ACR-ACNM-SNMMI-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF RADIONUCLIDE CYSTOGRAPHY

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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 care 1. 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 lowa 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, Stanley v. McCarver, 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

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR).

This practice parameter is intended to guide interpreting physicians in performing radionuclide cystography (RNC) in adult and pediatric patients. Properly performed imaging with radiopharmaceuticals provides a sensitive means of detecting, evaluating, and following certain conditions of the bladder and ureters. As with all scintigraphic examinations, correlation of findings with the results of other imaging and nonimaging procedures, as well as clinical information, is necessary for maximum diagnostic yield.

Application of this practice parameter should be in accordance with the <u>ACR-ACNM-SNMMI-SPR Practice</u> <u>Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures</u> [1].

RNC involves filling the urinary bladder with a radiopharmaceutical, either by direct (retrograde) administration via urethral catheter or by indirect (antegrade) drainage of an intravenously administered radiopharmaceutical excreted by the kidneys and subsequent imaging with a gamma camera.

II. INDICATIONS

Clinical indications [2-4] for RNC in evaluating vesicoureteral reflux (VUR) include, but are not limited to, the following:

- 1. Initial diagnosis in patients with female anatomy with urinary tract infection
- 2. Diagnosis in asymptomatic children with a family history of VUR
- 3. Diagnosis and follow-up in infants (including persistent antenatal hydronephrosis) and children with hydronephrosis
- 4. Diagnosis in renal transplant recipients
- 5. Diagnosis and evaluation of patients with neurogenic bladder
- 6. Follow-up examination to assess spontaneous resolution of VUR
- 7. Follow-up examination to evaluate resolution of VUR after antireflux procedures

For information on radiation risks to the fetus, see the <u>ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation</u> [5].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the <u>ACR-ACNM-SNMMI-SPR Practice Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures</u> [1].

IV. RADIOPHARMACEUTICALS

The direct (retrograde) technique (see Section V.A.) employs technetium-99m (Tc-99m) sodium pertechnetate, Tc-99m sulfur colloid, or Tc-99m diethylenetriamine penta-acetic acid (DTPA). Tc-99m sodium pertechnetate should not be used in individuals who have undergone bladder augmentation with gastric or intestinal tissue, as gastrointestinal musosa may facilitate systemic absorption of pertechnetate. An administered activity of 7.4 to 37 MBq (0.2-1.0 mCi) is introduced aseptically into the urinary bladder via a urethral catheter. Administered activity in children should be as low as reasonably achievable (ALARA) for diagnostic image quality. The North American Consensus Guidelines for Administered Radiopharmaceutical Activities in Children and Adolescents recommend no more than 37 MBq (1 mCi) for each cycle of filling in pediatric patients. No weight-based administered activity has been defined for RNC [6].

The indirect (antegrade) technique (see Section V.B.) may employ Tc-99m mercaptoacetyltriglycine or Tc-99m DTPA.

Administered radiopharmaceutical activity should be titrated according to the pediatric dosing tables provided by either the European Association of Nuclear Medicine or the SNMMI and are also detailed on the imagegently.org website [7, 8].

V. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for radionuclide cystography 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)

V. SPECIFICATIONS OF THE EXAMINATION

A. Retrograde (Direct) Technique

1. Patient preparation/catheterization

In patients with male anatomy, application of urethral anesthesia (eg, lidocaine jelly) before catheterization may decrease discomfort [9]. If direct measurement of the postvoid residual bladder volume is needed, adults and toilet-trained pediatric patients should be asked to void immediately before catheterization. Urine collected during catheterization represents the residual bladder volume [4]. Latex materials should be avoided and should not be used in patients with a known latex allergy or who are at high risk for latex allergy (eg, older patients with multiple surgical procedures of the spine or genitourinary tract). Sedation should be avoided because it precludes obtaining the voiding phase of the examination. Bladder catheterization should be performed by an individual trained in the procedure using aseptic technique and, if clinically desired, a urine specimen for analysis or culture can be obtained at this time.

2. Radiopharmaceutical infusion

The radiopharmaceutical is administered aseptically into the bladder through the urethral catheter and then sterile normal saline is infused until the bladder reaches its estimated capacity with the patient either lying supine or in the sitting or semirecumbent position. Bladder capacity (in mL) in children can be approximated with a reference table [10]:

Table 1
Observed FBCs in Milliliters by Sex, by Reflux Status, and for All Children

Age Group (y)	Girls	Boys	Reflux	No Reflux	All Children
<1	106 ± 42	103 ± 41	113 ± 41	97 ± 41	105 ± 42
1-2	168 ± 53	156 ± 57	169 ± 56	158 ± 53	164 ± 55
2-3	204 ± 60	200 ± 58	203 ± 60	203 ± 59	203 ± 59
3-4	242 ± 69	229 ± 70	242 ± 74	237 ± 66	239 ± 70
4-5	254 ± 70	242 ± 63	255 ± 75	249 ± 64	252 ± 69
5-6	269 ± 71	268 ± 91	269 ± 76	269 ± 72	269 ± 74
6–7	279 ± 76	270 ± 75	279 ± 77	277 ± 75	278 ± 76
7–8	291 ± 83	289 ± 72	296 ± 78	288 ± 84	291 ± 81
8–9	314 ± 85	304 ± 78	321 ± 86	308 ± 83	313 ± 84
9-10	335 ± 80	326 ± 95	334 ± 83	333 ± 82	333 ± 82
10-11	360 ± 90	307 ± 108	366 ± 81	347 ± 99	354 ± 93
11-12	383 ± 90	354 ± 131	371 ± 108	382 ± 94	378 ± 99
12-13	392 ± 95	386 ± 95	398 ± 87	387 ± 99	391 ± 94
13-14	430 ± 118	372 ± 125	423 ± 108	420 ± 130	421 ± 120
All Age Groups	254 ± 100	210 ± 100	242 ± 100	246 ± 104	244 ± 102
<2	144 ± 57	132 ± 57	147 ± 57	132 ± 57	140 ± 57
2-14	279 ± 91	259 ± 90	273 ± 91	277 ± 91	275 ± 91

Note.—Data are presented as the mean ± standard deviation.

During infusion, the saline container typically is placed no more than 100 cm above the tabletop. Warming the saline solution to room or body temperature and infusing at a slow rate may improve the patient's comfort. Alternatively, in adults, the radiopharmaceutical may be added to 500 mL of sterile normal saline for infusion. Some centers also use this approach for younger patients. Patients with a neuropathic bladder might require more than 500 mL.

A cyclic (more than one filling and voiding) examination may increase sensitivity in both children and adults [11] and can be considered in patients with a high pretest probability of having reflux. Repeat filling and voiding cycles are obtained with the catheter remaining in place for all cycles.

3. Image acquisition

Imaging is performed with a low-energy collimator. In all patients during filling, the pelvis and abdomen are imaged continuously in the posterior projection, with the patient lying in a supine position. During voiding, images are obtained continuously. If the camera set-up permits, adults and toilet-trained children who are able to sit may be imaged while seated upright on a bedpan or toilet. If the camera set-up does not permit seated imaging (or rapid conversion from supine to seated) or if the patient is unable to sit on a bedpan, imaging may be performed in the supine position.

If reflux occurs during filling of the bladder, the volume at which reflux occurred should be recorded. The end of the filling phase usually is indicated by a reduction or cessation of the rate of flow of infusate or the patient is unable to tolerate additional infusate. Special care should be taken to estimate maximum bladder capacity [4] in patients with a history of neurogenic bladder or chronic bladder outlet obstruction because the volume obtained from reference tables may be underestimated in these cases. Ultimately, clinical judgement is needed in determining the maximum bladder capacity on a case-by-case basis.

When the bladder fills to maximum capacity, the patient should be instructed to void with continuous image acquisition until the bladder is empty. Postvoid posterior images of the bladder should be obtained in either the supine or upright position after bladder emptying is complete. If the patient cannot void on request or if the patient voids incompletely, the degree of bladder emptying should be recorded. On occasion, it may be appropriate to perform more than one cycle of bladder filling and voiding. At the end of the study, if there is substantial residual volume (RV), the bladder should be drained through the urinary catheter, if it remains in place. The drained volume should be recorded.

4. Processing

For visual analysis of digital images, a consistent image display technique capable of contrast enhancement and cine mode should be used to maximize the sensitivity of the test. If desired, quantification of reflux during the bladder-filling phase and during the voiding phase may be achieved using region-of-interest (ROI) analysis, with ROI placed over the kidneys and the ureters.

For quantification of postvoid RVs, prevoid and postvoid images of the bladder should be acquired anteriorly or posteriorly. ROIs are drawn around the bladder on both the pre- and postvoid images. The volume of voided urine is recorded. RV can be estimated by the following formulas:

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RV (mL) =
(voided vol (mL)) × (post-void bladder ROI count)
(prevoid bladder ROI count) – (postvoid bladder ROI count)
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RV may be calculated if the volume to which the bladder was filled is known. The equation then becomes:

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RV (mL) = (prevoid bladder vol (mL)) × (postvoid bladder ROI count) pre-void bladder ROI count
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5. Interpretation

The degree of reflux is estimated using a visual grading scale with RNC grades 1 to 3 as below [4, 12-14]:

RNC Grades	Finding	Analogous Radiographic Grades
1 (Mild)	Activity limited to ureter	1
2 (Moderate)	Activity reaching the renal collecting system	II and III
3 (Severe)	Activity in markedly dilated renal collecting system and ureter	IV and V

Careful review of available previous radiographic, ultrasound, and radionuclide examinations will add to the accuracy of interpretation of the current examination.

The presence of incomplete drainage of refluxed radiotracer, particularly from a dilated renal pelvis, after complete voiding and/or drainage of the bladder should be noted because it could be indicative of coincident ureteropelvic junction or ureterovesical junction obstruction.

6. Instructions to patient/parent

The radiation exposure to the bladder is low and well within accepted diagnostic imaging levels. It can be further reduced by complete drainage of any unvoided activity and by encouraging hydration and voiding after the examination. Instruction to drink fluids by mouth for several hours with frequent voiding following the examination should be given to the patient, parent, or caregiver.

V. SPECIFICATIONS OF THE EXAMINATION

B. Indirect (Antegrade) Technique

This test usually is performed as the final part of a dynamic renal scan. No additional radiotracer is administered beyond what was already administered for renal scintigraphy (see the <u>ACR-ACNM-SPR Practice Parameter for the Performance of Renal Scintigraphy</u> [15]), which can be combined with this technique.

The advantages of the indirect technique are that it is noninvasive (ie, does not require catheterization) and it provides information about renal function and collecting system drainage. A significant disadvantage of the indirect technique is a lower sensitivity than direct RNC because 1) the bladder may only partially fill, 2) reflux may be detected only during the voiding phase unless time activity curves are created in which case spikes in activity during drainage can signify reflux, and 3) it may be difficult to differentiate between reflux and residual antegrade excretion [16-18]. Use of ROIs over the collecting systems and time-activity curves may enhance the sensitivity of indirect RNC for detecting VUR. Indirect cystography should not be used if the patient has not been toilet trained or has impaired renal function [13, 16-18].

In general, nuclear cystography should be avoided during active urinary tract infection.

VI. DOCUMENTATION

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging Findings</u> [19].

The report should include the radiopharmaceutical used, the administered activity, the route of administration, the number of bladder filling cycles, and any other pharmaceuticals administered, including their dose and route of administration. Any limitations or complications of the study also should be included in the report.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the <u>ACR-AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras</u> [20].

A gamma camera with a low-energy all-purpose/general all-purpose or high-resolution collimator is usually desirable. If the clinical question relates to VUR, the field of view (FOV) must be large enough to include both the bladder and kidneys. For infants and small children, magnification may be used if a large FOV camera head (400 mm) is employed.

A framing rate of 10 to 30 seconds per frame is suggested during the filling phase of the study and no more than 5 seconds per frame during micturition. The collimator face and the entire imaging field must be protected from radiopharmaceutical contamination using plastic-backed absorbent pads or other similar material. Plans for collection, disposal, storage, or decontamination of radioactive urine and materials must be considered.

VIII. RADIATION SAFETY

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

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals in accordance with ALARA principles. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by applicable state, local, or other relevant regulatory agencies and accrediting bodies, as appropriate. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol, using body habitus or other customized method when such guidance is available.

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.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). 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).

IX. 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 ACR Position Statement on Quality Control and 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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