ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF CONTRAST ENEMA EXAMINATION IN ADULTS

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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

1 Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

The fluoroscopic/radiographic examination of the colon by single-contrast or double-contrast technique is a proven and useful procedure for the detection of intrinsic or extrinsic colonic pathology. It could be the primary imaging study or used as an adjunct to endoscopic or cross-sectional imaging evaluation. The purpose of this examination is to establish the presence or absence of disease and its nature by luminal distension with or without mucosal coating.

II.

INDICATIONS AND CONTRAINDICATIONS

- A. The indications for a fluoroscopic contrast enema examination include, but are not limited to [1-4]:
 - 1. Diverticular disease
 - 2. Inflammatory bowel disease
 - 3. Colon cancer screening, including the completion of screening in incomplete colonoscopy [5-7] only if other methods such as repeat colonoscopy or performance of CT colonography are not available or if the patient's clinical condition precludes these examinations.
 - 4. Distal intestinal obstruction syndrome or meconium ileus equivalent in cystic fibrosis patients [8,9]
 - 5. Evaluation of questionable findings on other imaging examinations such as computed tomography (CT) or magnetic resonance imaging (MR)
 - 6. Colonic volvulus
 - 7. Assessing the integrity of rectal or colonic anastomosis or ileal pouch before take down of diverting colostomy or ileostomy
 - 8. Assessment of possible colonic fistulae
 - 9. Diseases involving the colon with familial inheritance pattern
 - 10. Preoperative evaluation of the colon for surgical planning and postoperative follow-up
 - 11. Evaluation of suspected colonic intrinsic or extrinsic strictures or large bowel obstruction, if equivocal results on CT or type/length of stricture are needed for surgical planning
 - 12. Therapeutic enema in cases in which nurse or patient administered enemas have been ineffective as well as in patients with cystic fibrosis
 - 13. Evaluation for potential colonic perforation or leak
 - 14. Evaluation of remaining colonic anatomy in a postoperative patient
- B. Pertinent symptoms for the fluoroscopic contrast enema examination include, but are not limited to:
 - 1. Abdominal pain
 - 2. Diarrhea
 - 3. Constipation
 - 4. Other changes in bowel habits
 - 5. Abdominal distension
 - 6. Gastrointestinal bleeding, acute or chronic leading to anemia (only if colonoscopy, CT colonography, and/or CT/angiographic techniques are not available or cannot be performed)
 - 7. Weight loss

C. The possible contraindications for a fluoroscopic contrast enema examination include, but are not limited to:

- 1. Unexplained pneumoperitoneum or pneumoretroperitoneum (not contraindicated if water soluble contrast is used)
- 2. Acute colitis, including toxic megacolon
- 3. Combative or uncooperative patient
- 4. In the setting of recent endoscopic intervention, there should be a 7-day interval between the fluoroscopic double contrast enema examination and the performance of large forceps biopsy

through a rigid colonoscope or proctoscope, snare polypectomy, hot biopsy, or biopsy of any size or type in infectious or active inflammatory bowel disease.

5. Acute presentation of known malignant colon obstruction except if a single contrast enema is used for guiding or planning intervention (eg, before stent placement if not a surgical candidate)

For the pregnant or potentially pregnant patient, see the <u>ACR–SPR Practice Parameter for Imaging Pregnant or</u> <u>Potentially Pregnant Patients with Ionizing Radiation [10]</u>.

III.

QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

For qualifications of physicians, registered radiologist assistants, radiologic technologist, and other ancillary personnel see the <u>ACR–AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic</u> <u>Procedures [11]</u>.

IV.

SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for a fluoroscopic contrast enema examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

IV.

SPECIFICATIONS OF THE EXAMINATION

Α.

Colon Preparation

The preparation should consist of an effective combination of dietary restriction, hydration, osmotic laxatives, contact laxatives, and cleansing enemas. These preparations are intended to rid the colon of fecal material and excess fluid as much as possible, particularly for the double contrast screening enema evaluation. In appropriate clinical situations, preparation may be limited and, in the setting of suspected bowel obstruction or colonic volvulus, should be omitted [12-14]. There is also no routine need for colonic preparation in the case of existing ileal or colonic diversion.

IV.

SPECIFICATIONS OF THE EXAMINATION

B. Examination Preliminaries

- 1. An appropriate medical history should be available, including results of laboratory tests and imaging, endoscopic, and surgical procedures as applicable.
- 2. The enema tip should be inserted by a physician or a trained assistant (eg, technologist, radiologist assistant, nurse, or physician assistant). Rectal perforations are rare but often would require surgical intervention if barium was used with a reported improvement in outcome in these cases due to the early intervention [15,16]. A retention cuff may be used, which should be inflated carefully in accordance with the manufacturer's guidelines and under fluoroscopic guidance and after the instillation of a small amount of contrast for better visualization of the balloon whenever possible. A retention cuff should be avoided for recent low rectal anastomoses (in rare instances it may be inflated under extreme care and under strict fluoroscopic guidance to avoid anastomotic dehiscence), following pelvic radiation therapy and in very distal rectal strictures. In patients with an ileo-anal anastomosis, a small caliber catheter should be used rather than an enema tip, and the tube should be secured to the patient's skin surface with adhesive rather than inflating a balloon.
- 3. Medications (eg, glucagon) may be administered to facilitate the examination in the case of suspected muscle spasm.

IV.

SPECIFICATIONS OF THE EXAMINATION

С.

Examination Technique

The following fluoroscopic contrast examination procedures should be tailored by the physician to the individual patient, as warranted by clinical circumstances and the condition of the patient, to produce a diagnostic-quality examination [1,12,13].

1. Single-contrast examination

a. A sufficient volume of an appropriate low-density (ie, 15%–25% weight/volume) barium suspension or water-soluble iodinated contrast should be administered to provide luminal opacification.

In early postsurgical patients, if perforation or leak is suspected or if preparation is contraindicated or not possible for other reasons, water-soluble contrast should be used. Examination of residual or constructed colonic segments (eg, rectal remnant following the Hartmann procedure or an ileal pouch) is most commonly performed with water-soluble contrast. Water-soluble contrast contains 300–370 mg of iodine/mL, equivalent to 60%–76% density. It may be diluted with water to 20%–30%, depending on the indication. Water-soluble contrast is also recommended in patients with suspected colonic obstruction or volvulus.

- b. Water-soluble contrast should also be used if the patient is at high risk for formation of barium concretions that can lead to obstruction (eg, intestinal diversion or motility disorders) [17].
- c. For barium studies, a kilovoltage of 100 kVp or greater should be used (depending on patient size) during image acquisition. A lower kilovoltage of 70–80 kVp optimizes iodine contrast visualization on water-soluble contrast studies.
- d. Palpation (manual or mechanical compression) in conjunction with patient rotation should be applied as appropriate to all accessible segments of the colon during fluoroscopy.
- e. Spot large-format images should demonstrate all fluoroscopically identified suspicious findings as well as those segments of the colon in profile that may not routinely be demonstrated on overhead projections
- f. Images should include frontal and oblique views of the entire filled colon, an angled-beam view of

the sigmoid colon, and a lateral view of the rectum. Whenever possible, the lateral rectal view should include an image obtained after the enema tip has been removed

- g. Postevacuation images are usually obtained in the evaluation for leak
- h. The quality assurance indicators specific to the single-contrast enema examination are:
 - i. Compression views may be helpful
 - ii. Each accessible segment of the colon is seen during fluoroscopy
 - iii. Each segment of the entire colon should be seen without overlap, if possible
 - iv. Imaging technique should optimize visualization of all segments of the colon
 - v. Complete visualization of the entire colon should be ensured through the demonstration of ileocecal valve, terminal ileum, appendix or ileocolic anastomosis (if the right side of the colon has been resected)
- i. In the setting of distal intestinal obstruction syndrome/meconium ileus equivalent in patients with cystic fibrosis, a water-soluble contrast enema examination can demonstrate the level of the obstruction and possibly be therapeutic by promoting evacuation of inspissated bowel contents. The water-soluble contrast material enema procedure has become an accepted supplement to other nonsurgical therapeutic measures, and multiple enemas with water-soluble contrast agents over several days may be required to mobilize the tenacious stool plugs [8,9]. Repeat enemas in this setting may be performed without fluoroscopic guidance.
- 2. Double-contrast barium examination
 - a. Commercially prepared high-density (80% weight/volume or greater) barium suspension is used.
 - b. Kilovoltage of 90 kVp or greater, depending on the patient's size, is used.
 - c. Barium suspension followed by air is introduced under fluoroscopic control to achieve adequate coating and distention of the entire colon.
 - d. The entire colon should be examined fluoroscopically during the course of the examination.
 - e. Images should be taken to attempt to demonstrate all segments of the colon in double contrast. Suggested views include the following:
 - i. Spot images of the rectum, sigmoid colon, flexures, and cecum in double contrast
 - ii. Large-format images, including prone and supine views of the entire colon, an angled-beam view of the sigmoid colon, and a lateral view of the rectum, either cross-table lateral or vertical beam, preferably with the enema tip removed
 - iii. Both lateral decubitus views of the entire colon using a horizontal beam (a wedge filter is recommended)
 - iv. Erect or semierect flexure views, and postevacuation views, when possible, may be helpful
 - f. The quality assurance indicators specific to the double-contrast barium enema examination are as follows:
 - i. Adequate barium coating of the entire colon has been achieved
 - ii. The colon is well distended with air
 - iii. Each segment of the colon is seen in double contrast on at least 2 images taken in different positions, whenever possible
 - iv. Complete visualization of the entire colon is ensured through demonstration of the ileocecal valve, terminal ileum, or appendix
- 3. Colostomy or colonic mucous fistula fluoroscopic contrast enema
 - a. These procedures are indicated when disease is suspected involving a colostomy or colonic mucous fistula or to delineate anatomy in preparation for colostomy revision/takedown. A single contrast enema technique should always be used. The ostomy should be examined by the radiologist or a trained assistant. An appropriate device should be inserted into the ostomy. Examples of appropriate devices include, but are not limited to:
 - i. Foley catheter
 - ii. Red rubber catheter
 - iii. Cone colostomy tip

If a Foley catheter is used, the balloon should be inflated on the outside of the stoma and held

firmly against the stoma by the patient's gloved hand. Alternatively, the Foley balloon may be inflated under care inside the stoma and under strict fluoroscopic guidance to avoid injury.

b. Low-density barium or water-soluble contrast should be instilled into the ostomy through the device under fluoroscopic observation. The examination should attempt to answer the clinical question and should be recorded on spot radiographic images.

IV. SPECIFICATIONS OF THE EXAMINATION

D.

Quality Assurance

- 1. The following quality assurance indicators should be applied as appropriate to all fluoroscopic contrast enema examinations:
 - a. Colon preparation should be adequate for the clinical indication.
 - b. When examinations are completed, patients should be held in the fluoroscopic area until the physician has reviewed the images.
 - c. An attempt should be made to resolve questionable radiologic findings before the patient leaves. Repeat fluoroscopy of the patient should be performed as necessary.
- 2. The following step is suggested for a quality assurance and continuing quality improvement program:
 - a. Correlation of radiologic, endoscopic, and pathologic findings
 - b.

v.

DOCUMENTATION

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging</u> <u>Findings</u>

VI.

EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the <u>ACR–AAPM Technical Standard for</u> <u>Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment</u> and the <u>ACR–AAPM Technical</u> <u>Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment [19,20]</u>.

Examinations should be performed with fluoroscopic image intensification and radiographic equipment that meets all applicable federal and state radiation standards.

Equipment should provide diagnostic fluoroscopic image quality and recording (image, video, or digital) capability. Equipment should be capable of producing kilovoltage >100 kVp. Equipment necessary to compress and isolate regions of the colon should be readily available.

VII.

RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775 web.pdf

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>[®], should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently[®] for children (<u>www.imagegently.org</u>) and Image Wisely[®] for adults (<u>www.imagewisely.org</u>). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VIII.

QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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Writing Committee – members represent their societies in the initial and final revision of this practice parameter

<u>ACR</u>

Mahmoud M. Al-Hawary, MD, Chair

Mark Early Baker, MD, FACR

David J. DiSantis, MD, FACR

Chenchan Huang, MD

Farnoosh Sokhandon, MD

Committee on Practice Parameters – General, Small, Emergency and/or Rural Practices (GSER)

(ACR Committee responsible for sponsoring the draft through the process)

Candice Johnstone, MD, Chair	Nathan J. Rohling, DO
Justin P. Dodge, MD	Samir S. Shah, MD
Brian D. Gale, MD, MBA	Derrick Siebert, MD
Rachel Gerson, MD,	Michael Straza, MD, Ph.D

Mallikarjunarao Kasam, PhD

Committee on Body Imaging - Abdominal

(ACR Committee responsible for sponsoring the draft through the process)

Committee on Body Imaging - Abdominal

Benjamin M Yeh, MD, Chair	Erick Remer, MD, FACR
Olga R. Brook, MD	Kumar Sandrasegaran, MD
Alessandro Furlan, MD	Mary A. Turner, MD, FACR
David Kim, MD, FACR	Ellen L. Wolf, MD, FACR
Diego Martin, MD, PhD	Adam S. Young, MD, MBA
Alec Megibow, MD, MPH, FACR	Ashish Wasnik, MD
Achille Mileto, MD	Paula Yeghiayan, MD

Robert S. Pyatt, Jr., MD, FACR, Chair, Commission on General, Small, Emergency and/or Rural Practice Andrew B. Rosenkrantz, MD, Chair, Commission on Body Imaging David B. Larson, MD, MBA, Chair, Commission on Quality and Safety Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comments Reconciliation Committee

Elizabeth Hawk, MD, MS, Ph.D-CSC Chair	David A. Larson, MD
Nolan J. Kagetsu, MD, FACR-CSC Co-Chair	Paul A. Larson, MD, FACR
Mahmoud M. Al-Hawary, MD	Kambiz Motamedi, MD
Mark Early Baker, MD, FACR	Terry L. Levin, MD, FACR
Laura Carucci, MD	Mary S. Newell, MD, FACR
Timothy A. Crummy, MD, MHA, FACR	Andrew B Rosenkrantz, MD

Comments Reconciliation Committee

David J. DiSantis, MD, FACR

Farnoosh Sokhandon, MD

Chenchan Huang, MD

Roland Wong, ScM

Amy L. Kotsenas, MD, FACR

Benjamin Yeh, MD

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