, Office of the Inspector General. Health Care Inspection: Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities. Washington, DC. June 16, 2009. Report Number 09-01784-146. (10) AAAHC Institute for Quality Improvement. Colonoscopy. Skokie, IL: AAAHC Institute for Quality Improvement. 2005-2009.	
1b.4 Summary of Data on disparities by population group: N/A	
1b.5 Citations for data on Disparities: N/A	
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): A substantial body of scientific evidence indicates that breaches in appropriate colonoscope reprocessing can lead to disastrous consequences for large numbers of patients who have been exposed to improperly processed endoscopes. 1c.2-3. Type of Evidence: Evidence-based guideline, Other Documentation of episodes where there has been variation from recommendations or overall poor performance.	
been variation from recommendations or overall poor performance.	
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): In the 2008 Centers for Disease Control and Prevention Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, the second part of recommendation 7.bb. is "Require competency testing on a regular basis (e.g., beginning of employment, annually) of all personnel who reprocess endoscopes." Sources cited are in the citations of evidence section below. (1-9)	
1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): The authors consider this to be a Level IA recommendation (please see rating information below).	1c C□ P□
1c.6 Method for rating evidence: Evidence supporting this process measure includes the CDC Guideline for	M H
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Disinfection and Sterilization in Healthcare Facilities, 2008, which uses a rating scale including: Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and by a strong theoretical rationale.

Category IC. Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or by a theoretical rationale.

No recommendation. Unresolved issue. These include practices for which insufficient evidence or no consensus exists regarding efficacy.

The grade of evidence supporting instructions is categorized as I.A. by the CDC; this is similar to the USPSTF "A."

- **1c.7 Summary of Controversy/Contradictory Evidence:** The number of cases of transmission of infection associated with GI endoscopy is very low; yet, "in the absence of defective equipment, every reported case of nosocomial infection associated with a contaminated GI endoscope has been linked to a specific breech or violation of at least one of several requisite reprocessing steps." (10)
- **1c.8 Citations for Evidence (***other than guidelines***):** (1) Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. Ann Intern Med. 1993. 118:117-28.
- (2) Weber DJ, Rutala WA, DiMarino AJ, Jr. The prevention of infection following gastrointestinal endoscopy: the importance of prophylaxis and reprocessing. In: DiMarino AJ, Jr, Benjamin SB, eds. Gastrointestinal Diseases an endoscopic approach. Thorofare, NJ: Slack Inc. 2002. 87-106.
- (3) American Society of Gastrointestinal Endoscopy. Position statement: reprocessing of flexible gastrointestinal endoscopes. Gastrointest Endosc. 1996. 43:541-546.
- (4) Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. Association for Professionals in Infection Control. Am J Infect Control. 2000. 28:138-155.
- (5) Society of Gastroenterology Nurses and Associates. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. Gastroenterol Nurs. 2006. 29:142-148.
- (6) Nelson DB, et al. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. Infect Control Hosp Epidemiol. 2003. 24:532-537.
- (7) Kruse A. Rey JF. Guidelines on cleaning and disinfection in GI endoscopy. Update 1999. The European Society of Gastrointestinal Endoscopy. Endoscopy. 2000. 32:77-80.
- (8) British Society of Gastroenterology. Cleaning and disinfection of equipment for gastrointestinal endoscopy. Report of a working party of the British Society of Gastroenterology Endoscope Committee. Gut. 1998. 42:585-593.
- (9) Food and Drug Administration, Centers for Disease Control and Prevention, FDA and CDC public health advisory: Infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system, Food and Drug Administration, Rockville, MD. 1999.
- (10) Nelson DB, Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. World J Gastroenterol. 2006. 12: 3953-3964.
- 1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): In the 2008 Centers for Disease Control and Prevention Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, the second part of recommendation 7.bb. is "Require competency testing on a regular basis (e.g., beginning of employment, annually) of all personnel who reprocess endoscopes." (p.88)
- **1c.10 Clinical Practice Guideline Citation:** Rutala WA, Weber DJ. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centers for Disease Control and Prevention. 2008. **1c.11 National Guideline Clearinghouse or other URL:**

http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):

See Method of Rating the Evidence above.

1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe

rating and how it relates to USPSTF): See Method of Rating the Evidence above.	
1c.14 Rationale for using this guideline over others: This guideline was developed by a federal government agency, the Centers for Disease Control and Prevention, with the Healthcare and Infection Control Practices Advisory Committee, which includes representatives of several types of health care professionals from several health care settings across the United States. As can be seen in the citations above, guidelines from different types of professional organizations and from not only the United States, but also Europe, have been considered in the recommendations made within the CDC guideline.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y□ N□
2. 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. (<u>evaluation criteria</u>)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome): Colonoscope reprocessing personnel who are documented to be competent at reprocessing colonoscopes on initial assignment and at least annually thereafter, as well as whenever any changes are made in colonoscope equipment or in manufacturers' recommendations	
2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator): On initial assignment of any colonoscope reprocessing task or responsibility and at least annually (every 12 months) thereafter, as well as whenever any changes are made in colonoscope equipment or in manufacturers' recommendations	
 2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions): Ambulatory surgery center (ASC) or office-based practice (OBP): a health care facility that provides medical services including surgery and procedures to patients who leave the facility within 23 hours of admission. 	
• Appropriately: in accordance with device specific reprocessing instructions for proper cleaning and high-level disinfection or sterilization derived from at least annual review, as well as any changes made in colonoscope equipment or in manufacturers' recommendations, and revision to reflect changes (see Colonoscope Processing Maintenance Measure) in guidelines on endoscope processing issued by a widely recognized professional and/or governmental body, (such as the: Association for Professionals in Infection Control and Epidemiology [APIC], American Society for Gastrointestinal Endoscopy [ASGE], Center for Disease Control Prevention [CDC], or Society of Gastroenterology Nurses & Associates [SGNA]) and on endoscope processing products (such as sterilants, disinfectants, automated washer) recommendations (such as the optimal amount of soaking time and temperature of level disinfectants, compatibility of products with colonoscopes, frequency and type of product testing, and safety precautions health care workers and patients).	2a- specs C□
 ASC or OBP personnel who reprocess colonoscopes include full, part time, agency/temporary staff, "floats" and "intern" staff assigned any colonoscope reprocessing task or responsibility. Colonoscope: a video endoscope used to examine the inside of the colon and also, often, to take tissue 	P

samples.

- Colonoscope reprocessing: preparation of a colonoscope after patient use to prepare for next patient use, via "method to ensure the proper disinfection or sterilization; [tasks or responsibilities] can include: cleaning, inspection, wrapping, sterilizing [or disinfecting], and storing." [Rutala WA, Weber DJ. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centers for Disease Control and Prevention. 2008].
- Competence: "demonstrated as achieved skill level required to independently and appropriately perform an assigned reprocessing task or responsibility" and indicates there should be "documented" initial and continued staff competence at least annually. [Veterans Health Administration (VHA) Directive 2009-004: February 9, 2009].
- Documented: written or electronically recorded attestation by an authorized legal representative of the ASC or OBP.
- Independently: without the assistance of others.
- **2a.4 Denominator Statement** (Brief, text description of the denominator target population being measured):

All colonoscope reprocessing personnel at Ambulatory Surgery Centers or Office-Based Practices

- 2a.5 Target population gender:
- 2a.6 Target population age range:
- **2a.7 Denominator Time Window** (The time period in which cases are eligible for inclusion in the denominator):

Initial assignment of colonoscope processing task or responsibility and at least annually (every 12 months) thereafter, as well as whenever any changes are made in colonoscope equipment or in manufacturers' recommendations

- **2a.8 Denominator Details (**All information required to collect/calculate the denominator the target population being measured including all codes, logic, and definitions):
- Ambulatory surgery center (ASC)or office-based practice (OBP): a health care facility that provides medical services including surgery and procedures to patients who leave the facility within 23 hours of admission.
- ASC or OBP personnel who reprocess colonoscopes include full, part time, agency/temporary staff, "floats" and "intern" staff assigned any colonoscope reprocessing task or responsibility.
- Colonoscope: a video endoscope used to examine the inside of the colon and also, often, to take tissue samples.
- Colonoscope reprocessing: preparation of a colonoscope after patient use to prepare for next patient use, via "method to ensure the proper disinfection or sterilization; [tasks or responsibilities] can include: cleaning, inspection, wrapping, sterilizing [or disinfecting], and storing." [Rutala WA, Weber DJ. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centers for Disease Control and Prevention. 2008].
- 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population); None
- **2a.10 Denominator Exclusion Details (**All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

 N/A
- **2a.11 Stratification Details/Variables** (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):

 None
- 2a.12-13 Risk Adjustment Type: No risk adjustment necessary
- **2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

N/A--process measure

- 2a.15-17 Detailed risk model available Web page URL or attachment:
- 2a.18-19 Type of Score: Rate/proportion

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- **2a.21 Calculation Algorithm** (Describe the calculation of the measure as a flowchart or series of steps):
- 1. How many people at the ASC or OBP have are assigned any colonoscopy reprocessing task or responsibility? This number is the denominator.
- 2. For each of the people in the denominator, determine when the most recent assignment of any colonoscopy reprocessing task or responsibility took place.
- A. For all people who received their most recent assignment of any new colonoscope reprocessing task or responsibility less than 12 months ago, how many have the demonstrated skill level required to independently and appropriately perform all assigned reprocessing tasks or responsibilities documented on the initial assignment of this most recently assigned reprocessing task or responsibility, as well as new skills or knowledge required because of changes made in colonoscope equipment or in manufacturers' recommendations?
- B. For all people who received their most recent assignment of any new colonoscope reprocessing task or responsibility 12 months or more ago, how many have the demonstrated skill level required to independently and appropriately perform all assigned reprocessing tasks or responsibilities, including new skills or knowledge required because of changes made in colonoscope equipment or in manufacturers' recommendations, documented within the last 12 months?
- C. The sum of the numbers in A and B is the numerator.
- 3. Divide 2C by 1 to calculate the ASC or OBP score for this measure.
- **2a.22 Describe the method for discriminating performance** (e.g., significance testing): Anything less than 100% indicates an opportunity to improve quality.
- **2a.23 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): N/A
- **2a.24 Data Source** (Check the source(s) for which the measure is specified and tested) Management data, Survey: Provider
- **2a.25** Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):

 Documentation of the competence of ASC or OBP personnel who reprocess colonoscopes would be reported to a registry or submitted via a claims-based reporting system using Category II CPT codes. During testing data will be collected on a survey form used in the AAAHC Institute for Quality Improvement Clinical Colonoscopy Study.
- 2a.26-28 Data source/data collection instrument reference web page URL or attachment: Attachment AAAHC Institute Colonoscope Reprocessing Competency Measure 11-10.doc
- **2a.29-31 Data dictionary/code table web page URL or attachment:** Attachment AAAHC Institute Scope Reproc Competency Meas Def 11-10.doc
- **2a.32-35 Level of Measurement/Analysis** (Check the level(s) for which the measure is specified and tested)

Facility/Agency

- **2a.36-37 Care Settings** (Check the setting(s) for which the measure is specified and tested) Ambulatory Care: Amb Surgery Center, Ambulatory Care: Office
- **2a.38-41 Clinical Services** (Healthcare services being measured, check all that apply) Technicians

TESTING/ANALYSIS	
2b. Reliability testing	2b
2b.1 Data/sample (description of data/sample and size): 100% sample.	C
2b.2 Analytic Method (type of reliability & rationale, method for testing):	N_

The measure will be prospectively tested for reliability against AAAHC survey results when the facilities participating in the 2010 Colonoscopy Study undergo triennial AAAHC accreditation survey. The Institute will use an appropriate test of reliability between two measures, such as the kappa statistic.	
2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted):	
2c. Validity testing	
2c.1 Data/sample (description of data/sample and size): 100% sample.	
2c.2 Analytic Method (type of validity & rationale, method for testing): The same method used for reliability testing will be used for validity testing. That is, observations independent of the facilities' performance reporting will be derived from reports from AAAHC accreditation surveyors. Results of this direct observation will be compared with results reported by the facilities.	2c C∏
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):	P M N
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s): N/A (no exclusions).	
2d.2 Citations for Evidence:	
2d.3 Data/sample (description of data/sample and size):	2d
2d.4 Analytic Method (type analysis & rationale):	C□
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):	P M N NA
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): N/A	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):	
2e.3 Testing Results (risk model performance metrics):	2e C□ P□ M□
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA
2f. Identification of Meaningful Differences in Performance	
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): Testing will be performed on a 100% sample.	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale): Any level of compliance lower than 100% is unacceptable. (See section on "Importance" above.)	2f C□
	P
2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in	N□

performance): N/A	
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): Survey information, submitted directly by the ASC, will be used as the source of performance data. Independent data acquired through accreditation surveyor observation, will be used for testing reliability and validity of the primary source.	2-
2g.2 Analytic Method (type of analysis & rationale): See sections on relibility and validity testing above.	2g C□ P□ M□
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	N NA
2h. Disparities in Care	
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): Measure is not stratified.	2h C□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A	P M N NA NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:	2 C P M N
3. USABILITY	N
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)	Eval Rating
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand	Eval
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)	Eval
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) 3a. Meaningful, Understandable, and Useful Information	Eval
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3a.5 Methods (e.g., focus group, survey, QI project): Participant and non-participant evaluation surveys.	
3a.6 Results (qualitative and/or quantitative results and conclusions): The Institute has received consistent high ratings on Likert scale questions (4 or 5, on a scale of 1 to 5, with 5 = most desirable score) and positive comments, indicating that the information provided is valuable and unique, in response to open-ended questions.	
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures:	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why?	3b C P M NA
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures:	3c C
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality: N/A	M NO NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C P M N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	4a
4a.1-2 How are the data elements that are needed to compute measure scores generated? Survey, Other Organizational personnel records	P M N
4b. Electronic Sources	
4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) No 4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	4b C□ P□
The AAAHC Institute plans to develop an online system for ASCs to report the data specified in the performance measure.	M D
4c. Exclusions	4c C□

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No	P
4c.2 If yes, provide justification.	NA.
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. Errors in reporting are more likely to occur if ASCs uses temporary personnel or if ASCs experience high turnover of endoscope processing personnel. Currently approximately 1/3 of AAAHC accredited ASC organizations are specifically surveyed on this issue via AAAHC deemed status surveys for the Centers for Medicare and Medicaid services. The AAAHC is currently considering including this issue in surveys for all ASCs; this can serve as an audit.	4d C P M N
4e. Data Collection Strategy/Implementation	
4e.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/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues: AAAHC Institute for Quality Improvement has carried out more than 50 studies based on survey data over the past 10 years. The Institute has continuously refined its survey questions over the years to make them more understandable, cost-effective, reliable, and valid. The studies have pertained to Colonoscopy, Cataract Surgery, Knee Arthroscopy, Liposuction, and Myringotomy.	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): It is anticipated that this will not be adding any substantial cost.	
4e.3 Evidence for costs: It is anticipated that this will not be adding any substantial cost because a very small portion of the AAAHC Institute study survey and of the audit via the conventional AAAHC survey is involved—these are tools/processes that are already established and implemented in ASCs.	4e C□
4e.4 Business case documentation: Please see information on estimated costs of HAIs in Summary of Evidence of High Impact.	P
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C P M N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization	

AAAHC Institute for Quality Improvement, 5250 Old Orchard Road, Suite 250, Skokie, Illinois, 60077

Co.2 Point of Contact

Naomi, Kuznets, PhD, Managing Director, nkuznets@aaahc.org, 847-853-6079-

Measure Developer If different from Measure Steward

Co.3 Organization

AAAHC Institute for Quality Improvement, 5250 Old Orchard Road, Suite 250, Skokie, Illinois, 60077

Co.4 Point of Contact

Naomi, Kuznets, PhD, Managing Director, nkuznets@aaahc.org, 847-853-6079-

Co.5 Submitter If different from Measure Steward POC

Naomi, Kuznets, PhD, Managing Director, nkuznets@aaahc.org, 847-853-6079-, AAAHC Institute for Quality Improvement

Co.6 Additional organizations that sponsored/participated in measure development

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.

AAAHC Institute for Quality Improvement Measure Development Work Group:

D. Scott Endsley MD, MSc (Cleveland Clinic Foundation)

Lee Fleisher, MD (University of Pennsylvania)

Ronald A. Gabel, MD (Emeritus, University of Rochester)

Deborah Jinks, RN, CPHQ (HCA Healthcare)

Sam JW Romeo, MD, MBA (Tower Health Care)

Reviewed AAAHC Institute data, CDC NSAS data, and scientific research literature, for information needed to meet NQF criteria. Deliberated over issues such as strength of evidence, gaps in care, feasibility of applying the proposed measure, and likelihood that the measure would effectively close the widely acknowledged gap in care. Engaged in a conference call with national experts on healthcare-associated infections related to colonoscopy: Drs. William Rutala and David Weber, authors of the 2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities and the textbook chapter titled, "The Prevention of Infection Following Gastrointestinal Endoscopy: The Importance of Prophylaxis and Reprocessing" in Gastrointestinal Disease: An Endoscopic Approach, Second Edition. Also present on the conference call were Drs. Melissa Schaefer and Joseph Perz, who performed ASC pilot studies for CDC and CMS to identify and quantitate problems with healthcare-acquired infections associated with colonoscopies. The AAAHC Institute Performance Measure Work Group integrated information derived from these national experts into the proposed performance measure.

Edward Bentley, MD (representative to the AAAHC Board of Directors from the American Society for Gastrointestinal Endoscopy)

Dianna Burns, CGRN (Past-President of the Society of Gastroenterology Nurses and Associates)

Frank Chapman (representative to the AAAHC Board of Directors from the American Society for Gastrointestinal Endoscopy)

Larry Kim, MD (representative to the AAAHC Board of Directors from the American Gastroenterological Association) Michael Safdi, MD (representative to the AAAHC Board of Directors from the American College of Gastroenterology) Reviewed proposed measures and provided expert professional feedback.

Ad.2 If adapted, provide name of original measure: N/A

Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released: 2009

Ad.7 Month and Year of most recent revision: 2009

Ad.8 What is your frequency for review/update of this measure? At least annually; the measure was actually released in 2010 (not option for Ad.6.)

Ad.9 When is the next scheduled review/update for this measure? 06, 2010

Ad.10 Copyright statement/disclaimers: Copyright 2010 AAAHC Institute for Quality Improvement. ALL RIGHTS RESERVED.

Ad.11 -13 Additional Information web page URL or attachment: URL More information about the Institute and its activities is available at www.aaahciqi.org; additional information on AAAHC can be found at www.aaahc.org.

Date of Submission (MM/DD/YY): 11/05/2010