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ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF THERAPY WITH UNSEALED RADIOPHARMACEUTICAL SOURCES

PREAMBLE

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

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

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

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

The goal of therapy with unsealed radiopharmaceutical sources is to provide either cure or effective palliation of disease while minimizing untoward side effects and complications.

II. DEFINITION

Therapy with unsealed sources involves administration of radiopharmaceuticals for the treatment of medical conditions.

III. INDICATIONS

Examples of therapy with unsealed radiopharmaceutical sources include, but are not limited to, the following:

1. Iodine-131 (sodium iodide)
   a. Treatment of hyperthyroidism
   b. Ablation of postoperative thyroid remnant and therapy of iodine-avid thyroid cancer.

2. Strontium-89 (strontium chloride), samarium-153 lexidronam ethylene diamine tetra methylene phosphonic acid (EDTMPA), and radium-223 (radium dichloride)
   For adjuvant and palliative treatment of painful skeletal metastases

3. Phosphorus-32 (sodium phosphate)
   Treatment of myeloproliferative disorders such as polycythemia vera and thrombocytosis

4. Phosphorus-32 (colloidal chromic phosphate)
   Intracavitary therapy of malignant ascites, malignant pleural effusions, malignant pericardial effusions, and malignant brain cysts

5. Yttrium-90 ibritumomab tiuxetan, murine monoclonal antibody targets the CD20 antigen, for treatment of patients with CD20-positive follicular B-cell non-Hodgkin lymphoma, with or without transformation, including but not limited to disease that is refractory to rituximab and has relapsed following chemotherapy. On September 3, 2009, the FDA granted expanded approval for the use of yttrium-90 ibritumomab tiuxetan in patients with previously untreated follicular non-Hodgkin’s lymphoma who have demonstrated partial or complete response to first-line chemotherapy (consolidation after chemotherapy) [2,3].

For more information on radioembolization, see the ACR–SIR Practice Parameter for Radioembolization with Microsphere Brachytherapy Device (RMBD) for Treatment of Liver Malignancies [4].

IV. 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–SNM Technical Standard for Diagnostic Procedures Using
Radiopharmaceuticals [1] and/or the ACR–ASTRO Practice Parameter for Radiation Oncology [5]. In addition, training and experience must be in compliance with the applicable laws and regulations.

V. SPECIFICATIONS OF THE EXAMINATION AND TREATMENT

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)

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 [5,6]. The treating physician’s initial evaluation of the patient must include review of the patient’s history, physical examination, and pertinent diagnostic studies and reports, including a complete history of all previous radiotherapy and radiopharmaceutical therapy. These findings should be communicated to the referring physician and other physicians involved in the patient’s care. For the radiopharmaceutical treatments that are potentially marrow-toxic, a complete blood count with differential and platelet count should be part of the initial assessment and of each pretreatment evaluation.

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

3. Informed consent – Informed consent must be obtained and documented. See the ACR Practice Parameter on Informed Consent – Radiation Oncology [7].

4. Treatment – The procedure and follow-up should be performed according to an established system of procedural steps that may be unique for each type of application.

5. Regardless of whether the radiopharmaceutical route is oral, intravenous, or intraperitoneal, a patient should not be pregnant, breastfeeding, or lactating at the time of radiopharmaceutical administration. Pregnancy should be excluded prior to radiopharmaceutical administration by one of the following:
negative human chorionic gonadotropin (hCG) test, documented hysterectomy, postmenopausal state (absence of menstrual bleeding for 2 years), or by premenarche (child age 10 years or younger).

The lactating breast concentrates significant iodine/radioiodine. Thus, radioiodine therapy during lactation will cause a high radiation exposure to the breast and to a nursing infant. If radioiodine therapy is to be administered, breastfeeding must be stopped completely for that infant but may be resumed during a subsequent pregnancy. A 3-month delay in radioiodine therapy is recommended after discontinuing breastfeeding [8]. It is recommended that pregnancy be delayed at least 6 months after radioiodine therapy [8].

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

Under the guidelines of federal code 10 CFR 35.75 [9,10] and key sections of NUREG 1556 [11], 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). And, if the total effective dose equivalent is likely to exceed 1 mSv (0.1 rem) to any individual, instructions, including written instructions, must be provided to the patient on actions to maintain doses to others by utilizing ALARA the “as low as reasonably achievable” principle. Agreement States may have specific rules and regulations regarding release of patients with significant residual activity.

The dose limits specified by the NCRP differ somewhat from the NRC regulations [12]. Because the fetus and children are more sensitive to radiation injury than adults, the NCRP specifies that children and pregnant women, whether or not they are members of the patient’s household, should be limited to 1 mSv (0.1 rem). Any individual who has no familial connection to the patient and for whom there is no emotional benefit should also be limited to 1 mSv, which is also the NRC dose limit to a member of the public.

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

All routine blood work and laboratory specimens should be obtained prior to treatment with the radiopharmaceutical. If confinement in a health care facility is needed, it is not usually necessary to store body effluents such as urine, stool, or vomitus. For effluent disposal, the toilet should be flushed 2 or 3 times after each use to ensure sufficient dilution of radioactivity. Food trays and linens should be stored in the patient’s room until monitored and cleared by radiation safety staff. The patient must stay in the room except in a medical or nonmedical (eg, fire) emergency, and access by personnel and visitors must be limited. All trash and residual nondisposable items must be monitored after the patient’s release and stored until radiation levels reach the statutory level defined for safe disposal or reuse. (In some jurisdictions items in decay storage must reside there for 10 half-lives or when radiation levels are indistinguishable from background.) Once all known contamination is removed from the room, the room must be surveyed to verify that the radiation levels and removable contamination are sufficiently low to permit its general use. The room may not be used until this survey is performed [12].

If the admitting physician is different from the physician who administers the radiopharmaceutical, there must be a mechanism to prevent premature discharge or release of the patient from confinement.
B. Iodine-131 (sodium iodide)

1. Therapy for Hyperthyroidism

   a. Background
   Iodine-131 has a physical half-life of 8.02 days. It emits beta radiation as well as gamma radiation that allows imaging, though imaging of the dose administered for treatment of hyperthyroidism is not performed in practice.

   b. Summary of selected data
   i. 50% to 90% of hyperthyroid patients reach a euthyroid or hypothyroid state within 1 year of treatment with iodine-131 [13].
   ii. In a study of 1,278 patients seen over an approximate 20-year time period, hyperthyroid patients were rendered euthyroid or hypothyroid after a single dose of 600 MBq (16.2 mCi), 370 MBq (10 mCi), or 185 MBq (5 mCi) in 84.1%, 74.9%, and 63% of cases, respectively [14].
   iii. Failure rates for iodine-131 treatment for Graves disease as a cause for hyperthyroidism are higher in patients with large thyroid volumes, high iodine uptake, and high iodine turnover [15].

   c. Treatment recommendations
   Patient preparation – A recent radioiodine thyroid uptake should be available (See the ACR-SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [16]). The size of the thyroid gland should be noted. Optimally, the patient’s system should be free of iodide-containing medications, iodinated contrast radiopharmaceuticals, exogenous thyroid hormone, and antithyroid medications. The patient should avoid foods containing very large amounts of iodine for the week prior to therapy; however, a strict low-iodine diet is usually unnecessary. Ideally, patients should not receive thioamide medications (eg, propylthiouracil or methimazole) for at least 2 to 7 days prior to therapy [17-19].

   d. Administered activities
   i. Diffuse hyperfunctioning thyroid/Grave’s Disease
   Initial activity of 1.85 to 7.4 MBq (50 to 200 μCi) per gram of thyroid (after adjusting for current 24-hour radioiodine uptake) may be administered. Rarely, it may be necessary to administer an activity greater than 1.22 GBq (33 mCi). Alternatively, an empiric adult administered activity of 185 to 555 MBq (5 to 15 mCi) may be given. The measurement of radioiodine uptake before therapy is necessary to establish the cause of the patient’s hyperthyroid state, to avoid the inappropriate administration of radioiodine in the setting of subacute thyroiditis or factitious hyperthyroidism, and to provide information on the radiation emanating from the patient for purposes of counseling the patient on radiation safety matters.
   ii. Toxic nodular goiter and solitary toxic nodule
   These conditions tend to be more resistant to radioiodine therapy. Activity of up to 1.22 GBq (33 mCi) or more may be administered.

   Administered activity for pediatric patients can be empiric, weight-based, or based on dosimetry [20].

   e. Side effects/complications
   Side effects are usually minor. Patients may occasionally experience neck tenderness and/or odynophagia from radiation thyroiditis. Serious complications are rare. However, on occasion patients with severe hyperthyroidism may experience exacerbation of symptoms within the first 2 weeks following iodine-131 therapy. These symptoms usually respond to short term beta blocker therapy, but rarely may progress to frank thyroid storm. Patients should be instructed to contact their referring physician or seek immediate medical care should such symptoms occur.

   Hypothyroidism is often considered to be a likely or even desired outcome of successful therapy of Graves disease or toxic nodular goiter and can occur within the first few months following therapy or even decades later, with a small, ongoing annual incidence. If a solitary toxic nodule has fully
suppressed the function of the remaining thyroid, the risk of resulting hypothyroidism is decreased, but hypothyroidism may still occur.

Hypothyroidism is treated with carefully monitored hormone-replacement therapy. Based on previous multicenter trials, there is no evidence of increased risk of thyroid carcinoma or other malignancy, infertility, or increased incidence of birth defects following iodine-131 therapy for hyperthyroidism.

f. Treatment failures and subsequent therapies
In 5% to 10% of patients, the initial therapeutic dosage of iodine-131 fails to sufficiently control hyperthyroidism. In patients who have not adequately responded to prior iodine-131 therapy, subsequent radioiodine treatments may be given. An equal or higher treatment dosage is generally used for retreatment. To achieve the maximal therapeutic effect, repeat therapies are usually not recommended until at least 6 months after the most recent radioiodine therapy. In the setting of diffuse hyperthyroidism, the likelihood of residual hyperthyroidism is greater for lower initial radioiodine administered activities.

2. Therapy for Thyroid Remnant Ablation, Residual Thyroid Cancer, or Metastases from Thyroid Cancer

a. Background
Iodine-avid thyroid cancers frequently take up radioiodine in the absence of significant amounts of residual normal thyroid tissue. In order to optimize ablative radioiodine therapy for residual or metastatic disease, or to facilitate the follow-up of patients, the thyroid remnant should be eliminated by surgery and/or radioiodine treatment. In planning therapy for a suspected thyroid remnant or metastasis, a total-body radioiodine scan may be of assistance in assessing extent of disease. Details regarding risk stratification of patients with thyroid cancer, appropriateness of radioiodine therapy in various clinical situations, and overall management of patients with thyroid cancer are covered extensively elsewhere [21,22].

b. Summary of selected data
i. A study evaluating thyroid cancer over a 40-year period reported that for patients with cancers greater than or equal to 1.5 cm in diameter post-thyroidectomy and without distant metastases, the addition of iodine-131 therapy alone for remnant thyroid ablation reduced the rate of recurrence and cancer death by at least one-half and reduced the risk of recurrence by more than two-thirds [23].

ii. In a phase III trial comparing results of iodine-131 therapy in patients with low-risk thyroid cancer post-thyroidectomy using thyroid hormone withdrawal versus use of recombinant human thyrotropin, the ablation rate was found to be equivalent between iodine-131 doses of 30 mCi and 100 mCi. There was also no difference in the ablation rate between patients withdrawn from thyroid hormone versus those who received recombinant human thyrotropin [24].

iii. In one study assessing the effectiveness of radioiodine therapy for pulmonary metastases in differentiated thyroid cancer, a better outcome was seen in patients with lower pre-ablation stimulated TG and iodine-131 positive but anatomically negative disease [25].

c. Treatment recommendations
Iodine-131 has a physical half-life of 8.02 days. It emits beta radiation as well as gamma radiation, which is suitable for imaging. Because of increased sensitivity afforded by the therapeutic dosage of iodine-131, post-therapy imaging (usually performed 2 to 10 days after treatment) is useful to identify sites of disease not detected on pretherapy iodine imaging.

d. Patient preparation
The serum TSH must be elevated, usually to a level in excess of 30 µIU/mL, either by withholding oral thyroid hormone to induce endogenous TSH secretion or by injecting recombinant human TSH (rH TSH) to raise the patient’s blood level of this hormone before therapy [26]. If a remnant is suspected, scintigraphy may be performed to determine how avidly the thyroid remnant is accumulating radioiodine. If a large thyroid remnant is present, performing a completion thyroidectomy before the iodine-131 therapy should also be considered. Documentation of an elevated TSH level as well as adherence to a low-iodine diet for 1 to 2 weeks prior to treatment is recommended. Optimally, the patient’s system should be free of iodide-containing medications, iodinated contrast radiopharmaceuticals and exogenous thyroid hormone (for withdrawal therapy).
The patient should be fasting and should abstain from eating 2 to 4 hours before and 1 to 2 hours after therapy.

e. Administered activities

Iodine-131 may be administered to all ages in the management of thyroid cancer, but pediatric dosages should be weight-adjusted.

The patient may need to be placed on radiation precautions.

i. Ablation of thyroid remnant

Activities of 1.11 to 3.7 GBq (30 to 100 mCi) of iodine-131 (sodium iodide) administered orally are most often used. Higher dosages may be used for more extensive disease.

ii. Known or suspected residual thyroid cancer

For residual tumor in the thyroid bed or in the setting of local lymph node metastases in the neck without evidence of distant metastasis, activities of 3.7 to 5.55 GBq (100 to 150 mCi) are usually administered.

iii. Known or suspected distant metastases will usually require administered radioiodine activities equal to or greater than 5.55 GBq (150 mCi).

f. Side effects/complications

The most commonly reported side effect is salivary gland dysfunction due to acute sialadenitis. Some investigations suggest that these effects are dose related [27,28], however, studies addressing this complication report varied results. Following radiiodine therapy, copious hydration is recommended, however the use of sialagogues is debatable. Acute sialadenitis is often transient. Permanent xerostomia is rare and reported in 2 to 4% of affected patients [27,29,30] and is generally associated with a history of single or multiple high administered activities of radioiodine.

Reports of pulmonary fibrosis and/or pneumonitis have been described. A whole-body retention threshold of 2.96 GBq (80 mCi) at 48 hours has been used for intense iodine-avid diffuse pulmonary metastases to avoid lung injury. This administered activity is approximately 7.4 GBq (200 mCi), ie, the upper limit of the administered activity should be 200 mCi. Pulmonary function studies should be considered prior to treatment if there are widespread pulmonary metastases [22,31,32]

Discussion of fertility should be considered, particularly in young patients who may need multiple treatments. However, a recent study of 2,673 pregnancies in differentiated thyroid cancer patients who had been treated with radiiodine showed no effect on outcome of subsequent pregnancies [33]. Most experts recommend that pregnancy should be delayed by at least 6 months after radiiodine therapy [34] to complete follow-up evaluation of therapeutic effectiveness and completion of therapy.

The potential for the development of secondary primary malignancies (SPM) following high administered activities of therapeutic radioiodine is controversial. A large European study of 6,871 patients reported an increase in solid tumors and leukemia after radiiodine therapy [35]. A recent literature review, however, reassessed the data and reported a nonlinear dose effect [36]. Review of the Surveillance, Epidemiology, and End Results (SEER) program with a database of 18,882 patients, with a mean follow-up of 61.8 months, concluded that radiiodine therapy did not increase the risk of SPM [37]. However, a significantly greater risk of leukemia or other SPM was reported for patients treated with cumulative activities of 22 GBq (600 mCi) of radioiodine, particularly if combined with external beam radiotherapy [38]. Almost all cases of SPM have occurred in patients who received cumulative administered activities in excess of 29.6 GBq (800 mCi) [34]. Significant bone marrow depression is likely when cumulative administered activities exceed 29.6 GBq (800 mCi) [34].

Radiation fibrosis may develop in patients with diffuse lung metastases who have received repeated administered activities of over 5.55 GBq (150 mCi) of radioiodine at short intervals, especially if within 6 months [39]. This risk increases if the cumulative administered activity exceeds 22 GBq (600 mCi) [34].
g. Residual or recurrent disease

After successful remnant ablation, a measurable serum thyroglobulin level suggests functioning thyroid tissue and the possibility of recurrent disease and may be an indication for additional treatment. However, both high and low thyroglobulin levels are unreliable in the presence of antithyroglobulin antibodies. In particular, falsely low thyroglobulin levels may occur in antibody-positive patients; therefore, antibody assays should accompany all thyroglobulin measurements. Even when a diagnostic whole-body scan is negative, if the stimulated thyroglobulin level is greater than 10 ng/mL or there is other evidence of disease in a patient with a high risk of recurrence, empiric therapy with 3.7 to 5.55 MBq (100 to 150 mCi) can be considered [21,40].

In the setting of a negative whole-body scan and suspected metastatic disease, an FDG-PET/CT scan may be helpful to identify and localize non–iodine-avid disease (See the ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease [16]).

h. Interactions with other forms of treatment

i. Patients with a high risk of local/regional recurrent disease may be treated with both iodine-131 and external beam irradiation. The use of external beam irradiation prior to or alternating with radioiodine treatment has not been shown to be associated with a subsequent reduction in tumor uptake of radioiodine. Therefore, external beam irradiation, if indicated, need not be delayed. The toxicity, acute and late, is likely to be additive within the field of irradiation. Dosimetry calculations should be considered if iodine-131 therapy and external beam radiotherapy are both being considered or have previously been performed in patients with spinal lesions, to avoid potential radiation-induced spinal cord damage.

ii. Distant metastatic lesions that are painful or are a threat to life or function may be treated with external beam irradiation or surgery in addition to iodine-131.

3. Strontium-89

a. Background

Strontium-89 has a physical half-life of 50.6 days. It emits beta radiation and is taken up by metastatic bone lesions with approximately 10 times greater efficiency than is observed with normal bone. The radiopharmaceutical can remain in these lesions for as long as 100 days. Strontium emits a comparatively small fraction of gamma photons and hence poses reduced radiation risk to those in contact with the patient. Given that the radiopharmaceutical is excreted by the kidneys, precautions should be directed toward excreted urine or urinary obstruction.

b. Summary of selected data

Strontium-89 has primarily been investigated in the context of metastatic prostate cancer. The use of this radiopharmaceutical in other malignancies, including breast cancer, has also been investigated.

i. A phase III placebo-controlled randomized controlled trial evaluated conventional palliative radiotherapy ± strontium-89 as a single injection of 10.8 mCi or placebo in 126 patients with metastatic castration-resistant prostate cancer (CRPC) [41].

1. Complete pain relief at 3 months was achieved in a greater number of patients treated with strontium-89 compared to placebo (40% versus 23%).
2. There was a significant reduction in the need for subsequent and continued analgesic use in the strontium-89 group (P < 0.05).
3. Significantly fewer patients in the strontium-89 group experienced new sites of pain compared with placebo (P < 0.002), which translated into a longer disease-free interval and subsequent retreatment with radiotherapy (35 weeks versus 20 weeks).
4. Quality-of-life analysis demonstrated superiority of strontium-89 with alleviation of pain and improvement in physical activity being statistically significant (P < 0.05).

ii. A study of 284 patients with symptomatic bone metastases from prostate cancer were randomly allocated for conventional palliative radiotherapy or 5.4 mCi of strontium-89 treatment [42].

1. Analgesic effect was similar in both treatment groups, but fewer patients developed new sites of pain in the strontium-89 group (P < 0.05).
2. Significantly fewer patients required local radiotherapy to new sites following strontium-89 treatment compared to the local radiotherapy group (P < 0.01).
3. Platelets and leukocytes fell by approximately 35% after strontium-89 treatment, but functional sequelae were rare.
4. Notably, there was no significant difference in overall survival between groups \( (P = 0.1) \).
c. General treatment recommendations – For strontium-89, the standard administered activity is 1.48 to 2.22 MBq (40 to 60 µCi per kilogram of body weight, approximately 4 mCi [148 MBq] for standard weight) given by intravenous infusion over several minutes.

4. Samarium-153 lexidronam
   a. Background
   Samarium-153 is bound to ethylenediamine tetramethylene (EDTMP) to produce the bone-seeking therapeutic complex. Compared to strontium-89 it has a short physical half-life of only 46.3 hours. Samarium-153 emits both beta particles and gamma radiation. The gamma radiation can be detected using gamma camera for a low-resolution bone scan.
   b. Summary of selected data
   Samarium-153 has primarily been investigated in the context of metastatic prostate cancer.
   i. A phase III randomized controlled trial of 152 patients with CRPC randomized patients to radioactive samarium-153 at 1 mCi/kg vs. nonradioactive samarium-152 [43].
      1. There was a significant improvement in pain descriptor scale scores by week 1 and in pain intensity visual analogue scale scores by week 2 for patients treated with samarium-153.
      2. There was significant reduction in opioid consumption by week 3 with samarium-153 use.
      3. Grade 3 thrombocytopenia and leukopenia developed in 3% and 5% of patients, respectively, in the samarium-153 treatment arm. Counts returned to baseline after approximately 8 weeks.
      No grade 4 hematologic toxicity in either platelets or white bloods cells was noted.
      4. Notably, there was no significant difference in overall survival between groups.
   c. General treatment recommendations
   The recommended samarium-153 lexidronam activity is 37.0 MBq (1.0 mCi) per kilogram of body weight, given intravenously over several minutes. When samarium-153 lexidronam is used, whole-body gamma camera imaging may be performed between 2 and 24 hours postinjection.

5. Radium-223 dichloride
   a. Background
   Radium-223 is a bone-seeking calcium analogue that is unique in that, rather than emitting beta energy, it emits high-energy alpha particles. Radium-223 has a half-life of 11.4 days. Alpha particles have high biologic effectiveness and linear energy transfer to cause double-strand DNA breaks. Alpha particles travel the width of approximately 4–10 cells, thus limiting toxicity on the adjacent underlying bone marrow. In addition, radium-223 has primarily intestinal clearance.
   
   Radium-223 chloride has been approved for the treatment of symptomatic bone metastases from CRPC [44]. Radium-223 joins samarium-153 and strontium-89 as approved radiopharmaceuticals for treating painful skeletal sites of disease. All 3 have demonstrated significant improvements in pain scores and symptomatic relief; however, radium-223 is the first to demonstrate an overall survival benefit in a large prospective randomized phase III trial. For this reason, radium-223 is now often utilized prior to strontium-89 and samarium-153 as first-line therapy, however all 3 radionuclides are therapeutic options.
   b. Summary of selected data
   Radium-223 is FDA approved for the treatment of CRPC and is actively being investigated in earlier stages of metastatic prostate cancer and other cancers, such as breast cancer [44].
   i. A multinational phase III, double-blinded, randomized controlled trial of 922 men with symptomatic CRPC to 6 injections of radium-223 (50 kBq/kg intravenous (i.v.)) over 4 weeks versus placebo. Unique to this study was that the primary endpoint was overall survival.
   ii. The trial was stopped early at a planned interim analysis after an overall survival benefit was already reached. The benefit in median overall survival with radium-223 treatment was 2.8 months (14.0 versus 11.2 months; \( P = 0.0019 \); hazard ratio 0.695 [95%CI 0.552–0.875]).
iii. Lower incidence of skeletal related events in the radium-223 group, including reduction in development of spinal-cord compression (3% versus 6%; \( P = 0.016 \)).

iv. Reduction in time to first skeletal-related event was significantly delayed with radium-223 (13.6 versus 8.4 months; \( P = 0.0005 \)).

v. Treatment with radium-223 was well tolerated with low incidence of grade 3 or 4 neutropenia (1.8% versus 0.8%) and thrombocytopenia (4% versus 2%).

vi. There were no significant differences between radium-223 and placebo in terms of adverse events.

c. General treatment recommendations
The recommended radium-223 dosing schedule is 6 injections of radium-223 (50 kBq/kg intravenous (i.v.)) with one injection occurring each month for 6 months.

6. General recommendations for all radiopharmaceuticals used to treat skeletal metastases (since hematologic toxicity is less with radium-223, clinical judgment should be exercised for less strict criteria).

a. Patient
Patients with multiple osseous metastases that show increased tracer uptake on bone imaging, who are obtaining diminishing relief from other methods of pain management (eg, analgesics, bisphosphonates, external beam irradiation), and whose bone marrow is competent, are candidates for radiopharmaceutical therapy. Complete blood cell count with platelets should be obtained within 7 days prior to therapy. Platelet count should be greater than 60,000 to 100,000/µL, leukocyte count greater than 2,400 to 5,000/µL absolute granulocyte count greater than 2,000/µL. Patients with disseminated intravascular coagulation (DIC) must be excluded from therapy. Others may be treated after a case-by-case evaluation as adjuvant therapy to delay symptomatic skeletal metastases. Urinary incontinence is not a contraindication to treatment, although the patient or caregiver should be instructed on how to minimize radiation contamination from spilled urine. For samarium-153 lexidronam and strontium-89, bladder catheterization should be considered for patients incontinent of urine, to minimize the risk of radioactive contamination. This is less of an issue with radium-223 dichloride as it is primarily excreted through the intestine.

b. Complications
A “flare” phenomenon occurs in some patients, with transient worsening of pain within several days after treatment. This is a self-limited process, although it can be severe. Patients should be counseled concerning the possibility of a flare phenomenon. The pain associated with the flare phenomenon can usually be managed with analgesics or steroidal medication. For intravenously administered radiotherapy, extravasation of the radiopharmaceutical should be avoided. It is imperative to have excellent intravenous access that is confirmed prior to injection. Although local skin damage is unusual, some experts believe it is prudent to follow a vesicant protocol for radiotherapy infusion [45]. For samarium and strontium, bone marrow depression occurs transiently, with a nadir at about 3 to 6 weeks and with recovery in about 3 to 6 additional weeks. Complete blood and platelet counts should be followed routinely for 8 to 12 weeks.

c. Interactions with other forms of treatment
i. Hormone administration need not be discontinued before the administration of radiopharmaceutical therapy, since it does not interfere with the mechanism of action and does not potentiate any side effects.

ii. External beam radiation therapy may be used in concert with radiopharmaceutical therapy for local treatment of selected sites, especially those in which pathologic fracture or cord compression might occur. Careful evaluation of complete blood and platelet counts is required when these therapies are combined.

iii. Caution should be exercised when delivering concomitant myelosuppressive chemotherapy to these patients. There are multiple trials that have been and are ongoing to determine the clinical efficacy and safety, primarily with taxane-based chemotherapy.
7. Radiation precautions
There are none for strontium-89 as long as the patient is continent of urine and feces. For samarium-153 lexidronam, the patient may be released if the total effective dose equivalent to any other individual who is exposed to the patient is not likely to exceed 5 mSv (0.5 rem) per year. When in doubt, check state and facility regulations, as they should be followed.

8. Retreatment
Retreatment may be administered if initial treatment fails or symptoms recur. Special attention should be paid to recovery of bone marrow and blood counts. Retreatment may be given after adequate bone marrow recovery occurs, which is typically 2 to 3 months. Data are currently limited on retreatment with radium-223 chloride, so caution should be exercised.

9. As with all other forms of therapy with unsealed sources, patient management should be coordinated with clinical services and with other involved parties, especially radiation oncology, if external beam irradiation has been used or is being considered.

C. Phosphorus-32 (sodium phosphate) for Polycythemia Rubra Vera Associated With Thrombocytosis

a. Background
Phosphorus-32 (sodium phosphate) may be used for treatment of thrombocytosis associated with polycythemia vera unresponsive to other therapies such as phlebotomy. Given its association with increased risk of the development of leukemia, Phosphorus-32 treatment is generally not used as a first-line agent [46] and is generally reserved for patients who fail chemotherapy and in the elderly (greater than 65–70 years old) [47]. However, the relationship between phosphorus-32 and development of leukemia and other effects as well as its side-effect profile relative to other agents radiopharmaceuticals used to treat polycythemia vera are complex [48].

b. Summary of selected data
i. In the Polycythemia Vera Study Group, which included 400 patients, median survival was 11.8 years for the individuals randomly assigned to the phosphorus-32 treatment arm, versus 13.9 years for the phlebotomy group and 8.9 years for the chlorambucil group [49].

ii. In the French Polycythemia Group study (461 patients over the age of 65 years), the administration of low-dose maintenance treatment with hydroxyurea (HU) after phosphorus-32 significantly prolonged the duration of phosphorus-32-induced remissions but was also associated with a significant increase in carcinomas and in the leukemia rate when therapy went beyond 8 years. The study concluded that the use of HU as maintenance therapy was only appropriate when a patient had rapid recurrence (less than 2 years) following phosphorus-32 therapy [48].

iii. Favorable response to phosphorus-32 has been reported in patients with extramedullary hematopoiesis with a painful spleen, hypersplenism, abdominal pain, splenic infarcts, pruritus, or uncontrolled hyperuricemia [50].

c. Treatment recommendations
The administered activity may be based on body surface area (85 MBq [2.3 mCi] per square meter intravenously) but may also be standardized to a dose of 111 to 185 MBq [3.0 to 5 mCi] intravenously but should not exceed 185 MBq (5.0 mCi). Relapse or failure to respond within 12 weeks may require retreatment with dosages up to 259 MBq (7.0 mCi). Phosphorus-32 should not be given if the platelet count is less than 100,000/μL or the leukocyte count is less than 3,000/μL. Duration of response ranges from months to years with the potential for retreatment at the time of disease progression.

D. Phosphorus-32 (colloidal chromic phosphate) for Malignant Ascites, Pleural Effusion or as an Adjunct to Treatment of Borderline Ovarian Neoplasms
a. Background
Phosphorus-32 (colloidal chromic phosphate) may be used in the treatment of malignant ascites or pleural effusion. This is a palliative therapy and can be administered again to treat recurring effusion/ascites [51].

b. Summary of selected data
The therapy has not been shown to prevent relapse or affect mortality in the largest study to date [52].

c. Treatment recommendations
The usual activity for intracavitary therapy is 222 to 555 MBq (6 to 15 mCi) in the pleural cavity and 370 to 740 MBq (10 to 20 mCi) in the peritoneum, although the largest study to date used a fixed dose of 555 MBq (15 mCi) injected into the intraperitoneal cavity. The ability of the radiopharmaceutical to spread uniformly throughout the cavity should be documented using technetium-99m sulfur colloid (See the ACR–SNM–SPR Practice Parameter for the Performance of Gastrointestinal Scintigraphy [53].) as an intraperitoneal or intrapleural injection followed by appropriate imaging. The patient should be turned to distribute the radiopharmaceutical. After documented dispersal, ie, no evidence of loculation or penetration into the bowel, the patient may be treated. The combination of intraperitoneal phosphorus-32 colloidal chromic phosphate and external irradiation to the pelvis has been reported to be associated with a high incidence of morbidity, particularly bowel obstruction; accordingly, caution must be observed when this combination of therapies is used.

E. Yttrium-90 Ibritumomab Tiuxetan for Radioimmunotherapy of Non-Hodgkin’s Lymphoma

1. Radiopharmaceuticals
The marker CD20 is expressed in the pro-B-cell stage, as the B-cell evolves from the stem cell precursor and throughout the life of the mature B-cell but is neither present in the stem cells nor in plasma cells derived from B-cells. CD20 is also expressed on many of the B-cell lymphomas: follicular lymphoma and diffuse large B-cell lymphoma. Thus, CD20 is an attractive target, sparing stem cells and allowing regeneration of normal B-cells.

Yttrium-90 ibritumomab tiuxetan consists of ibritumomab, the murine IgG1 kappa monoclonal antibody from which rituximab was developed, and tiuxetan, which stably chelates yttrium-90 for therapy. Iodine-131 tositumomab is a murine IgG2a lambda monoclonal antibody covalently linked to iodine-131. Both antibodies are directed against the CD20 antigen.

Iodine-131 tositumomab was discontinued by the manufacturer in February 2014 and is currently not available.

2. Patients
a. Patients with CD20-positive follicular B-cell non-Hodgkin’s lymphoma, including patients who are refractory to rituximab, are candidates for radioimmunotherapy. The radiopharmaceutical is indicated for the treatment of relapsed or refractory low-grade or follicular B-cell NHL [54] as well as the treatment of previously untreated follicular NHL in patients who achieve a partial or complete response to first-line chemotherapy [55].

b. Summary of selected data
i. A study evaluated ibritumomab tiuxetan in the treatment of rituximab-refractory follicular NHL [54].
   - Fifty-seven patients were treated. The median age was 54 years, 74% had tumors ≥ 5 cm, and all were extensively pretreated.
   - The overall response rate for the 57 patients with follicular NHL was 74% (15% complete response [CR] and 59% partial response [PR]).
   - The Kaplan-Meier-estimated TTP was 6.8 months for all patients and 8.7 months for responders.
   - Adverse events were primarily hematologic; the incidence of grade 4 neutropenia, thrombocytopenia, and anemia was 35%, 9%, and 4%, respectively.

ii. An international, randomized, phase III trial evaluated the efficacy and safety of consolidation with yttrium-90 ibritumomab tiuxetan in patients with advanced-stage follicular lymphoma in
A total of 414 patients (consolidation, n=208; control, n=206) were enrolled at 77 centers.

- Yttrium-90 ibritumomab tiuxetan consolidation significantly prolonged median progression-free survival (PFS) regardless of whether patients achieved partial response (PR) or complete response (CR)/complete response, unconfirmed (CR/u).
- The most common toxicity was hematologic, and grade 3 or 4 infections occurred in 8% of patients.

3. Dosimetry and assessment of biodistribution
   a. Altered biodistribution is uncommon, and hence pretherapy biodistribution imaging is no longer required.

4. Administered activity
   a. According to manufacturer’s instructions, the therapeutic dose of yttrium-90 ibritumomab tiuxetan is administered on days 7 to 9, with day 1 being the day of the administration of the cold antibody (see below).
   b. Biodistribution of radiolabeled antibody is improved by concurrent administration of unlabeled radiopharmaceuticals in order to saturate readily accessible CD20-positive sites, including circulating B-cells and cells in the spleen. Biodistribution of radiolabeled ibritumomab tiuxetan is improved with the prior administration of rituximab (cold antibody).
   c. The therapeutic dosage of yttrium-90 ibritumomab tiuxetan, after an infusion of rituximab, is 14.8 MBq/kg (0.4 mCi/kg) for patients with a platelet count greater than 150,000 cells/μL and 11.1 MBq/kg (0.3 mCi/kg) for patients with platelet count of 100,000 to 149,000 cells/μL. The maximum allowable dosage of yttrium-90 ibritumomab tiuxetan is 1.184 GBq (32.0 mCi).
   d. Since yttrium-90 is a pure beta emitter, onsite administered-dose measurement can be very difficult. A precise technique with careful attention to detail should be established with the help of a radiopharmacist or a medical physicist.

5. Complications
   a. Hypersensitivity reactions occur and may be severe. Patients who have received murine proteins previously should be screened for human antimouse antibodies (HAMA). Patients who are positive are likely to be at increased risk of anaphylaxis and serious hypersensitivity and may show altered biodistribution of the antibody. Known hypersensitivity to rituximab or murine proteins is considered a contraindication to administration of yttrium-90 ibritumomab tiuxetan. Premedication with acetaminophen and diphenhydramine is recommended and should be considered prior to infusion. Reactions to the infusion of unlabeled rituximab are common. Although reactions to subsequently infused ibritumomab tiuxetan are uncommon, a physician must be present during the infusion. Medications for the treatment of hypersensitivity reactions (eg, epinephrine, antihistamines, and corticosteroids) and equipment for resuscitation should be immediately available.
   b. The most common serious adverse reactions associated with yttrium-90 ibritumomab tiuxetan are severe or life-threatening cytopenias. Retrospective studies showed grade 3 or 4 thrombocytopenia in 57% of patients. The percent decline in platelets was 79% (± 17%). The ANC nadir for yttrium-90 ibritumomab tiuxetan was ± 36 days [50]. Precautions include not treating patients who have more than 25% of bone marrow involved, or who have poor bone marrow reserve (including but not limited to prior stem-cell or bone marrow transplant, ANC less than 1,500 cells/μL, or previous failure of stem-cell collection). The dose is modified according to the pretreatment platelet counts. Blood counts are monitored weekly for at least 10 to 12 weeks, or more frequently as needed until recovery
occurs. Stem-cell support and/or transfusions are provided as necessary, and cases of febrile neutropenia or infection are treated as appropriate.

6. Interactions with other forms of treatment
   a. A time interval sufficient to allow for bone marrow recovery after cytotoxic chemotherapy is recommended. Concomitant use of chemotherapy with yttrium-90 ibritumomab tiuxetan has not been fully evaluated and should be considered with caution when not performed in conjunction with a defined research protocol.
   b. Prior to radiopharmaceutical therapy, external beam radiation therapy may be necessary for local treatment of selected sites, especially when life-threatening or function-threatening involvement such as fracture or spinal cord compression exists or is likely to occur without such treatment. Careful consideration must be given to the amount of bone marrow treated, as treatment of a large percentage of the patient’s bone marrow is likely to significantly affect the ability to tolerate radioimmunotherapy.
   c. The concern that patients treated with yttrium-90 ibritumomab tiuxetan will have severe marrow impairment rendering them ineligible for further therapy is not substantiated by the results of several studies comparing retreatment with chemotherapy, stem-cell mobilization, and successful autotransplantation of treated patients to otherwise matched control groups [57].

7. Radiation precautions
   a. For yttrium-90 ibritumomab tiuxetan there are no special precautions beyond the usual care taken to minimize radiation exposure to patients and to medical personnel, consistent with institutional radiation safety practices and patient management procedures. Yttrium-90 is a pure beta emitter, and safety precautions for medical professionals are universal precautions, with the addition of acrylic shielding for the yttrium-90 ibritumomab tiuxetan. Patients may be released immediately, with basic instructions, after administration of yttrium-90 ibritumomab tiuxetan.
   b. If state or facility regulations are more restrictive, they should be followed.

8. As with all other forms of therapy with unsealed sources, patient management should be coordinated with clinical services and other involved parties, especially medical and radiation oncology.

F. Treatment and Palliation of Neuroendocrine Tumors

1. Peptide-receptor radionuclide therapy (PRRT) for metastatic or inoperable neuroendocrine tumors
   a. Background
      The high prevalence of somatostatin receptors in neuroendocrine tumors allows for the rational design of a series of agonists and antagonists labeled with therapeutic nuclides in metastatic or inoperable patients with primary neuroendocrine tumors. Ongoing and completed trials primarily in Europe and recently in the United States have demonstrated the efficacy of these therapies in patients with adequate expression of the targeted somatostatin receptor type [58,59]. In the future, these therapies are likely to be carried out in phase III trials in the United States. Patient selection and endpoints will determine the speed of the approval process.

G. Follow-Up After Treatment

Physicians using unsealed radiopharmaceutical sources for therapy should participate with the patient’s primary physician in the follow-up and management of all patients treated with 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) and significant sequelae [60].

VI. DOCUMENTATION

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology [6].
The report should include the radiopharmaceutical used, the dose and route of administration, as well as any other pharmaceuticals administered, also with dose and route of administration.

VII. ACR STATEMENT ON THERAPEUTIC USE OF UNSEALED RADIOPHARMACEUTICAL SOURCES

On the basis of their education, training pathway(s), initial board certification(s), and maintenance of certification(s), Nuclear Regulatory Commission (NRC) Authorized User (AU) status, and clinical work experience, diagnostic radiologists (DR), nuclear radiologists (NR), nuclear medicine physicians (NM), and radiation oncologists (RO) may have the qualifications to supervise and perform therapies using unsealed radioisotopes. Although it is recognized that individual physician variations and state and federal regulatory requirements may, of necessity, dictate site-specific practice patterns, these physicians may best participate in the practice according to their special interests and qualifications. In most clinical settings, one of the following common practice paradigms generally applies:

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

- Physicians who are board-certified in DR, NR, NM, or RO and hold AU status based on that certification and site-specific credentialing: These physicians may practice radioisotope therapy consisting of oral radioiodine at all dosage levels under their own AU qualifications.

- Physicians who are board-certified in DR, NR, NM, or RO and hold the appropriate AU statuses and site-specific credentialing: These physicians may practice parenteral radioisotope therapy(ies) as permitted by their own specific training leading to such AU statuses.

VIII. RADIATION SAFETY

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) [http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578_web-57265295.pdf].

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals and that they are adhered to in accordance with ALARA. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

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

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

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Regular auditing of patient dose indices should be performed by comparing the facility’s dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director’s National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

IX. 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 (http://www.acr.org/guidelines).

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

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