REFERENCE COMMITTEE II

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Commission on Economics  Commission on Government Relations
Commission on Human Resources  Commission on Interventional & Cardiovascular
Commission on Neuroradiology  Journal of the American College of Radiology
Commission on Leadership & Practice Development  Commission on Medical Physics

<table>
<thead>
<tr>
<th>No.</th>
<th>RESOLUTION</th>
<th>TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Ten-Year Extension of Policies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(a) DRUGS AND EQUIPMENT</td>
<td>REVISIEd</td>
</tr>
<tr>
<td></td>
<td>5. PORTABLE IMAGE MEDIA (CDS AND DVDS)</td>
<td>POLICY</td>
</tr>
<tr>
<td></td>
<td>(b) DRUGS AND EQUIPMENT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7. RADIOGRAPHICALLY IDENTIFIABLE MARKERS ON MEDIA DEVICES</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(c) PROFESSIONAL LIABILITY</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. TORT MEDICAL LIABILITY REFORM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(d) WORKFORCE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. FEDERAL/STATE RESTRICTIONS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(e) RADIOLOGICAL PRACTICE AND ETHICS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. ACCREDITATION</td>
<td></td>
</tr>
</tbody>
</table>

13. ACR–AAPM–ACNM–SNMMI Practice Parameter for Reference Levels and Achievable Administered Activity for Nuclear Medicine and Molecular Imaging  REVISIEd PP

14. ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Neuroendocrine Tumor Scintigraphy (with Gamma Cameras)  REVISIEd PP

15. ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Radionuclide Cystography  REVISIEd PP


17. ACR–ACNM–ASTRO–SNMMI Practice Parameter for Lutetium-177 (Lu-177) DOTATATE Therapy  NEW PP

18. SUNSET: ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy  REVISIEd PP

19. Supervising Radiologist Understanding for Imaging Indication  NEW POLICY

20. Extension of Review Cycle for One Practice Parameter  NEW POLICY

21. Conflict of Interest  NEW POLICY

22. Paid Family/Parental Leave  Resolution Withdrawn

ACR STAFF
Director      Brian Monzon  Assistant      Nicole Vega
Moderator     Jennifer Walter  Attorney      Tom Hoffman
Recorder      Shannon Rexrode  Assistant to Society Reps  Ashraful Azim
RESOLUTION NO. 12

Ten Year Extension of Policy

WHEREAS, the ACR bylaws state that “All official actions and policies of the Council are effective for only ten years unless extended for an additional ten year period by the Council…,” and

WHEREAS, the various components of the College feel that the following policy should be extended for an additional ten year period; therefore

BE IT RESOLVED, that the following policies of the American College of Radiology be extended for an additional ten year period:

(a) B. DRUGS AND EQUIPMENT

5. PORTABLE IMAGE MEDIA (CDS AND DVDS)

The ACR strongly encourage the nation’s PACS vendors to adopt the IHE standards-based profiles; adopted 2010 (Res. 36).

(b) B. DRUGS AND EQUIPMENT

7. RADIOGRAPHICALLY IDENTIFIABLE MARKERS ON MEDICAL DEVICES

The American College of Radiology recommends that manufacturers include radiographic markers that are identifiable in vivo on all devices designed for use in the body; 1990, 2000, amended 2010 (Res. 1-c).

(c) D. PROFESSIONAL LIABILITY

3. TORT MEDICAL LIABILITY REFORM

The American College of Radiology supports federal and state legislative initiatives for medical liability reforms to reduce the burden of unwarranted claims and unjustified damage awards on the nation’s physicians. Such reforms might include:

• limitations on recovery of non-economic damages;
• the mandatory offset of collateral sources of plaintiff compensation;
• decreasing sliding scale regulation of attorney contingency fees;
• periodic payment for future awards of damages;
• limiting the period of suspension of statutes of limitations for minors to no more than six years;
• a certificate of merit requirement as a condition to filing medical liability suits; and
• the imposition of regulation of expert witness qualifications; 1990, 2000, amended 2010 (Res. 39e).
E. WORKFORCE

1. FEDERAL/STATE RESTRICTIONS

The ACR believes it to be contrary to the public interest for federal and/or state authorities to:
• arbitrarily or artificially manipulate or restrict postgraduate training in various medical specialties; or
• dictate or restrict freedom of choice of medical practice opportunities by arbitrary or artificial means; 1980, 1990, 2000, amended 2010 (Res. 39-f).

I. RADIOLOGICAL PRACTICE AND ETHICS

1. ACCREDITATION

b. Accreditation Programs: Council Approval

The Council recognizes the success of the existing ACR accreditation programs. Future accreditation programs in radiology shall be approved by the ACR Council prior to their development. Each completed accreditation program shall be presented to the Council Steering Committee for comment prior to presentation to the Board of Chancellors for final approval prior to implementation; 1994, amended 2004, 2014 (Res. 21-a).

Once a completed accreditation program has been reviewed by the Council Steering Committee and approved by the Board of Chancellors, that program may only be modified by the accreditation committee which developed it, either acting on its own volition to improve the program based on annual or more frequent review, or by a majority vote of the accreditation committee members in response to an appropriately filed, written appeal (Appendix C) by any active or eligible participant. Any modification to a program, which includes the Certificate of Accreditation that is or will be issued, must be submitted for review to the Speaker and Vice Speaker, and if they deem material, shall be presented to the Council Steering Committee and approved by the Board of Chancellors, but in any event, the Board of Chancellors may require that any modification, material or immaterial, be submitted for such review and approval; Any modification to a program, which includes the Certificate of Accreditation that is or will be issued, must be submitted for review to the Speaker and Vice Speaker, and if they deem material, shall be presented to the Council Steering Committee and approved by the Board of Chancellors, but in any event, the Board of Chancellors may require that any modification, material or immaterial, be submitted for such review and approval; 2000, amended 2010 (Res. 10-b).

Sponsored by: ACR Council Steering Committee
Fiscal Note

Ten Year Extension of Policy

To support the resolution for Ten Year Extension of Policy, the ACR would incur the following estimated costs:

Costs:

De minimis (< $10,000)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–AAPM–ACNM–SNMMI Practice Parameter for Reference Levels and Achievable Administered Activity for Nuclear Medicine and Molecular Imaging

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

ACR–AAPM–ACNM–SNMMI PRACTICE PARAMETER FOR REFERENCE LEVELS AND ACHIEVABLE ADMINISTERED ACTIVITY FOR NUCLEAR MEDICINE AND MOLECULAR IMAGING

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication.

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, 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.

Reference Levels
2020 Resolution No. 13
of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter has been developed revised collaboratively by the American College of Radiology (ACR), and the American Association of Physicists in Medicine (AAPM), the American College of Nuclear Medicine (ACNM), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) to guide appropriately trained and licensed physicians and Qualified Medical Physicists involved in nuclear medicine and molecular imaging procedures.

The establishment of reference levels (RLs) in nuclear medicine and molecular imaging requires close cooperation and communication between the physicians responsible for the clinical management of the patient and the Qualified Medical Physicist responsible for monitoring equipment, image quality, and estimating patient dose. Adherence to this practice parameter should help to maximize the efficacious use of these procedures, minimize radiation dose to patients, minimize radiation dose to and staff, maintain safe conditions, and ensure compliance with applicable standards. This is particularly important for children, who are more vulnerable than adults to the potential risks adverse effects of ionizing radiation.

The goal of this practice parameter is to provide benchmark national nuclear medicine and molecular imaging achievable administered activities (AAA) and RLs for the United States in order to help practices optimize radiopharmaceutical administered activity while meeting the diagnostic needs of the medical imaging procedure.

RLs are used to help manage the radiation dose to the patient. The medical radiation exposure must be optimized, avoiding unnecessary radiation that does not contribute to the clinical objective of the procedure. By the same token, an administered activity that is significantly lower than the AAA may also be a cause for concern because it may indicate that adequate image quality is not being achieved. The specific purpose of the RL is to provide a benchmark for comparison, not to establish regulatory limits. The goal in medical imaging is to obtain image quality consistent with the medical imaging task provide guidance to physicians and Qualified Medical Physicists on the establishment and implementation of RLs in the practice of nuclear medicine and molecular imaging.

RLs for nuclear medicine and molecular imaging should be based on administered activity or (dosage²). There are published surveys and guidelines of administered activity from various professional organizations that can be used to establish RLs are usually based on published surveys from professional organizations or of representative groups performing nuclear medicine and molecular imaging procedures [1-4].

An RL in nuclear medicine is an investigational (action) level that, when it is exceeded, indicates the use of a higher than typical administered activity activities for a routine nuclear medicine and molecular imaging procedure [5-8]. A procedure RL is set at approximately around the 75th percentile of the range of the available administered activity data. The International Commission on Radiological Protection (ICRP) Publication 135

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2 Dosage is the term used by the U.S. Nuclear Commission and other agencies that regulate radioactive materials to describe the patient administered activity and differentiate it from absorbed dose.
Reference Levels [2020 Resolution No. 13] on Diagnostic Reference Levels (DRL) in Medical Imaging provides the current guidance on how to develop RLs [8]. RLs are derived thresholds from radiation metric data that are obtained locally and collected nationally or regionally. If a facility or practice consistently exceeds an RL, it should review its procedures and equipment to determine if acceptable image quality can be achieved with a lower administered activity.

AAA is a concept that can be used with RLs to assist in optimization of image quality and dose to the patient. Although no formal system exists for determining AAA, the concept The AAA is based on the median value (the 50th percentile) of the distribution of a DRL quantity, which, for nuclear medicine and molecular imaging, is the administered activity [3]. The AAA provides a goal that facilities should strive to achieve through the optimization of image quality and patient absorbed doses. in that 50% of facilities are producing images below that administered activity. AAAs for nuclear medicine and molecular imaging are set at approximately the 50th percentile of the range of administered activities.

Further information on RLs and AAAs in nuclear medicine and molecular imaging is available in ICRP Publication 135 [8] and the National Council on Radiation Protection and Measurements (NCRP) Report 172 [3].

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [9].

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The ACR considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physicists in Medicine, or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [10]. (ACR Resolution 17, adopted in 1996 – revised in 2012, Resolution 42)

The appropriate subfields of medical physics for this practice parameter is Nuclear Medical Physics (including medical physics certification categories of Radiological Physics, Medical Nuclear Physics, and Nuclear Medicine Physics).

Certification by the American Board of Science in Nuclear Medicine in Nuclear Medicine Physics and Instrumentation is also acceptable.

The Qualified Medical Physicist must be familiar with the principles of imaging physics and radiation protection; the guidelines guidance of the NCRP; the laws and regulations pertaining to nuclear medicine; the function, clinical uses, and performance specifications of nuclear medicine imaging equipment; and the calibration processes and limitations of the equipment. The Qualified Medical Physicist must also be familiar with the relevant clinical procedures.
III. NUCLEAR MEDICINE RLS FOR IMAGING WITH IONIZING RADIATION

The concept of the RL can be a practical tool in nuclear medicine. Achieving acceptable diagnostic information, consistent with the medical imaging task, is the overriding clinical objective. The quantity that is recommended for RLs and AAAs is the administered activity (dosage) or dosage [8]. Administered activity RLs (in MBq or MBq/kg of body mass weight) are then used to help manage the radiation dose to patients so that the organ doses are appropriate for the clinical purpose.

Determining RLs for nuclear medicine procedures in the United States has previously been difficult because of the limited amount of available survey data, the large number of radiopharmaceuticals that are used, and variability in procedures among practitioners. In the absence of survey data for adults, other guidance has been used. For adults, manufacturers recommend a standard administered activity based on a standard 70-kg person in their package insert as required by the US Food and Drug Administration (FDA). Guidance for minimum and maximum administered activities for adults and children is available from various sources [3,11-21].

The individual(s) listed as an authorized user(s) on the regulatory license or permit is ultimately responsible for the supervision and appropriate use of all radiopharmaceuticals received, prepared, or administered under the user’s direction [22]. The physician listed on the regulatory license or certificate (often called the authorized user) is ultimately responsible for the supervision and appropriate utilization of all radiopharmaceuticals received, prepared, or administered under his or her direction.

It is strongly recommended that each administered dosage be assayed onsite at the medical facility prior to administration to verify the prescribed activity [9].

Determining RLs for nuclear medicine procedures is difficult due to the limited available survey data, number of radiopharmaceuticals used, and variability in procedures. Due to the limited availability of survey data, local assessment may be necessary. For pediatric procedures, the standard is based on recommended activity per unit body mass. For adults, manufacturers recommend a standard administered activity based on a standard 70-kg person in their package insert as required by the US Food and Drug Administration. Guidelines for minimum and maximum administered activities for adults and children are available from various publications [4,8,11-20,23,24]. This is the initial practice parameter on nuclear medicine RLs. Although the recommendations are based on limited survey data, they are the best available data we have for the modality.

RLs and AAAs are part of the optimization process. It is essential to assure that image quality appropriate for the diagnostic purpose is maintained when modifying administered activity. Optimization must balance image quality and patient absorbed dose, i.e., image quality must be maintained at an appropriate level as administered activity is decreased. If diagnostic quality images are not achievable using the RLs or AAAs presented in Tables 1 and 2 due to requirements of particular imaging devices or patient weight, the recommended RLs may need to be exceeded.

A. Adult Examinations

Table 1 summarizes the RLs and AAAs for common some radiopharmaceuticals that are commonly administered to adults. Administered activity information that was recently provided by thousands of U.S. nuclear medicine facilities to accreditation programs during the accreditation process [1,2,4] has updated or added to the limited survey data of nine academic facilities that were available for NCRP 172 [3]. The RLs and AAAs for the specific radiopharmaceutical in Table 1 were determined using the 75th percentile and 50th percentile, respectively of the ACR accreditation data or the NCRP 172 survey data. NCRP 172 values for RLs are based on the 75th percentile of the maximum administered activities, and AAAs are based on the median value of routine administered activities from the survey. It uses data obtained from NCRP 172 and Collaborative Practice Parameters and Procedural Guidelines from the ACR, Society of Nuclear Medicine and Molecular Imaging, and American Society of Nuclear Cardiology [1,11,20]. It is important to note that the NCRP 172 data tables are the results of multiple surveys of clinical facilities and the Collaborative Practice Parameters and Procedural Guidelines are recommended administered activity ranges. The RLs and AAAs in Table 1 were
determined using the 75th percentile and 50th percentile of the NCRP data, respectively, and 75% and 50% of the range of recommended administered activities for the Collaborative Practice Parameters and Procedural Guidelines, respectively.

**TABLE 1**
Radiopharmaceutical Achievable Administered Activities and Reference Levels for Adults

<table>
<thead>
<tr>
<th>Radiopharmaceutical - Examination</th>
<th>Achievable Administered Activity$^1$</th>
<th>Reference Level Administered Activity$^2$</th>
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</thead>
<tbody>
<tr>
<td>$^{99m}$Tc-Hydroxymethylene Diphosphonate (HDP)/Methylene Diphosphonate (MDP) – whole body bone $^{[1,4]}$</td>
<td>929 MBq (25.1 mCi)</td>
<td>988 MBq (26.7 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Iminodiacetic Acid (IDA) analog – hepatobiliary imaging $^{[4]}$</td>
<td>204 MBq (5.5 mCi)</td>
<td>241 MBq (6.5 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Macroaggregated Albumin (MAA) – perfusion lung $^{[4]}$</td>
<td>185 MBq (5.0 mCi)</td>
<td>215 MBq (5.8 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Sulfur Colloid – liver/spleen $^{[4]}$</td>
<td>222 MBq (6.0 mCi)</td>
<td>255 MBq (6.9 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Dimercaptosuccinic Acid (DMSA) $^{[3]}$</td>
<td>185 MBq (5.0 mCi)</td>
<td>289 MBq (7.8 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Mercaptoacetyltriglycine (MAG3) $^{[3]}$</td>
<td>278 MBq (7.5 mCi)</td>
<td>379 MBq (10.0 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-RBC – tagged RBC $^{[4]}$</td>
<td>840 MBq (22.7 mCi)</td>
<td>925 MBq (25 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Pertechnetate – thyroid imaging $^{[4]}$</td>
<td>370 MBq (10.0 mCi)</td>
<td>407 MBq (11.0 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-labeled solids – GI Emptying $^{[3]}$</td>
<td>37 MBq (1.0 mCi)</td>
<td>50 MBq (1.3 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Exametazime (HMPAO) $^{[3]}$</td>
<td>740 MBq (20.0 mCi)</td>
<td>1,193 MBq (32.0 mCi)</td>
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<tr>
<td>$^{123}$I-Sodium Iodide (NaI) – thyroid imaging $^{[4]}$</td>
<td>9.0 MBq (0.255 mCi)</td>
<td>11.0 MBq (0.300 mCi)</td>
</tr>
<tr>
<td>$^{123}$I-Metaiodobenzylguanidine (MIBG) $^{[3]}$</td>
<td>370 MBq (10.0 mCi)</td>
<td>391 MBq (11.0 mCi)</td>
</tr>
<tr>
<td>$^{131}$I-Sodium Iodide (NaI) – whole body imaging thyroid cancer $^{[4]}$</td>
<td>148 MBq (4.0 mCi)</td>
<td>185 MBq (5.0 mCi)</td>
</tr>
<tr>
<td>$^{111}$Indium Pentetreotide – octreotide SPECT imaging $^{[4]}$</td>
<td>226 MBq (6.1 mCi)</td>
<td>237 MBq (6.4 mCi)</td>
</tr>
<tr>
<td>$^{111}$In-Oxine Leukocytes $^{[16,23]}$</td>
<td>24 MBq (0.7 mCi)</td>
<td>30 MBq (0.8 mCi)</td>
</tr>
<tr>
<td>$^{67}$Ga citrate-inflammatory disease $^{[3]}$</td>
<td>185 MBq (5.0 mCi)</td>
<td>371 MBq (10.0 mCi)</td>
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<tr>
<td>$^{18}$F-Fluorodeoxyglucose (FDG) – oncology PET $^{[1,4]}$</td>
<td>485 MBq (13.1 mCi)</td>
<td>555 MBq (15.0 mCi)</td>
</tr>
<tr>
<td>$^{18}$F-Fluorodeoxyglucose (FDG) – brain PET $^{[4]}$</td>
<td>370 MBq (10 mCi)</td>
<td>414 MBq (11.2 mCi)</td>
</tr>
<tr>
<td>$^{18}$F-Florbetaben – brain PET $^{[4]}$</td>
<td>363 MBq (9.8 mCi)</td>
<td>377 MBq (10.2 mCi)</td>
</tr>
</tbody>
</table>
B. Pediatric Examinations

ICRP 135 [8] specifies that the data quantities collected to develop RLs for pediatric nuclear medicine studies should be based on administered activity with adjustments for the size or weight of the child.

Because of limited accreditation or survey data for pediatric nuclear medicine, development of AAAs or RLs that are linked to pediatric size or weight is not practical at this time. However, applicable guidance is available from the 2016 Update: North American Consensus Guidelines for Pediatric Administered Radiopharmaceutical Activities [21]. These guidelines were developed as a result of surveys and consensus workshops by nuclear medicine experts in North America and Europe. Conforming to the North American Consensus Guidelines is the recommendation of NCRP 172. Availability of the North American Consensus Guidelines has been shown to reduce the variability of pediatric radiopharmaceutical administration in the United States [25-27].

C. Adult and Pediatric RL Summary

RLs and AAAs are part of the optimization process for both adult and pediatric examinations. It is essential to ensure that image quality appropriate for the diagnostic purpose is maintained when modifying administered activity. Optimization must balance image quality and patient absorbed dose (ie, image quality must be maintained at an appropriate level as administered activity is decreased). If diagnostic-quality images are not achievable using the RLs and AAAs presented in Table 1 or the recommendations provided

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<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Reference Levels</th>
<th>Adult (MBq)</th>
<th>Pediatric (MBq)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F-Flurbiprofen – brain PET/CT [4]</td>
<td>374 MBq (10.1 mCi)</td>
<td>411 MBq (11.1 mCi)</td>
<td></td>
</tr>
<tr>
<td>99mTc-Sestamibi – one-day protocol (cardiac rest/stress) [2]</td>
<td>388/1,169 MBq (10.5/31.6 mCi)</td>
<td>425/1,251 MBq (11.5/33.8 mCi)</td>
<td></td>
</tr>
<tr>
<td>99mTc-Tetrofosmin – one-day protocol (cardiac rest/stress) [2]</td>
<td>388/1,147 MBq (10.5/31.0 mCi)</td>
<td>425/1,221 MBq (11.5/33.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>99mTc-Sestamibi – two-day protocol (cardiac rest/stress) [2]</td>
<td>1089/1,110 MBq (29.4/30.0 mCi)</td>
<td>1165/1,184 MBq (31.5/32.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>99mTc-Tetrofosmin – two-day protocol (cardiac rest/stress) [2]</td>
<td>1084/1,110 MBq (29.3/30.0 mCi)</td>
<td>1214/1,199 MBq (32.8/32.4 mCi)</td>
<td></td>
</tr>
<tr>
<td>99mTc-Sestamibi – (cardiac stress only) [3]</td>
<td>925 MBq (25.0 mCi)</td>
<td>1,452 MBq (39.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>99mTc-Tetrofosmin – (cardiac stress only) [3]</td>
<td>833 MBq (23.0 mCi)</td>
<td>1,459 MBq (39.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>201TI-Chloride/99mTc-Sestamibi – one-day protocol (cardiac rest/stress) [2]</td>
<td>148/1,110 MBq (4.0/30 mCi)</td>
<td>152/1,184 MBq (4.1/32.0 mCi)</td>
<td></td>
</tr>
<tr>
<td>201TI-Chloride/99mTc-Tetrofosmin – one-day protocol (cardiac rest/stress) [2]</td>
<td>141/1,110 MBq (3.8/30.0 mCi)</td>
<td>148/1,189 MBq (4.0/32.1 mCi)</td>
<td></td>
</tr>
<tr>
<td>201TI-Chloride (cardiac rest/stress) [3]</td>
<td>111 MBq (3.0 mCi)</td>
<td>172 MBq (4.6 mCi)</td>
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</tbody>
</table>

1. 50th percentile of median values obtained in a survey of representative centers
2. 75th percentile of median values obtained in a survey of representative centers
3. Stunning of the thyroid gland occurs when 131I administered for imaging causes a decrease in uptake of radioiodine subsequently given for ablation. Because of concerns about the possible effects of stunning on 131I therapy, administered activities of 74 MBq (2 mCi) or less for diagnostic imaging may be preferable because these dosages do not cause stunning [24].
4. AAA and DRL for 111In-Oxine Leukocytes are based on recommended dose ranges [16,23]

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NOT FOR PUBLICATION, QUOTATION, OR CITATION
in the North American Consensus Guidelines for Pediatric Radiopharmaceuticals Activities because of the requirements of particular imaging devices or patient weight, the guidance may need to be exceeded.

Table 2 summarizes the RLs and AAAs for radiopharmaceuticals commonly used for pediatric procedures. It uses data obtained from NCRP 172 and North American Consensus guidelines [4,26,27]. It is important to note that the NCRP 172 survey data are based on multiple surveys of clinical facilities, and the North American Consensus Guidelines are not intended to be used for diagnostic quality images. If diagnostic quality images are not achievable for the RLs and AAAs presented in Table 2, then the recommended RLs may need to be exceeded.

### TABLE 1

Radiopharmaceutical-Administered Activity in Adults

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Minimum Administered Activity</th>
<th>Achievable Administered Activity</th>
<th>Reference Level Administered Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{18}$F-Fluorodeoxyglucose (FDG)</td>
<td>370 MBq (8.0 mCi)</td>
<td>555 MBq (15.0 mCi)</td>
<td>650 MBq (18.5 mCi)</td>
</tr>
<tr>
<td>$^{67}$Ga-Citrate</td>
<td>185 MBq (5.0 mCi)</td>
<td>280 MBq (7.5 mCi)</td>
<td>325 MBq (8.8 mCi)</td>
</tr>
<tr>
<td>$^{123}$I-Metaiodobenzylguanidine (MIBG) (+1)</td>
<td>185 MBq (5.0 mCi)</td>
<td>280 MBq (7.5 mCi)</td>
<td>325 MBq (8.8 mCi)</td>
</tr>
<tr>
<td>$^{123}$I-Sodium Iodide (NaI)</td>
<td>7.4 MBq (0.2 mCi)</td>
<td>11 MBq (0.3 mCi)</td>
<td>13.0 MBq (0.35 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Dimercaptosuccinic Acid (DMSA) (+1)</td>
<td>130 MBq (3.5 mCi)</td>
<td>160 MBq (4.25 mCi)</td>
<td>170 MBq (4.6 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Disofenin or Methrofenin (hepatobiliary) (+1)</td>
<td>111 MBq (3.0 mCi)</td>
<td>150 MBq (4.0 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Exametazime (HMPAO) Leukocytes</td>
<td>185 MBq (5.0 mCi)</td>
<td>460 MBq (12.5 mCi)</td>
<td>600 MBq (16.2 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Labeled Solids (GI emptying)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>41 MBq (1.1 mCi)</td>
<td>50 MBq (1.3 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Macroaggregated Albumin</td>
<td>111 MBq (3.0 mCi)</td>
<td>150 MBq (4.0 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Mertiatide (MAG3)</td>
<td>130 MBq (3.5 mCi)</td>
<td>250 MBq (6.8 mCi)</td>
<td>310 MBq (8.4 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Medronate (MDP)</td>
<td>555 MBq (15 mCi)</td>
<td>835 MBq (23 mCi)</td>
<td>970 MBq (26 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Sestamibi or Tetrofosmin One-day Protocol (cardiac rest/stress)</td>
<td>296/888 MBq (8/24 mCi)</td>
<td>370/1110 MBq (10/30 mCi)</td>
<td>407/1221 MBq (11/33 mCi)</td>
</tr>
<tr>
<td>$^{99m}$Tc-Sestamibi or Tetrofosmin Two-day Protocol (cardiac rest/stress)</td>
<td>925 MBq per day (25 mCi per day)</td>
<td>1018 MBq per day (27.5 mCi per day)</td>
<td>1073 MBq per day (29 mCi per day)</td>
</tr>
</tbody>
</table>
TABLE 2
Radiopharmaceutical—Administered Activity for Children

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Recommended Administered Activity (based on weight only)</th>
<th>Minimum Administered Activity</th>
<th>Achievable Administered Activity</th>
<th>Reference Level Administered Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>123I-Fluorodeoxyglucose (FDG)</strong></td>
<td>3.7—5.2 MBq/kg (0.10—0.14 mCi/kg)</td>
<td>26 MBq (0.7 mCi)</td>
<td>195 MBq (5.3 mCi)</td>
<td>280 MBq (7.5 mCi)</td>
</tr>
<tr>
<td><strong>18F-Fluorodeoxyglucose (FDG)</strong></td>
<td>3.7 MBq/kg (0.10 mCi/kg)</td>
<td>14 MBq (0.4 mCi)</td>
<td>137 MBq (3.7 mCi)</td>
<td>198 MBq (5.4 mCi)</td>
</tr>
<tr>
<td><strong>18F-Sodium Fluoride</strong></td>
<td>2.22 MBq/kg (0.06 mCi/kg)</td>
<td>14 MBq (0.4 mCi)</td>
<td>85 MBq (2.3 mCi)</td>
<td>120 MBq (3.3 mCi)</td>
</tr>
<tr>
<td><strong>99mTc Ga (for inflammatory disease)</strong></td>
<td>4.08—2.59 MBq/kg (0.01—0.07 mCi/kg)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
<td>167 MBq (4.5 mCi)</td>
</tr>
<tr>
<td><strong>99mTc Ga (for tumor imaging)</strong></td>
<td>2.96—5.25 MBq/kg (0.08—0.14 mCi/kg)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>333 MBq (9.0 mCi)</td>
<td>333 MBq (9.0 mCi)</td>
</tr>
<tr>
<td><strong>123I-Ti-Metaiodobenzylguanidine (MIBG)</strong></td>
<td>5.2 MBq/kg (0.14 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>204 MBq (5.5 mCi)</td>
<td>287 MBq (7.8 mCi)</td>
</tr>
<tr>
<td><strong>123I-Sodium Iodide (NaI) for Thyroid</strong></td>
<td>0.06—0.22 MBq/kg (0.002—0.006 mCi/kg)</td>
<td>0.56 MBq (0.015 mCi)</td>
<td>8.14 MBq (0.2 mCi)</td>
<td>9.45 MBq (0.3 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Dimercaptosuccinic Acid (DMSA)</strong></td>
<td>1.85 MBq/kg (0.05 mCi/kg)</td>
<td>18.5 MBq (0.5 mCi)</td>
<td>50.3 MBq (1.6 mCi)</td>
<td>80 MBq (1.9 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Disofenin (IDA)</strong> (hepatobiliary)</td>
<td>1.85 MBq/kg (0.05 mCi/kg)</td>
<td>18.5 MBq (0.5 mCi)</td>
<td>74.3 MBq (2.0 mCi)</td>
<td>102 MBq (2.8 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Macroaggregated Albumin—If 99mTe-used for Ventilation</strong></td>
<td>2.50—4.88 MBq/kg (0.07—0.13 mCi/kg)</td>
<td>34.5 MBq (0.9 mCi)</td>
<td>188 MBq (5.0 mCi)</td>
<td>265 MBq (7.0 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Macroaggregated Albumin—No 99mTe Ventilation</strong></td>
<td>1.11 MBq/kg (0.03 mCi/kg)</td>
<td>14.8 MBq (0.4 mCi)</td>
<td>46.3 MBq (1.3 mCi)</td>
<td>62 MBq (1.7 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Mertiatide (MAG3) without Flow Study</strong></td>
<td>3.7 MBq/kg (0.10 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>92.5 MBq (2.5 mCi)</td>
<td>120 MBq (3.3 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Mertiatide (MAG3) with Flow Study</strong></td>
<td>5.55 MBq/kg (0.15 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>213 MBq (5.8 mCi)</td>
<td>301 MBq (8.1 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Medronate (MDP)</strong></td>
<td>9.3 MBq/kg (0.25 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>740 MBq (20.3 mCi)</td>
<td>820 MBq (13.375 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Pertechnetate (mesial diverticulum imaging)</strong></td>
<td>4.85 MBq/kg (0.05 mCi/kg)</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>70 MBq (1.9 mCi)</td>
<td>100 MBq (2.7 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Sulfur Colloid (for oral liquid gastric emptying)</strong></td>
<td>Not weight based</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>23.1 MBq (0.6 mCi)</td>
<td>30 MBq (0.8 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Sulfur Colloid (for solid gastric emptying)</strong></td>
<td>Not weight based</td>
<td>9.25 MBq (0.25 mCi)</td>
<td>13.9 MBq (0.4 mCi)</td>
<td>16.2 MBq (0.4 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Ultratage (for GI bleeding)</strong></td>
<td>3.7—11.0 MBq/kg (0.10—0.30 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>13.9 MBq (0.4 mCi)</td>
<td>16.2 MBq (0.4 mCi)</td>
</tr>
<tr>
<td><strong>99mTc-Sestamibi</strong></td>
<td>5.7—11.0 MBq/kg (0.154—0.50 mCi/kg)</td>
<td>37 MBq (1.0 mCi)</td>
<td>777 MBq (21.0 mCi)</td>
<td>702 MBq (21.0 mCi)</td>
</tr>
<tr>
<td><strong>99mTc—(different forms) for Cystography</strong></td>
<td>Not weight based</td>
<td>18.5 MBq (0.5 mCi)</td>
<td>28 MBq (0.75 mCi)</td>
<td>28 MBq (0.75 mCi)</td>
</tr>
</tbody>
</table>
IV. PATIENT-SPECIFIC DOSIMETRY

Internal absorbed dose can be estimated from anthropomorphic computer models and used for comparison of radiation doses among procedures. Although dose estimates are available for children of various ages, adult individuals males and females, as well as pregnant patients females at different gestational stages, they are based on specific generic body-size estimates and tracer kinetics, which may be very different for from those of any individual patient [26,28-30].

On occasion, the need may arise it may be necessary to estimate the dose delivered to an individual patient because of a specific situation (eg, pregnancy or the request of a referring physician request). In these situations, it is recommended that the physician have a written medical physics consider executing a formal written medical physics consultation consult with the a Qualified Medical Physicist. Using the information about the patient’s weight, administered activity, and the radiopharmaceutical, the Qualified Medical Physicist can render an estimate of the specific dose to tissue and organs in the patient. The consultation request and the Qualified Medical Physicist’s report should be duly signed by the requesting physician and the Qualified Medical Physicist and should be incorporated into the patient’s medical record.

V. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) [20-22].


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 and that they are adhered to in accordance with ALARA. 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 state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).
For the purpose of this practice parameter, the radiation dose index that is used is the administered activity of the radiopharmaceutical.

VI. 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).

Performance evaluation, quality control, acceptance testing, written survey reports, and follow-up procedures of all nuclear medicine and PET imaging systems and support equipment should be in accordance with the appropriate ACR Medical Physics Technical Standards (http://www.acr.org/Quality-Safety/Standards-Guidelines/Technical-Standards-by-Modality/Medical-Physics).

The Qualified Medical Physicist should annually review the common nuclear medicine and PET protocols for adults and pediatric patients performed at the facility and report the results of that review. The report should include estimates of radiation dose based on administered activity and a comparison of these estimates with the current RLs. It should provide recommendations for improvement if the dose estimates or administered activity exceeds the RLs.

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters and Technical Standards – Medical Physics of the ACR Commission on Medical Physics and the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging in collaboration with the AAPM, the ACNM, and the SNMMI.

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PRACTICE PARAMETER

Reference Levels

2020 Resolution No. 13

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REFERENCES


OLD REFERENCES


APPENDIX A

This addendum table is taken from the NCRP Report 172 to illustrate survey results for adult administered activities. The survey data was reflective of the responses from “selected nuclear medicine departments at academic centers.” The minimum and maximum values are reflective of the practice of nuclear medicine in 2010 without necessarily assessing if the administered activity was optimized by the respective facility or recommended from another source. Accordingly, the range from the survey is wide for some radiopharmaceutical studies.

**Recommended Radiopharmaceutical Administered Activity for Adults**

*From NCRP Report 172, Table 6.16*

<table>
<thead>
<tr>
<th>Radiopharmaceutical</th>
<th>Minimum Administered Activity</th>
<th>Maximum Administered Activity</th>
<th>Recommended Achievable-Administered Activity</th>
<th>Recommended Reference Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>¹⁸F-Fluorodeoxyglucose (FDG)</td>
<td>269 MBq (8.0 mCi)</td>
<td>814 MBq (22.0 mCi)</td>
<td>666 MBq (18.0 mCi)</td>
<td>710 MBq (19.0 mCi)</td>
</tr>
<tr>
<td>Radioisotope</td>
<td>Median maximum value used</td>
<td>75th percentile maximum value used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------</td>
<td>-----------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I-123Metaiodobenzylguanidine (MIBG)</td>
<td>19.0 MBq (0.5 mCi)</td>
<td>397 MBq (10.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I-123Sodium Iodide (NaI)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>12 MBq (0.3 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mDimercaptosuccinic Acid (DMSA)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>185 MBq (5.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mDisofenin or Mbrofenin (hepatobiliary)</td>
<td>19.0 MBq (0.5 mCi)</td>
<td>222 MBq (6.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mLabeled Solids (GI emptying)</td>
<td>3.7 MBq (0.1 mCi)</td>
<td>241 MBq (6.6 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mMacroaggregated Albumin</td>
<td>19.0 MBq (0.5 mCi)</td>
<td>222 MBq (6.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mMertiatide (MAG3)</td>
<td>11.1 MBq (0.3 mCi)</td>
<td>370 MBq (10.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mMedronate (MDP)</td>
<td>370 MBq (10.0 mCi)</td>
<td>1480 MBq (40.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mSestamibi (cardiac rest)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1665 MBq (45.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mSestamibi (cardiac stress)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1665 MBq (45.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mTetrofosmin (cardiac rest)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1665 MBq (45.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Te-99mTetrofosmin (cardiac stress)</td>
<td>148 MBq (4.0 mCi)</td>
<td>1776 MBq (48.0 mCi)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tl-201Chloride (cardiac rest/stress)</td>
<td>37 MBq (2.0 mCi)</td>
<td>185 MBq (5.0 mCi)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Median maximum value used
275th percentile maximum value used

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter
2015 (Resolution 53)
BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Neuroendocrine Tumor Scintigraphy (with Gamma Cameras)

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

Revised 2015 (Resolution 48) *

ACR–ACNM–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF NEUROENDOCRINE TUMOR SCINTIGRAPHY (WITH GAMMA CAMERAS)

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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

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, 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

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 performing neuroendocrine tumor scintigraphy in adult and pediatric patients. Properly performed imaging with gamma-emitting radiopharmaceuticals that localize in neuroendocrine tumors is a sensitive method for assessing certain tumors. See the ACR–SPR Practice Parameter for the Performance of Parathyroid Scintigraphy, ACR–SPR Practice Parameter for the Performance of Gastrointestinal Scintigraphy, ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy, ACR–SPR Practice Parameter for the Performance of Skeletal Scintigraphy (Bone Scan), and ACR–SNMMI–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease for specific tumors [1-5]. This practice parameter will center on gamma-emitting radiopharmaceuticals rather than organ systems.

Tumor scintigraphy is a rapidly evolving field. Discussion will be confined primarily to gamma-emitting radiopharmaceuticals that the US Food and Drug Administration (FDA) has approved for use as of January 2014 but will also consider some gamma-emitting radiopharmaceuticals used for tumor imaging under specific physician direction.

As with all scintigraphic examinations, correlation of findings with results of other imaging and nonimaging modalities, as well as with clinical information such as serum tumor biomarkers, is necessary for maximum diagnostic yield.

Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

Neuroendocrine tumor scintigraphy involves the intravenous or oral administration of a gamma-emitting radiopharmaceutical that localizes in certain tumor tissues, allowing subsequent imaging. This practice parameter is limited to scintigraphic agents used for gamma camera imaging. Positron emission tomography (PET) imaging of neuroendocrine tumors is covered in the ACR–SPR Practice Parameter for Performing FDG-PET/CT in Oncology and the ACR Practice Parameter for the Performance of Gallium-68 DOTATATE PET/CT for Neuroendocrine Tumors [2,3]. Information concerning the imaging of tumors not discussed in this practice parameter may be found in organ specific parameters, such as those for thyroid, parathyroid, musculoskeletal and gastrointestinal procedures.

(For pediatric considerations see section VI.)
II. GOAL
The goal of tumor scintigraphy is to enable the interpreting physician to detect and evaluate local (primary), regional nodal, distant metastatic, and residual or recurrent tumor tissue by producing images of diagnostic quality.

II. INDICATIONS
Indications for neuroendocrine tumor scintigraphy include, but are not limited to, the following:

1. Detection of certain primary and metastatic neuroendocrine tumors
2. Neuroendocrine tumor staging
3. Assessment of tumor response to therapy
4. Detection and restaging of residual disease after completion of therapy
5. Detection and restaging of recurrent disease in patients who had been clinically and radiologically free of disease after prior therapy
6. Evaluation of abnormal imaging and nonimaging findings in patients with a history of certain neuroendocrine tumors
7. Planning of treatment with unsealed radiopharmaceuticals using either empirical or dosimetric dosage calculations

Specific clinical applications depend on the specific radiopharmaceutical.

For information on radiation risks to the fetus, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [4].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for neuroendocrine tumor scintigraphy should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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)

A. Radiopharmaceuticals

1. Radioiodinated Metaiodobenzylguanidine (MIBG)

MIBG is a chemical analog of norepinephrine. Iodine-123 (I-123-iodide)-labeled MIBG is used specifically for evaluating neuroendocrine tumors such as pheochromocytoma, paraganglioma, neuroblastoma,
ganglioneuroma, ganglioneuroblastoma, carcinoid tumors, medullary thyroid carcinoma, Merkel cell tumor, and multiple endocrine neoplasia (MEN) type 2 syndromes [5-11].

In adults, the administered activity is 5.0 to 10 mCi (185 to 370 MBq) of I-123-iodide MIBG injected intravenously [5-7,11-13]. For children, the administered activity should be as low as reasonably achievable for diagnostic image quality [9,14,15]. For children, the minimum administered activity is 1.0 mCi (37 MBq), and the maximum administered activity is 8.8 mCi (326 MBq). See table 4 below (the table is a picture file and cannot be struck so we have inserted the ‘x’).

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<thead>
<tr>
<th>Table 4: Activity values and effective dose for a whole-body scan with 123I-MIBG (ICRP 80 [7])</th>
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*a Minimum activity
*b Changes to the 2007 version (as depicted in orange in Fig. 1)

2. Indium-111 Pentetreotide (In111-pentetreotide)

In111-pentetreotide is an octapeptide similar to the active component of somatostatin [16-20]. It interacts with somatostatin receptors in both normal tissue and certain tumors, especially those of neuroendocrine origin that have high expression of somatostatin receptors (eg, sympathoadrenal system tumors [pheochromocytoma, neuroblastoma, ganglioneuroma, and paraganglioma]), gastroenteropancreatic tumors (GEP) [eg, carcinoid, gastrinoma, insulinoma, glucagonoma, vasoactive intestinal peptide (VIP) VIPoma, etc], medullary thyroid carcinoma, pituitary adenoma, Merkel cell carcinoma, and small-cell lung carcinoma [19]. However, certain nonneuroendocrine tumors and nonneoplastic conditions can express somatostatin receptors, resulting in In111-pentetreotide avidity [19].

The usual adult administered activity is 4 to 6 mCi (148 to 222 MBq). Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality.

B. Patient Preparation and Imaging

1. Radioiodinated Metaiodobenzylguanidine (MIBG)

Patient Preparation: Many classes of drugs (eg, tricyclic antidepressants and sympathomimetic amines) may interfere with the uptake or vesicular storage of MIBG [5]. Patients should be screened for interfering medications, which should be discontinued whenever possible in coordination with the referring physician. For a majority of medications, a withdrawal time of 24 to 48 hours is sufficient; however, for some medications, a withdrawal period of up to several weeks is optimal [5,13]. Over-the-counter decongestants and “cold” remedies also should be discontinued. Thyroid blockade can be achieved by administering oral potassium iodide (150-300 mg/day) or potassium perchlorate (400-600 mg/day) [5-7,9,11]. Thyroid blockade may be administered 1 day prior to or at the time of planned radiopharmaceutical injection and should be continued for 1 to 2 additional days for I-123-iodide MIBG. Oral potassium iodide preparation includes tablets (65, 130, and 170 mg), supersaturated potassium iodide solution (SSKI; 1,000 mg/mL), or...
Lugol solution (1% solution contains 25.3 mg/mL). For solutions dispensed as drops, 1 drop is 0.05 mL (20 drops per milliliter). Suggested pediatric dosing of potassium iodide is 32 mg/day for children from 1 month to 3 years; 65 mg/day for children 3 to 13 years; and 130 mg/day for children over 13 years [9]. Newborns may receive 16 mg potassium iodide only on the day before tracer injection [9]. For I-123-iodide MIBG, breastfeeding should be discontinued for 12 hours (4 mCi dosage) or 24 hours (10 mCi dosage).

Imaging Technique: For I-123-iodide MIBG, imaging typically is performed at 24 hours (18-48 hours) after administration using low-energy or medium-energy collimators [5,6,21]. Total-body imaging (5-10 cm/min) or 500,000 counts static images are obtained. Single-photon emission CT (SPECT) or SPECT/CT imaging of areas of abnormality or clinical concern (128 × 128 × 16 matrix, 3° stops, 30 seconds per stop) can should be performed and may be of additional diagnostic benefit [22-24].

2. In111-pentetreotide

Patient Preparation: For In111-pentetreotide imaging, interruption of breastfeeding is usually unnecessary because a radiation dose to the child is unlikely to exceed 100 mrem. No dietary restrictions are necessary; however, patients should be encouraged to drink fluids. A mild laxative taken the evening before the injection may facilitate detection of abdominal and pelvic lesions. The examination should be carefully considered in patients who have severely impaired renal function because this is the primary route of excretion for the radiopharmaceutical. Hemodialysis might improve image quality [19]. Temporary withdrawal of somatostatin analogue therapy prior to In111-pentetreotide imaging (eg, 1 day for short-acting and 3-4 weeks for long-acting somatostatin analogues) is controversial and should be performed (if feasible) in coordination with the referring physician [19]. In111-pentetreotide should not be administered through a total parenteral nutrition (TPN) line or injected into TPN solution. In patients with insulinoma or in patients with diabetes receiving high dosages of insulin, administration of pentetreotide can cause severe hypoglycemia; in these patients, blood glucose should be checked prior to pentetreotide administration, and an intravenous line with 5% dextrose in 0.9% NaCl (D5 NS) should be continuously infused prior to and during radiopharmaceutical administration.

Imaging Technique: Imaging with In111-pentetreotide is usually performed 4 to 24 hours, or 24 and 48 hours, after injection using medium-energy collimators (172 and 245 keV photopeaks [19]). Additional imaging at 48 to 72 hours after injection may sometimes be helpful. Between 24 and 48 hours, laxative therapy can be administered to achieve clear physiologic bowel activity [19]. Planar imaging, SPECT, and SPECT/CT practice parameters are similar to those described in section VII.A.

A. Gallium-67 Citrate

(See the ACR–SPR Practice Parameter for the Performance of Scintigraphy for Inflammation and Infection [25].)

Injected intravenously, gallium-67 is bound by plasma transferrin and lactoferrin. Although the exact mechanism is not known with certainty, its localization within a tumor is believed to relate to intracellular ferritin and/or lactoferrin [26]. Though many different tumors are reported to have a variable affinity for gallium-67, this radiopharmaceutical has been used most commonly in assessing Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, lung cancer, and hepatocellular carcinoma [27-35]. Note that FDG-PET/CT has replaced gallium-67 citrate for Hodgkin and non-Hodgkin lymphoma, melanoma, and lung cancer [36]. Although CT and MRI are mainstay modalities for the evaluation of hepatocellular carcinoma, gallium-67 might be useful in differentiating hepatocellular carcinoma from regenerating nodule [37]. The usual adult administered activity is 5.0 to 10.0 millicuries (185 to 370 MBq) injected intravenously. Due to the high radiation exposure, gallium-67 should not be used in children younger than 14 years of age, unless there is a clear evidence of malignancy and imaging with gallium-67 is absolutely necessary to address the clinical question [29]. Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality [14].
C. Indium-111 Capromab Pendetide

Capromab pendetide is an indium-111-labeled immunoconjugate of the murine monoclonal antibody that reacts with a prostate-specific membrane antigen expressed by prostate epithelial cells [38]. The examination can be performed to either stage newly diagnosed prostate cancer prior to definitive treatment [39-43] or more commonly to detect prostate cancer recurrence after definitive treatment in the setting of rising prostate-specific antigen (PSA) [38,42,44]. The examination is considered more effective for detecting local and nodal regional or metastatic disease than for detecting osseous metastatic disease [43,45,46].

The usual adult administered activity of indium-111 capromab pendetide is 4 to 7 millicuries (150 to 260 MBq).

E. Thallium-201 (Thallous Chloride)

(See the ACR-SPR Practice Parameter for the Performance of Parathyroid Scintigraphy [1]). Thallium-201 is a potassium analog that enters cells in proportion to local blood flow. For reasons that are not well understood, it appears to have an affinity for certain tumors (eg, glioblastoma, osteosarcoma, soft-tissue tumors, and lymphoma) [47-51]. Currently, thallium-201 is rarely used as a tumor-imaging radiopharmaceutical, but it might be helpful as a problem-solving tool, for example in differentiating toxoplasmosis from lymphoma in the brain and for differentiating radiation necrosis from glioma recurrence [50,51].

The usual adult administered activity is 3 to 5 millicuries (111 to 185 MBq). Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic image quality.

F. Technetium-99m Sestamibi

(See the ACR-SPR Practice Parameter for the Performance of Parathyroid Scintigraphy [1]). Technetium-99m sestamibi is a nonpolar lipophilic radiopharmaceutical that crosses the cell membrane, undergoes deamination, and becomes trapped within the cell. Localization is dependent on local blood flow and mitochondrial uptake. In addition to imaging of parathyroid lesions, this radiopharmaceutical is useful for evaluating breast lesions [52-61]. The usual adult administered activity is 20 to 30 millicuries (740 to 1,110 MBq) for single detector breast specific gamma-imaging devices. Molecular breast imaging with a dual-headed configuration with solid-state (nonscintillating) detectors allows for a lower administered activity (eg, 8 millicuries or less) [62-64]. Administered activity in children should be determined based on body weight and should be as low as reasonably achievable for diagnostic imaging quality [13].

Although technetium-99m sestamibi has an affinity for many other tumors (eg, bone and soft tissue, lung, head and neck, and thyroid tumors [65-72]), it is rarely used for tumor imaging other than parathyroid and breast due to widespread availability of 18F-FDG PET/CT. At the present time, technetium-99m sestamibi retains a prominent role in tumor imaging only when 18F-FDG PET/CT is not available.

A. Gallium-67 Citrate

(See the ACR-SPR Practice Parameter for the Performance of Scintigraphy for Inflammation and Infection [25].)

Patient Preparation: In the pregnant patient, risks versus benefits need to be considered prior to performing any procedure. For gallium-67 tumor imaging, breastfeeding should be discontinued for at least 1 month to avoid exceeding dose of 100 mrem to the breastfeeding infant [73]. Food and liquid restrictions are not mandatory, and bowel preparation is optional [29]. Normal colonic radiopharmaceutical activity may interfere with evaluation of abdominal disease; mild laxatives (given at least 18 hours prior to imaging) or enemas may occasionally be necessary for colon cleansing. Vigorous catharsis should probably be avoided in patients who are on chemotherapy or are otherwise immunosuppressed. The procedure should be avoided within 24 hours after blood transfusion or gadolinium-enhanced MRI scanning, which may alter gallium-67 biodistribution [29].

Imaging Technique: Imaging is normally performed 48 to 96 hours after administration and may be repeated daily for as long as 7 to 10 days afterwards, using the lower 2 or lower 3 photopeaks (93, 184, and 300 keV [29,31]). The patient should be instructed to fully empty the bladder, change incontinence pad, or empty urine drainage bag immediately prior to positioning on the imaging table. Whole body imaging is obtained, supplemented by spot images or a series of static planar images of the whole body. For whole-body imaging, anterior and posterior views are obtained; with approximately 1,500,000 counts; matrix 256 or 512 x 1024 x 16; scan speed 5 to 10 cm/min. For spot images of the chest, abdomen, and pelvis, at least 50,000 counts should be obtained, with desirable counts of 100,000 counts or more.

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*Radiopharmaceuticals made from murine sources may cause immunologic response in some patients. Anaphylactic reactions are uncommon, but injection should be carried out where resuscitation equipment and personnel are available. Some patients develop human antimouse antibodies (HAMA), and this may interfere with subsequent imaging.*
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ranging between 1,000,000 and 2,000,000; matrix 256 or 512 x 512 x 16. Due to moderate hepatic activity, images of the chest and pelvis should avoid including the liver. Single photon emission computed tomography (SPECT) imaging can be performed to increase contrast resolution for detecting disease in deep structures to better separate intraluminal gallium in the gastrointestinal tract from intra-abdominal lesions and to correlate with other cross-sectional imaging modalities. For single-headed SPECT cameras, a 64 x 64 matrix, 360° rotation, and 64 or 128 stops with 20 to 25 seconds per stop are recommended. For multiheaded SPECT cameras, a 128 x 128 matrix, 360° of data collection with 3° steps, and 20 to 40 seconds per stop are suggested. SPECT/CT imaging of relevant sites may be of additional diagnostic benefit, providing attenuation correction of the SPECT image data and improving anatomic lesion localization and characterization.

C. — Indium-111 Capromab Pendetide

For indium-111 capromab pendetide imaging, no patient preparation is required, although bowel cleansing may be useful. Newer indium-111 capromab pendetide imaging protocols performed 5 to 7 days after the radiopharmaceutical injection, combining delayed planar whole body imaging (scan speed 5 cm/min) with limited area SPECT/CT, provides attenuation correction for SPECT imaging data and may improve anatomic lesion localization and characterization and thus obviate the need for immediate imaging and technetium-99m RBC imaging [74-76]. The field of view (FOV) should include the penile blood pool at the bottom of the FOV and as much of the pelvis and abdomen as possible (early regional nodal and osseous metastatic disease typically occur in the pelvis). Additional body regions can be included as needed. For multiheaded SPECT systems, a 128 x 128 x 16 matrix, 360° of data collection with 3° steps, and 60 seconds per stop are suggested. If SPECT/CT is not available, 2-SPECT imaging acquisition procedures may be utilized [36]. The first, and preferred, technique uses the simultaneous dual-radiopharmaceutical SPECT acquisition performed 4 to 5 days after the injection of indium-111 capromab pendetide and shortly after technetium-99m autologous labeled red blood cells injection. The abdomen and pelvis, extending below the level of the pubic symphysis, should be included in the FOV [42]. The technetium-99m window should be centered 140 keV with a 10% window. The indium-111 windows should be centered at 173 keV and 247 keV with a 10% and 20% window, respectively. The second, and less desirable protocol due to potential anatomic misalignment, consists of indium-111 capromab pendetide imaging of the abdomen and pelvis caudal to the symphysis pubis performed 30 minutes after injection of indium-111 capromab pendetide to obtain a blood-pool image set; the second imaging session is performed 4 to 5 days after injection and should be as identical as possible in position and location of the abdomen and pelvis as the first day. Another consideration should be taken into account on day 4 to 5 imaging secondary to the activity in the bladder. If filtered back projection (FBP) reconstruction is utilized for the SPECT images, then consideration should be taken for the use of a catheter with bladder wash. If iterative reconstruction (IR) is utilized, then a bladder catheter may not be as important. Planar imaging with SPECT or SPECT/CT imaging practice parameters are similar to those described in sections VII.A and VII.C.

E.— Thallium-201 (Thallous Chloride)

For thallium-201 tumor imaging, no special patient preparation is required. Breastfeeding should be discontinued for 2 weeks after thallium-201 [73]. No special preparation is required. Imaging may be performed 15 to 20 minutes (early) or 2 to 4 hours (delayed) after injection. Imaging at multiple time points might be helpful in distinguishing benign and malignant tumors or assessing tumor aggressiveness or response to therapy [77]. Planar and SPECT or SPECT/CT imaging is performed using low-energy high-resolution parallel hole collimator with 20% windows centered at 80 and 167 keV. Imaging may be limited to the area of interest (eg, brain). Alternatively, whole-body planar imaging (scan speed 5 to 10 cm/min) with SPECT (64 x 64 x 16 matrix, 360° in 64 projections of 40 seconds each) or SPECT/CT of areas of interest may be performed.

F.— Technetium-99m Sestamibi

The whole-body radiation doses from scintimammography are substantially higher than the dose of a digital mammogram, thus scintimammography is not indicated for routine breast cancer screening in its present form [78-80]. However, scintimammography may be useful in selected patients (eg, breast cancer screening in selected patients, evaluation of indeterminate breast abnormalities, initial staging, and recurrence detection) [81]. Patient Preparation: For scintimammography, no special patient preparation is required. Known hypersensitivity to technetium-99m sestamibi and pregnancy are contraindications. Scintimammography should preferably be performed between days 2 and 12 of the menstrual cycle in premenopausal patients and at least 3 months after cessation of lactation. To minimize false-positive results, scintimammography ideally should be performed either
prior to interventional procedures or at least 2 weeks after fine-needle aspiration of a cyst and at least 3 weeks after core or excisional biopsy. False positive results also are less likely if scintimammography is performed within 72 hours of an interventional procedure.

Imaging Technique: Prior to imaging, the patient should remove clothing from the waist up and should wear a mammography cape or gown. After the venous catheter injection of 20 to 30 millicuries (740 to 1,110 MBq) of technetium-99m sestamibi followed by a 10 to 20 mL flush of normal saline, the intravenous line is removed. To decrease vascular trapping of the radiopharmaceutical, patients may raise their arm above their head for one minute while squeezing a ball. Radiopharmaceutical injection should be in the arm opposite the side of clinical concern or in a foot vein if bilateral disease is suspected.

For image acquisition, the sitting position is preferred; however, the patient may need to stand to optimize lesion detection. Imaging is performed 5 to 10 minutes after radiopharmaceutical injection with a low energy high-resolution small-field-of-view (FOV) gamma camera dedicated for breast imaging (140 keV photopeak, 20% energy window). Planar images are acquired with light breast compression for 10 minutes each or 175,000 counts (7-minute minimum), with acquisition mimicking the mammographic projections (eg, craniocaudal—detector inferior to the breast; mediolateral oblique—detector positioned at an oblique inferior lateral angle aligning to the long axis of the pectoralis muscle). Routine 4 views include right and left cranio-caudal and right and left mediolateral oblique; additional views, most often mimicking mammographic views, may be obtained to optimize lesion detection.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [82].

The report should include the radiopharmaceutical used, the administered activity, and route of administration as well as any other pharmaceuticals administered, including their dose and route of administration.

A relevant oncologic history should also be included with a brief overview of any prior oncologic treatments, emphasizing the specific indication for the current study.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [83].

A gamma camera with low-energy collimation is used for thallium-201 and technetium-99m sestamibi imaging (including scintimammography). For gallium-67 citrate and For In111-labeled radiopharmaceuticals, medium-energy collimation (up to about 300 keV) is used. For I-123-iodide, a low-energy high-resolution or medium-energy collimator may be used. A SPECT/CT hybrid camera may provide additional diagnostic benefit, as discussed above.

VII. RADIATION SAFETY

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.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 and that they are adhered to in accordance with ALARA. 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 state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52)

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 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).

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ACNM, the SNMMI, and the SPR.

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PRACTICE PARAMETER 10
Neuroendocrine Tumor Scintigraphy
2020 Resolution No. 14
REFERENCES


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NOT FOR PUBLICATION, QUOTATION, OR CITATION


OLD REFERENCES


*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter

1996 (Resolution 10)
Revised 2000 (Resolution 28)
Revised 2005 (Resolution 23)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 28)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 48)
RESOLUTION NO. 15

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Radionuclide Cystography

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

Revised 2015 (Resolution 47) *

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

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

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, 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.
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

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 of the bladder 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 ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [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 that is excreted by the kidneys and subsequent imaging with a gamma camera.

(For pediatric considerations see sections VI and VII.)

III. GOAL

The goal of RNC is to enable the performing/interpreting physician to detect and quantify physiologic and anatomic abnormalities of the urinary system by producing diagnostic-quality images.

II. INDICATIONS

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

1. Initial diagnosis of vesicoureteral reflux in female patients with urinary tract infection
2. Diagnosis of vesicoureteral reflux in asymptomatic children with a family history of VUR
3. Diagnosis of vesicoureteral reflux in renal transplant recipients
4. Diagnosis and follow-up of vesicoureteral reflux in infants (including persistent antenatal hydronephrosis) and children with hydronephrosis (eg, persistent prenatal hydronephrosis)
5. As a Follow-up examination to assess spontaneous resolution of known vesicoureteral reflux
6. As a Follow-up examination to evaluate resolution of vesicoureteral reflux after medical or surgical antireflux procedures management
7. Serial evaluation of vesicoureteral reflux in patients with bladder dysfunction
8. Quantification of postvoid residual urine in bladder
For information on radiation risks to the fetus, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [5].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [1].

IV. RADIOPHARMACEUTICALS

The direct (retrograde) technique (see Section VII.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. An administered activity of 18.5 ± 7.4 to 37 MBq (0.5 ± 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 VII.B.) employs may employ Tc-99m mercaptoacetyltriglycine (MAG-3) or Tc-99m DTPA.

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)

A. Retrograde (Direct) Technique

1. Patient preparation/catheterization

To measure In male patients, application of urethral anesthesia (eg, lidocaine jelly) before catheterization may decrease discomfort [7]. 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] [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). In male patients, application of urethral anesthesia (eg, lidocaine jelly) before catheterization may decrease discomfort [8]. Sedation should be avoided because it precludes obtaining the voiding phase of the examination. sedatives relax the ureterovesicular junction musculature, interfering with the normal ureterovesicular valvular mechanism and potentially causing pharmacologically.
induced reflux. 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. The bladder is catheterized for culture.

2. Radiopharmaceutical infusion

The radiopharmaceutical is administered aseptically into the bladder through the urinary 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 [8] or calculated as follows [9]:

\[< 1 \text{ year of age: weight in kg} \times 7\]
\[> 1 \text{ year of age: (age + 2)} \times 30\]

**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. Patients with neurogenic a neuropathic bladder might require more than 500 mL. It is, however, a less suitable alternative, as some of the radiopharmaceutical does not arrive in the bladder until maximal filling.

A cyclic (more than one filling and voiding) examination may increase sensitivity for both children and adults [10] 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

In all patients during filling, the pelvis and abdomen are imaged continuously in the posterior projection, with the patient lying supine. During voiding, images are obtained continuously, either in the seated upright position in adults and toilet-trained children who are able to sit on the bedpan or in the supine position in patients who are unable to sit. A low-energy collimator should be used. Digital data acquisition is recommended.

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 infusate’s rate of flow or by achieving maximum bladder capacity [4]. In children, bladder volume can be approximated either with the formula ((age in years + 2) x 30 mL = bladder volume) or with a reference table [8].

When the bladder fills to maximum capacity, the patient is should be instructed to void or when the patient begins to void spontaneously, imaging is continued with continuous image acquisition until the bladder is empty. In patients able to cooperate, voiding images may be obtained with the patient upright. 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 upon request or if the patient voids incompletely, the bladder should be emptied emptying the bladder via the urinary catheter, will reduce radiation exposure. In infants and children, a cyclic (more than one filling and voiding) examination may increase sensitivity. Repeat filling and voiding cycles are obtained with the catheter remaining in place for all cycles.
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. and by detecting the smallest amounts of reflux. 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 residual volumes, prevoid and postvoid images of the bladder should be acquired anteriorly or posteriorly. ROIs are drawn over the bladder on both sets of the pre- and postvoid images. The volume of voided urine is recorded. Residual volume (RV) can be estimated by the following formulas:

\[
RV \text{ (mL)} = (\text{voided vol [mL]} \times \text{postvoid bladder ROI count}) - (\text{initial prevoid bladder ROI count})
\]

RV may be calculated if the volume to which the bladder was filled is known. The equation then becomes:

\[
RV \text{ (mL)} = \frac{(\text{initial prevoid bladder vol [mL]} \times \text{postvoid bladder ROI count})}{\text{initial prevoid bladder ROI count}}
\]

5. Interpretation

The degree of reflux is estimated using a visual grading scale with RNC grades 1 to 3 as below [4,11-13]:

<table>
<thead>
<tr>
<th>RNC Grades</th>
<th>Finding</th>
<th>Analogous Radiographic Grades</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (Mild)</td>
<td>Activity limited to ureter</td>
<td>I</td>
</tr>
<tr>
<td>2 (Moderate)</td>
<td>Activity reaching the renal collecting system</td>
<td>II and III</td>
</tr>
<tr>
<td>3 (Severe)</td>
<td>Activity in dilated renal collecting system and ureter</td>
<td>IV and V</td>
</tr>
</tbody>
</table>

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 obstruction.

6. Instructions to patient/parent

The radiation exposure to the bladder although is small 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.
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.** Administered activity is the same for renal scintigraphy (see the ACR–SPR Practice Parameter for the Performance of Renal Scintigraphy [14]), which can be combined with this technique.

The advantages of the indirect technique are that it is noninvasive (i.e., does not require catheterization) and it provides information about renal function. A disadvantage of the indirect technique is a lower sensitivity than direct RNC because a) the bladder may only partially fill, b) reflux can be detected only during the voiding phase, and c) it may be difficult to differentiate between reflux and residual antegrade excretion [15-17]. Use of ROIs over the collecting systems and time-activity curves may enhance the sensitivity of indirect RNC for detecting vesicoureteral reflux. Indirect cystography should not be used if the patient has not been toilet trained or has impaired renal function [12,15-17].

For infants and children, refer to the ACR-SPR Practice Parameter for the Performance of Voiding Cystourethrography in Children [7].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [18].

The report should include the radiopharmaceutical used, the administered activity, and route of administration as well as any other pharmaceuticals administered, including their dose and route of administration.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [19].

A gamma camera with a low-energy all-purpose/general all-purpose (LEAP/GAP) or high-resolution collimator (LEHR) may be desirable. If the clinical question relates to vesicoureteral reflux, 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.

Digital acquisition may be desirable, and is necessary if quantification is performed. A $64 \times 64$ acquisition matrix is sufficient for detectors up to 400 mm in diameter. For larger detectors, a $128 \times 128$ matrix is needed. 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, registered radiologist assistants, 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 that work with ionizing radiation must understand the key...
principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels). [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf](http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.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 and that they are adhered to in accordance with ALARA. 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 state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children ([www.imagegently.org](http://www.imagegently.org)) and Image Wisely® for adults ([www.imagewisely.org](http://www.imagewisely.org)) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52)

### 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](https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement)).

### ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website ([https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards](https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards)) by the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ACNM, the SNMMI, and the SPR.
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REFERENCES


OLD REFERENCES


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Development Chronology for this Practice Parameter

1996 (Resolution 12)
Revised 2000 (Resolution 26)
Revised 2005 (Resolution 24)
Amended 2006 (Resolution 17, 35)
Revised 2010 (Resolution 25)
Amended 2012 (Resolution 8 – title)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 47)
RESOLUTION NO. 16

BE IT RESOLVED, that the American College of Radiology adopt the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Gastrointestinal Tract, Hepatic, and Splenic Scintigraphy

Sponsored By: ACR Council Steering Committee

ACR–ACNM–SNMMI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF GASTROINTESTINAL TRACT, HEPATIC, AND SPLENIC SCINTIGRAPHY

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication.

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, 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.
of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

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 physicians performing and interpreting gastrointestinal, hepatic, and splenic scintigraphy in adult and pediatric patients. Gastrointestinal scintigraphy involves the intravenous (IV), oral, transcatheter (to include enteric tubes), or intraperitoneal administration of a radiopharmaceutical that localizes in or transits the salivary glands, gastrointestinal tract, or peritoneal cavity. Hepatic and splenic scintigraphy involves IV administration of radiopharmaceuticals that localize in the reticuloendothelial system (RES) or blood pool of the liver and/or spleen. Imaging is performed with a gamma camera and may also include additional hybrid scintigraphic and anatomical imaging, such as single-photon emission computed tomography (SPECT) with or without computed tomography (CT) imaging, which assists with further localization of an abnormality [1]. As with all scintigraphic studies, correlation of findings with the results of other imaging and nonimaging procedures, as well as clinical information, is necessary to achieve maximum diagnostic yield.

Properly performed imaging with radiopharmaceuticals that localize in or are introduced into the gastrointestinal tract or peritoneum is a sensitive means for detecting, evaluating, and quantifying numerous conditions affecting the gastrointestinal tract and peritoneum.


Application of this practice parameter should be in accordance with the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4].

II. INDICATIONS

Clinical indications are varied and include, but are not limited to, the following:

A. Gastrointestinal Tract

1. Salivary Gland
   a. Demonstration of salivary gland function and/or tumors

2. Gastrointestinal Transit
   a. Verification of suspected aspiration
b. Evaluation and quantification of esophageal motility transit through and reflux into the esophagus

c. Evaluation of gastroesophageal and enterogastric reflux

d. Quantification of the rate of gastric emptying of liquid solid and/or solid liquid meals from the stomach

e. Demonstration of intestinal transit through the small and large intestine

3. Gastrointestinal Bleeding

a. Demonstration of the presence and site of acute gastrointestinal bleeding

b. Detection of ectopic functioning gastric mucosa as seen in Meckel’s diverticulum

4. Peritoneum

a. Assessment of peritoneovenous shunt patency

b. Detection of congenital or acquired perforation of the pleuroperitoneal diaphragm (pleuroperitoneal fistula)

c. Demonstration of the presence or absence of peritoneal loculations prior to intraperitoneal chemotherapy or radiopharmaceutical therapy

B. Liver and Spleen

1. Assessing the size, shape, and position of the liver and/or spleen

2. Differentiation of hepatic or splenic hemangiomas and other mass lesions, such as focal nodular hyperplasia (FNH)

3. Evaluating for residual or ectopic functioning splenic tissue and suspected functional asplenia

9. Detection of ectopic functioning gastric mucosa

10. Demonstration of the presence and site of acute gastrointestinal bleeding

For information on radiation risks to the fetus, see the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation [5].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for gastrointestinal, hepatic, and splenic scintigraphy should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of 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)
A. Radiopharmaceuticals

Several radiopharmaceuticals are currently available. The radiopharmaceutical used should be chosen based on the clinical indications and circumstances. Administered activity for children should be based on body weight and should be as low as reasonably achievable (ALARA) for diagnostic image quality as outlined in the 2016 Update of the North American Consensus Guidelines for Pediatric Administered Radiopharmaceutical Activities [6]. In the United States, technetium-99m (Tc-99m) sulfur colloid (SC) is the only FDA-approved agent for oral administration, and the additional radiopharmaceuticals mentioned below for oral administration may require specific radioactive licensing amendments.

1. Gallium-67 Citrate (Ga-67)

Ga-67 is not commonly used and is not first line, but it is an alternative radiopharmaceutical in certain circumstances when others are not available. Given orally, Ga-67 is not absorbed from the gastrointestinal tract and may be used as a liquid-phase marker of gastric emptying. Like indium-111 (In-111) diethylenetriamine-penta-acetic acid (DTPA), this radiopharmaceutical can be used with a concomitant solid meal labeled with Tc-99m SC for gastric imaging and measurement of small-bowel or colon transit. Its long half-life (physical half-life: 78.3 hours) allows extended imaging of the abdomen up to 96 hours or longer. Administered activity is typically 0.056 kBq/kg (0.0015 mCi/kg) for dual-phase gastric emptying examinations in pediatric patients. For adults needing evaluation of colonic transit or liquid gastric emptying, a dosage of 3 to 7 MBq (0.08-0.2 mCi) can be used [7,8]. For a liquid-only gastric emptying examination, Tc-99m SC should be used instead of Ga-67 to reduce radiation exposure.

2. In-111 DTPA

Given orally, with an administered activity of 5.55 to 18.5 MBq (0.15-0.50 mCi), In-111 DTPA may be used to evaluate liquid gastric emptying when a concomitant solid meal labeled with Tc-99m SC is used. Also, due to its longer half-life (physical half-life: 67.3 hours), additional imaging of the abdomen is possible up to 72 hours for measurement of small-bowel or colon transit. Administered activity of In-111 DTPA in water for colon transit is 3.7 to 37 MBq (0.1-1.0 mCi) [9-11]. However, for a liquid-only gastric examination, Tc-99m SC should be used instead of In-111 DTPA to reduce radiation exposure.

3. Tc-99m (Stannous - Sn) DTPA

Given orally, Tc-99m DTPA may be used for liquid gastric emptying evaluation or for small-bowel transit when only a single liquid meal transit examination is performed. It cannot be used simultaneously for a combined liquid- and solid-phase gastric emptying examination when a Tc-99m solid-phase radiopharmaceutical is also used. When dual-phase (solid and liquid) gastrointestinal examinations are performed, In-111 DTPA (or Ga-67 citrate) is used to measure the liquid phase, and Tc-99m SC is used for the solid phase. Tc-99m DTPA in water can also be used for esophageal transit time evaluation. The administered activity for Tc-99m DTPA is 18.5 to 37 MBq (0.5-1.0 mCi) for adults. The administered activity of the radiopharmaceutical and the volume to be fed to the pediatric patient should be based on patient factors such as age, body weight, and the usual feeding volume [12].

4. Tc-99m Macroaggregated Albumin (MAA)

Given intraperitoneally, Tc-99m MAA is not absorbed and is used as a qualitative marker of the movement of ascitic fluid through peritoneovenous shunt devices or congenital/traumatic diaphragmatic fenestrations. The usual adult administered activity is 18.5 to 185 MBq (0.5-5.0 mCi) in 3 to 5 mL of 0.9% saline [12].
5. **Tc-99m Red Blood Cells (RBCs)**

Tc-99m RBCs remain intravascular and are commonly used for detecting and localizing the source of an active gastrointestinal bleed. The usual adult IV-administered activity for gastrointestinal blood loss detection is 555 to 1,100 MBq (15-30 mCi) [13]. For pediatric patients, the recommended administered activity is 11.39 to 26.67 MBq/kg (0.31-0.72 mCi/kg). The highest RBC-labeling efficiency is achieved with the in vitro method (≥ 97%), which is recommended and widely used [14]. See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals for handling of radiolabeled cells [4].

The usual IV-administered activity of Tc-99m–labeled autologous RBCs for hepatic hemangioma evaluation ranges from 740 to 925 MBq (20-25 mCi).

6. **Tc-99m RBCs (autologous and heat-damaged)**

Autologous RBCs are radiolabeled, preferably by the in vitro method, with an activity of 37 to 222 MBq (1-6 mCi) for planar imaging or 555 to 1,110 MBq (15-20 mCi) for SPECT or SPECT/CT imaging and heated for 15 minutes in a preheated water bath between 49.0°C and 50.0°C. After cooling to at least body temperature, the heat-damaged RBCs are administered intravenously (IV), with imaging performed 20 to 30 minutes postinjection. The heat-damaged RBCs will be preferentially sequestered by splenic tissue. See the ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals [4] for handling of radiolabeled cells.

7. **Tc-99m Sodium Pertechnetate**

During the first 1 or 2 minutes after IV administration, Tc-99m sodium pertechnetate may be used as a blood flow and blood pool marker. Within minutes after injection, this radiopharmaceutical begins to concentrate normally in the salivary glands and in mucin-producing cells of the gastric mucosa, making it suitable for evaluation of salivary gland function and for detection of ectopic gastric mucosa. The usual adult IV-administered activity is 296 to 444 MBq (8-12 mCi). For pediatric patients, 1.85 MBq/kg (0.05 mCi/kg) is recommended. Physiologic renal excretion results in visualization of the kidneys and bladder. Rapid absorption by the stomach and peritoneum makes Tc-99m sodium pertechnetate unsuitable for oral or intraperitoneal administration [15].

8. **Tc-99m SC**

Tc-99m SC, when administered orally, is not absorbed and is an excellent radiopharmaceutical for imaging and quantification of numerous parameters of swallowing and gastrointestinal motility and transit. A small volume (up to 1 mL) of Tc-99m SC containing no more than 18.5 MBq (0.5 mCi) can be used for gastropharyngeal aspiration imaging. In adults, 10 to 30 mL of water containing 3.7 to 11.1 MBq (0.1-0.3 mCi) of Tc-99m SC or Tc-99m DTPA can be given for esophageal transit studies [16]. For gastric emptying, an administered activity of 18.5 to 74 MBq (0.5-2 mCi) is generally used as a radiolabel for liquid and solid meals in adults. The affinity of this radiopharmaceutical for the protein matrix of egg whites facilitates the egg white labeling as the solid phase component of the meal [17]. There is no weight-based dosage for children, but 9.25 to 37 MBq (0.25-1.0 mCi) can be used to label a liquid meal and 9.25 to 18.5 MBq (0.25-0.5 mCi) for a solid meal.

When administered IV, Tc-99m SC is also utilized for functional imaging of the RES of the liver, spleen, and bone marrow. Tc-99m SC consists of particles composed of Tc-99m sulfide stabilized with gelatin. These particles range in size from 0.1 to 1.0 μm. Given IV, they are phagocytized by the RES cells of the liver, spleen, and bone marrow in proportion to relative blood flow, functional capacity of the phagocytic cells, and particle size. Maximum concentration in the liver and spleen occurs within 10 to 20 minutes, and the rate of biologic clearance from the RES is very slow. The usual administered activity is 111 to 222 MBq (3.6 mCi) for planar imaging in adults and up to 370 MBq (10 mCi) for SPECT imaging.
If administered intraperitoneally, Tc-99m SC is not absorbed and becomes a qualitative marker of movement of ascitic fluid through congenital or traumatic diaphragmatic fenestrations and peritoneovenous shunts. It can be used to assess for free flow or loculation prior to P32 colloidal therapy for malignant ascites. The administered activity of 18.5 to 185 MBq (0.5-5.0 mCi) Tc-99m SC is used [12].

Although less superior to Tc-99m RBCs (autologous), Tc-99m SC can also be utilized to identify a gastrointestinal bleed.

B. Imaging and Patient Preparation

1. Gastrointestinal Imaging

a. Salivary Gland

Salivary gland imaging may help in the differential diagnosis of salivary gland disorders and certain masses. A sialogogue, such as lemon juice, may be given to stimulate salivary gland emptying in cases of salivary duct obstruction or ligation, sialadenitis, or suspected Warthin’s tumor. The collimator surface should be protected from contamination by using a plastic-backed pad or other similar material. The patient should lie supine in a Water’s position in front of a gamma camera (chin and nose touching the collimator). During the IV administration of Tc-99m sodium pertechnetate, a 1 to 2 minute radionuclide angiogram of the face (3-5 seconds/frame) is followed by serial dynamic imaging for 20 to 30 minutes (2-3 minutes/frame). Additional planar views may also be obtained in the oblique and lateral projections as needed [18]. The position of palpable nodules should be identified using a radioactive source marker. Computer-generated regions of interest can be drawn over the salivary glands to produce time-activity curves to demonstrate the pattern of accumulation and clearance over time. Quantitative analysis can be applied to the time-activity curves [16].

2. Gastrointestinal Transit

a. Aspiration (Gastric or Pharyngeal Contents)

These examinations are usually limited to pediatric patients or as a preoperative pulmonary evaluation prior to lung transplantation. The patient should have nothing by mouth or by tube-feeding prior to the study. The length of time that the patient should refrain from intake depends upon the patient’s age and the clinical circumstances, but in most cases, 4 hours should be sufficient. The patient should be in the supine position, and images should include the mouth and stomach in the field of view (FOV). Radioactive source markers are placed for anatomic reference (eg, shoulder markers as reference of the relative location of the lungs). An alternative for pediatric patients is administration of a radiolabeled liquid meal at bedtime with imaging performed the following morning [19].

i. Aspiration of pharyngeal contents

A small volume of activity of Tc-99m SC is placed on the dorsal surface of the posterior portion of the tongue or in the buccal fossa. Images are obtained in the posterior projection over the course of 30 to 60 minutes. Delayed images can also be acquired up to 24 hours. Radioactivity detected in the bronchi or lungs confirms aspiration.

ii. Aspiration of gastric contents

An appropriate amount of Tc-99m SC is placed in a small amount of the patient’s feeding, administered orally or by tubing (nasogastric, gastrostomy) depending on the clinical
situation and in consultation with the referring provider. If the material is administered orally, once the feeding is completed, an additional nonradioactive liquid feeding is given to clear any remaining radioactivity from the esophagus. Images are obtained immediately after ingestion (baseline), and serially for 60 minutes thereafter. Additional planar imaging at 4 hours or 24 hours may be helpful. In infants and children, evaluation for aspiration of gastric contents is included as a routine component of nuclear gastric emptying and gastroesophageal reflux examinations. Radioactivity seen in the lungs confirms the diagnosis of aspiration. Imaging is terminated after the radioactivity has cleared from the stomach.

b. **Esophageal Transit**

Scintigraphy of esophageal transit may yield unique and useful physiologic information about esophageal motility in patients with conditions that cause impaired transit of esophageal contents from the pharynx to the stomach (eg, scleroderma, stricture, achalasia) or following therapy for these conditions [20]. This can be by qualitative or quantitative global or regional (dividing the esophagus into thirds) esophageal evaluation. The patient should have nothing by mouth or by tube-feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases, 4 hours is sufficient. The patient typically is studied in the supine position, and data are collected in the anterior projection to include the entire esophagus and proximal stomach in the FOV. As with barium esophagography, use of multiple (up to 6) swallows can increase the sensitivity of the examination in detecting an abnormal swallow. The patient swallows the appropriate administered activity of Tc-99m SC in water or a semisolid as a bolus. The initial rapid bolus transit should be recorded in a dynamic mode of 0.25 to 0.5 seconds per frame up to 30 seconds [21] and reviewed using a cinematic (movie) display to evaluate the bolus transit. Additional data acquisition for up to 10 minutes is also helpful, during which time the patient is asked to perform serial dry swallows to measure clearance from the esophagus and to look for possible gastroesophageal reflux. Comparison of at least one upright and one supine swallow can be helpful to differentiate disorders such as achalasia from scleroderma. Time-activity curves may be generated regionally for the proximal, middle, and distal portions of the esophagus, but visual inspection of the entire cine bolus transit is more important for differentiating the various primary esophageal motor disorders. Esophageal transit time (ETT) is the time from initial bolus entry into the esophagus until clearance of 90% of peak activity [22]. The normal value for esophageal transit time is generally under 14 seconds [16], although each facility should validate its own normal range for its specific technique or closely follow a validated technique and normal range from literature. No significant activity should be in the esophagus after 10 minutes [21,22].

c. **Gastroesophageal Reflux**

Scintigraphy for gastroesophageal reflux may yield unique and useful physiologic information in patients whose history, signs, or symptoms suggest possible incompetence of the gastroesophageal sphincter associated with acute or chronic reflux of gastric contents into the esophagus [20]. Observation of gastroesophageal reflux, however, during an esophageal transit examination can be important as an etiology to reflux esophagitis and associated esophageal dysmotility. In infants and children, a gastroesophageal reflux examination (also called milk scan) is often combined with a liquid gastric emptying examination. The patient should have nothing by mouth or by tube-feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases, 4 hours would be sufficient. A liquid consisting of formula, milk, or orange juice containing an appropriate amount of Tc-99m SC is administered orally or by tubing (nasogastric, gastrostomy). If feasible, when the liquid is introduced via an orogastric or nasogastric tube, the tube should be removed prior to image acquisition. The patient is then positioned supine in a left anterior oblique position beneath the gamma camera, and dynamic images (5-10-second frame images) of the
esophagus and stomach are obtained for 60 minutes [23]. Further delayed images can also be obtained for gastric emptying and possible aspiration evaluation. It is often appropriate to image small children in the supine position with the gamma camera under the imaging table. In adults, a Valsalva maneuver or an abdominal binder may be of benefit. Use of an abdominal binder is contraindicated in children. The number of recorded reflux events detected during the recording session should include the duration and the proximal extent of reflux. Gastroesophageal reflux greater than 4% is considered abnormal. This is determined by dividing the maximum counts in the esophagus by counts in the stomach at the beginning of the study [16]. The examination may be repeated to assess the effectiveness of medical therapy.

d. Gastric Emptying
Evaluation of gastric motility utilizing a radiolabeled meal provides functional information that is indispensable in the management of patients presenting with various upper gastrointestinal signs and symptoms [24]. The patient should have nothing by mouth or by tube-feeding prior to the examination. This is typically done by instructing the patient to have nothing by mouth overnight prior to the examination. The patient’s glucose level should be below 200 mg/dL. Prokinetics and medications that delay gastric emptying must be discontinued 2 days prior to the examination [25]. Three approaches are used: liquid phase, solid phase, and combined liquid-solid phase. In general, the liquid phase is preferred in infants and in neurologically impaired children, whereas the solid phase is used when the patient is capable of ingesting solid food. In both cases, the “meal” needs to be introduced into the stomach fairly quickly (ie, within 10 minutes). It is a good general practice to cover the camera detectors with protective wrap to prevent contamination. A large FOV camera should be used to include the distal esophagus, entire stomach, and proximal small bowel. A region of interest (ROI) is drawn around the stomach, and the counts are decay-corrected. The gastric emptying time-activity curves, halftime of emptying and/or percent of emptying are provided. Anterior posterior imaging to provide for geometric mean attenuation correction should be applied [26]. Posterior projection imaging only may be sufficient in children. Currently, there are no published standardized protocols or normal values for pediatric examinations, and there is a lack of age-related normal values [27].

i. Solid-phase meal gastric emptying in adults
The Consensus Recommendations for Gastric Emptying Scintigraphy: a Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine [28] details recommendations for normal values, patient preparation, image acquisition, and data processing. The ACR supports adoption of the recommendations of this consensus guideline and recommends adoption of its recommended normal values, patient preparation, image acquisition, and data processing. Various solid meals have been evaluated. However, the standardized solid radiolabeled meal per consensus guidelines published in 2008 consists of Tc-99m SC mixed and cooked in 120 g of scrambled liquid egg whites and then ingested along with 2 slices of white toast with 30 g of strawberry jelly and 120 mL of water [29]. Subsequently, 1-minute static imaging at 0, 1, 2, and 4 hours is performed with the patient upright. A dual-head gamma camera can be used in order to obtain simultaneous anterior and posterior projections [17,25]. Alternatively, the patient can rotate from an anterior image to a posterior image if a dual-head camera is not available. The geometric mean of the anterior and posterior counts is calculated from a ROI drawn over the stomach. The percentage remaining at each time point is compared with established normal ranges to determine the presence or absence of gastroparesis. Details can be found in the appendix to the consensus guideline, Consensus Recommendations for Gastric Emptying Scintigraphy: a Joint Report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine [28].
ii. **Liquid-phase gastric emptying in adults and children**

Liquids may detect abnormal gastric emptying in some patients when solid gastric emptying scintigraphy is normal. The liquid-phase study can be performed on a separate day, immediately before or concurrently with a solid-phase study. Tc-99m SC (alternatively, Tc-99m DTPA or In-111 DTPA) is mixed with an appropriate volume of a liquid carrier and introduced into the stomach by swallowing or tubing (nasogastric, orogastric, or gastric depending on the clinical situation) and in consultation with the referring clinician. In adults, the liquid meal typically consists of the radiopharmaceutical mixed in 300 mL of water. Imaging with a single-head gamma camera in the left anterior oblique projection is performed over the course of 30 to 60 minutes (1-minute frames continuously). A geometric mean should also be calculated for a liquid meal study [25]. In adult patients, the liquid meal exits from the stomach in a monoexponential fashion. In children, imaging is usually performed during the first hour, and the percent of emptying is obtained at 60 minutes or later, if indicated. For normal values, details can be found in a 2009 publication by Ziessman et al [26].

iii. **Liquid-phase gastric emptying in infants**

Liquid-phase gastric emptying may be combined with evaluation of esophageal motility, gastroesophageal reflux, and aspiration. The radiopharmaceutical esophagram may be performed initially or following the completion of the gastric emptying portion of the examination. For the esophagram, the patient is placed in the supine position with the gamma camera posteriorly positioned. Dynamic images of the esophagus at 5 seconds/frame for 2 to 3 minutes are obtained for evaluation of esophageal motility and possible aspiration. If the patient is normally fed by mouth, this may be accomplished as the initial part of the gastric emptying procedure that is then followed by continuous imaging of the chest and abdomen for 60 minutes for evaluation of the presence and severity of gastroesophageal reflux. Gastric emptying at 60 minutes and at 2 or 3 hours after completion of feeding is calculated. If the patient is not orally fed, the esophagram should be performed at the end of the gastric emptying examination using a small volume of radiolabeled sterile water or saline.

iv. **Combined liquid- and solid-phase gastric emptying**

For this purpose, In-111 DTPA should be utilized for the liquid meal portion of the study, and Tc-99m SC for the solid meal portion [19,30].

e. **Intestinal Transit (Small and/or Large Bowel)**

Although small- and/or large-bowel transit can be performed separately or in conjunction with gastric emptying scintigraphy, they are most commonly combined with a radiolabeled solid-liquid gastric emptying examination. Medications that may affect transit should be discontinued prior to the examination. No change in diet is necessary. These scans are not commonly performed in pediatric patients. The imaging FOV should include the entire area of interest if possible.

i. **Small-bowel transit**

This study is performed to evaluate for possible dysmotility of the small bowel. Tc-99m SC or Tc-DTPA in water can be utilized for a single-isotope study. Imaging occurs over 6 hours and is considered normal if > 40% of the radiolabeled liquid has progressed into the terminal ileum reservoir and/or progressed beyond the terminal ileum into the cecum and colon [31].

ii. **Large-bowel transit**

This study is most commonly utilized for evaluation of constipation or for the effectiveness of prokinetic medications. In-111 DTPA is the preferred radiopharmaceutical for this purpose.
(Ga-67 is an alternative). Images may be acquired at 6, 24, 48, and 72 hours. At each time point, anterior and posterior abdominal images are obtained for 4 minutes. The geometric-mean-center technique is the most widely used to determine regional transit through the colon. The colon is divided into either 5 or 7 segments, and each is given a numeric value. A geometric center, as a weighted average of the counts in each of these segments, is determined in order to determine progression of the radioactivity in the colon. Higher values indicate activity is mostly in the left colon, and lower values indicate activity is closer to the cecum. Reference values can be found in the publication by Watersham et al [11,32]. Technique details are also published by Maurer et al [10].

iii. Whole-gut transit
An advantage provided by this technique includes the ability to measure solid/liquid gastric emptying in addition to measurement of small-bowel and colon transit resulting in evaluation of the entire gut [10]. A Tc-99m SC–labeled solid meal is given with an In-111 DTPA-labeled liquid meal (water). Gastric emptying and small-bowel transit imaging occurs on day 1, and large-bowel transit typically occurs at 6, 24, 48, and 72 hours. The longer half-life of In-111 DTPA allows for transit evaluation through the colon [31].

3. Gastrointestinal Bleeding
a. Acute Gastrointestinal Bleeding
Diagnosis and localization of an active bleeding site requires that the patient be actively bleeding and imaged during the time the radiopharmaceutical is present in the blood pool. Although this procedure is generally used for gastrointestinal bleeding, it can be useful for other sites of active bleeding. The use of Tc-99m RBCs (autologous) is the recommended method because they remain intravascular and permit a longer imaging time. The clinical detection rate for a gastrointestinal bleed with Tc-99m RBCs can be as low as 0.04 mL/min [26]. Tc-99m SC is an alternative radiopharmaceutical but is less superior to Tc-99m RBCs for this purpose, and if utilized, imaging is usually performed for 20 to 30 minutes because of the rapid clearance of SC from the intravascular space. No patient preparation is required. The patient should void immediately before imaging. The radiolabeled cells are injected IV and dynamic imaging of the anterior abdomen is then performed to first include a blood flow/angiographic phase (rate of 1 frame per 1-3 seconds for 60 seconds) and then for another 60 to 120 minutes (preferably 1 frame per 10-20 seconds) [13]. Oblique, lateral, or delayed static abdominal images may be obtained to supplement the basic examination. If the examination is negative, continued imaging may be appropriate for up to 24 hours. SPECT/CT, although not routinely performed, can be of value to more definitively localize the site of bleeding. If gastric activity is noted, further static images of the head and neck can be acquired to assess for possible thyroid and salivary gland uptake to help differentiate between gastric bleeding versus the presence of free pertechnetate.

b. Ectopic Gastric Mucosa (Meckel’s Scan)
Pharmacologic enhancement prior to radiopharmaceutical administration with H2 blockers (cimetidine, famotidine, or ranitidine) or proton pump inhibitors (omeprazole) to enhance free pertechnetate retention and/or glucagon to decrease gastrointestinal peristalsis can be used. Although not required, the patient should fast for 3 to 4 hours prior to imaging to increase sensitivity for detection of ectopic gastric mucosa. The radiopharmaceutical Tc-99m pertechnetate is given IV, and then dynamic imaging of the abdomen is performed. A rapid sequence of images (blood flow/angiographic phase) taken at 1 to 3 seconds per frame over 60 seconds is obtained in the anterior projection to evaluate the presence of hypervascular abdominal lesions that could be mistaken for ectopic gastric mucosa. Subsequent imaging for 30 to 60 minutes is then acquired as serial static views or continuous dynamic imaging (30-60 seconds per image). Continuous dynamic imaging is preferred to better visually discriminate normal
physiologic activity (such as renal activity) from ectopic gastric mucosa. A lateral view can be useful to distinguish renal activity and identify retrovesical ectopic gastric mucosa. Additional SPECT/CT imaging may help localization. Prone or right anterior oblique positioning can be used to delay gastric emptying into the small bowel if the patient has not been pretreated with H2 blockers. A urinary catheter or administration of 1 mg/kg of IV furosemide may be needed to help clear activity from the ureters and bladder [14].

4. Peritoneal Imaging

No specific preprocedure patient preparation is required. A local anesthetic may be administered prior to injection of the radiopharmaceutical.

a. Evaluation of patency of peritoneovenous shunt

Tc-99m SC or Tc-99m MAA is directly administered into the peritoneal cavity using aseptic technique. An immediate image of the abdomen may be helpful to determine whether the radiopharmaceutical is free in the peritoneum and not loculated. The patient may need to roll from side to side to mix the radioactivity within the ascites. Also, normal saline (50-200 mL) can be infused intraperitoneally to facilitate distribution. Static anterior images are typically acquired at 10, 30, 60, and 120 minutes. If the shunt is functioning correctly, activity will eventually appear in the liver and spleen (with Tc-99m SC) or lungs (with Tc-99m MAA) over 1 to 2 hours. Activity in the shunt tubing may or may not be visualized [12,33].

b. Detection of congenital fenestrations or traumatic perforations of the diaphragm

Tc-99m SC or Tc-99m MAA is administered intraperitoneally. The radiopharmaceutical can also be instilled with up to 500 mL of sterile normal saline in order to facilitate movement of the radiopharmaceutical into the pleural cavity. If activity appears in the pleural space, the diagnosis of fenestrated or perforated diaphragm is confirmed [34-36].

c. Demonstration of peritoneal loculation of fluid

Tc-99m SC or Tc-99m MAA is administered intraperitoneally. Immediate and delayed static images over the abdomen will reveal the pattern of distribution of the radiopharmaceutical in the peritoneal cavity.

C. Liver and Spleen Imaging

1. Assess size, shape, and/or position of the liver and/or spleen

Tc-99m SC can be used to identify the size and location of functional hepatic and splenic tissue. Approximately 10 to 20 minutes after IV administration of Tc-99m SC, static planar images of the liver and spleen are obtained. Anterior, posterior, right anterior oblique (RAO), left anterior oblique (LAO), right posterior oblique (RPO), and right lateral images should be acquired. Additional views (left posterior oblique [LPO] and left lateral) may be indicated for more comprehensive evaluation of the spleen. Another anterior image may also be acquired with a lead marker of known length to help determine organ sizes. Additional SPECT or SPECT/CT localizes any focal abnormality seen on planar imaging. The normal distribution of Tc-99m SC in the RES is approximately 85% to the liver, 10% to the spleen, and 5% to the bone marrow. A shift away from the normal biodistribution can be seen in severe liver dysfunction and is termed “colloid shift” in which there is greater splenic and marrow uptake [37].

2. Differentiation of hepatic or splenic hemangiomas and other mass lesions
Hepatic or splenic hemangiomas are conspicuous with Tc-99m RBCs imaging because of their relatively greater blood volume than that of the surrounding parenchyma. They are typically identified when the radiolabeled RBCs reach equilibrium within the intravascular space of the hemangioma, which may take between 30 and 120 minutes postinjection or longer (may require up to 24 hours or more for larger hemangiomas [12]). Following IV administration of Tc-99m RBCs (autologous), immediate angiographic images (1-second intervals for 60 seconds) may yield useful information on the vascularity of particular lesions. Hemangiomas show typical low flow in the arterial phase with late “filling in” on delayed images. This is followed by blood pool imaging (eg, delayed imaging). SPECT or SPECT/CT imaging is particularly helpful in identifying lesions smaller than 3 cm.

Depending upon whether there are functioning or nonfunctioning Kupffer cells, the uptake pattern with Tc-99m SC can help differentiate between different types of mass lesions in the spleen and liver. Types of photopenic lesions include infarcts, cysts, hepatic adenoma, etc. FNH typically has increased uptake in the liver [16]. Up to 30% FNH will be photopenic on a liver scan.

3. Evaluating for residual or ectopic functioning splenic tissue and suspected functional asplenia

The radiopharmaceutical Tc-99m RBCs (autologous and heat damaged) is administered IV (preparation technique in Welch et al [38]). Imaging of the abdomen may commence 30 to 120 minutes later. Planar and SPECT or SPECT/CT imaging parameters are similar to those for liver and spleen imaging. If the test is being performed to identify residual or ectopic splenic tissue, the abdomen and pelvis should be imaged. If the patient has had prior trauma that might have ruptured the diaphragm, the chest should be imaged as well. Alternatively, Tc-99m SC can be utilized instead, but it is less sensitive and specific as compared with Tc-99m heat-damaged RBCs [12].

A. Technetium 99m Sodium Pertechnetate

During the first 1 or 2 minutes after intravenous administration, technetium-99m pertechnetate may be used as a blood flow and “blood pool” marker. Within minutes after injection, this radiopharmaceutical begins to concentrate in the salivary glands and gastric mucosa, making it a suitable radiopharmaceutical for evaluation of the salivary glands and for detection of ectopic gastric mucosa. The usual adult administered activity is 296 to 444 MBq (8 to 12 mCi) intravenously. Lower administered activity (111 to 185 MBq [3 to 5 mCi]) may be used if flow imaging is not performed. For pediatric patients, 1.85 MBq/kg (0.05 mCi/kg) is recommended. Physiologic renal excretion results in visualization of the kidneys and bladder. Rapid absorption by the stomach and peritoneum makes technetium-99m pertechnetate unsuitable for oral or intraperitoneal administration.

B. Technetium-99m Sulfur Colloid

Technetium-99m sulfur colloid, when administered orally, is not absorbed and is an excellent radiopharmaceutical for imaging and quantification of numerous parameters of swallowing and gastrointestinal motility and transit. A small volume (up to 1 mL) of technetium-99m sulfur colloid containing no more than 18.5 MBq (0.5 mCi) can be used for pharyngeal aspiration imaging. Administered activity of 18.5 to 74 MBq (0.5 to 2 mCi) is generally used as a radiolabel for liquid and solid meals in adults. There is no weight-based dosage for children, but 9.25 to 37 MBq (0.25 to 1.0 mCi) of administered activity can be used to label a liquid meal, and 9.25 to 18.5 MBq (0.25 to 0.5 mCi) can be used to label a solid meal. The affinity of this radiopharmaceutical for the protein matrix of egg whites makes it easy to use to label egg as a solid-phase radiopharmaceutical [17]. The administered activity of the radiopharmaceutical and the volume to be fed to the patient should be based on patient factors such as age, body weight, and the usual feeding volume. Administered intraperitoneally, it is not absorbed and becomes a qualitative marker of movement of ascitic fluid through congenital or traumatic diaphragmatic fenestrations and peritoneovenous shunts. For this purpose, the administered activity of 18.5 to 185 MBq (0.5 to 5.0 mCi) technetium-99m sulfur colloid is used.

C. Technetium-99m (Stannous – Sn) Diethyleneetriamine-Pentaacetic Acid (DTPA)

PRACTICE PARAMETER 12 GI Hepatic and Splenic Scintigraphy 2020 Resolution No. 16
Given orally, technetium-99m (Sn) DTPA may be used as a liquid-phase marker of gastric emptying or of small-bowel transit when only a single liquid meal transit examination is performed. It cannot be used simultaneously for a combined liquid-phase and solid-phase gastric emptying examination when a technetium-99m solid-phase radiopharmaceutical is also used. When dual-phase (solid and liquid) gastrointestinal examinations are performed, indium-111 DTPA or gallium-67 citrate is used to measure the liquid phase, and technetium-99m sulfur colloid is used for the solid phase.

The administered activity for technetium-99m DTPA is 18.5 to 37 MBq (0.5 to 1.0 mCi) for adults. The administered activity of the radiopharmaceutical and the volume to be fed to the patient should be based on patient factors such as age, body weight, and the usual feeding volume.

D. Indium-111 DTPA

Given orally, with an administered activity of 5.55 to 18.5 MBq (0.15 to 0.50 mCi), indium-111 DTPA may be used as a liquid-phase marker of gastric emptying when a concomitant solid meal labeled with a technetium-99m radiopharmaceutical is used. Due to the longer half-life of indium-111, additional imaging of the abdomen is possible up to 72 hours and allows measurement of small bowel or colon transit [10,25]. Administered activity of indium-111 DTPA for colon transit is 3.7 to 37 MBq (0.1 to 1.0 mCi). For a liquid-only gastric examination, technetium-99m sulfur colloid should be used instead of indium-111 DTPA to reduce radiation exposure.

E. Gallium-67 Citrate

Given orally, gallium-67 is not absorbed from the gastrointestinal tract and may be used as a liquid-phase marker of gastric emptying. Like indium-111 DTPA, this radiopharmaceutical can be used with concomitant solid meal labeled with technetium-99m for imaging and measurement of small bowel or colon transit. Its long half-life allows extended imaging of the abdomen up to 96 hours or longer. Administered activity is typically 0.056 kBq/kg body weight (0.0015 mCi/kg) for dual-phase gastric emptying examinations in pediatric patients. For adults needing evaluation of colonic transit, a dosage of 3 to 7 MBq (0.08 to 0.2 mCi) can be used [7,8]. For a liquid-only gastric emptying examination, technetium-99m sulfur colloid should be used instead of gallium-67 to reduce radiation exposure.

F. Technetium-99m Autologous Red Blood Cells (RBCs)

Technetium-99m RBCs remain intravascular and are commonly used for detecting and localizing active gastrointestinal bleeding. The usual adult intravenous administered activity for gastrointestinal blood loss detection is 740 to 1,010 MBq (20 to 30 mCi). The highest RBC labeling efficiency is achieved with the in vitro method, which is recommended and widely used.

G. Technetium-99m Macroaggregated Albumin (MAA)

Given intraperitoneally, technetium-99m MAA is not absorbed and is used as a qualitative marker of the movement of ascitic fluid through peritoneovenous shunt devices or congenital/traumatic diaphragmatic fenestrations. The usual adult administered activity is 0.5 to 5.0 mCi (18.5 to 185 MBq).

A. Salivary Gland Imaging

The collimator surface should be protected from contamination by using a plastic-backed pad or other similar material. The patient’s face is positioned in front of a gamma camera in the Water’s (nose-chin) position. Technetium-99m pertechnetate is given intravenously. Serial anterior images of the face are obtained over a period of 30 minutes. If needed, these views may be supplemented by oblique or lateral static images of the head and neck. A sialogogue, such as lemon juice, may be given to stimulate salivary gland emptying in cases of salivary duct obstruction or ligation, sialadenitis, or suspected Warthin’s tumor. The position of palpable nodules should be identified using a radioactive source marker.

B. Aspiration of Gastric or Pharyngeal Contents

These examinations are usually limited to pediatric patients or as a preoperative pulmonary evaluation prior to lung transplantation. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours should be sufficient.

1. Aspiration of pharyngeal contents

A small volume of appropriate administered activity of technetium-99m sulfur colloid is placed on the dorsal surface of the posterior portion of the tongue or in the buccal fossa. Images of the chest are obtained
in the posterior projection over the course of 30 to 60 minutes. Radioactivity detected in the bronchi or lungs confirms aspiration.

2. Aspiration of gastric contents

Radioactive source markers are placed for anatomic reference (eg, shoulder markers as reference of the relative location of the lungs). Appropriate administered activity of technetium 99m sulfur colloid is placed in a small amount of the patient’s feeding, administered orally, by nasogastric tube, or by gastrostomy tube depending on the clinical situation and in consultation with the referring provider. If the material is administered orally, once the feeding is completed, an additional nonradioactive liquid feeding is given to clear any remaining radioactivity from the esophagus. Images of the thorax are obtained immediately after ingestion (as a baseline) and serially for 60 minutes thereafter. Additional planar imaging at 4 hours or 24 hours may be helpful. In infants and children, evaluation for aspiration of gastric contents is included as a routine component of the radiopharmaceutical gastric emptying and gastroesophageal reflux examinations (see VII.D and VII.E). Radioactivity seen in the lungs confirms the diagnosis of aspiration. Imaging is terminated after the radioactivity has cleared from the stomach.

C. Esophageal Transit

Scintigraphy of esophageal transit may yield unique and useful physiologic information about esophageal motility in patients with conditions (eg, scleroderma, stricture, achalasia) that cause impaired transit of esophageal contents from the pharynx to the stomach or following therapy for these conditions [20]. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours would be sufficient. Data are collected in the posterior projection. As with barium esophagography, use of multiple (up to 5) dry swallows can increase the sensitivity of the examination in detecting an abnormal swallow. Comparison of at least one upright and one supine swallow can be helpful to differentiate disorders such as achalasia from scleroderma.

The examination involves the patient swallow the appropriate administered activity of technetium 99m sulfur colloid in 10 to 15 mL of water or a semisolid as a bolus. The initial rapid bolus transit should be recorded in a dynamic mode of 0.25 to 1 second per frame and reviewed using a cinematic (movie) display to evaluate the bolus transit. Additional data acquisition for up to 10 minutes is also helpful, during which time the patient may be asked to dry swallow to measure clearance from the esophagus and to look for possible gastroesophageal reflux. The normal value for esophageal bolus transit time is generally under 5 seconds, although each facility should validate its own normal range for its specific technique and normal range from the literature.

Time activity curves may be generated for the proximal, middle, and distal portions of the esophagus, but visual inspection of the cine bolus transit is more important for differentiating the various primary esophageal motor disorders.

D. Gastroesophageal Reflux

Scintigraphy for gastroesophageal reflux may yield unique and useful physiologic information in patients whose history, signs, or symptoms suggest possible incompetence of the gastroesophageal sphincter associated with acute or chronic reflux of gastric contents into the esophagus [20]. Observation of gastroesophageal reflux, however, during an esophageal transit examination can be important as an etiology to reflux esophagitis and associated esophageal dysmotility.

In infants and children, a gastroesophageal reflux examination is often combined with a liquid gastric emptying examination. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient’s age and the clinical circumstances, but in most cases 4 hours would be sufficient. A liquid meal consisting of formula, milk, or orange juice containing an appropriate concentration of technetium 99m sulfur colloid is administered orally, by nasogastric tube, or by gastrostomy tube. If feasible, when the meal is introduced via an orogastric or nasogastric tube, the tube should be removed prior to image acquisition. The patient is then positioned supine beneath the gamma camera detector, and serial 10-second to 30-second images of the esophagus and stomach are obtained. It is often appropriate to image small children in the supine position with the gamma camera detector under the imaging table. In adults, a Valsalva maneuver or an abdominal binder may be of benefit. Use of an abdominal binder is contraindicated in children.
The number of reflux events detected during the recording session, the duration, and the proximal extent of reflux are reported. The examination may be repeated to assess the effectiveness of medical therapy.

E. Gastric Emptying

Evaluation of gastric motility through a radiolabeled meal provides functional information that is indispensable in the management of patients presenting with various upper gastrointestinal signs and symptoms [24,37]. The patient should have nothing by mouth or by tube feeding prior to the examination. The length of time that the patient should refrain from intake depends on the patient's age and the clinical circumstances, but in most cases 4 hours should be sufficient. Three approaches are used: liquid phase, solid phase, and combined liquid-solid phase.

In general, the liquid phase is preferred in infants and in neurologically impaired children, whereas the solid phase is used when the patient is capable of ingesting solid food. In both cases, the "meal" needs to be introduced into the stomach fairly quickly (ie, within 10 minutes). It is a good general practice to cover the camera detectors with protective wrap to prevent contamination. Digital acquisition is required to determine the half-time of emptying and/or percent of emptying and to generate gastric emptying time activity curves. Given the oblique lie of the stomach in the abdomen, images should be acquired in both the anterior and posterior projection with gastric emptying determined based on the geometric mean. Posterior-projection imaging only may be sufficient in children.

Currently there are no published standardized protocols or normal values for pediatric examinations [27].

1. Solid-phase gastric emptying in adults

- ACR supports the published consensus guideline on the scintigraphic measurement of gastric emptying in adults by the Society of Nuclear Medicine and Molecular Imaging (SNMMI) and the American Neurogastroenterology and Motility Society (ANMS) [28]. The ACR supports adoption of the recommendations of this consensus guideline and recommends adoption of its recommended normal values, patient preparation, image acquisition, and data processing. Following ingestion of a radiolabeled low-fat, egg-white meal, 1 minute static imaging at 0, 1, 2, and 4 hours is performed with the patient upright, if possible [17]. The percentage remaining at each time point is compared with established normal ranges to determine the presence or absence of gastroparesis. Details can be found in the appendix to the consensus guideline [28].

2. Liquid-phase gastric emptying in adults and children

For some time liquid-phase gastric emptying examinations have not been used since it was believed that abnormal liquid gastric emptying was a late phenomenon and that a solid meal would detect abnormal gastric emptying better than a liquid meal. Recent studies suggest that liquids may detect some patients with abnormal gastric emptying when solid gastric emptying scintigraphy is normal [26]. There are, however, no consensus recommendations at present on the best liquid-phase gastric emptying meal or protocol.

- Technetium-99m sulfur colloid or technetium-99m (Sn) DTPA is mixed with an appropriate volume (30 to 240 mL) of liquid carrier (eg, orange juice, formula, milk) and is introduced into the stomach by swallowing, nasogastric tube, orogastric tube, or gastric tube depending on the clinical situation, in consultation with the referring clinician. Sequential imaging and computer data acquisition are performed over the course of 30 to 60 minutes. A region of interest (ROI) is drawn over the stomach, and a decay-corrected time-activity curve is generated. In adult patients, the radiopharmaceutical exits from the stomach in an approximately monoexponential fashion for liquid meals. In children, imaging is usually performed during the first hour, and the percent of emptying is obtained at 60 minutes and later, if indicated. Unfortunately, there are currently no well-defined normal values for the various liquid meals used. Each facility must validate its own normal range for its specific meal and technique.

3. Liquid-phase gastric emptying ("milk scan") in infants

Liquid-phase gastric emptying may be combined with evaluation of esophageal motility, gastroesophageal reflux, and aspiration. The radiopharmaceutical esophagram may be performed initially or following the completion of the gastric emptying portion of the examination. For the esophagram, the patient is placed in the supine position with the gamma camera posteriorly positioned. Dynamic images of the esophagus at 5 seconds/frame for 2 to 3 minutes are obtained for evaluating esophageal motility and possible aspiration. If the patient is normally fed by mouth, this may be accomplished as the initial part of the gastric emptying procedure, which is then followed by continuous imaging of the chest and abdomen for 60 minutes for...
evaluation of the presence and severity of gastroesophageal reflux. Gastric emptying at 60 minutes and at
2 or 3 hours after completion of feeding is calculated. If the patient is not orally fed, the esophagram should
be performed at the end of the gastric emptying examination using a small volume of radiolabeled sterile
water or saline.

A solid-phase examination (see section VII.E.1 above) may be combined with the liquid-phase examination
(see section VII.E.2 above), using technetium 99m sulfur colloid for the solid phase and indium 111 DTPA
or gallium-67 for the liquid phase. With the use of proper administered activity of dual
radiopharmaceuticals and availability of simultaneous dual-isotope image acquisition and processing
capability, it is possible to acquire data simultaneously using photopeaks of both radiopharmaceuticals. An
added advantage provided by this combined solid-phase and liquid-phase technique includes the ability to
follow the liquid-phase to measure small bowel and colon transit resulting in evaluation of the whole gut.

There are increasing reports on the utility of whole-gut scintigraphy using simultaneous dual
radiopharmaceutical solid-liquid meal in patients with various abdominal symptoms but no consensus
recommendations on its use exist to date [37,38].

E. Ectopic Gastric Mucosa (Meckel’s scan)
The radiopharmaceutical technetium 99m pertechnetate is given intravenously. A rapid sequence of images (blood
flow/angiographic phase) taken at 1 to 2 seconds per frame, over 1 minute, may be obtained in the anterior projection
to evaluate the presence of hypervascular abdominal lesions that could be mistaken for ectopic gastric mucosa.
Immediate serial imaging for 30 to 45 minutes can then be acquired as serial static views (300,000 to 500,000 counts
per image) or continuous dynamic imaging (30 to 60 seconds per image). Continuous dynamic imaging is preferred
better visually discriminate normal physiologic activity (such as renal activity) from ectopic gastric mucosa. A
lateral view can be useful to distinguish renal activity and identify retrovesical ectopic gastric mucosa. The
examination may be supplemented with oblique, postvoid single photon emission computed tomography (SPECT)
imaging or delayed views of the abdomen, as indicated. Pharmacologic enhancement prior to administration of the
radiopharmaceutical with H2 blockers (cimetidine, famotidine, or ranitidine) to enhance free pertechnetate retention
and/or glucagon to decrease gastrointestinal peristalsis can be used. Prone or right anterior oblique positioning can
be used to delay gastric emptying into the small bowel if the patient has not been pretreated with H2 blockers.

G. Gastrointestinal Blood Loss
All methods for diagnosing and localizing an active bleeding site require that the patient be actively bleeding and
imaged during the time the radiopharmaceutical is present in the blood pool. Although this procedure is generally
used for gastrointestinal bleeding, it can be useful for other sites of active bleeding.
The use of technetium-99m labeled autologous RBCs is the recommended method because they remain
intraocular and permit a longer imaging time. The radiolabeled cells are injected intravenously. Blood
flow/angiographic phase and continuous cine or images of the abdomen are obtained for 60 to 120 minutes. Cine
images (maximum of 15 seconds per image) and display are preferred as these improve the initial detection and
more accurate localization of subtle gastrointestinal bleeding sites. Oblique, lateral, or delayed static abdominal
images may be obtained to supplement the basic examination. If the examination is negative, continued imaging
may be appropriate. SPECT/CT, although not routinely performed, can be of value to more definitively localize
sites and identify the cause of gastrointestinal hemorrhage.

H. Peritoneal Imaging

1. Evaluation of patency of peritoneovenous shunts
Technetium-99m sulfur colloid or technetium-99m MAA is directly administered into the peritoneal cavity,
using aseptic technique. An immediate image of the abdomen may be helpful to determine that the
radiopharmaceutical is free in the peritoneum and not loculated. On occasion, normal saline (50 to 200 mL)
can be infused intraperitoneally to facilitate distribution. If the shunt is functioning correctly, serial images
obtained over 1 or 2 hours will reveal radiopharmaceutical in the shunt tube, and radioactivity will
eventually appear in the liver and spleen (with technetium-99m sulfur colloid) or lungs (with technetium-
99m MAA).

2. Detection of congenital fenestrations or traumatic perforations of the diaphragm
Technetium-99m sulfur colloid or technetium-99m MAA is administered intraperitoneally as described in section VII.H.1. Occasionally, the radiopharmaceutical can be instilled with up to 500 mL of sterile normal saline in order to facilitate movement of the radiopharmaceutical into the pleural cavity. If activity appears in the pleural space, the diagnosis of perforated diaphragm is confirmed.

3. Demonstration of peritoneal loculation of fluid

Technetium-99m sulfur colloid or technetium-99m MAA is administered intraperitoneally as described in section VII.H.1. Immediate and delayed static images over the abdomen will reveal the pattern of distribution of the radiopharmaceutical in the peritoneal cavity.

V. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings [39].

The report should include the radiopharmaceutical used, the administered activity, and the route of administration as well as any other pharmaceuticals administered, including their dose and route of administration.

VI. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [40].

A gamma camera with a low-energy all purpose (LEAP) or high-resolution collimator is used for Tc-99m–labeled radiopharmaceuticals. A medium-energy collimator is needed for In-111 and Ga-67. SPECT or SPECT/CT may also be useful in select cases.

VII. RADIATION SAFETY

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.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 and that they are adhered to in accordance with ALARA. 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 state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria®, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

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 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).

II. DEFINITION

Gastrointestinal scintigraphy involves the intravenous, oral, transcatheter (to include enteric tubes), or intraperitoneal administration of a radiopharmaceutical that localizes in or transits the salivary glands, gastrointestinal tract, or peritoneal cavity, followed by gamma camera imaging with digital acquisition [5]. (For scintigraphy of the hepatobiliary tract or liver and spleen, see the ACR–SPR Practice Parameter for the Performance of Hepatobiliary Scintigraphy [2] and the ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy [6].)

III. GOAL

The goal of gastrointestinal scintigraphy is to enable the interpreting physician to identify and/or quantify anatomic or physiologic disturbances of the salivary glands, gastrointestinal tract, or peritoneum.

ACKNOWLEDGEMENTS

This practice parameter was revised according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging of the ACR Commission on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Pediatric Radiology of the ACR Commission on Pediatric Radiology in collaboration with the ACNM, the SNMMI, and the SPR.

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PRACTICE PARAMETER 18 GI Hepatic and Splenic Scintigraphy 2020 Resolution No. 16
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REFERENCES


*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards
published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter

1996 (Resolution 16)
Revised 2000 (Resolution 22)
Revised 2005 (Resolution 20)
Amended 2006 (Resolution 35)
Revised 2010 (Resolution 29)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 45)
RESOLUTION NO. 17

BE IT RESOLVED,
that the American College of Radiology adopt the ACR–ACNM–ASTRO–SNMMI Practice Parameter for Lutetium-177 (Lu-177) DOTATATE Therapy

Sponsored By: ACR Council Steering Committee

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

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.

NEW

ACR–ACNM–ASTRO–SNMMI PRACTICE PARAMETER FOR LUTETIUM-177 (Lu-177) DOTATATE THERAPY

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. 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 in light of 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 the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

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, 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.

PRACTICE PARAMETER

1 Lutetium (Lu-177 DOTATATE)

2020 Resolution No. 17
The practice of medicine involves not only the science, but also 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 sole purpose of this document is to assist practitioners in achieving this objective.

I. INTRODUCTION

This practice parameter was developed collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society for Radiation Oncology (ASTRO), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

This practice parameter is intended to guide appropriately trained and licensed physicians performing therapy with lutetium-177 (Lu-177) DOTATATE. Such therapy requires close cooperation and communication between the physicians who are responsible for the clinical management of the patient, those who administer radiopharmaceutical therapy and those who manage the attendant side effects. Adherence to this parameter should help to maximize the efficacious use of these procedures, maintain safe conditions, and ensure compliance with applicable regulations.

Application of this parameter should be in accordance with the ACR–AAPM–SPR Technical Standard for Therapeutic Procedures Using Radiopharmaceuticals [1], in so far as that standard relates to the handling of radiopharmaceuticals, radiation safety, and radiation protection of patients, personnel, and the public. There must also be compliance with applicable laws and regulations.

The goal of therapy with Lu-177 DOTATATE is to provide either cure, extended time to disease progression, or effective palliation of disease while minimizing untoward side effects and complications.

Neuroendocrine tumors (NETs) are relatively rare and typically slow-growing neoplasms that originate in neuroendocrine tissue distributed throughout the body. They secrete bioactive amines and hormones, giving rise to variable clinical presentations [2]. Surgical resection of the tumor is the preferred initial therapy; however, because of the indolent course and nonspecific presentation of the disease, many patients are diagnosed with locally advanced or metastatic disease, making curative resection difficult or impossible. Alternative conventional treatments include use of nonradioactive somatostatin analogues that take advantage of the overexpression of somatostatin receptors (SSRs) by these NETs. Use of other agents, including cytotoxic chemotherapy, can be limited because of the unwanted side effects and minimal effectiveness in certain grade of tumor. Despite use of these currently available conventional treatments, many patients continue to progress with life-altering signs and symptoms, such as unrelenting diarrhea, flushing, or right-sided heart disease [3,4].

Lu-177 DOTATATE is an effective therapy for patients with inoperable, locally advanced, or metastatic NETs that progress on conventional treatments [3-6]. Improvement in disease control rates, progression-free survival, overall survival, and quality of life have advanced this radiopharmaceutical agent to a place of primary consideration in advanced disease management [7]. Lu-177 DOTATATE specifically binds to the SSRs that are overexpressed on the cell surfaces of most NETs, with highest affinity for subtype 2. The complex formed is chemically stable and is internalized into the cell resulting in a favorable position to irradiate the nucleus to induce DNA damage–related inhibition of growth and death [8]. This treatment process is called peptide receptor radionuclide therapy (PRRT). Beta (β-) emission from Lu-177 has a maximum energy (Q-value) of 0.5 MeV, range in soft tissues of 2 mm, and half-life of 6.7 days. Lu-177 also emits low-energy gamma rays at 208 keV (11% abundance) and 113 keV (6.4% abundance) that can be used for gamma camera imaging and dosimetry if desired [9]. Although PRRT with Lu-177...
DOTATATE has been proven to be effective in NET, there are adverse side effects and safety issues that must be understood and taken into consideration by the treating physicians so that appropriate plan and required interventions can be instituted [5].

Side effects associated with PRRT with Lu-177 DOTATATE can be categorized as acute, subacute, or delayed [5]. It is highly advisable that a multidisciplinary team coordinate the care of a patient being considered for treatment with Lu-177 DOTATATE [6].

General: Abdominal pain, nausea, and vomiting can occur typically within 24 hours of treatment. In addition, patients can also experience fatigue and diarrhea. In most cases, these symptoms are self-limiting and rarely require more than supportive therapy.

Nephrotoxicity: Lu-177 DOTATATE is excreted by the kidneys through glomerular filtration and is reabsorbed by the proximal tubules where radiation damage can occur [9]. Reduction of proximal tubular reabsorption has been effectively achieved with use of other ligands that can competitively bind to the receptors in the proximal tubular cells without affecting the SSR targets of Lu-177 DOTATATE in the circulation [10]. The most efficacious solution to date to reduce renal uptake of somatostatin analogues consists of a combination of basic amino acids lysine (25 g) and arginine (25 g) [9,11]. Renal toxicity is generally mild and well-tolerated with amino acid co-infusions. However, grade 1 nephrotoxicity in 20% and grade 2 nephrotoxicity in 4% of patients has been reported [5,7]. Higher-grade toxicities are rare (0% to 0.4%) [4,5]. Many studies have shown improvement of renal function over time, but long-term renal impairment remains a clinical concern, with some studies reporting an annual decrease in creatinine clearance of 3.4% to 3.8% [12,13]. Details on administration are provided in the “Specific Procedures” section of this document (IV.B).

Hematologic: The bone marrow is a rapidly dividing organ and is thus radiosensitive. Mild subacute myelosuppression can be seen in the first days to weeks after treatment and typically reverses within weeks after cessation of treatment [5]. The most frequently seen effects include anemia, thrombocytopenia, and leukopenia. Grade 3 and 4 bone marrow toxicity are seen less frequently and are generally reversible without intervention within 2 to 3 months but may take up to 12 months [4,14,15]. Bone metastases can increase the likelihood of myelotoxicity [15,16]. Rarely, 1% to 2% of patients can develop leukemias and myelodysplastic syndrome (MDS), which can lead to a fatal outcome in patients heavily pretreated with myelosuppressive therapies prior to receiving Lu-177 DOTATATE [4,5,13,14].

Hepatic: Liver dysfunction has been noted with increase in bilirubin and transaminases. A few patients have developed grade 3 toxicity that progressed to liver failure and death within one year after PRRT [5].

Hormonal Crisis: This is a rare complication that presents as flushing and significant diarrhea and, less frequently, heart failure, emesis, and bronchoconstriction. It typically occurs within 48 hours of infusion, with greater likelihood in patients with large tumor burden [17,18]. This is a serious adverse side effect requiring prompt in-hospital care for continuous somatostatin analogue infusion and supportive care.

Risk of Infertility: The recommended cumulative activity of 800 mCi (29.6 GBq) Lu-177 DOTATATE results in radiation absorbed dose to the testis and ovaries within the range where temporary or permanent infertility may ensue, such as seen following pelvic external-beam radiotherapy [4,6,7,19].

Facilities and their responsible staff should consult with their radiation safety officer (RSO) to ensure that there are policies and procedures specific to Lu-177 DOTATATE that address 1) required instrumentation, calibration, and calibration frequency and 2) ordering and receiving, recordkeeping, safe use, and waste disposal in compliance with the applicable laws and regulations as described in ACR–AAPM Radiation Safety Officer Resources [19].
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II. INDICATIONS

Lu-177 DOTATATE is indicated for the treatment of SSR-bearing gastroenteropancreatic NETs (GEP-NETs), including foregut, midgut, and hindgut NETs in adults [6].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

The qualifications and responsibilities of physicians and other personnel performing these therapeutic procedures should be in accordance with the ACR–AAPM–SPR Technical Standard for Therapeutic Procedures Using Radiopharmaceuticals and/or the ACR–ASTRO Practice Parameter for Radiation Oncology [1,20].

In addition, training and experience must be in compliance with the applicable laws and regulations.

IV. SPECIFICATIONS OF THE EXAMINATION AND TREATMENT

The written or electronic request for a Lu-177 DOTATATE procedure should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance.

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 procedure or diagnosis would be helpful and may at times be needed to allow for the proper performance of the procedure.

The request for the procedure 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)

A. Clinical Evaluation:

The clinical evaluation should be in concordance with the ACR–ASTRO Practice Parameter for Radiation Oncology and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [20,21]. The treating physician’s initial evaluation of the patient must include review of the patient’s history, physical examination, pertinent diagnostic studies, laboratory reports, and complete history of all previous pertinent therapies, including, but not limited to, myelosuppressive systemic therapy and/or radiotherapy.

1. Verification of Pathology and Indication for Therapy: A pathology report confirming diagnosis of GEP-NET should be reviewed and included in the patient’s record. Efficacy of Lu-177 DOTATATE is well documented, particularly in well-differentiated NET often with Ki-67 index of <20% [22]. Because Lu-177 DOTATATE localizes to NET expressing SSR, it is of paramount importance to confirm that the NET being treated expresses the required SSR through positive indium-111 octreotide scan or gallium-68 DOTATATE PET/CT (see ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Neuroendocrine Tumor Scintigraphy and ACR Practice Parameter for the Performance of Gallium-68 DOTATATE PET/CT for Neuroendocrine Tumors) [23,24].

2. Discontinuation of Somatostatin Analogue Therapy with Baseline Laboratory Evaluation: If the patient is being treated with long-acting somatostatin analogue, this should be stopped for 4 weeks prior to Lu-177 DOTATATE infusion. Short-acting analogues can be stopped 24 hours prior to PRRT. In anticipation of possible side effects, each patient should have a complete blood count with differentials and metabolic panel including renal and hepatic function tests. Such monitoring should be performed before each infusion and as needed for hematologic monitoring in between treatments. Dose reduction based upon laboratories is discussed in Section IV.B.2. Although institution and patient-specific considerations take precedence, a
creatinine clearance >50 mL/min and grade 1 to 2 or less hepatic enzyme elevation or myelosuppression is sufficient to allow therapy. Women of childbearing age should undergo pregnancy testing [6].

3. Special Populations: Lu-177 DOTATATE has not been tested in lactating patients, and these patients should be advised to stop breastfeeding while receiving treatment and for 2.5 months after the last treatment fraction, as effects on infants have not been determined. For patients of reproductive potential, discussion should be carried out to use effective contraceptive measures during and after PRRT. For female patients, because of the possibility of fetal harm, effective contraception should be continued for 7 months following the last treatment fraction of PRRT. For male patients with female partners, contraception should be continued until 4 months following the last treatment fraction [6]. Sexual activity should be avoided following therapy for 7 days. The radiopharmaceutical has not been tested in pediatric (<18 years old) and pregnant patients. Caution should be exercised in these patient populations, with extensive discussion regarding risk of radiation.

4. Quality Management: In order to use radiopharmaceuticals as unsealed sources for therapy, including Lu-177 DOTATATE, a “quality management” program must be in place as required by applicable state and federal regulations. (An Agreement State is any state with which the Nuclear Regulatory Commission (NRC) or the US Atomic Energy Commission has entered into an effective agreement under subsection 274.b of the Atomic Energy Act of 1954 as amended, 73 Stat, 689). Key elements of such a program include written directives, duplicative procedures for identifying patients, careful record keeping to ensure prescribed administered activity, minimization of the possibility of infiltration for radiopharmaceuticals that are administered intravenously (IV), procedures for minimizing radiation exposure or radiopharmaceutical contamination of personnel, family members of patients, and the public (eg, alerts regarding possible current or future pregnancy), procedures for containment of radioactivity; and an audit mechanism to ensure compliance with the program.

5. Informed Consent: Informed consent must be obtained and documented. See the ACR Practice Parameter on Informed Consent – Radiation Oncology [25].

6. Treatment: The procedure and follow-up should be performed according to an established system of procedural steps unique for Lu-177 DOTATATE [26].

7. Radiation Precautions: Radiation precautions and patient release criteria may be regulated federally by the NRC in many states or by the state (with regulations that are closely patterned on the federal regulations and may be more restrictive). The radiation safety officer, medical physicist, or health physicist for the local facility can provide information on the applicable regulations. Details on the federal regulations can be obtained at the NRC website (www.nrc.gov).

Under the guidelines of federal code 10 of the Code of Federal Regulations (CFR) 35.75 [27] and key sections of NUREG-1556 [28], a patient may be released to the public if the total effective dose equivalent to any other individual (including any caregiver or family member) who is exposed to the patient is not likely to exceed 5 mSv (0.5 rem). If the total effective dose equivalent is likely to exceed 1 mSv (0.1 rem) to any individual, instructions (including written instructions) must be provided to the patient on actions to limit radiation exposure to others by utilizing the “as low as reasonably achievable” (ALARA) principle. Some states may have specific rules and regulations regarding release of patients with significant residual activity.

The dose limits specified by the National Council on Radiation Protection and Measurements (NCRP) differ somewhat from the NRC regulations [29]. Because the fetus and children are more sensitive to radiation injury than adults, the NCRP specifies that children and pregnant women, whether or not they are members of the patient’s household, should be limited to 1 mSv (0.1 rem). Any individual who has no familial
connection to the patient and whose presence offers no emotional benefit should also be limited to 1 mSv, which is also the NRC dose limit to a member of the public.

Many radiation meters measure exposure rates in milliroentgens per hour (mR/h). For purposes of radiation protection and for low linear energy transfer (LET) radiation (including beta particles and most x-rays and gamma rays), the authors of this document accept the approximation that 1 mR, 0.01 mSv, and 1 mrem are equivalent. Thus, an exposure rate of 7 mR/h at 1 m is an adequate approximation to the dose rate, 0.07 mSv/h (7.0 mrem/h) at 1 m.

Specific Considerations During Lu-177 DOTATATE Therapy and Patient Release:

According to radiation exposure calculations based on whole-body clearance data, patients may need to be kept in radiation isolation for 4 to 5 hours following the administration of the typical dose of 200 mCi (7.4 GBq) Lu-177 DOTATATE [30]. Postinfusion survey by physics or other radiation safety is performed to determine an acceptable maximum exposure rate that conforms to the 10 CFR 35.75 requirement of <5 mSv exposure anticipated to other individuals. An established protocol for documenting this survey result should be used and available. Until the patient has been released, the patient must be kept in an area with suitable radiation shielding to protect others from unnecessary exposure. An administration of 200 mCi Lu-177 DOTATE typically results in exposure levels on the order of 2 mR/h at 1 m immediately after administration, declining to 1 mR/h after 24 hours, allowing outpatient treatment in most cases with appropriate training, protocols, infrastructure, and patient counseling. The procedures and practical example guidance for instruction of patients upon discharge have been reviewed in published literature [31]. For further information, see Appendix A.

Modeling per the NUREG-1556 assumption of 0.25 occupancy factor estimates 1.8 mSv exposure dose to other individuals, thus requiring written instructions be given to the patient on ALARA principles. During therapy, involvement of trained radiation safety personnel qualified in safe management of unsealed sources, waste, accidental contamination, and counseling of patients is important. The patient and, as relevant, caregivers should be compliant with all radiation safety precautions and instructions. Education should occur before treatment, preferably at the time of consultation so that the patient and caregivers can plan ahead. Inability to comply with the precautions may require an admission or other special accommodations to account for the realities of patient life at home, as determined by the authorized user. The specific instructions and considerations for admission or other special accommodations will vary from institution to institution, but key features are summarized below.

Urinary Contamination:

Specific concern is paid to disposal of urine as the most common potential source of contamination. During therapy, a dedicated toilet is preferred, and although lead shielding is not needed because of the short range of beta emission, disposable lining of the floors and toilet/sink surfaces is recommended to contain radioactive urine or other contamination [31]. Urinary incontinence, if present, would require catheterization prior to administration and for at least 2 days thereafter to minimize radiation contamination. Other simple measures used to minimize urinary contamination upon discharge include:

- Use of private room with its own bathroom
- Washing of hands for 20 seconds after each use of the restroom
- Instructing the patient to urinate while seated
- Flushing 2 to 3 times with the toilet lid closed
- Rinsing of sinks and showers after use
- Cleanup of urinary spills with damp toilet paper that can be flushed down the toilet (to minimize accumulation of waste product trash requiring long-term storage).
Other Potential Sources of Contamination:
Peritoneal and hemodialysis are not contraindications for treatment, but they may impact the administered activity of Lu-177 given the prolonged residence time within the patient and complicate handling of hemodialysis machines because of the likelihood of retained radioactivity after use, thus requiring logistics planning with dialysis facilities and the patient. Another infrequent but special consideration for Lu-177 DOTATATE therapy given its target population is in patients with indwelling drains, such as biliary drains, which require confirmation of ability of caregivers to safely manage disposal of waste with the same precautions applied to urine. When possible, these sources of waste should be flushed down the toilet similar to urine, with use of disposable gloves by the caregiver when handling and cleaning drain equipment and collection bags.

Release to Health Care Facility/Admission to Hospital Considerations:
If confinement in a health care facility is needed, it is not usually necessary to store body effluents, such as urine, stool, or vomitus. In general, for patients who have been released to the public, precautions for the patient should be according to ALARA principles and universal precautions. A discussion should be had in such cases with a facility or hospital’s radiation safety department and/or involved parties (clinical leadership) to determine any additional precautions that will be taken for care workers. Furthermore, should a patient receiving Lu-177 DOTATATE require admission to a hospital or transfer to an emergency department, it is highly recommended that the administering team contact the receiving personnel for a “signout.”

Although not explicitly required, examples of “extra” precautions include the following. For effluent disposal where acceptable under state or federal regulations, the toilet can be flushed two or three times after each use to ensure sufficient dilution of radioactivity. Food trays, linens, and all other contaminated products may be stored in the patient’s room until monitored and cleared by radiation safety staff. The patient must stay in the room except in a medical or nonmedical (eg, fire) emergency, and access by personnel and visitors can be limited. All trash and residual nondisposable items can be monitored after the patient’s release and stored until radiation levels reach the statutory level defined for safe disposal or reuse. In some jurisdictions, items in decay storage must reside there for 10 half-lives (67 days for Lu-177) or until radiation levels are indistinguishable from background. Once all known contamination is removed from the room, the room must be surveyed to verify that the radiation levels and removable contamination are sufficiently low to permit its general use. The room may not be used until this survey is performed and safe level documented. Individual institution’s radiation safety procedures may vary somewhat.

If the admitting physician is different from the physician who administers the radiopharmaceutical, there must be a mechanism to prevent premature discharge or release of the patient from confinement.

Waste Disposal:
As above, trash and nondisposable items contaminated by patient fluids must be stored and monitored until their radiation levels reach safe disposal limits, which may vary between institutions and jurisdictions, with one prominent guideline being 10 half-lives (67 days for Lu-177).

Distance of Caregivers and Considerations for Travel:
There is no specific regulation on required distance of caregivers following discharge. However, to meet guidance from NUREG-1556’s use of a 0.25 occupancy factor for estimating exposure of public allowing safe discharge of patients after administration, it is assumed that exposed persons will maintain a distance of 1 m (3 ft) for at least 3 days and not sleep in the same bed as the patient for 7 days. There is a further assumption of following ALARA principles to minimize exposure to potential contamination, such as may occur during use of the same toilet facilities.
Prolonged use of personal or public transportation (bus, train, etc) in the company of others for more than one hour is discouraged for the first 3 days following therapy. Although Title 10 of the CFR, part 35.75, does not expressly prohibit release of a radioactive patient to a location other than a private residence such as a hotel, the NRC strongly discourages this practice because it can result in radiation exposure to members of the public for which the licensee may not be able to assess full compliance with the code.

Nonetheless, when travel is unavoidable in the first 3 days after therapy, the patient should be instructed to discuss the matter with treating personnel.

Furthermore, although patients are recommended to travel immediately home, it is acknowledged that some patients may need to reside in a hotel or other public facility. Again, precautions to maximize distance from other members of the public are recommended (>1 m at a minimum) in the 3 days after Lu-177 DOTATATE administration.

B. Treatment Procedures for Infusion of Lu-177 DOTATATE

1. Preparation:
Before ordering Lu-177 DOTATATE solution for PRRT, confirm that treatment with Octreotide analogues has been discontinued for at least 4 weeks for long-acting preparation and for 24 hours for short-acting preparation before scheduled therapy.

Lu-177 DOTATATE is a radiopharmaceutical that requires effective radiation shielding before handling. The vial containing the radiopharmaceutical is delivered in a lead- or Plexiglas-shielded container. It is highly advised that the personnel assigned to prepare or infuse the radiopharmaceutical wear double gloves.

Before the actual administration of Lu-177 DOTATATE, patients should be started on a renoprotective amino acid infusion and may be premedicated with antiemetics according to institutional/physician preference. Depending on institutional preferences and resources, coordination should be made between all involved staff, including the referring physician and the physician administering the radiopharmaceutical to ensure that the steps and processes involved with PRRT are carried out. Two separate IV access sites are preferred: one for the amino acid infusion and one for Lu-177 DOTATATE infusion.

2. Dosage:
The recommended dosage is 200 mCi (7.4 GBq) Lu-177 DOTATATE, administered every 8 weeks for a total of 4 doses as tolerated. Dosage can be halved, according to the US Food and Drug Administration (FDA)--approved clinical notes, in special clinical situations, such as hematological toxicity [32].

Prophylaxis: Amino Acid Solution and Antiemetics:
The Lu-177 DOTATATE solution needs to be administered with concomitant amino acid infusion to reduce radiation absorbed dose and toxicity to the kidneys. Amino acid infusion should be initiated 30 minutes prior to infusion of Lu-177 DOTATATE and continued for at least 4 to 5 hours after completion of PRRT. There are different amino acid formulations available. The extemporaneously compounded formulation contains only 25 g lysine HCl and 25 g arginine HCl with 1 L of appropriate sterile solvent (eg, water for injection). This formulation has lower osmolality and less patient emetic effects. The commercially available amino acid solutions have a lysine content between 18 and 24 g and arginine content between 18 and 25 g in a volume of 1.5 - 2.2 L of solution having <1,050 mOsmol/L. Aminosyn II 10% used in clinical trials in the United States contained additional essential and nonessential amino acids as well as electrolytes resulting in osmolality of 1,040 mOsmol/L. This preparation was associated with a high incidence of nausea and vomiting. Choice of amino acid formulations depends on institutional resources.
Due to nausea with or without vomiting observed in some patients receiving amino acid infusion, it is advised that use of prophylactic antiemetic medications be considered, as used in each institution with any chemotherapy, 30 minutes prior to commencing amino acid solution administration. Other adjunct treatment for persistent vomiting is reasonable depending on physicians’ experiences.

3. **Infusion Methods:**

It is highly preferred that the IV access for administration of Lu-177 DOTATATE solution be separate from IV access for amino acid infusion. Separate access allows removal of the radiopharmaceutical access materials from the patient after PRRT, ensuring no radioactive medical line leaves the confines of the administering facility. Prior to infusion, measure the source activity to confirm prescribed activity. In some centers, a double lumen peripherally inserted central catheter (PICC) line is preferred can be used for infusion to avoid delivery failures.

Lu-177 DOTATATE is delivered in a vial under positive pressure. It can be administered via gravity method, infusion pump method or via automated syringe pump injector, as detailed with illustrative figure at the available link: [http://jnm.snmjournals.org/content/60/7/937/F3.expansion.html](http://jnm.snmjournals.org/content/60/7/937/F3.expansion.html) [26]. Each institution can choose the best technique of radiopharmaceutical administration.

**Gravity Method:**

- Insert a 2.5-cm-long, 20-gauge needle (short needle) into the Lu-177 DOTATATE vial, ensuring that the beveled tip inside the vial does not touch the solution at any time during the infusion. The hub of the short needle is fastened to the IV tubing of a previously prepared 500-mL sterile 0.9% sodium chloride solution. Keep the IV tubing clamped close until the entire setup has been completed and is ready for infusion.
- Insert a second needle that is 9 cm long, 18 gauge (long needle) into the Lu-177 DOTATATE vial, ensuring that the beveled tip of this long needle touches and is secured to the bottom of the vial during the entire infusion. Fasten a connecting tube prefilled with sterile 0.9% sodium chloride to the hub of the long needle, ensuring that there are no air bubbles inside the plastic tubing. Check the designated IV access for Lu-177 DOTATATE to ensure patency; once confirmed, fasten the male Lauer lock of the connecting tube to the IV access, keeping clamp closed.
- Do not remove the needles to reposition once the seal is punctured, as this may make the seal ineffective and prevent dose delivery by this method.
- Open the clamp in the connecting tube from the vial to the patient, and then open the clamp of the tubing from the bag of normal saline solution. Regulate the flow of the sodium chloride solution via the short needle into the Lu-177 DOTATATE vial at a rate of 50 mL/h to 100 mL/h for 5 to 10 minutes and then 200 mL/h to 300 mL/h for an additional 25 to 30 minutes. During infusion, ensure that the level of solution in the Lu-177 DOTATATE vial remains constant and that the vial does not fill up completely. Total duration of infusion is about 30 to 40 minutes.
- Do not administer Lu-177 DOTATATE as an IV bolus.
- Clamp the saline line once the level of radioactivity is stable for at least five minutes.
- Clamp the connecting line from the vial and disconnect from the long needle, taking care that no fluid spills out. Open the connecting tube again and flush with 25 mL of 0.9% sterile sodium chloride to wash off any radiopharmaceutical remaining within the tubing into the patient.
- Remove the IV access used. Measure the remaining activity in the setup, including the vial, and subtract from the measured preinfusion activity to obtain the net activity administered.

**Infusion Pump Method:**

For the infusion pump method, the short and long needles are also used. The tubing that connects to the long needle should be primed with normal saline solution before attachment to an infusion pump. The other end of this tubing is attached to the IV access of the patient. A 3-way stopcock is connected to the hub of
the short needle before it is inserted into the vial with a filter attached to the vent tip. Again, the tip of the long needle should stay above the fluid level, whereas the tip of the long needle is at the bottom of the vial. The positive pressure within the Lu-177 DOTATATE vial drives fluid into the patient and is controlled by the infusion pump, which is usually programmed to deliver 0.8 to 0.9 mL/min for total infusion time of 25 to 30 minutes. Remove the IV access used. Measure the remaining activity in the setup, including the vial, and subtract from the measured preinfusion activity to obtain the net activity administered.

**Automated Syringe Pump Injector Method:**

Another method involves drawing the Lu-177 DOTATATE solution from inside the vial into a sterile lead-shielded syringe that is then mounted on an automated syringe pump injector to administer the Lu-177 DOTATATE. This method exposes the individual drawing the solution to radiation risk. A connecting tube prefilled with sterile 0.9% sodium chloride solution is used to connect the syringe containing the radiopharmaceutical to the IV access of the patient. Before starting the infusion, confirm patency of patient’s IV access. The pump is programmed to deliver the contents of the syringe over 30 minutes, eg, 30 mL at 60 mL/h. Once infusion is completed, the connecting tube can be flushed with 25 mL of 0.9% sterile sodium chloride to wash off any radiopharmaceutical remaining within the tubing into the patient. Attention is required to safely handle the setup to avoid spillage as well as minimize radiation exposure by using tongs. Remove IV access used and measure remaining radioactivity in the setup and vial, and subtract it from preinfusion activity to determine net activity administered.

C. Posttherapy Survey

All personnel involved with Lu-177 DOTATATE therapy should perform a survey of their hands and clothing for any contamination, and appropriate measures should be performed if such contamination is discovered. The room used for infusion should be surveyed for contamination before releasing the room to another patient. All medical wastes associated with the PRRT should be stored as required by radiation safety procedures, making sure that they are separated from other wastes associated with short-acting radiopharmaceuticals.

Care of the patient after Lu-177 DOTATATE therapy follows established institutional protocol for care of patient after radionuclide therapy with special consideration to ALARA principles. Therapy with octreotide LAR or lanreotide is usually given 4 to 24 hours after Lu-177 DOTATATE at the discretion of the attending oncology physician and stopped 4 weeks prior to subsequent PRRT. Short-acting octreotide maybe given for symptomatic management during PRRT cycles and withheld 24 hours prior to next dose of Lu-177 DOTATATE after determination by treating team of physicians.

If desired, posttherapy 3-D imaging may be obtained for the purposes of dosimetry. Personalized dosimetry may be used to assess and estimate potential risk to organs for the individual patient, as data collection for correlative studies seeking to establish maximum organ dose thresholds or lesion treatment efficacy thresholds, or for dose reporting in case of future radiation treatments [26].

V. DOCUMENTATION

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [21].

A summary of the patient’s history, pathologic findings, imaging results and laboratory findings should be included in the report to document the indication and tolerability for treatment with Lu-177 DOTATATE. The report should include the radiopharmaceutical used, the administered activity, site and route of administration, safety precautions for other staff involved in the patient’s care, and any associated incident encountered during therapy. If dosimetry is performed, salient organ absorbed dose values, both in directly calculated dose and in equivalent dose (EQD2), should be reported, and, if available, a dose map in DICOM format with the associated CT. On subsequent PRRT,
interval history should include a summary of prior Lu-177 DOTATATE treatments, interval imaging to assess
treatment efficacy, and pertinent laboratory findings to determine and confirm appropriateness and safety of
additional therapy [26].

VI. STATEMENT ON THERAPEUTIC USE OF UNSEALED RADIOPHARMACEUTICAL SOURCES

On the basis of their education, training pathway(s), initial board certification(s), and maintenance of
certification(s), NRC or Agreement State Authorized User (AU) status, and clinical work experience, diagnostic
radiologists (DRs), nuclear radiologists (NRs), nuclear medicine physicians (NMs), and radiation oncologists (ROs)
may have the qualifications to supervise and perform therapy with Lu-177 DOTATATE. Although it is recognized
that individual physician variations and state and federal regulatory requirements may, of necessity, dictate site-
specific practice patterns, these physicians may best participate in the practice according to their special interests
and qualifications. In most clinical settings, one of the following common practice paradigms generally applies:

- Physicians who are NRC and/or Agreement State recognized, board-eligible or board-certified in DR, NR, NM, or RO but do not hold AU status. These physicians may participate in the practice of PRRT under the supervision of an AU. Although they may not issue written directives for Lu-177 DOTATATE, they may administer such a dosage as designated and supervised by an AU.

- Physicians who are NRC and/or Agreement State–recognized and board certified in DR, NR, NM, or RO and hold AU status based on that certification and site-specific credentialing: These physicians may administer Lu-177 DOTATATE therapy under their own AU qualifications and licensure.

- Physicians who are NRC and/or Agreement State–recognized and board certified in DR, NR, NM, or RO and hold the appropriate AU statuses and site-specific credentialing. These physicians may practice parenteral Lu-177 DOTATATE therapy as permitted by their own specific training leading to such AU statuses.

VII. RADIATION SAFETY

Radiologists, medical physicists, registered radiologist assistants, 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 that work with ionizing radiation must understand the key
principles of occupational and public radiation protection (justification, optimization of protection and application
of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and
the use of dose reference levels) [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.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 and that they are adhered to in
accordance with ALARA. 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 state and/or
other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by
prescription or protocol.

Nationally developed guidelines, such as the ACR Appropriateness Criteria®, should be used to help choose the
most appropriate imaging procedures to prevent unwarranted radiation exposure.

Additional information regarding patient radiation safety in imaging is available at the Image Gently® for children
(www.imgegently.org) and Image Wisely® for adults (www.imagewisely.org) websites. 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 measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the 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. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

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

Policies and procedures related to quality control and improvement, 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).

Equipment performance monitoring should be in accordance with the ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras [33].

ACKNOWLEDGEMENTS

This practice parameter was developed according to the process described under the heading The Process for Developing ACR Practice Parameters and Technical Standards on the ACR website (https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards) by the Committee on Practice Parameters – Nuclear Medicine and Molecular Imaging of the ACR Commissions on Nuclear Medicine and Molecular Imaging and the Committee on Practice Parameters – Radiation Oncology of the ACR Commission on Radiation Oncology, in collaboration with the ACNM, the ASTRO, and the SNMNI.

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

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PRACTICE PARAMETER 12 Lutetium (Lu-177 DOTATATE) 2020 Resolution No. 17
Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging
(ACR Committee responsible for sponsoring the draft through the process)

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REFERENCES


APPENDIX A

Post Treatment Instructions to Patient Following Lu-177 DOTATATE Therapy

Name of Patient: ______________________________ Medical Record Number: ______________

Last name, First name

Date of Treatment: ______________ Isotope: Lu-177 Activity: ______________

Before this date: ______________, please show this form to every physician, healthcare worker or emergency personnel that provide you care.

Special Precautions

1. Maintain a distance of at least 3 feet (1 meter) from others for 3 days since radiation exposure decreases with distance, the further away you are from others, the less radiation they get.

PRACTICE PARAMETER 15 Lutetium (Lu-177 DOTATATE)

2020 Resolution No. 17
2. Minimize visits by family or friends for 3 days. If you have visitors, try to stay at least 3 feet away.
3. Minimize close contact with others at work for 3 days.
4. For woman of childbearing age (<55 years old), pregnancy must be excluded before initiating the treatment.
   Both men and women of child-bearing potential must refrain from procreation by using effective contraceptive methods during the treatment and for 6 months after.
5. For women who are breastfeeding, discontinue breast feeding for this child.
6. Sleep alone for at least 7 nights. Sleeping together with another adult exposes them to the radiation coming from you. Sexual activity is not advised for 7 days after LUTATHERA administration.
7. No children should sleep with you for 7 days. No pregnant person should sleep with you for 15 days. Children and fetuses are much more sensitive to radiation than adults, and special care is needed. Limit close contact to brief periods for 7 days.
8. Take particular care when urinating for 3 days. Toilets must be used in a seated position, even for men. Use private bathroom or flush 2 to 3 times and clean any spills with disposable gloves and damp cloth after each use. Wash hands thoroughly. The radiation leaves your body mainly from your urine.
9. Wash dishware and utensils and bathroom accessories separately for 3 days.
10. Do not travel by public transportation (bus, train, plane) for more than 1 hour for 3 days. If you are planning to travel while radiation safety precautions are in effect, please inform Nuclear Medicine or Radiation Facility personnel at (area code) _____-_______.
   **For flights, travelers may call TSA Cares toll free at 1-855-787-2227 prior to traveling with questions about screening policies, procedures, and what to expect at the security checkpoint. For more information, visit https://www.tsa.gov/travel/special-procedures.**
11. No prolonged car trip (more than 1 hour) with others for 3 days.
12. Drink plenty of fluid (4-8 glasses) per day for 3 days.

If you are admitted to the ER or hospitalized while radiation safety precautions are in effect, inform the hospital staff to notify the above contact person immediately. During off-hours, contact Nuclear Medicine or Radiation Facility via the operator at ________________________.

Instructions for Radioactive Trash Generated by patient

Please be aware that the following items that may be contaminated with urine and blood cannot be disposed into regular trash:

1. Pads, tampons
2. Toilet papers, tissue
3. Towels, linens, sheets
4. Any other items that are contaminated with urine, blood, and wound or drainage secretions for the first 3 days post treatment

Towels, linens and sheets can be washed separately and reused. Toilet paper and tissue need to be flushed down the toilet. Any other contaminated items that cannot be washed or flushed down the toilet needs to be kept for at least 70 days or bring it to the Nuclear Medicine or Radiation Oncology Facility to be stored.

I have read the above precautions and instructions and have spoken with the Nuclear Medicine or Radiation Facility personnel and agree to comply.

Patient (print name): ______________________________
Signature: _______________________________ Date/time: __________________
Witness (print name) ____________________________

Signature: __________________ Date/time: ________________

Authorized User or Supervised Designee (print name) ____________________________

Signature: __________________ Date/time: ________________

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.
RESOLUTION NO. 18

Sunset the ACR-SPR Practice Parameter for the performance of Liver and Spleen Scintigraphy

WHEREAS, the ACR Commission on Nuclear Medicine and Molecular Imaging and the ACR Commission on Pediatric Radiology agree conditionally to sunset the ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy, and

WHEREAS, the ACR–SPR Practice Parameter for the Performance of Gastrointestinal Scintigraphy has been revised and expanded to cover the information in the ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy, and

WHEREAS, the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Gastrointestinal Tract, Hepatic, and Splenic Scintigraphy is expected to be adopted or adopted as revised at the 2020 Annual Meeting, and

WHEREAS, in the event that the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Gastrointestinal Tract, Hepatic, and Splenic Scintigraphy is not adopted or referred by ACR Council during the ACR 2020 Annual Meeting, the ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy and the ACR–SPR Practice Parameter for the Performance of Gastrointestinal Scintigraphy will be extended until the aforementioned replacement practice parameter is adopted or adopted as revised at a subsequent ACR Annual Meeting; therefore,

BE IT RESOLVED, that in the event that the ACR–ACNM–SNMMI–SPR Practice Parameter for the Performance of Gastrointestinal Tract, Hepatic, and Splenic Scintigraphy is adopted or adopted as referred by ACR Council, the ACR–SPR Practice Parameter for the Performance of Liver and Spleen Scintigraphy is hereby sunset.

Sponsored by: ACR Council Steering Committee
Fiscal Note

Sunset the ACR-SPR Practice Parameter for the performance of Liver and Spleen Scintigraphy

To support the resolution for Sunset the ACR-SPR Practice Parameter for the performance of Liver and Spleen Scintigraphy, the ACR would incur the following estimated costs:

Costs:
De minimis (< $10,000)
RESOLUTION NO. 19

Supervising Radiologist Understanding for Imaging Indication

WHEREAS,

the language in some MRI practice parameter documents that indicates that “the supervising radiology physician must have complete understanding of the indications, risks and benefits of the examination” (e.g. lines 41-42 of the liver MRI parameter) might be interpreted to represent the individual patient’s clinical indications, risks, benefits; therefore,

BE IT RESOLVED,

that the language in the ACR MRI practice parameter documents be revised to include the word “imaging” before the word examination to clarify that this phraseology is intended to indicate complete familiarity with the imaging examination being performed rather than the individual patient being examined, and therefore read as follows “The supervising radiology physicians must understand the indications, risks, and benefits of the imaging examination, as well as alternative imaging procedures”; and

BE IT FURTHER RESOLVED,

that working with the appropriate ACR members, staff will identify all relevant practice parameters in which the edits should be implemented.

Sponsored by: Texas Radiological Society
Fiscal Note

Supervising Radiologist Understanding for Imaging Indication

To support the resolution **Supervising Radiologist Understanding for Imaging Indication**, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
RESOLUTION NO. 20

Extension of Review Cycle for One Practice Parameter

WHEREAS,

the policy governing the revision cycle of the ACR Practice Parameters and Technical Standards as published in the Digest of Council Actions (see Section II-Professional and Public Policy Statements, 1.-Radiological Practice and Ethics, 2.-ACR Policy on Development of Practice Guidelines and Technical Standards, r. Revision of Practice Guidelines and Technical Standards Review Cycle) states, 

‘ACR practice guidelines and technical standards will be reviewed by the Council every five years, or sooner if directed by the Council Steering Committee, the Board of Chancellors, or the Commission on Quality and Safety; 2000, amended 2010 (Res. 10-d).’; and,

WHEREAS,

after initial review of the thirty-nine (39) practice parameters and technical standards to be revised for the 2021 cycle, and consultation with staff and respective commission and committee chairs, the Chair of the Practice Parameters and Technical Standards Committee and the Chair of the Commission on Quality and Safety, identified one (1) document whose review cycle could be extended, and

WHEREAS,

there is no significant scientific reason compelling the review of these document for presentation at the 2021 annual meeting; therefore,

BE IT RESOLVED,

that the review cycle for the practice parameters listed below is hereby extended by one additional year and that these practice parameters are to be presented for consideration at the 2022 ACR Annual Meeting:

(a) ACR–ASNR–ASSR–SPR Practice Parameter for the Performance of Computed Tomography (CT) of the Spine

Sponsored by: Council Steering Committee
To support the resolution Extension of Review Cycle for One Practice Parameter, the ACR would incur the following estimated costs:

**Costs:**

- De minimis (<$10,000)
RESOLUTION NO. 21

ACR Conflict of Interest Policy

WHEREAS, physicians in the United States have confronted increased scrutiny of their relationships and interests that might affect their service to organized medicine, including medical specialty societies; and

WHEREAS, Such scrutiny increases organizational risk to the American College of Radiology (ACR) and individual risk to its members and others who are serving in an official capacity; and

WHEREAS, these factors motivated the ACR Board of Chancellors to form a Workgroup to study whether ACR had sufficient processes to evaluate risk stemming from potential Conflict of Interest (COI) issues relating to members’ outside relationships and financial interests; and

WHEREAS, the BOC Workgroup undertook a comprehensive review and recommended a new approach to address identified gaps in prior ACR processes; and

WHEREAS, the BOC acted on the recommendation by adopting a COI policy in May 2018, which the Council Steering Committee supported; and

WHEREAS, The Council Steering Committee then appointed a Workgroup to consider an organizational COI policy that is based on the BOC COI policy; and

WHEREAS, the ACR’s legislative body should join in affirming a unified organizational position for managing relationships and interests that may pose a risk to the College and its’ members; therefore,

BE IT RESOLVED, that the Council of the American College of Radiology adopt the revised Conflict of Interest Policy in lieu of the Conflict of Interest Disclosure provision adopted in 2011 as Resolution 47-h.

Sponsored by: Board of Chancellors
          Council Steering Committee
ACR Conflict of Interest Policy

To support the resolution for ACR Conflict of Interest Policy, the ACR would incur the following estimated costs:

Costs:
De minimis (< $10,000)
American College of Radiology: Conflict of Interest (COI) Policy

I. INTRODUCTION

The American College of Radiology (ACR) has the fiduciary responsibility to hold the public trust in fulfilling its charitable mission. ACR meets this responsibility in abiding by applicable laws and regulations, and striving to foster professionalism and the integrity of professional judgment in support of its core purpose to serve patients and society by empowering members to advance the practice, science, and professions of radiological care. ACR demonstrates its commitment to these values by disclosing, managing, and, in some cases, restricting relationships that could be perceived to compromise its objective voice.

The Council of Medical Specialty Societies (CMSS) Code for Interactions With Companies (“CMSS Code”) is a set of principles that requires signatory societies to adopt policies for transparency and independence in transactions and activities involving for-profit entities that develop, produce, market, or distribute drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions. ACR signed on to the CMSS Code in April 2010 and has adopted policies and practices in compliance with the Code.

The following Conflicts of Interest Policy (“Policy”) describes ACR’s comprehensive approach to addressing relationships held by ACR and its affiliates, its key leaders and volunteers, or any other person serving in an official ACR capacity.

II. SCOPE

This policy applies to the activities of the ACR and its affiliates including but not limited to the American College of Radiology Association, the American College of Radiology Foundation, the American Institute for Radiologic Pathology (herein referred to as ACR), and all interested persons as defined unless specific terms or the context dictates otherwise. For purposes of this Policy, the term “ACR” refers to all of these entities and related activities, collectively and as applicable.

III. POLICY STATEMENT

All ACR interested persons must complete annually, and update if there are any changes to prior disclosures, a COI Questionnaire through ACR’s electronic system. Interested persons must comply with this Policy to participate in ACR activities.

IV. INFORMATION TO BE DISCLOSED

Disclosures under this Policy generally includes but may not be limited to the following: professional relationships, financial interests, leadership positions, consulting and advisory activities, honoraria, speaking engagements, business courtesies, sanction and exclusions, expert testimony, research funding (to the individual or the institution), and licensing fees and royalties associated with intellectual property interests. Such disclosures
extend to individuals with whom an interested persons have a close personal relationship. ACR interested persons are not required to disclose information pertaining to direct clinical or patient care administrative services. (Certain terms are further defined in the Glossary.)

Collection of disclosures from all interested persons emphasizes ACR’s commitment to transparency, objectivity, and to fulfill its legal obligations. Disclosures of relationships or financial interests do not create a presumption of impropriety.

V. POTENTIAL CONFLICTS OF INTEREST

Disclosures will assist the ACR to identify actual, potential, and perceived conflicts of interest based on an interested person’s service to the ACR. Submitting and keeping current, a COI questionnaire is sufficient to resolve many potential COIs.

Listed below are types of services to the ACR and outlines of COI expectations in these areas, including any legal or external obligations. When a potential conflict has been identified that may affect an interested person’s service to the ACR, various activity-specific management strategies may be employed.

Leadership and Key Persons

For the purposes of this Policy, Leadership and Key Persons are defined as Board of Chancellors (BOC), Board members of ACR affiliates, Council Steering Committee members, the Chief Executive Officer, and the Editor-in-Chief and Deputy Editor of the Journal of the American College of Radiology (JACR). These individuals are required to disclose relationships and other financial interests for themselves and individuals with whom they have a close personal relationship. The BOC Chair or Chief Executive Officer (CEO) may identify others as ACR Key Persons for purposes of this policy.

Councilors, Alternate Councilors, and All Other Annual Meeting Attendees

ACR Councilors and Alternate Councilors serve unique and vital roles participating in the ACR’s Council. Elected and selected by state chapters and specialty societies, they represent those constituencies at the ACR Annual Meeting. Other ACR members and non-members also participate in the Annual Meeting, representing themselves and other constituencies. All attendees must ensure the integrity, independence and objectivity of Council activities. As a condition of attendance, all Annual Meeting attendees must complete a conflict of interest questionnaire as approved by the Council Steering Committee. All potentially relevant disclosures must be verbally conveyed when addressing the Council. Summary information from COI questionnaire disclosures will be available to all Annual Meeting participants. Councilors and Alternate Councilors with potential conflicts may address the Council on relevant matters but should recuse themselves from voting on them.

Officers, Directors, and Key Employees

As a 501(c)(3) tax-exempt organization, the ACR is subject to Internal Revenue Service (IRS) regulations governing "Transactions With Interested Persons". Should a covered transaction, as defined by the IRS, be under consideration, any affected Officer, Director or Key Employee must follow ACR processes for covered transactions.

Continuing Medical Education Activities

As an accredited provider of continuing medical education (CME) for physicians, the College offers CME in accordance with the Accreditation Council for Continuing Medical Education Standards for Commercial Support.
All interested persons serving as planners, presenters, and other individuals who are in a position to control the content of ACR CME, or an activity jointly sponsored by ACR must meet disclosure requirements and management strategies as outlined by ACCME and ACR’s CME compliance program.\textsuperscript{3}

**Journal Manuscripts**

The mission of the Journal of the American College of Radiology (JACR, or “the Journal”) is to fill the gap for information on health services research and policy, clinical practice management, training and education, and leadership. The ACR supports the International Committee of Medical Journal Editors (ICMJE) COI process that requires all disclosures pertaining to the planning, implementation, writing, peer review, editing, and publication of scientific work are submitted according to these standards.\textsuperscript{4}

**Clinical Research Activities**

The development of new devices and pharmaceuticals and increasingly sensitive and quantitative methodologies for the diagnosis, monitoring, and treatment of human disease is dependent on partnerships among industry, academia, and government. It is essential that these relationships are guided by integrity, transparency, and consideration for the public trust.

ACR participates in numerous federally supported grants through the National Institutes of Health (NIH) and other federal agencies. All Interested Persons participating in federally funded Clinical Research Activities must submit all federally mandated disclosures through the annual ACR COI process. Additionally, all Interested Persons who participate in private (non-federally supported) research activities must disclose relationships and other financial interests according to the ACR Financial Conflict of Interest in Research Policy.

**ACR Practice Parameters, Technical Standards and Appropriateness Criteria and Accreditation Activities**

ACR sponsors the development of radiology practice documents and materials based on scientific evidence and consensus in a manner that minimizes the risk of actual or perceived bias, including intended or unintended influence introduced by an individual’s interests. All committee members and others participating in drafting, reviewing, and approving radiology practice documents and other Committee activities must complete a COI questionnaire annually. Additionally, the majority of committee members, including the committee chair, must not hold relationships or financial interests with a company where there is a reasonable likelihood of direct regulatory or commercial impact on the entity as a result of care delivered in accordance with Committee published guidance documents. ACR does not accept Company funding to support the development or initial publication or dissemination of ACR Documents or their updates.

**Grants Selection**

In support of its Core Purpose, the ACR has established various grant programs. To minimize the potential for bias in awarding ACR supported grants, those serving in a grant decision making capacity must complete a COI Questionnaire annually. Those individuals serving in any grant decision making capacities are not eligible to serve as the Principal Investigator in grants they oversee.

**VI. ENFORCEMENT OF POLICY**

Failure to comply with this policy may result in disciplinary action up to and including removal from ACR service. Noncompliance includes failure to disclose, in good faith, an accurate and complete questionnaire, timely reporting of any changes to a previously submitted questionnaire, or failure to comply with a management plan.
VII. EFFECTIVE DATE OF POLICY

This Policy is effective on the date of publication. Earlier ACR Conflict of Interest policies are no longer in effect.

VIII. GLOSSARY

COMPENSATION – Direct and indirect remuneration as well as gifts or favors in aggregate received by interested persons and their close personal relationships.

CONFLICT OF INTEREST – A COI occurs whenever an interested person or someone with whom they have a close personal relationship has a direct or indirect interest or relationship, financial or otherwise, which may conflict or be inconsistent with the interested person’s duties, responsibilities, or independent judgment in any transaction or matter involving ACR.

CLOSE PERSONAL RELATIONSHIP – Any relationship that may create an actual, potential or perceived COI. These may include immediate family members, other relatives, or other persons close to you where you know about their relationships or other financial interests.

COVERED TRANSACTIONS – Any transaction in which there may be an actual, potential or perceived conflict of interest, which occurs when the interests of an Officer, Director, or key employee may be seen as competing with the interests of the ACR.

FINANCIAL INTEREST – Financial relationships of interested persons or those of their close personal relationships with any entity related to or doing business with ACR or to any activities associated with research, practice, or education, in the fields of diagnostic radiology, radiation oncology, interventional radiology, nuclear medicine and medical physics. Financial interests include, but are not limited to:

- Salary
- Consulting fees
- In-kind donations
- Honoraria
- Speaker’s bureau payments
- Equity interest
- Ownership or intellectual property rights, including copyrights, patents, and royalties
- Research grant funding
- Reimbursement for travel or other expenses
- Investment income such as stocks, bonds, mutual funds
- Other payments viewed as compensation

INTERESTED PERSON – Any officer, chancellor, councilor, alternate councilor, member of an ACR commission, committee or task force, persons responsible for public or private research activities related to ACR, annual meeting attendee, or any other person serving in an official ACR capacity.

Whereas certain interested persons are further defined in this policy as ACR Leadership and Key Persons, this group includes officers, members of the Board of Chancellors (BOC), Board members of ACR affiliates, Council Steering Committee members, and the Editor-in-Chief and Deputy Editor of the Journal of the American College of Radiology (JACR). The BOC Chair or Chief Executive Officer (CEO) may identify others as ACR Key Persons for purposes of this policy.
REFERENCES


