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ACR–ACNM–ASTRO–SNMMI–SPR PRACTICE PARAMETER FOR TREATMENT OF BENIGN AND MALIGNANT THYROID DISEASE WITH I- 131 SODIUM IODIDE

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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

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

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

I. INTRODUCTION

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

This practice parameter is intended to guide appropriately trained and licensed physicians treating thyroid disease with I-131 Sodium Iodide.

Therapy with I-131 Sodium Iodide takes advantage of the fact that benign and malignant thyroid tissue is capable of producing thyroid hormone and trapping and organifying iodine to include its radioactive isotopes. Once taken up by functioning thyroid tissue, the therapeutic effect of I-131 Sodium Iodide is achieved by the emission of ionizing radiation in the form of high-energy beta particles, which results in cell death.

I-131 Sodium Iodide is both a beta particle and gamma ray emitter, with a physical half-life of 8.02 days. Its primary means of decay is via beta particle emission, which provides cytotoxic properties. The principle beta particle emitted by I-131 Sodium Iodide has a maximum energy of 0.61 MeV, an average energy of 0.192 MeV, and a tissue range of 0.6 to 2 mm [1]. I-131 Sodium Iodide also emits gamma rays, with its principle gamma ray having an energy of 364 KeV, which allows for imaging.

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–AAPM–SPR Technical Standard for Therapeutic Procedures Using Radiopharmaceuticals](#) as that standard relates to the handling of radiopharmaceuticals, radiation safety, and radiation protection of patients, personnel, and the public [2]. There must also be compliance with applicable laws and regulations.

II. DEFINITION

Therapy with I-131 Sodium Iodide involves its oral administration for the treatment of benign and malignant thyroid diseases.

III. INDICATIONS

Examples of therapy with I-131 Sodium Iodide for disease include the following:

1. Benign Disease:
 - a. Treatment of Graves disease (primary or recurrent)
 - b. Treatment of toxic autonomous functioning nodule
 - c. Treatment of autonomous functioning multinodular goiter
 - d. Treatment of nontoxic nodular goiter
2. Malignant Disease:
 - a. Treatment of Iodine-avid papillary and follicular thyroid cancer metastases
 - b. Thyroid remnant ablation
 - c. Treatment of recurrent thyroid cancer (to include suspected recurrence based upon elevated thyroglobulin levels)

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–AAPM–SPR Technical Standard for Therapeutic Procedures Using](#)

[Radiopharmaceuticals](#) and/or the [ACR–ASTRO Practice Parameter for Radiation Oncology](#) [2,3]. 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 - revised in 2016, Resolution 12-b)

For further information on benign thyroid disease, thyroid uptake measurement, and thyroid scintigraphy see the [ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease](#) [4].

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](#) [3,5], the treating physician’s initial evaluation of the patient must include review of the patient’s history, including medications, physical examination, pertinent diagnostic studies, laboratory and pathology reports that include 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. Evaluation of pregnancy test (serum preferred) should be performed in those of reproductive potential. Likewise, inquiring about breastfeeding is recommended. The patient should have discontinued breastfeeding long enough to result in the cessation of lactation, which is generally 6 to 12 weeks prior to therapy, to mitigate ill effects to the child and reduce radiation dose to the maternal breasts.

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 United States Nuclear Regulatory Commission (NRC) or by Agreement State regulations (an Agreement State is any state with which the NRC or the U.S. 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 relevant to I-131 therapies include written directives; duplicative procedures for identifying patients; careful record keeping to ensure prescribed administered activity; procedures for minimizing radiation exposure or radiopharmaceutical contamination of personnel, family members of patients, and the public (eg, instructions regarding possible current or future pregnancy); procedures for containment of radioactivity; and an audit mechanism to ensure compliance with the program.

3. Treatment

The procedure and follow-up should be performed according to an established system of procedural steps specific for treatment of benign and malignant conditions. The treating physician must discuss the risks, benefits, and alternatives of I-131 treatment with the patient in detail and obtain an informed consent and reconfirm the ability of the patient to comply with the prescribed radiation precautions. Specific precautions and caution should be used when treating patients with ophthalmopathy, large thyroid glands, or significant postthyroidectomy residual or metastatic disease to the brain or spine. The patient must not be pregnant, breastfeeding, or lactating at the time of I-131 sodium iodide therapy. Pregnancy must be excluded prior to

radiopharmaceutical administration by one of the following: negative human chorionic gonadotropin (hCG) test within 24 hours of treatment, documented hysterectomy, postmenopausal state (absence of menstrual bleeding for 2 years), or by premenarche (child age 10 years or younger). Providing that the patient remains sexually abstinent, this can be done within 72 hours. Caution is advised for patients who have had recent unprotected intercourse as pregnancy testing may remain negative for 7 to 10 days. The patient should be advised against planning future pregnancy for 6 to 12 months after treatment. Breastfeeding should be stopped long enough to cease lactation prior to radioiodine therapy and not resumed after treatment for that infant, but may be undertaken for subsequent pregnancies. Education and prevention strategies for early complications, such as nausea and vomiting, sialadenitis, loss or alteration of taste, neck pain and swelling, and oral mucositis, should be discussed and provided to the patient. Written radiation safety instructions and a letter confirming treatment will be provided with contact details of the treating facility radiation safety officer (RSO).

4. 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 RSO, medical physicist, or health physicist for the local facility should 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 [8,9] and key sections of NUREG 1556 [10], 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). However, 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 the “as low as reasonably achievable” (ALARA) principle. Some states may have specific rules and regulations regarding release of patients with significant residual activity.

The dose limits specified by the National Council on Radiation Protection and Measurements (NCRP) differ somewhat from the NRC regulations. 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 linear energy transfer (LET) radiation (including beta particles and most x-rays and gamma rays), the authors of this document accept the approximation that 1 mR, 0.01 mSv, and 1 mrem are equivalent. Thus, an exposure rate of 7 mR/h at 1 m is an adequate approximation to the dose rate, 0.07 mSv/h (7.0 mrem/h) at 1 m. The patient should be compliant with all radiation safety precautions and instructions. Inability to comply with the precautions might require an admission, as determined by the authorized user. Urinary incontinence, if present, would require catheterization to prevent radiation contamination. Peritoneal and hemodialysis are not contraindications for treatment but may impact the administered activity of I-131 given the prolonged residence time within the patient. These procedures should be performed within NRC guidelines and comply with state requirements and hospital practices.

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 where acceptable under State or Federal regulations, the toilet should be flushed two or three 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. Individual institution's radiation safety procedures may vary somewhat.

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

B. Malignant Thyroid

1. Clinical evaluation

There are multiple imaging studies that increase the suspicion for the presence of thyroid carcinoma, including features on thyroid ultrasound, abnormalities on thyroid uptake and scan, and fluorodeoxyglucose (FDG)-positron emission tomography (PET), or F-18 FDG PET imaging. Less commonly, incidental nodular abnormalities demonstrated on standard diagnostic computed tomography (CT) imaging of the thorax or neck may prompt further workup for thyroid carcinoma.

Suspicion for locally advanced thyroid carcinoma may also be suggested by lymphadenopathy in the neck on soft-tissue neck ultrasound imaging, CT, or magnetic resonance imaging (MRI) or as detected by physical examination.

As the use of F-18 FDG PET/CT increases, incidental thyroid carcinomas are increasingly detected by this method. In one study of 285 patients with incidental thyroid hypermetabolism, the overall cancer risk in this population was 23.2%. with focal thyroid hypermetabolism yielding a risk of 30.9% [6].

Some studies have suggested that F-18 FDG standardized uptake values (SUV) max of >6.2 can be relatively specific for the differential identification of malignancy from benign thyroid hypermetabolism in incidental thyroid nodules [7]. Using this cutoff value as suggested in this study of 34 patients with hypermetabolic incidentaloma would yield a sensitivity, a specificity, a positive predictive value, and a negative predictive value of 82, 87, 75, and 90 %, respectively.

When there is suspicion for thyroid carcinoma by any of the above imaging modalities or physical examination, fine-needle aspiration should be considered.

A variety of ultrasound features help to characterize the risk of malignancy. Highly suspicious features include a solid hypoechoic nodule or a solid hypoechoic component of a partially cystic nodule that also contain either one or more of the following: irregular margins (infiltrative, microlobulated), microcalcifications, taller-than-wide shape, rim calcifications with small extrusive soft-tissue component, and/or evidence of extrathyroidal extension.

The following link, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4739132/figure/f2/>, is from the 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer and demonstrates a stratification of malignancy risk by feature, illustrated with ultrasound appearance examples [8].

This next link, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854274/>, is from the 2015 Management Guidelines for Children with Thyroid Nodules and Differentiated Thyroid Cancer, the American Thyroid Association guidelines task force on pediatric thyroid cancer, and it demonstrates a stratification of malignancy risk by feature, illustrated with ultrasound appearance examples [9,10].

2. Indications for ultrasound evaluation of the thyroid and/or soft-tissue neck [8,11-16]

Some of the indications for performing diagnostic ultrasound related to thyroid carcinoma are listed in the [ACR–AIUM–SPR–SRU Practice Parameter for Performing and Interpretation of Diagnostic](#)

[Ultrasound of the Extracranial Head and Neck](#) [17]. Indications for a thyroid head and neck ultrasound (US) examination include, but may not be limited to:

- a. Evaluation of the location and characteristics of palpable neck masses.
- b. Evaluation of abnormalities detected by other imaging examinations (eg, a thyroid nodule or other neck mass detected on CT, PET-CT, MRI, or seen on other ultrasounds (eg, carotid ultrasound)).
- c. Evaluation of patients at high risk for thyroid malignancy.
- d. Imaging of previously detected thyroid nodules that meet criteria for follow-up imaging.
- e. Evaluation for regional nodal metastases in patients with proven or suspected thyroid carcinoma prior to thyroidectomy.
- f. Evaluation for recurrent disease or regional nodal metastases after total or partial thyroidectomy for thyroid carcinoma.
- g. Evaluation of the thyroid gland for malignancy prior to neck surgery for nonthyroid disease.
- h. Evaluation of the thyroid gland for malignancy prior to radioiodine ablation of the gland.
- i. Guidance for aspiration or biopsy of thyroid abnormalities or other masses of the neck.

Ultimate detection and confirmatory diagnosis of the presence of primary thyroid carcinoma is by ultrasound-guided needle biopsy and/or fine-needle aspiration, with pathologic confirmation. Diagnosis of metastatic thyroid carcinoma is typically made by an excisional biopsy or surgical specimen evaluation of the metastatic lymph node or organ.

3. Quality Control and Improvement, Safety, Infection Control, Patient Education Concerns [18-24]

a. Clinical Use of Radiopharmaceutical

- i. All radiopharmaceuticals dispensed and administered must be pursuant to an order (eg, prescription) by an authorized physician;
- ii. Prescribing physicians are ultimately responsible for the safety, quality, and correctness of all radiopharmaceuticals prepared and dispensed for administration under their direction;
- iii. Nuclear pharmacists are ultimately responsible for the safety, quality, and correctness of radiopharmaceuticals prepared and dispensed under their supervision;
- iv. The preparation, quality control, dispensing, and administration to patients of radiopharmaceuticals and adjunctive drugs may be delegated to qualified personnel, in accordance with applicable state and local laws;
- v. There must be a signed and dated written directive for each patient for I-131 sodium iodide in quantities of 1.1 MBq (30 μ Ci) or more and for all therapeutic doses.
- vi. The identity of the radiopharmaceutical and patient and the route of administration must be verified before administration. Syringes and outer shields or containers must be labeled for verification of contents.
- vii. Female patients who are postmenarcheal and premenopausal should be asked about pregnancy, lactation, and breastfeeding before administration. Pregnancy testing in females of child-bearing capability should be performed before administration.
- viii. The quantity of each radiopharmaceutical dose must be determined before administration to patients and must be consistent with that ordered by the physician or as stipulated in the applicable standing orders in the nuclear medicine procedure manual. The quantity of radioactivity dispensed should be within 10% of the prescribed dose or dose range, and the actual quantity administered should be within 20% unless otherwise directed by the authorized physician and recorded in the patient's medical record.

- ix. Radiopharmaceuticals should not be used beyond the expiration date or time recommended by the manufacturer unless quality control testing demonstrates that the product still meets the specifications of the U.S. Pharmacopeial Convention at the time of use.
- x. Any discrepancies must be resolved before administration.

b. Radiation precautions

Radiation safety issues for pregnancy, breastfeeding, and lactation are discussed under section V.A.3-4.

Regulatory requirements for hospitalization and other radiation protection vary among states and countries. Many of those guidelines are more stringent than those of the Nuclear Regulatory Commission (NRC). The NRC has three alternate criteria for allowing patient release from the hospital after I-131 Sodium Iodide therapy. They are:

- i. When no individual member of the public is likely to receive more than 5 mSv (500 mrem) from that patient, assuming all other regulatory requirements for patient instructions and record keeping are met. NUREG-1556, volume 9, “Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses,” describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (500 mrem). This guidance is not a regulation. Realistic and scientifically valid, less conservative calculations on patient release, based on the realities of patient life at home, have been published [18,19,25,26].
- ii. When the survey meter reading is less than 0.07 mSv/h (7.0 mrem/h) at 1 m. Some radiation meters measure exposure rates in milliroentgens per hour, but for low LET radiation (including b-particles and most x-rays and gamma rays), the exposure rate at 7 mR/h will be equivalent to the dose rate at 0.07 mSv/h (7 mrem/h) [27].
- iii. When the administered activity is 1.22 GBq (33 mCi) or less.

If the patient is to be treated as an inpatient with radioactive iodine, nursing personnel must be instructed in all relevant radiation safety procedures. Selected nursing personnel should be provided with appropriate radiation monitors (film badge, direct-reading dosimeters, etc). Nurses who are or may be pregnant are excluded from direct patient care. Any significant medical conditions should be noted and contingency plans made in case radiation precautions must be breached for a medical emergency, as concern about radiation exposure should not interfere with prompt, appropriate medical treatment of the patient should an acute medical problem develop.

Written instructions describing methods to limit the dose to others must be given to the patient if an individual member of the public is likely to receive a radiation dose exceeding 1 mSv (100 mrem) from that patient and if the administered dosage is greater than 0.26 GBq (7 mCi). Individual Agreement States may have specific rules and regulations regarding the release of patients with significant residual activity. Details on the relevant federal regulations can be obtained at the NRC website (<https://www.nrc.gov>) or by telephone (301-415-7000).

As a precaution, before releasing the patient, the licensee should instruct the patient on how to reduce unnecessary radiation exposure to family members and members of the public. Written instructions must be provided to reduce the radiation dose both to the patient and to members of the public and may be required in some jurisdictions [23]. With simple precautions, the radiation dose to family members is low (considerably less than the NRC upper limit of 5 mSv [500 mrem]) even when patients are not admitted to a hospital [20]. In a study where the patients were to sleep alone and avoid prolonged personal contact for 2 days after therapy, 65 household members received a mean dose of 0.24 mSv (24 mrem) (range, 0.01–1.09 mSv [1–109 mrem]) [21].

Radiation safety precautions should be provided to the patient to minimize the radiation exposure of other individuals who may be in close contact with the patient following a therapeutic administration of I-131 Sodium Iodide, with the goal of limiting the exposure of other individuals to a total of $< 5\text{mSv}$ (500mR). Although these procedures may vary somewhat from institution to institution, typical precautions would include limiting close contact of less than 1 yard away to less than 1 hour per day, especially for any pregnant women or young children the patient may encounter. The patient should use a separate bathroom at home if possible if living with others and flush the toilet twice when using the bathroom for the first week, wash their hands carefully after going to the bathroom or preparing food for others, and use paper plates and plastic silverware.

There is no hazard to any member of the family arising from sites where the patient sits, what the patient has touched, or what the patient cooks. Internal exposure of family members from items contaminated by patient saliva or urine must be prevented. Although telephone mouthpieces and other devices touched frequently may have minimal I-131 Sodium Iodide contamination detected on them, this is not a health hazard because of the minute amount of radiation present compared with ambient background radiation. Disposable plates and utensils are not only unnecessary but, if used, can trigger sensitive waste facility alarms; dishes and utensils should not be shared before washing. It is unnecessary to wash the patient's laundry separately. Patients should flush the toilet twice after use and wash their hands for 20 s. Men should urinate sitting down to avoid contamination in the toilet area. Although certain proprietary products are advertised for specifically decontaminating I-131 Sodium Iodide in the home, such products are not necessary in the typical home situation.

Prolonged use of public transportation is discouraged for the first 24 h after I-131 Sodium Iodide therapy. Although Title 10 of the Code of Federal Regulations, part 35.75, does not expressly prohibit the release of a radioactive patient to a location other than a private residence, such as a hotel, the NRC strongly discourages this practice because it can result in radiation exposure to members of the public for which the licensee may not be able to assess full compliance with Title 10 of Code of Federal Regulations, part 35.75(a) and may result in doses that are not ALARA [24].

Most experts recommend that both men and women wait 6 to 12 months after I-131 Sodium Iodide therapy before trying to conceive a child, although there are no reliable data on the validity of this suggested interval. A 12-month interval also allows for follow-up imaging to evaluate the effectiveness of the treatment and for retreatment if deemed appropriate [22].

Patient-specific calculations of radiation exposure to others can be performed using several assumptions and specific recommendations given to each patient about the time and distance to stay away from others. Radiation surveys of the thyroid gland on personnel administering I-131 Sodium Iodide are performed periodically, depending on local regulations and institutional policy. Patients should be provided with a written document stating they have been given a radioactive substance, the date of administration, the name of the radiopharmaceutical, and the activity administered in the event that it is detected by monitoring devices during travel.

4. Treatment

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 selected patients following near-total thyroidectomy, the thyroid remnant may be ablated by radioiodine. A large thyroid remnant (eg, following a hemithyroidectomy) may require a completion thyroidectomy prior to radioiodine ablation. To optimize radioiodine therapy for locoregional or distant disease, the remnant normal thyroid must be eliminated and can be detected on a pretherapy diagnostic whole-body scan, the latter of which can also aid in assessing the extent of the disease. Details regarding risk stratification of patients with thyroid cancer, appropriateness of radioiodine therapy in various clinical situations, and the overall management of patients with thyroid cancer are covered extensively elsewhere.

- 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 postthyroidectomy and without distant metastases, the addition of I-131 Sodium Iodide 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 two phase III trials comparing results of I-131 Sodium Iodide therapy in patients with low-risk thyroid cancer postthyroidectomy using thyroid hormone withdrawal versus use of recombinant human thyrotropin, the ablation rate was found to be equivalent between I-131 Sodium Iodide activities of 1.1 GBq (30 mCi) and 3.7 GBq (100 mCi) [28,29]. There was also no difference in the ablation rate between patients withdrawn from thyroid hormone versus those who received recombinant human thyrotropin. A retrospective study raised some concerns about the effectiveness of activities lower than 2 GBq (54 mCi) in patients older than 45 years [30].

- c. Treatment recommendations

I-131 Sodium Iodide 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 I-131 Sodium Iodide, posttherapy imaging (usually performed 2 to 10 days after treatment) is useful and usually recommended to identify sites of disease not detected on pretherapy iodine imaging.

- d. Patient preparation

The serum thyroid-stimulating hormone (TSH) must be elevated, usually to a level in excess of 30 μ IU/mL. Traditionally, this TSH elevation is achieved either by not administering thyroid hormone following thyroidectomy for 2 to 4 weeks or by withholding thyroid hormone from a patient at a more remote time after surgery to induce an endogenous TSH elevation. Recently, an alternative practice of administering recombinant human TSH (rhTSH) to raise the patient's blood level of this hormone before therapy has become more commonly used. 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 I-131 Sodium Iodide 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, and exogenous thyroid hormone (for withdrawal therapy). For further information, please refer to the Compounds That May Decrease Thyroid Iodine Uptake table in the [ACR–SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease](#) [4]. The patient should be fasting and abstain from eating 2 to 4 hours before and 1 to 2 hours after therapy.

- e. Administered activities

I-131 Sodium Iodide may be administered to all ages in the management of thyroid cancer, but pediatric dosages should be weight adjusted [9,10].

The patient may need to be placed on radiation precautions.

- i. Ablation of thyroid remnant
 - Activities of 1.1 to 3.7 GBq (30-100 mCi) of I-131 Sodium Iodide (sodium iodide) administered orally are most often used. Higher dosages may be used for more extensive disease.
- ii. Known or suspected residual thyroid cancer (adjuvant treatment)
 - 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 (100-150 mCi) are usually administered.
- iii. Known or suspected distant metastases will usually require administered radioiodine activities equal to or greater than 5.55 to 7.4 GBq (150-200 mCi).

f. 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 7.4 MBq (100-200 mCi) can be considered. Typical treatment doses would include 150 mCi for lymph node involvement, 175 mCi for pulmonary involvement, and 200 mCi for skeletal involvement. If dosimetry is performed, single treatment dosages of greater than 200 mCi (7.4 GBq) may be administered to selected patients with advanced metastatic disease.

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](#) [4].)

g. Interactions with other forms of treatment:

Patients with a high risk of local/regional recurrent disease or distant metastatic lesions may be treated with I-131 Sodium Iodide, external beam irradiation, surgery, systemic therapy, and/or other treatments as clinically indicated.

5. Radiation precautions

Discussion of fertility should be considered, particularly in young patients who may need multiple treatments. Most experts recommend that pregnancy should be delayed by at least 6 to 12 months after radioiodine therapy to complete follow-up evaluation of therapeutic effectiveness and completion of therapy.

6. Complications

a. Side effects/complications

The use and protocol for administering sour candy or other sialagogues following high-dose I-131 sodium iodide therapy is somewhat controversial, but the administration of such agents beginning within 24 hours following therapy is commonly done to minimize salivary gland uptake and the subsequent development of sialadenitis. Permanent xerostomia following I-131 sodium iodide therapy is rare.

Following radioiodine therapy, 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 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 unless dosimetry is performed). Pulmonary function studies should be considered prior to treatment if there are widespread pulmonary metastases.

The potential for the development of secondary primary malignancies (SPMs) is low, mainly found with leukemia following high administered activities of therapeutic radioiodine, and is controversial. No increased risk of secondary primary solid tumors has been identified. A large European study of 6,871 patients reported an increase in solid tumors and leukemia after radioiodine therapy. A recent literature review, however, reassessed the data and reported a nonlinear dose effect. Review of the

Surveillance, Epidemiology, and End Results (SEER) program with a database of 18,882 patients and a mean follow-up of 61.8 months concluded that radioiodine therapy slightly increased the risk of SPM. 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. Almost all cases of SPM have occurred in patients who received cumulative administered activities in excess of 29.6 GBq (800 mCi). Significant bone marrow depression is likely when cumulative administered activities exceed 29.6 GBq (800 mCi).

- b. Interactions of I-131 Sodium Iodide with other forms of diagnosis or treatment (combinations and/or interactions with clinical external-beam radiation therapy)

Patients with advanced local or regional recurrent disease or distant metastases, such as those with involvement of the central nervous system or aerodigestive tract, may be treated with both I-131 Sodium Iodide and external-beam radiation postthyroidectomy. The toxicity, acute and late, is likely to be additive within the field of irradiation.

To avoid potential radiation-induced spinal cord damage in patients with spinal metastases where I-131 Sodium Iodide therapy and external-beam radiotherapy are to be used in combination, dosimetry calculations are particularly important. A treatment planning method for combination external-beam therapy with radiopharmaceutical therapy is described by Hobbs et al. [31].

C. I-131 Sodium Iodide (sodium iodide)

1. Therapy for Hyperthyroidism

a. Background

I-131 Sodium Iodide 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 clinical practice.

b. Summary of selected data

- i. Fifty percent to 90% of hyperthyroid patients reach a euthyroid or hypothyroid state within 1 year of treatment with I-131 Sodium Iodide [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 I-131 Sodium Iodide 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](#) [4].) The size of the thyroid gland should be noted. Optimally, the patient should be free of iodide-containing medications, iodinated contrast, 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.

d. Administered activities

i. Diffuse hyperfunctioning thyroid/Graves disease

Initial activity of 3.0 to 7.4 MBq (80-200 μ Ci) 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 (33.0 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 of 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. Sialadenitis is a common side effect with higher administered activities that may be managed by the oral administration of sialagogues and/or anti-inflammatory medications. Serious complications are rare. However, on occasion, patients with severe hyperthyroidism may experience exacerbation of symptoms within the first 2 weeks following I-131 Sodium Iodide 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 I-131 Sodium Iodide therapy for hyperthyroidism.

f. Treatment failures and subsequent therapies

In 20% of patients, the initial therapeutic dosage of I-131 Sodium Iodide fails to sufficiently control hyperthyroidism [32]. In patients who have not adequately responded to prior I-131 Sodium Iodide 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.

VI. DOCUMENTATION

Reporting should be in accordance with the [ACR–ASTRO Practice Parameter for Communication: Radiation Oncology](#) [5].

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), NRC Authorized User (AU) status, and clinical work experience, diagnostic radiologists (DRs), nuclear radiologists (NRs), nuclear medicine physicians (NMs), and radiation oncologists (ROs) may have the

qualifications to supervise and perform 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 I-131 Sodium Iodide (oral and parenteral administration) under the supervision of an AU for the specific therapeutic radiopharmaceutical. Although they may not issue written directives for I-131 Sodium Iodide therapy, 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 I-131 Sodium Iodide 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 I-131 Sodium Iodide 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 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 (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

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

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