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

The American College of Radiology, with more than 40,000 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.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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

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

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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.

I. INTRODUCTION

This practice parameter has been revised collaboratively by the American College of Radiology (ACR), 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, optimize radiation dose to patients, minimize radiation dose to 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 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.

RLs for nuclear medicine and molecular imaging should be based on administered activity (dosage[2]). RLs are based on published surveys from professional organizations or 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 for a routine nuclear medicine and molecular imaging procedure [5-8]. A procedure RL is set at around the 75th percentile of the range of the available administered activity data. The International Commission on Radiological Protection (ICRP) Publication 135 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. 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.

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].

[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.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

See the ACR-ACNM-SNMMI-SPR Practice Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures [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, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A Qualified Medical Physicist should meet the ACR Practice Parameter for Continuing Medical Education (CME) [10].

The appropriate subfields of medical physics for this practice parameter is Nuclear Medical Physics. (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

The Qualified Medical Physicist must be familiar with the principles of imaging physics and radiation protection; the 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 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) [8]. Administered activity RLs (in MBq or MBq/kg of body mass) are then used to help manage the radiation dose to patients.

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].

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

A. Adult Examinations

Table 1 summarizes the RLs and AAAs for 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.

TABLE 1

Radiopharmaceutical Achievable Administered Activities and Reference Levels for Adults

Radiopharmaceutical - Examination	Achievable Administered Activity[1]	Reference Level Administered Activity[2]
^{99m}Tc-Hydroxymethylene Diphosphonate (HDP)/Methylene Diphosphonate (MDP) – whole body bone [1,4]	929 MBq (25.1 mCi)	988 MBq (26.7 mCi)
^{99m}Tc-Iminodiacetic Acid (IDA) analog – hepatobiliary imaging [4]	204 MBq (5.5 mCi)	241 MBq (6.5 mCi)

^{99m}Tc-Macroaggregated Albumin (MAA) – perfusion lung [4]	185 MBq (5.0 mCi)	215 MBq (5.8 mCi)
^{99m}Tc-Sulfur Colloid – liver/spleen [4]	222 MBq (6.0 mCi)	255 MBq (6.9 mCi)
^{99m}Tc-Dimercaptosuccinic Acid (DMSA) [3]	185 MBq (5.0 mCi)	289 MBq (7.8 mCi)
^{99m}Tc-Mercaptoacetyltriglycine (MAG3) [3]	278 MBq (7.5mCi)	379 MBq (10.0 mCi)
^{99m}Tc-RBC – tagged RBC [4]	840 MBq (22.7 mCi)	925 MBq (25 mCi)
^{99m}Tc-Pertechnetate – thyroid imaging [4]	370 MBq (10.0 mCi)	407 MBq (11.0 mCi)
^{99m}Tc-labeled solids – GI Emptying [3]	37 MBq (1.0 mCi)	50 MBq (1.3 mCi)
^{99m}Tc-Exametazime (HMPAO) [3]	740 MBq (20.0 mCi)	1,193 MBq (32.0 mCi)
^{123}I-Sodium Iodide (NaI) – thyroid imaging [4]	9.0 MBq (0.255 mCi)	11.0 MBq (0.300 mCi)
^{123}I-Metaiodobenzylguanidine (MIBG) [3]	370 MBq (10.0 mCi)	391 MBq (11.0 mCi)
^{131}I-Sodium Iodide (NaI) – whole body imaging thyroid cancer [4][3]	148 MBq (4.0 mCi)	185 MBq (5.0 mCi)
^{111}Indium Pentetreotide – octreotide SPECT imaging	226 MBq	237 MBq

[4]	(6.1 mCi)	(6.4 mCi)
^{111}In-Oxine Leukocytes [16,23][4]	24 MBq (0.7 mCi)	30 MBq (0.8 mCi)
^{67}Ga citrate-inflammatory disease [3]	185 MBq (5.0 mCi)	371 MBq (10.0 mCi)
^{18}F-Fluorodcoxyglucose (FDG) – oncology PET [1,4]	485 MBq (13.1 mCi)	555 MBq (15.0 mCi)
^{18}F-Fluorodcoxyglucose (FDG) – brain PET [4]	370 MBq (10 mCi)	414 MBq (11.2 mCi)
^{18}F-Florbetaben – brain PET [4]	363 MBq (9.8 mCi)	377 MBq (10.2 mCi)
^{18}F-Florbetapir – brain PET/CT [4]	374 MBq (10.1 mCi)	411 MBq (11.1 mCi)
^{99m}Tc-Sestamibi – one-day protocol (cardiac rest/stress) [2]	388/1,169 MBq (10.5/31.6 mCi)	425/1,251 MBq (11.5/33.8 mCi)
^{99m}Tc-Tetrofosmin – one-day protocol (cardiac rest/stress) [2]	388/1,147 MBq (10.5/31.0 mCi)	425/1,221 MBq (11.5/33.0 mCi)
^{99m}Tc-Sestamibi – two-day protocol (cardiac rest/stress) [2]	1089/1,110 MBq (29.4/30.0 mCi)	1165/1,184 MBq (31.5/32.0 mCi)
^{99m}Tc-Tetrofosmin – two-day protocol (cardiac rest/stress) [2]	1084/1,110 MBq (29.3/30.0 mCi)	1214/1,199 MBq (32.8/32.4 mCi)
^{99m}Tc-Sestamibi – (cardiac stress only) [3]	925 MBq (25.0 mCi)	1,452 MBq (39.0 mCi)

^{99m}Tc-Tetrofosmin – (cardiac stress only) [3]	833 MBq (23.0 mCi)	1,459 MBq (39.0 mCi)
^{201}Tl-Chloride/^{99m}Tc-Sestamibi – one-day protocol (cardiac rest/stress) [2]	148/1,110 MBq (4.0/30 mCi)	152/1,184 MBq (4.1/32.0 mCi)
^{201}Tl-Chloride/^{99m}Tc-Tetrofosmin – one-day protocol (cardiac rest/stress) [2]	141/1,110 MBq (3.8/30.0 mCi)	148/1,189 MBq (4.0/32.1 mCi)
^{201}Tl-Chloride (cardiac rest/stress) [3]	111 MBq (3.0 mCi)	172 MBq (4.6 mCi)

[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 ^{131}I administered for imaging causes a decrease in uptake of radioiodine subsequently given for ablation. Because of concerns about the possible effects of stunning on ^{131}I 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 ^{111}In-Oxine Leukocytes are based on recommended dose ranges [16,23]

B. Pediatric Examinations

ICRP 135 [8] specifies that the 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 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.

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 , as well as pregnant patients at different gestational stages, they are based on generic body-size estimates and tracer kinetics, which may be very different from those of any individual patient [26,28-30].

On occasion, 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). In these situations, it is recommended that the physician have a written medical physics consult with a Qualified Medical Physicist. Using the information about the patient's weight, administered activity, and the radiopharmaceutical, the Qualified Medical Physicist can estimate the dose to tissue and organs. 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, non-physician radiology providers**,** radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

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

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

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

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

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 recommend means of improvement if the dose estimates or administered activity exceeds the RLs.

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