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ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF GALLIUM-68 DOTATATE PET/CT FOR NEUROENDOCRINE TUMORS

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.

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.

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

I. INTRODUCTION

This practice parameter was created by the American College of Radiology (ACR) to guide physicians requesting and interpreting oncologic positron emission tomography (PET) and computed tomography (CT) gallium-68 DOTA-Tyr³-octreotate (⁶⁸Ga DOTATATE) scans for adult and pediatric patients.

Radiopharmaceuticals targeting cell surface expression of somatostatin receptors (SSTRs) are particularly useful in the evaluation of neuroendocrine tumors. Several PET radiopharmaceuticals targeting SSTRs have been investigated. A few of these include gallium-68 DOTA-Tyr³-octreotate (⁶⁸Ga-DOTATATE), gallium-68 DOTA-NaI³-octreotide (⁶⁸Ga- DOTANOC) and gallium-68 DOTA-TyI3-octreotide (⁶⁸Ga-DOTATOC). While these radiopharmaceuticals share their characteristic usefulness for imaging SSTR expressing tumors, they differ in their affinity for specific subtypes of the receptors. Gallium-68 DOTATATE primarily binds to SSTR2 receptors, gallium-68 DOTA-NaI³-octreotide binds predominately to SSTR2, SSTR3, and SSTR5, while gallium-68 DOTA-TyI3-octreotide predominately binds to SSTR5 and reasonably well to SSTR2 [1]. This parameter will focus on gallium-68 radiolabeled-DOTATATE imaging, which is a sensitive method of detecting, staging, characterizing the disease, and monitoring the effects of therapy [2].

Gallium-68 DOTATATE PET/CT is proven to have high impact on the management of neuroendocrine patients compared to traditional anatomical imaging. Gallium-68 DOTATATE imaging also provides additional information over that of conventional nuclear medicine studies (indium-III DTPA-octreotide) and can result in changes in management of approximately 75% of patients. Gallium-68 DOTATATE is also more sensitive than meta-iodobenzylguanidine (MIBG) imaging. Gallium-68 DOTATATE and fluorodeoxyglucose (fluorine-18-2-fluoro-2-deoxy-D-glucose [FDG]) imaging are complementary, with the degree of uptake varying depending on the degree of differentiation of the tumor. Well-differentiated tumors maintain their SSTRs and are positive on gallium-68 DOTATATE scan, while dedifferentiated tumors are less likely to demonstrate uptake of gallium-68 DOTATATE but will demonstrate uptake with fluorodeoxyglucose-18 FDG PET/CT [3].

CT uses an external source of radiation to produce 3-D images that demonstrate the size, shape, and composition of organs and abnormalities within the body. Gallium-68 DOTATATE PET and CT are proven diagnostic procedures.

Techniques for registration and fusion of images obtained from separate PET and CT scanners have been available for years. Combined PET/CT devices [4,5] provide both the molecular information from gallium-68 DOTATATE and the anatomic information from CT in a single examination. The information obtained by these combined, hybrid PET/CT scanners is proven to be more accurate in evaluating patients with known or suspected malignancy than either PET or CT alone or than PET and CT obtained separately but interpreted together [6-8]. The advantages of having both PET and CT in a single device have resulted in rapid dissemination of this technology in the United States and throughout the world. This practice parameter pertains only to hybrid PET/CT devices.

Issues related to PET/CT practice include equipment specifications, image acquisition protocols, supervision, interpretation, professional qualifications, and safety. A discussion of these issues by representatives of the ACR, the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society of Computed Body Tomography and Magnetic Resonance (SCBT-MR) is available [9,10].

II. DEFINITIONS

For the purposes of this practice parameter, the following definitions apply:

PET/CT scanner: A hybrid device that includes a single patient table for acquiring a PET scan and CT scan in sequential fashion. If the patient stays reasonably immobile between the scans, the PET and CT data are aligned (coregistered) and can be accurately fused.

PET/CT acquisitions: The extent of tumor imaging can be tailored to suit the specific indications, such as skull vertex to mid thighs, with the following fields of view considered standard for oncology imaging [11]:

1. Vertex to mid thighs
2. Whole body from skull vertex through feet
3. Whole body or vertex to mid thighs with addition of a separate “high resolution” similar series of the head and neck region

PET/CT registration: The process of aligning PET and CT image sets that represent the same body volume such that there is a voxel-by-voxel match for the purpose of attenuation correction as well as combined image display (fusion).

PET/CT fusion: The simultaneous display (superimposed or not) of coregistered PET and CT image sets. When superimposed, the image sets are typically displayed with the PET data color-coded onto the grayscale CT data.

Neuroendocrine tumors (NETs): Neuroendocrine tumors comprise a heterogeneous group of neoplasms that arise from endocrine cells within the glands (eg, adrenomedullary, pituitary, parathyroid) or from endocrine islets in the pancreas, thyroid, respiratory system, and gastrointestinal system [12].

Somatostatin receptors (SSTRs): Somatostatin receptors are present on the cell surface of essentially all cells, but with especially high expression on neuroendocrine cells, providing a unique and specific molecular target for imaging. There are 5 major subtypes of SSTRs, referred to as SSTR1, SSTR2, SSTR3, SSTR4 and SSTR5. SSTR2 has two variants, SSTR2a and SSTR2b. The role of SSTR2b is poorly understood, but is probably similar to SSTR2a. When SSTR2 is used in the context of medicine, it refers to SSTR2a, unless otherwise specified [1,13].

Somatostatin (SST): Somatostatin is the hormone ligand for SSTRs. SST is responsible for the “carcinoid” symptoms, such as wheezing, flushing, cramps, and diarrhea. Octreotide is an SST analog that binds with very high affinity to the SSTRs (especially subtypes 2 and 5) and can control these symptoms with very few, if any, side effects. Octreotide requires injection. Long-acting release (LAR) octreotide is very popular with patients because it lasts about 30 days with one intragluteal injection, obviating the need for daily injections with standard octreotide. Short-acting IV or sub-q octreotide is used to control “carcinoid crisis” and to supplement LAR octreotide if needed. A similar SST analog medication, lanreotide, has an LAR form given subcutaneously every 4 weeks. In addition to controlling symptoms, there is evidence that SST analogs can have antiproliferative effects on the NET.

Peptide-receptor radionuclide therapy (PRRT): A therapy utilized for neuroendocrine tumors with high expression of SSTR2 using DOTATATE radiolabeled with lutetium-177 or yttrium-90 [14].

III. INDICATIONS

Gallium-68 DOTATATE PET/CT is indicated for localization of somatostatin receptor expressing NETs in adult and pediatric patients. Examples of indications for gallium-68 DOTATATE PET/CT include, but are not limited to, the following [15]:

1. Imaging of the NETs, such as arising from the pulmonary or gastrointestinal systems, (eg, carcinoid, gastrinoma), pancreas (eg, insulinoma, glucagonoma, VIPoma, and gastrinoma), and other organ systems
2. Detection of NETs in patients with multiple endocrine neoplasia (MEN) of various types
3. Identification of primary tumor in patients with known metastatic NETs
4. Accurately evaluating the full extent of disease prior to definitive surgical intervention
5. Helping to identify patients who are likely to benefit from octreotide hormonal therapy or PRRT

6. Confirming the diagnosis in patients with anatomic lesions that are suspicious for NET on conventional imaging
7. Detecting NET in patients with strongly suggestive symptoms and laboratory evidence of NET, but with no known primary tumor, though this role is not fully established
8. Gallium-68 DOTATATE PET/CT has been proven superior to iodine-123 meta-iodobenzylguanidine (MIBG) imaging in pediatric patients with neuroblastoma [16] and also to indium-111 diethylenetriaminepentaacetic acid (DTPA) octreotide scan in patients with tumor-induced osteomalacia (TIO), and paraganglioma [17-23]

The [ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#) provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [24].

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

All PET/CT examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

Certification in Radiology, Diagnostic Radiology, Interventional Radiology/Diagnostic Radiology (IR/DR), Nuclear Radiology, or Nuclear Medicine by the American Board of Radiology, American Board of Nuclear Medicine, American Osteopathic Board of Radiology, American Osteopathic Board of Nuclear Medicine, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec.

or

At a minimum, completion of a formal Accreditation Council for Graduate Medical Education (ACGME)–approved general nuclear medicine program that must include 200 hours in radiation physics and 500 hours of preparation in instrumentation, radiochemistry, radiopharmacology, radiation dosimetry, radiation biology, radiation safety and protection, and quality control. In addition, 1,000 hours of clinical training in general nuclear medicine is required and must cover technical performance, calculation of dosages, evaluation of images, correlation with other diagnostic modalities, and interpretation.

and

1. Twenty hours of CME in PET
2. At least 150 oncologic PET/CT examinations interpreted or multiread during the previous 3 years.

If interpreting oncologic PET/CT examinations, interpretation must include direct image correlation with prior CT or MRI examinations. Teaching cases are acceptable with documented interpretation.

Continuing Experience

Interpretation of a minimum of 150 PET/CT examinations in 3 years (multireading is acceptable).

Continuing Education

Completion of 150 hours of AMA-accredited CME, which must include at least 75 hours of Category 1 credit, during the preceding 3 years pertinent to the physician’s practice patterns, including PET imaging.

In addition, all physicians supervising and/or interpreting nuclear medicine examinations must satisfy all applicable state and federal regulations as well as any institutional policies that pertain to the in vivo use of radiopharmaceuticals, performance of imaging procedures, and the safe handling of radioactive materials.

B. Qualified Medical Physicist

For Qualified Medical Physicist qualifications, see the [ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment](#) [25].

C. Radiologic and Nuclear Medicine Technologist

Representatives of the SNMMI and the American Society of Radiologic Technologists (ASRT) met in 2002 to discuss the training and certification of technologists for PET/CT. The recommendations from that conference are outlined in the published consensus statement [26]. A key point is that technologists operating hybrid PET/CT units would ideally be credentialed in both CT and nuclear medicine. However, that is a goal and not a requirement, and any registered radiographer with the credential R.T.(R), registered radiation therapist with the credential R.T.(T), registered nuclear medicine technologist with the credentials R.T.(N), or a certified nuclear medicine technologist, C.N.M.T., may operate PET/CT equipment after obtaining appropriate additional education or training and demonstrating competency.

As a result of the consensus conference, a PET/CT Project Group meeting was convened by the ASRT and the Society of Nuclear Medicine Technologist Section to identify the skills and knowledge required for technologists performing PET/CT examinations and to recommend educational pathways for technologists to transition to PET/CT. The PET/CT curriculum was a product of this meeting (<http://www.asrt.org/educators/asrt-curricula/pet-ct>).

The Nuclear Medicine Technology Certification Board (NMTCB) has developed PET and CT specialty examinations (www.nmtcb.org), and the American Registry of Radiologic Technologists (ARRT) offers a CT certification examination (www.arrt.org).

For more information regarding training and certification, see the [ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography \(CT\)](#) and the [ACR–SPR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals](#) [27,28].

D. Radiation Safety Officer

The Radiation Safety Officer (RSO) must meet applicable requirements of the Nuclear Regulatory Commission (NRC) for training as specified in 10 CFR 35.50, or equivalent state regulations [29].

V. SPECIFICATIONS OF THE EXAMINATION

See the [ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography \(CT\) of the Extracranial Head and Neck](#), the [ACR–SCBT–MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography \(CT\)](#), and the [ACR–SPR Practice Parameter for the Performance of Computed Tomography \(CT\) of the Abdomen and Computed Tomography \(CT\) of the Pelvis](#) [30-32].

A. The written or electronic request for the examination

The written or electronic request for a gallium-68 DOTATATE PET/CT examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

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

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately

licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

B. Patient Preparation [33]

The major goals of patient preparation are to maximize the radiopharmaceutical uptake in the target tissues (neoplastic disease) and minimize patient radiation exposure. The preparation should include, but not be limited to, the following:

1. Prior to appointment:
 - a. Advise patients to drink enough water to ensure adequate hydration with a goal of 1 L (34 oz) in two hours prior to appointment.
 - b. Encourage patients to drink fluids and urinate as often as possible during the first hours following gallium-68 DOTATATE administration to reduce radiation exposure.
 - c. There is no need for fasting before the injection.
 - d. There is no need to restrict physical activity prior to the gallium-68 DOTATATE PET/CT.
2. Prior to gallium-68 DOTATATE injection:
 - a. Perform pregnancy testing when appropriate (see the [ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation](#)) [24].
 - b. Obtain a focused history that includes:
 - i. Reason for examination (symptoms, diagnoses, biochemical test results, and recent imaging examinations)
 - ii. Absence or presence of functional symptoms
 - iii. Treatment (surgical, radiation, and/or conventional chemotherapy, and/or PRRT, or liver-directed therapy, eg, yttrium-90 labeled microspheres)
 - iv. Results of other imaging modalities (CT, MRI, ultrasonography, plain radiography, indium-111 DTPA octreotide scan, etc)
 - v. Medications, specifically short-acting or long-acting SST analogs
 - vi. Presence of concurrent infection
 - vii. Specific details and dates should be obtained whenever possible
 - c. Consider premedication:
 - i. Anxiolytics can be administered in patients with claustrophobia or anxiety. Oral alprazolam (0.5 mg given 10 to 60 minutes prior to gallium-68 DOTATATE injection), or similar medication, is an option, though patients must be counseled against driving given the medication's sedative and motor-impairing effects.
 - d. Guidelines for patients on SST analogs therapy:
 - i. Most centers do not require octreotide therapy withdrawal before PET scanning. The best option is to perform the PET/CT just prior to the scheduled monthly dose of long-acting octreotide analog.
 - ii. Some authors recommend withdrawing short-acting SST analogs for one day and long-acting SST analogs for 3 to 4 weeks prior to scanning. However, this issue is still controversial [34,35].
3. Following injection (uptake period):
 - a. Patients should void immediately prior to being positioned on the PET/CT table for imaging. This will reduce the background noise as well as the radiation dose to the kidneys and bladder. In special circumstances, intravenous hydration, diuretic administration, and/or bladder catheterization can be used to reduce radiation burden and artifacts from accumulation of physiologic radiopharmaceutical activity in the ureters and urinary bladder.
 - b. Consider use of sedation as necessary in younger children or developmentally delayed patients. (See the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [36]).

C. Radiopharmaceutical

For adults, the administered activity of gallium-68 DOTATATE ranges from 100 to 200 MBq (2.7 to 5.4 mCi), average 150 to 185 MBq (4 to 5 mCi), given as a single IV bolus.

Experience in the pediatric population is limited [16]. For children, the administered activity of gallium-68 DOTATATE should be based on body weight and should be as low as reasonably achievable (ALARA) for diagnostic image quality. Typically, the dosage range for children is 2 MBq/kg of body weight (0.054 mCi/kg), up to 200 MBq (5.4 mCi), given as an IV bolus, with a minimum of 18.5 MBq (0.5 mCi).

The specific administered activity typically depends upon the local imaging protocol. The local protocol may require a standard activity, or the activity may vary as a function of various parameters such as patient size, scanning mode (2-D versus 3-D), percentage of scan bed (slice) overlap, or clinical indication. For variable dosages, other means of determining the administered activity can be based upon a combination of factors, which use the patient's weight, duration of bed positions in minutes, and percent of bed position overlap in certain PET/CT systems (some systems do not use bed positions). The variable dose calculation's goal is to optimize a personalized dosage with the ALARA principle. Without a dedicated dosage injector with the ability to precisely elute a calculated dosage, a fixed dose with a range may be more practical for adults. To date there are no clear data providing evidence of superiority of parameter-dependent administered activity protocols [37].

With PET/CT, the radiation dose to the patient is the combination of the administered activity from the PET radiopharmaceutical and the dose from the CT portion of the examination. Lower administered activities or changes in CT parameters resulting in decreased radiation dose may be appropriate with advances in PET/CT technology. However, the total effective dose from a typical gallium-68 DOTATATE PET/CT (~5 mSv) is less than for indium-111 DTPA octreotide (~6 mSv) or fluorodeoxyglucose (fluorine-18-2-fluoro-2-deoxy-D-glucose [FDG]) (~7 mSv) scans [38,39].

When feasible, the radiopharmaceutical should be injected intravenously at a site away from sites of known or suspected disease. The radiopharmaceutical should be administered using an indwelling catheter to avoid extravasation.

D. Protocol for the CT Portion of the PET/CT Imaging

The technologist should ascertain that the radionuclide on the PET/CT scanner is set to gallium-68, and then change it again before scanning a patient with a different radionuclide (eg, fluorodeoxyglucose-18). The CT performed as part of a PET/CT examination provides attenuation-correction information and diagnostic information that may be relevant to both PET interpretation and overall patient care. A variety of protocols exist for performing the CT scan in the context of PET/CT scanning. In some cases, low-dose CT scans are designed primarily to provide attenuation correction and anatomic localization. In other cases, the CT portion of the examination is performed with intravenous and/or oral contrast media and optimized CT parameters designed to lower image noise. If a diagnostic CT scan is requested as part of PET/CT, the CT protocol appropriate for the body region(s) requested should be used. Regardless of the CT technique used, a careful review of CT images is necessary for comprehensive interpretation of the PET/CT examination. Even if a nondiagnostic CT for attenuation correction and anatomic localization is being performed, due to the common occurrence of primary or metastatic NETs occurring in the GI tract and peritoneal/retroperitoneal regions, either no oral contrast or "negative" oral contrast use should be considered [40].

For a diagnostic CT scan of the abdomen and/or pelvis, intraluminal gastrointestinal contrast media may be administered to improve visualization of the gastrointestinal tract unless medically contraindicated or unnecessary for the clinical indication. Highly concentrated barium collections ("positive" oral contrast) may result in attenuation-correction artifacts and may also obscure the presence of peritoneal and retroperitoneal tumor that commonly occur with NETs and should be avoided. Either no oral contrast or "negative" oral contrast should be used [40-44].

When indicated, the CT scan can be performed with intravenous contrast media using appropriate injection techniques. High intravascular concentrations of intravenous contrast media may cause a localized attenuation-correction artifact on the PET image [41,45], but the impact is usually limited [41,46].

Breathing patterns during CT acquisition should be optimized so that the positions of the diaphragm on the PET emission and the CT transmission images match as closely as possible.

If a single-breath-hold technique is used for CT imaging, optimal alignment of the PET and CT images is obtained with respiration suspended in the quiet, end-expiratory (end-tidal volume) phase. If respiration is not suspended during CT imaging, the patient should be coached on shallow/quiet breathing. To optimize breathing pattern, gating of the PET and/or CT can be performed in more modern PET/CT scanners.

E. Protocol for PET Emission Imaging

After verifying that the scanner is set to the proper PET isotope, emission images are generally obtained 60 minutes following radiopharmaceutical administration. However, this time period may be shorter (no less than 45 minutes) or longer for certain trials or unique clinical situations. Note that consistency of standardized uptake value (SUV) measurements depends on strict observance of the uptake time; therefore, when using a 60-minute interval, an acceptable range of injection-to-scan time is 55 to 75 minutes [47].

Emission image acquisition time typically varies from 1 to 5 minutes or longer per bed position for body imaging and is based on the administered activity, patient body weight, and the sensitivity of the PET device (as determined largely by the detector composition and acquisition method). Acquisition time can be adjusted in certain clinical situations to provide higher count images in a given anatomic area. The most commonly used times per bed position are either 3 or 4 minutes in 3-D mode for current scanners, using similar filters and corrections for scanner and dead time as for FDG.

Semiquantitative estimation of gallium-68 DOTATATE accumulation using the SUV is based on local radioactivity concentration measured on images, corrected for attenuation, and normalized to the body weight, lean body mass, or body surface area. The accuracy of SUV measurements depends on the accuracy of the calibration of the PET device, among other factors. As the SUV is becoming a standard for determining tumor response over time, measures should be taken to minimize the factors that may affect it. These include using the same scanner configuration on subsequent examinations (including reconstruction algorithms, attenuation maps, etc), maintaining the same interval between injection and scanning, avoiding infiltration of injected activity, and using the same measurement techniques, (eg, VOI volumes, max/peak/mean measurements). Some factors that affect SUV currently remain beyond control, such as variations in patient motion/breathing-related attenuation-correction artifacts [48].

Krenning Score: Recording changes in the intensity of gallium-68 DOTATATE uptake with semiquantitative measurements, expressed in absolute values and percent changes, may be appropriate in some clinical scenarios. However, the technical protocol and analysis of images need to be consistent in the 2 data sets. A semiquantitative score that should be reported on gallium-68 DOTATATE scans is the “Krenning score.” The Krenning score compares the uptake in sites of known or suspected tumor to the uptake in the liver, with the uptake scored as 0 (no uptake above background tissue), Grade 1 (uptake greater than background tissue, but less than liver), Grade 2 (about the same uptake as liver), Grade 3 (uptake greater than the liver, but less than kidneys or spleen), and Grade 4 (same as, or greater than, uptake in the kidneys or spleen) [49]. Although the Krenning score was validated in predicting response to PRRT with lutetium-177 DOTATATE (still investigational), with indium-111 DTPA octreotide scans, with a score of 2 or greater required for eligibility for PRRT treatment, the Krenning score is also being used similarly with gallium-68 DOTATATE. The Krenning score also suggests that patients with a score of 2 or more are likely to respond to somatostatin analog medications, such as LAR octreotide, for symptomatic control, because of the high density of somatostatin receptors on their tumor.

F. Interpretation

With integrated PET/CT systems, the software packages typically provide a comprehensive platform for image review, including registered and aligned CT images, PET images with and without attenuation correction, and PET/CT fusion images in the axial, coronal, and sagittal planes. In addition, maximum-intensity-projection (MIP) images of the PET examination should be generated for review. PET images with and without attenuation correction should be available for review.

Although the pattern of radiopharmaceutical uptake and associated CT findings, as well as correlating with history, physical examination, laboratory findings, and other imaging modalities, are usually the most helpful in differentiating benign from malignant lesions, semiquantitative estimates (eg, SUV) may also be of value, especially for evaluating changes with time or therapy. Unlike with fluorodeoxyglucose-18 FDG, where high uptake generally identifies an aggressive tumor, high gallium-68 DOTATATE uptake generally indicates a well-differentiated tumor that is less aggressive, with low uptake suggesting a poorly differentiated tumor, typically with a poor prognosis. Patients with tumors of low uptake (Krenning score below 2) may be better imaged with fluorodeoxyglucose-18 FDG PET/CT.

The following issues should be taken into consideration while interpreting gallium-68 DOTATATE PET/CT:

1. Physiologic distribution: Normal distribution of gallium-68 DOTATATE is seen in the choroid plexus of the brain, pituitary gland, glandular tissues of the neck, liver, pancreas, spleen, hematopoietic marrow, and adrenal glands. Normal biodistribution patterns are published and should be reviewed by physicians who are inexperienced with this radiopharmaceutical [2,38,39].
2. Intensity of gallium-68 DOTATATE uptake relative to the liver (Krenning score) [49]. Possible presence of a mixed population (eg, some areas of tumor with good uptake and others without).
3. False-positive and false-negative results: Tissues other than neoplastic disease may show substantial gallium-68 DOTATATE uptake. On the other hand, some conditions may lead to poor gallium-68 DOTATATE uptake in neoplastic tissue. The following lists include, but are not limited to, the following:
 - a. Pituitary gland (close attention to the CT portion of the examination and other imaging may be needed to exclude a pituitary tumor)
 - b. Choroid plexus
 - c. Meningioma
 - d. Uptake in the uncinate region of the pancreas is variable and can be intense and can be a normal variance
 - e. Adrenal glands, including benign tumors of the adrenal glands
 - f. Spleen (typically the greatest uptake other than in the urine)
 - g. Accessory spleens/splenosis (may require a heat-damaged red-cell scan to differentiate peritoneal/retroperitoneal nodules due to splenic tissue from metastatic disease)
 - h. Kidneys and uroepithelium (filtering/excretion of gallium-68 DOTATATE)
 - i. Areas of active infection/inflammation (most white cells express high levels of SSTRs), including inflammatory arthritis, fractures, healing surgical wounds, inflammatory response to radiation, and pneumonia or abscess, etc
 - j. Granulomatous reactions (especially if “active”)
 - k. Osteoblastic activity including normal uptake (active epiphyseal plates) and bone disease (Paget disease, fibrous dysplasia, some bone islands, etc). These can be difficult to differentiate from bone metastases
 - l. Non-neuroendocrine cancers can have variable uptake, including a wide variety of epithelial tumors (head and neck, lung, esophageal, breast, colorectal, ovarian, testicular, lymphoma, etc) and primary brain tumors. Careful attention to the CT appearance on the PET/CT and pattern recognition of the overall context can assist in identifying second primary cancers, as with fluorodeoxyglucose-18 FDG PET/CT

4. Tissues with moderate somatostatin expression:
 - a. Lacrimal and salivary glands
 - b. Thyroid
 - c. Liver
 - d. Atherosclerotic disease (inflammatory or unstable plaque)
 - e. Prostate (chronic prostatitis)
 - f. Hemangiomas (especially vertebral bodies, but also liver and other organs). At times, hemangioma uptake can be intense [50,51].
 - g. Active (hematopoietic) normal bone marrow uptake should be diffuse, nonfocal, similar to appearance of fluorodeoxyglucose-18 FDG PET/CT. Intense heterogeneous or focal uptake is highly suggestive of metastatic disease unless the bony architecture suggests the presence of hemangioma or nonhealed fracture.
 - h. Breast tissue (variable), especially in pregnancy or with lactation
5. Artifacts
 - a. Misalignment between PET and CT data can cause attenuation correction artifacts. Fusion images and PET images without attenuation correction can be used to help identify these artifacts.
 - b. Inaccuracies in converting from polychromatic CT energies to the 511 keV energy of annihilation radiation can cause artifacts around implanted devices, metal, highly concentrated iodinated contrast, or dense barium, although these artifacts are less common with newer conversion algorithms.
6. Situations that can lead to false-negative FDG-PET/CT interpretation
 - a. Small lesions size (<2 times resolution of the system)
 - b. Low levels of somatostatin receptor expression (eg, poorly differentiated) tumor. Fluorodeoxyglucose-18 FDG PET/CT may be superior in this context.
 - c. Recent treatment
 - i. Chemotherapy
 - ii. Radiation therapy
 - iii. Recent liver-directed therapy (eg, bland or chemoembolization, or embolization with radiolabeled microspheres)
 - iv. Recent PRRT
 - v. Postsurgical inflammation obscuring tumor
 - vi. Tumors occurring in areas with normal high physiologic uptake (eg, near the uncinate process of the pancreas or the adrenal glands, splenic hilus (tail of the pancreas), etc.

VI. EQUIPMENT SPECIFICATIONS

See the [ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment](#), the [ACR–ASNR–SPR Practice Parameter for the Performance of Computed Tomography \(CT\) of the Extracranial Head and Neck](#), the [ACR–SCBT–MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography \(CT\)](#), and the [ACR–SPR Practice Parameter for the Performance of Computed Tomography \(CT\) of the Abdomen and Computed Tomography \(CT\) of the Pelvis](#). [25,30-32].

A. Performance Guidelines

For patient imaging, the PET/CT scanner should meet or exceed the following specifications:

1. For the PET scanner
 - a. In-plane spatial resolution: <6.5 mm
 - b. Axial resolution: <6.5 mm
 - c. Sensitivity (3-D): >4.0 cps/kBq
 - d. Sensitivity (2-D): >1.0 cps/kBq
 - e. Uniformity: <5%

2. For the CT scanner
 - a. Spiral scan time: <5 seconds (<2 seconds is preferable)
 - b. Slice thickness and collimation: <5 mm (<2 mm is preferable)
 - c. Limiting spatial resolution: >8 lp/cm for >32-cm display field of view (DFOV) and >10 lp/cm for <24-cm DFOV
3. For the combined PET/CT scanner
 - a. Maximum co-scan range (CT and PET): >160 cm
 - b. Maximum patient weight: >350 lb
 - c. Patient port diameter: >59 cm

B. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications, to include iodinated contrast media. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. A fusion workstation with the capability to display PET, CT, and fused images with different percentages of PET and CT blending should also be available. The workstation should also have the capability to measure SUV with volumetric ROI.

D. PET/CT scanning done specifically for radiation therapy planning should be performed with a flat table top, immobilization devices used as needed, with the use of appropriate positioning systems in order to best match patient positioning during radiation therapy.

VII. DOCUMENTATION

A. Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [52]

The report should include the radiopharmaceutical, administered activity, and route of administration, as well as any other pharmaceuticals administered, along with dosage and route of administration.

The technique section of the report should include the radiopharmaceutical (eg, gallium-68 DOTATATE), the administered activity, route and site of administration, as well as any pharmaceuticals administered (eg, diuretics, anxiolytics). Patient weight, height, and gender (to allow SUV normalization to lean body mass), time from injection to scanning, and technique for normalizing SUVs (ie, body weight, lean body weight, or body surface area) should be reported [53]. It should be noted if the patient is taking any short- or long-acting octreotide medications.

Details of oral or intravenous contrast agents, if used for the CT attenuation-correction portion of the examination, should also be reported to include the volume and route of administration. Other information relevant to contrast administration, such as steroid preparation, prehydration, or dialysis history, should be included. The report should also include documentation of contrast reactions and subsequent treatment, if observed during the examination.

The findings section should include a description of the location, extent, and intensity of abnormal gallium-68 DOTATATE uptake in relation to normal comparable tissues and should describe the relevant morphologic findings on the CT images. Ideally, image and series numbers should also be included. Additionally, background activity (eg, normal liver) should be measured to help ensure comparable SUV values [54]. Often injection-site infiltration, such as in arms, or attenuation-correction errors, can significantly alter SUV values in lesions, leading to false conclusions. An estimate of the intensity of gallium-68 DOTATATE uptake can be provided with the SUV; however, the intensity of uptake may be described as less than, about the same as, or greater than the liver and/or spleen (Krenning score).

If the CT scan was requested and performed as a diagnostic examination, the CT component of the examination should be reported separately to satisfy regulatory, administrative, or reimbursement requirements. In that case, the PET/CT report should refer to the diagnostic CT scan report for findings not related to the PET/CT combined findings [55-57]. Even if the CT scan was not requested as a diagnostic examination, clinically important nononcologic findings (eg, pneumothorax, aortic aneurysm, bowel obstruction, pneumoperitoneum, fracture) on the CT scan should be reported.

When gallium-68 DOTATATE PET/CT is performed for monitoring therapy, a comparison of extent and intensity of uptake may be summarized as progressive disease, stable disease, partial response, or complete response using published criteria for these categories. However, it is imperative to remember that strong correlation with CT and, if available, MRI imaging is required to make these determinations. Gallium-68 DOTATATE uptake is based on SSTR receptor density, not metabolic activity, and loss of uptake may actually identify a tumor that has become less differentiated and likely more proliferative, not a tumor that is responding to treatment. Accordingly, strict use of appropriate objective treatment response criteria is strongly recommended for determining treatment effectiveness, especially following PRRT or liver-directed therapy. [58-62]

VIII. EQUIPMENT QUALITY CONTROL

PET performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras](#) and the [ACR–AAPM Technical Standard for Medical Physics Performance Monitoring of PET/CT Imaging Equipment](#) [25,63].

CT monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography \(CT\) Equipment](#) [64].

The quality control (QC) procedures for PET/CT should include both the PET procedures and the CT procedures according to the ACR Technical Standards. The QC procedures for PET should include a calibration measurement of activity in a phantom containing a known radiopharmaceutical concentration, generally as a function of axial position within the scanner field of view. The QC procedures for the CT should include air and water calibrations in Hounsfield units for a range of kV. A daily check on the stability of the individual detectors should also be performed to identify detector failures and drifts.

In addition, for PET/CT, the alignment between the PET and CT scanners should be checked periodically. Such a check should determine an offset between the PET and CT scanners that is incorporated into the fused image display to ensure accurate image alignment.

IX. 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)

http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf.

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.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation

dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

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).

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

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

Only licensed, properly credentialed and trained individuals who are familiar with reconstituting radiopharmaceuticals should perform the preparation of clinical doses. Specific kit manufacture instructions should be followed, and only FDA-approved gallium-68 generator(s) and gallium-68 DOTATATE kit(s) should be used.

For specific issues regarding CT quality control, see the [ACR Practice Parameter for Performing and Interpreting Diagnostic Computed Tomography \(CT\)](#) [65].

For specific issues regarding PET and PET/CT quality control, see section VIII on Equipment Quality Control.

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography \(CT\) Equipment](#) [66].

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