ACR–ACNM–ARS–ASTRO–SNMMI PRACTICE PARAMETER FOR THE PERFORMANCE OF THERAPY WITH RADIOPHARMACEUTICALS

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.

---

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 was revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Radium Society (ARS), the American Society for Radiation Oncology (ASTRO), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

This practice parameter is intended to serve as a resource for appropriately trained and licensed physicians who perform therapeutic procedures with unsealed sources further referred to in this document using the more inclusive terminology of radiopharmaceuticals for which a written directive is required as authorized users under NRC 10 CFR 35.300. Such therapy requires close cooperation and communication between the treating physicians and other health care providers who are also responsible for the ongoing clinical management of the patient. The treating physician and care team determine and oversee the appropriateness, and timing, of administration of radiopharmaceutical therapy, as well as manage radiation safety and side effects of those interventions. Adherence to the elements of this practice parameter should help to maximize the efficacious use of these therapies; maintain safe conditions for patients, medical personnel, and others possibly exposed; and facilitate compliance with applicable state and federal laws and regulations.

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

Therapy with radiopharmaceutical agents entails the use of ionizing radiation, delivered internally via oral, parenteral, intravenous, intra-arterial, intrathecal, intra-articular, or intracavitary means, to treat cancer and certain benign disorders . Such therapy requires detailed attention to selection of appropriate radiopharmaceuticals, administered activity, applicable target, and nontarget radiation doses, personnel, equipment, patient and personnel safety, and continuing staff education along with close cooperation and communication with other physicians who are involved in the clinical management of the patient, and the clinical staff who will be in contact with the patient. Because the practice occurs in a variety of clinical environments, the judgment of a licensed physician authorized user (AU) under NRC 10CFR35.300 or the appropriate Agreement State should be used to apply these practice parameters to individual patients and practices.

This practice parameter addresses the overall role of the applicable physician AU, Qualified Medical Physicist, and other specialized personnel involved in the delivery of radiopharmaceutical therapy. Separate practice parameters and standards define the still-evolving appropriate use of more novel radiopharmaceuticals or other radiolabeled agents. Because use of these agents changes on a dynamic basis, users are encouraged to review literature available after publication of practice parameters.

AUs are specifically trained and responsible for weighing the benefits against the risks associated with exposure to ionizing radiation and should always follow the guiding principle of limiting radiation exposure to the patient and nontarget organs, while accomplishing the therapeutic goal.

Therapeutic radiopharmaceuticals include those administered as the elemental radioactive isotopes (radionuclides) or the radioactive element incorporated into a targeting molecule (ligand) by one or more chemical bonds. Examples of radionuclides that are administered in elemental form or as simple salt of the element include iodine-131 (I-131) administered as sodium iodide for targeting the sodium iodide symporter and radium-223 (Ra-223) administered as radium dichloride mimicking calcium during active bone formation. I-131 can also be covalently bonded to a targeting ligand such as a small molecule or an antibody. Metallic radionuclides such as Yttrium-90 (Y-90) and Lutetium-177 (Lu-177) can also be chemically bonded to a targeting molecule. Direct administration of radionuclides by interventional techniques without the use of a molecular target is also performed. Examples include glass or resin microspheres for delivery of Y-90 for hepatic lesions and direct injection of colloidal chromic phosphorous-32 (P-32) for joint space diseases. Selection of radiopharmaceuticals for therapeutic use is based on identification of an appropriate target or approach and the inherent properties of the radionuclide [2].

II. INDICATIONS

Examples of radioactive emissions from available therapy with unsealed radiopharmaceutical sources and specific agents include, but are not limited to, the following:

A. Alpha particles : Upon alpha decay an alpha particle (helium nucleus—two protons/two neutrons) is emitted at a very high velocity [3]. The combination of mass and high speed makes for highly energetic particles capable of substantial tissue damage. Alpha particles have short tissue penetration, usually in the range of 40 to 100 µm [4,5]. The limited penetration of alpha emissions mitigates the risk of adverse side effects away from the site of emission but increases the need for precise delivery to the end target. The linear energy transfer (LET) of alpha particles is approximately 80–100 keV/µm, 100–1,000-fold higher than that of beta particles, translating into a high density of biologic damage [6]. Tissue damage is predominantly in the form of DNA strand breaks, with a propensity for the alpha-induced DNA breaks to be double stranded and lethal to the cell. In general, double strand breaks are difficult to repair via normal DNA repair mechanisms [7]. Additionally, there is a potential role for immunologic factors to augment radiation-induced cell death [8].

   Ra-223 is an FDA-approved commercially available alpha-emitting agent (more detailed information can be found in the ACR–ACNM–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Radium-223) [9].

B. Betaparticles: Beta particles used for therapy are electrons emitted from the nucleus of decaying radioactive atoms during the conversion of a neutron to a proton. They have various energies, and thus a distribution of tissue penetration ranges from approximately 50 µm to 12 mm [5]. The LET of these energetic particles is an order of magnitude lower than that of alpha particles, approximately 0.2 keV/µm, making them sparsely ionizing [5]. Consequently, a very high radionuclide concentration is required in the targeted tissue, but the longer range of beta particles leads to the production of increased crossfire dose to normal tissues and bystander effects, potentially destroying additional cells within the range of the decaying atoms that were not directly targeted by the radiopharmaceutical. FDA-approved commercially available beta emitting agents include:

   I-131 (more detailed information can be found in the ACR–ACNM–ASTRO SNMMI-SPR Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with I-131Sodium Iodide) [10].

   Yttrium-90 microspheres. The FDA defines these as considered brachytherapy sealed sources and devices. (for further information see the ACR–ABS–ACNM–ASTRO–SIR–SNMMI Practice Parameter for Selective Internal Radiation Therapy (SIRT) or Radioembolization for Treatment of Liver Malignancies) [11].

   I-131 MIBG (meta-iodobenzylguanidine) for treatment of metastatic or unresectable pheochromocytoma, paraganglioma, and pediatric neuroblastoma (FDA approved July 2018). Lutetium-177 DOTATATE for treatment of certain neuroendocrine tumors. More information can be found in the ACR–ACNM–ASTRO–SNMMI Practice Parameter for Lutetium-177 (Lu-177) Dotatate Therapy [12].Lutetium-177 PSMA-617 (vipivotide tetraxetan) for treatment of patients with prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer who have been previously treated with androgen receptor pathway inhibition and taxane-based chemotherapy.

C. Mixed emission: Some of the therapeutic radionuclides cited have a variety of emissions in their decay pathways. When these emissions include a gamma component, imaging for localization and dosimetry may be feasible, but additional safety precautions may also be necessary.

   Additional unsealed radiopharmaceuticals historically used for therapy include phosphorus-32 (sodium phosphate) for treatment of myeloproliferative disorders, phosphorus-32 (colloidal chromic phosphate) for treatment of malignant ascites/effusions as well as intracranial cystic lesions (craniopharyngioma); Samarium-153 lexidronam ethylene diamine tetra methylene phosphonic acid (EDTMPA), and Strontium-89 for adjuvant and palliative treatment of painful skeletal metastases; and Yttrium-90-ibritumomab tiuxetan a for non-Hodgkin’s lymphoma (NHL). These radiopharmaceuticals are not currently commercially available.

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–SNMMI–SPR Technical Standard for Therapeutic Procedures Using Radiopharmaceuticals [1] and/or the ACR–ASTRO Practice Parameter for Radiation Oncology [13]. In addition, training and experience must be in compliance with the applicable laws and regulations, including 10 CFR 35.390 [14].

On the basis of their postgraduate training pathway(s), board certification(s), subsequent fellowship training, and continuing certification(s) (formerly maintenance of certification) , NRC AU status, facility licensure, and clinical work experience, nuclear medicine physicians (NMs), radiation oncologists (ROs), diagnostic radiologists (DRs), interventional radiologists (IRs), and nuclear radiologists (NRs) may have the necessary qualifications and credentials to supervise and perform therapies using radiopharmaceuticals. Individual specialty physician variations and state and federal regulatory requirements may, of necessity, dictate site-specific practice patterns. In most clinical settings, one of the following common practice paradigms may apply:

- Physicians who are board-eligible or board-certified in DR, NM, IR, or RO but do not hold AU status: These physicians may participate in the practice of therapy with specific radiopharmaceuticals under the supervision of an AU licensed to use the specific therapeutic radiopharmaceutical. Although they may not issue the written directives for those specific radiopharmaceuticals, they may administer such a dosage as designated by an AU under direct supervision.

- At the current time, physicians who are board-certified in DR, NM, IR, or RO and are AU licensed to use the specific therapeutic radiopharmaceutical and have appropriate site-specific licensure: These physicians may practice radiopharmaceutical therapy independently under their own AU and facility license qualifications.

IV. SPECIFICATIONS OF THE CONSULTATION REQUEST

The written or electronic request for a radiopharmaceutical 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's scope of practice requirements. (ACR Resolution 35, adopted in 2006 - revised in 2016, Resolution 12-b)

IV. SPECIFICATIONS OF THE CONSULTATION REQUEST

A. General Procedures

1. Clinical evaluation: In concordance with the ACR–ASTRO Practice Parameter for Radiation Oncology and the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [13,15], evaluation of the patient must include conducting a history and physical examination, review of medical records, pertinent diagnostic studies (including target organ specific laboratory evaluation), and history of all previous chemotherapy, targeted biological therapy, radiotherapy, and radiopharmaceutical therapies, with an emphasis on factors that might exert an impact on the current consideration of radiopharmaceutical therapy. Pregnancy testing, as appropriate, should be obtained before treatment. These findings should be communicated to the referring physician and other clinical health care providers through a consultation note to others involved in the patient's care in a timely manner. For radiopharmaceutical therapies that have potential marrow toxicity, a complete blood count obtained within the previous 7 to 10 days must be part of the initial assessment and of each pretreatment evaluation. Other pretreatment evaluations may be appropriate

based on the organ at risk and other susceptible healthy tissues depending on the specific radiopharmaceutical and patient factors. The physician(s) carrying out the evaluation must also consider the ability of the patient and their caregivers to understand and comply with essential postadministration radiation safety precautions. When appropriate, a pretreatment theranostic imaging examination should be performed/evaluated to demonstrate disease uptake and susceptibility of the disease process to the proposed radiopharmaceutical therapy. Pretreatment theranostic imaging should be interpreted/reviewed directly by the AU performing the treatment for adequate verification of expected risk/benefit of the proposed radiopharmaceutical administration.

2. Quality management: –Key elements of a quality management program include written directives; specified procedures for shipment acceptance, handling, and storage of radioactive materials; duplicative procedures for patient identification; careful record-keeping to ensure prescribed administered activity; procedures to minimize the possibility of infiltration for radiopharmaceuticals that are administered intravenously; procedures for minimizing radiation exposure or radiopharmaceutical contamination of personnel, family members of patients, and the public; procedures for containment of radioactivity; and an audit mechanism to ensure compliance with the program. Patients who may become pregnant or exposed pregnant individuals must be counseled about those special case radiation exposure risks and the counseling documented in the patient's medical record.

3. Informed consent: Informed consent must be obtained and documented before treatment. Given the unique nature of therapy with radiopharmaceuticals, the informed consent should ideally address known potential short-, mid- and long-term radiation risks to the patient. It is also encouraged that the consent and instructions include a statement regarding risk of exposing the public, caregivers, and household members to unnecessary radiation if radiation precautions are not appropriately followed. See the ACR-ARS Practice Parameter on Informed Consent Radiation Oncology [16].

4. Treatment: The procedure and follow-up should be performed according to predetermined facility policies and procedures that may be unique for each type of application.

5. Pregnancy must be evaluated before radiopharmaceutical administration. See the ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation [17]. The decision to provide therapy in a pregnant, breastfeeding, or lactating patient should only be made with full understanding and provided with careful patient and provider dialogue and be documented in the patient's medical record. Appropriate state regulations must be considered.

6. Radiation precautions: Radiation precautions and patient release criteria may be regulated by the NRC or by the Agreement State. The radiation safety officer (RSO) or the qualified designee for the facility in which the radioactive agent is to be administered should follow the applicable federal or state regulations. Details on the federal regulations can be obtained at the NRC website, nrc.gov.

   Under the guidelines of federal code 10CFR35.75 [18,19] and key sections of NUREG 1556 [19], the patient may be released 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, written instructions must be provided to the patient on actions to maintain doses to others by using the "as low as reasonably achievable" (ALARA) [20] principle. Agreement 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 & Measurements (NCRP) differ somewhat from the NRC regulations [21]. Because the fetus and children are more sensitive to radiation injury than adults, the NCRP specifies that children and pregnant patients, 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 should also be limited to 1 mSv, which is also the NRC dose limit to a member of the public.
   Many radiation survey meters measure exposure rates in milliroentgens/hour (mR/h). For purposes of radiation protection and for low LET radiation (including beta particles and most x-rays and gamma rays), the organizations that developed this consensus 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.

Radiopharmaceuticals can be volatile. When using volatile radiopharmaceuticals, for instance, in the case of certain liquid formulations of radioactive sodium iodide, staff may need to be appropriately screened for exposure through bioassay. Environmental contamination can occur with nonvolatile radiopharmaceuticals through spills and patient bodily fluids. Diligent surveys should be performed of the environment, equipment, and patient personal belongings following treatment with radiopharmaceutical therapy with the goal to minimize and properly contain any detectable or removable contamination.

All necessary blood work and laboratory specimens should be obtained before treatment with the therapeutic radiopharmaceutical to minimize exposure to laboratory staff and contamination of equipment. If confinement in a health care facility is required, it is not usually necessary to store bodily fluids, such as urine, stool, or vomitus. For body fluid disposal, where acceptable under state or federal regulations, the toilet should be flushed two or three times after each use to ensure sufficient dilution and disposal of radioactivity. All patients should be instructed to sit during urination. Food trays and linens should remain in the patient's room until monitored and cleared by radiation safety staff, as should soiled bandages or bedding. The patient must remain in the room except in a medical or nonmedical (eg, fire) emergency, and access by personnel and visitors should be limited. All trash and residual nondisposable items must be secured and 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 be contained in safe storage for 10 half-lives or when radiation levels are indistinguishable from background for radionuclides with half-lives =120 days. 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 the survey is performed [21] and released by the RSO or designee. The room and contents release survey must be documented in the patient and facility permanent records.

If the physician responsible for the patient's care during their confinement (eg, hospital admission) is different from the physician who is responsible for the management of the radiopharmaceutical, there must be a mechanism to prevent premature discharge or release of the patient from confinement. Discharge or release from confinement should not be accomplished until that action is documented by the physician managing the radiopharmaceutical agent or their radiation protection designee.

IV. SPECIFICATIONS OF THE CONSULTATION REQUEST

B. Posttherapy Follow-Up

Physicians using radiopharmaceuticals for therapy should participate in a primary role or together with the patient's other physician(s) in the follow-up and management of patients treated with either curative, adjuvant, or palliative intent and should document the outcome of therapy, including results of treatment (tumor control, survival, degree of palliation, time to retreatment, if applicable) and significant sequelae [22]. Because the effect of radiopharmaceutical therapy it may require time to become clinically manifested , patients should be seen in follow-up by a physician experienced in radiation-related sequelae within intervals appropriate for the specific therapeutic intent.

As appropriate, posttreatment theranostic imaging may be performed to evaluate appropriate uptake and excretion of the radiopharmaceutical and can also be used for quantification of delivered dose as appropriate (radiopharmaceutical dosimetry). Relevant imaging interpretations that should be documented include anticipated therapeutic efficacy, the impact of changes in radiopharmaceutical uptake between treatments, relevant incidental findings, and potential complications of the radiopharmaceutical therapy.

V. DOCUMENTATION

Documentation should be in accordance with NRC, Agreement State, and or institutional practices.

VI. RADIATION SAFETY PRECAUTIONS

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).

A. Whenever possible, removal of bodily fluids and/or tissue should be avoided following therapeutic instillation of radiopharmaceutical sources into any body area until such time as permitted by the facility RSO or other appropriate designee.
B. Instructions to patients should specify a time interval for safe removal of body fluids and/or tissues based on the therapeutic radiopharmaceutical employed in the procedure.
C. For in-patient facilities, patient orders should specify procedures for handling of removed bodily fluids and/or tissues as well as notification of the responsible RSO or appropriate designee.
D. In the unlikely event of a patient death following instillation of unsealed therapeutic radionuclides, the responsible RSO or appropriate designee should be notified immediately of the death; any handling of the body, including cremation, should be directed by that individual.

VII. 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 *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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 – 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 ARS, the ASTRO, and the SNMMI.

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

ACR

Paul E. Wallner, DO, Co-Chair

Don C. Yoo, MD, Co-Chair

Bryan M. Rabatic, MD, PhD

Zachary S. Morris, MD, PhD

ACNM

Carina Mari Aparici, MD

ASTRO

Jeff Michalski, MD

Freddy E. Escorcia, MD, PhD

ARS

Neha Vapiwala, MD

Navesh Sharma, MD

SNMMI

Jeremie Calais, MD

Michael Morris, MD, MS

Daniel Pryma, MD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging

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

Munir V. Ghesani, MD, FACR, Co-Chair

Rathan M. Subramaniam, MD, PhD, MPH, Co-Chair

Esma A. Akin, MD, FACR

Twyla B. Bartel, DO, MBA

Andrew Kaiser, MD

A. Tuba Karagulle Kendi, MD

Charles Marcus, MD

Justin G. Peacock, MD, PhD

Committee on Practice Parameters and Technical Standards – Nuclear Medicine and Molecular Imaging

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

Elizabeth H. Dibble, MD

Perry S Gerard, MD, FACR

K. Elizabeth Hawk, MD, MS, PhD

Eric Hu, MD

Eric M. Rohren, MD, PhD

Levi Sokol, MD

Devaki S. Surasi, MD

Andrew T. Trout, MD

Committee on Practice Parameters – Radiation Oncology

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

Naomi R. Schechter, MD, Chair

Brian Davis, MD

Anupriya Dayal, MD

Steven Jay Frank, MD

Laura Freedman, MD

Adam Garsa, MD

Matthew Harkenrider, MD

Simon Lo, MD

Bryan Rabatic, MD

Michael Reilly, PhD

Hina Saeed, MD

Paul E. Wallner, DO

Don C. Yoo, MD, FACR, Chair of the Commission Nuclear Medicine and Molecular Imaging

William Small, Jr, MD, FACR, Chair of the Commission on Radiation Oncology

David B. Larson, MD, MBA, FACR, Chair, Commission on Quality and Safety

Mary S. Newell, MD, FACR, Chair, Committee on Practice Parameters and Technical Standards

Comment Reconciliation Committee

Join Y. Luh, MD, Chair

Ashley Prosper, MD Co-Chair

Carina Mari Aparici, MD

John Buatti, MD

Jeremie Calais, MD

Timothy A. Crummy, MD

Ron Ennis, MD

Bill Erwin, MD

Freddy E. Escorcia, MD, PhD

Mark Green, MD

Mary Ellen Jafari, MS

David Walter Jordan, MD

Amy L. Kotsenas, MD

David B. Larson, MD, MBA

Paul Larson, MD

Gustavo Mercier, MD

Jeff Michalski, MD

Michael Morris, MD, MS

Zachary S. Morris, MD, PhD

Mary S. Newell, MD

Daniel Pryma, MD

Bryan M. Rabatic, MD, PhD

Marla Sammer, MD

Naomi R. Schechter, MD

Navesh Sharma, MD

Arif Sheikh, MD

William Small, Jr., MD

Neha Vapiwala, MD

Paul Wallner, DO

Gerald White, PhD

Roland Wong, Sc.M

Don Yoo, MD

REFERENCES

1. American College of Radiology. ACR–AAPM–SPR technical standard for theraputic procedures using radiopharmaceuticals. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RadioPharm.pdf. Accessed February 1, 2022.
2. Speer T. *Targeted radionuclide therapy*. Philadelphia Wolters Kluwer Health/Lippincott Williams & Wilkins.; 2011.
3. International Commission on Radiation Units & Measurements. ICRU Report 96, Dosimetry-Guided Radiopharmaceutical Therapy. https://www.icru.org/report/icru-report-96-dosimetry-guided-radiopharmaceutical-therapy/, 2023.
4. Sartor O, Sharma D. Radium and other alpha emitters in prostate cancer. Translational andrology and urology 2018;7:436-44.
5. Kassis AI. Therapeutic radionuclides: biophysical and radiobiologic principles. Seminars in nuclear medicine 2008;38:358-66.
6. Aghevlian S, Boyle AJ, Reilly RM. Radioimmunotherapy of cancer with high linear energy transfer (LET) radiation delivered by radionuclides emitting alpha-particles or Auger electrons. Advanced drug delivery reviews 2017;109:102-18.
7. Wieder HA, Lassmann M, Allen-Auerbach MS, Czernin J, Herrmann K. Clinical use of bone-targeting radiopharmaceuticals with focus on alpha-emitters. World journal of radiology 2014;6:480-5.
8. Gameiro SR, Jammeh ML, Wattenberg MM, Tsang KY, Ferrone S, Hodge JW. Radiation-induced immunogenic modulation of tumor enhances antigen processing and calreticulin exposure, resulting in enhanced T-cell killing. Oncotarget 2014;5:403-16.
9. American College of Radiology. ACR–ACNM–ASTRO–SNMMI practice parameter for the performance of therapy with radium-223. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Radium223.pdf. Accessed February 1, 2022.
10. American College of Radiology. ACR–ACNM–ASTRO SNMMI-SPR practice parameter for treatment of benign and malignant thyroid disease with I-131sodium iodide. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/I131SodiumIodide.pdf. Accessed February 1, 2022.
11. American College of Radiology. ACR–ABS–ACNM–ASTRO–SIR–SNMMI practice parameter for selective internal radiation therapy (SIRT) or radioembolization for treatment of liver malignancies. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RMBD.pdf?la=en. Accessed February 1, 2022.
12. American College of Radiology. ACR–ACNM–ASTRO–SNMMI Practice Parameter for Lutetium-177 (Lu-177) Dotatate Therapy. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Lutetium-177-DOTATATE.pdf. Accessed October 27, 2022.
13. American College of Radiology. ACR–ASTRO practice parameter for radiation oncology. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RadOnc.pdf. Accessed March 26, 2018.
14. United States Nuclear Regulatory Commission. § 35.390 training for use of unsealed byproduct material for which a written directive is required. Available at: https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html#part035-0390. Accessed October 17, 2018.
15. American College of Radiology. ACR–AAPM technical standard for medical physics performance monitoring of image-guided radiation therapy (IGRT). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/IRGT-TS.pdf. Accessed May 10, 2022.
16. American College of Radiology. ACR-ARS practice parameter on informed consent radiation oncology. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/informedconsent-ro.pdf. Accessed October 27, 2022.
17. American College of Radiology. ACR–SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Pregnant-Pts.pdf, 2023.
18. United States Nuclear Regulatory Commission. § 35.75 release of individuals containing unsealed byproduct material or implants containing byproduct material. Available at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html. Accessed May 13, 2014.
19. United States Nuclear Regulatory Commission. Consolidated guidance about materials licenses: program - specific guidance about medical use licenses (NUREG-1556, Volume 9, Revision 2, Page 8-73 and Appendix U) Available at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/. Accessed May 27, 2014.
20. United States Nuclear Regulatory Commission. ALARA. Available at: https://www.nrc.gov/reading-rm/basic-

ref/glossary/alara.html. Accessed October 17, 2018.
21. National Council on Radiation Protection and Measurements. NCRP No. 155, management of radionuclide therapy patients. Available (for purchase) at: http://www.ncrponline.org/Publications/Press_Releases/155press.html. Accessed September 2, 2014.
22. Schraml FV, Parr LF, Ghurani S, Silverman ED. Autopsy of a cadaver containing strontium-89-chloride. Journal of nuclear medicine : official publication, Society of Nuclear Medicine 1997;38:380-2.
23. Blake GM, Zivanovic MA, Blaquiere RM, Fine DR, McEwan AJ, Ackery DM. Strontium-89 therapy: measurement of absorbed dose to skeletal metastases. Journal of nuclear medicine : official publication, Society of Nuclear Medicine 1988;29:549-57.
24. Bos SD. An overview of current clinical experience with strontium-89 (Metastron). The Prostate. Supplement 1994;5:23-6.
25. Porter AT, McEwan AJ, Powe JE, et al. Results of a randomized phase-III trial to evaluate the efficacy of strontium-89 adjuvant to local field external beam irradiation in the management of endocrine resistant metastatic prostate cancer. International journal of radiation oncology, biology, physics 1993;25:805-13.
26. Quilty PM, Kirk D, Bolger JJ, et al. A comparison of the palliative effects of strontium-89 and external beam radiotherapy in metastatic prostate cancer. Radiotherapy and oncology : journal of the European Society for Therapeutic Radiology and Oncology 1994;31:33-40.
27. Sciuto R, Festa A, Pasqualoni R, et al. Metastatic bone pain palliation with 89-Sr and 186-Re-HEDP in breast cancer patients. Breast cancer research and treatment 2001;66:101-9.
28. Paes FM, Ernani V, Hosein P, Serafini AN. Radiopharmaceuticals: when and how to use them to treat metastatic bone pain. The journal of supportive oncology 2011;9:197-205.
29. Pandit-Taskar N, Batraki M, Divgi CR. Radiopharmaceutical therapy for palliation of bone pain from osseous metastases. Journal of nuclear medicine : official publication, Society of Nuclear Medicine 2004;45:1358-65.
30. Sartor O, Reid RH, Hoskin PJ, et al. Samarium-153-Lexidronam complex for treatment of painful bone metastases in hormone-refractory prostate cancer. Urology 2004;63:940-5.
31. Das T, Banerjee S. Radiopharmaceuticals for metastatic bone pain palliation: available options in the clinical domain and their comparisons. Clinical & experimental metastasis 2017;34:1-10.
32. Williams G, Palmer MR, Parker JA, Joyce R. Extravazation of therapeutic yttrium-90-ibritumomab tiuxetan (zevalin): a case report. Cancer biotherapy & radiopharmaceuticals 2006;21:101-5.
33. American College of Radiology. ACR–ABS–ACNM–ASTRO–SIR–SNMMI Practice Parameter for Selective Internal Radiation Therapy (SIRT) or Radioembolization for Treatment of Liver Malignancies. https://www.acr.org/-/media/ACR/Files/Practice-Parameters/rmbd.pdf. Accessed October 27, 2022.
34. Witzig TE, Flinn IW, Gordon LI, et al. Treatment with ibritumomab tiuxetan radioimmunotherapy in patients with rituximab-refractory follicular non-Hodgkin's lymphoma. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2002;20:3262-9.
35. Morschhauser F, Radford J, Van Hoof A, et al. Phase III trial of consolidation therapy with yttrium-90-ibritumomab tiuxetan compared with no additional therapy after first remission in advanced follicular lymphoma. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2008;26:5156-64.
36. Berlin NI. Treatment of the myeloproliferative disorders with 32P. European journal of haematology 2000;65:1-7.
37. Ansell SM, Schilder RJ, Pieslor PC, et al. Antilymphoma treatments given subsequent to Yttrium 90 ibritumomab tiuxetan are feasible in patients with progressive non-Hodgkin's lymphoma: a review of the literature. Clinical lymphoma 2004;5:202-4.

*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 11)

Revised 2000 (Resolution 27)

Revised 2005 (Resolution 21)

Amended 2006 (Resolution 35)

Revised 2010 (Resolution 26)

Amended 2014 (Resolution 39)

Revised 2015 (Resolution 49)

Revised 2019 (Resolution 41)
Revised 2023 (Resolution 27)