QUALITY MANAGEMENT PROGRAM

MEDICAL USES OF BYPRODUCT MATERIALS

Lake of the Ozarks General Hospital

24-18678-01

I. Use of Radiopharmaceuticals for Diagnostic Purpose Only

The follwoing are policies and procedures to be followed in the administration of radiopharmaceuticals to patients. Therapeutic administrations of radiopharmaceuticals are not allowed. Any request for therapeutic administrantions of radiopharmaceuticals are denied. For any patient to receive a diagnostic radiopharmaceutical, there must be a signed written directive from the authorized physician or a consult for a diagnostic procedure for which an authorized physician has prescribed the procedure and radiopharmaceutical to be used. If the person assigned to do any or all of the preparation and/or administration of a radiopharmaceutical does not understand any portion of a written directive, or a diagnostic procedure as approved by a nuclear medicine physician, they are to stop and ask sufficient questions to adequately clarify the radiopharmaceutical, dose, route of administration, patient identity, and any related details before proceeding with the procedure.

1. Written Directive for Diagnostic Radiopharmaceuticals, Doses of I-125, or I-131 Sodium Iodide over 30 Microcuries

A written directive which identifies the patient, radiopharmaceutical, dose and route of administration shall be signed and dated by an authorized physician prior to preparation and administration of any dose of I-125 or I-131 sodium iodide over 30 microcuries. Procedures for emergency oral directives, and revisions to written directives, and revisions to written directives are given in a footnote to 10 CFR 35.32(a).

2. Patient Identification

Prior to administering any radiopharmaceutical, the person who is to administer the radiopharmaceutical will verify the identity of the patient in the written directive or approved consult by at least two methods. The patient should be asked what is their name, and then this is to be confirmed by comparison with the recorded birth date, social security number, ID bracelet, or other hospital identification.

3. Verification of Dose Prior to Administration

Prior to administering a radiopharmaceutical, the person who will do the administration is to verify that the details of the administration are in accordance with the written directive or approved consult. In addition to verifying the patient's identity, the radiopharmaceutical, activity dose, and route of administration are to be verified to be in agreement with the written directive or approved nuclear medicine consult. The radiopharmaceutical gamma ray activity is to be measured in a calibrated dose calibrator, and the results recorded and compared to the written directive or approved consult.

4. Documentation of Administered Dose

After administering a radiopharmaceutical, the authorized physician, or a qualified person working under their supervision such as a nuclear medicine technologist will document the administration. This written record will include the patient's name, hospital number,radiopharmaceutical, dose, and date. The authorized physician or qualified person will sign or initial the written record.

II. Periodic Review of Medical Uses of Radiopharmaceuticals

No therapeutic procedures are performed which involve the use of radiopharmaceuticals and there are very few cases where I-125 or I-131 sodium iodide in quantities over

30 microcuries are used. Administrations of I-125 or I-131 sodium iodide over 30 microcuries will be reviewed on a quarterly basis to determine accordance with the written directive for each patient. The review will include the radiopharmaceutical used, dose administered, and route of administration. This quarterly review will be performed by a qualified nuclear medicine technologist or an authorized physician

For each patient radiopharmaceutical administration reviewed, deviations from the written directive will be identified which are recordable events, or misadministrations. If these deviations have not previously been identified and acted upon, then the actions required in 10CRF35.22(c) and 10CFR35.32 will be taken. This will include assembling the factors surrounding each deviation, organizing and retaining required records, and determining and initiation corrective action to prevent recurrence. In the case of misadministrations, the Nuclear Regulatory Commission (NRC) will be notified as required.

The results of these quarterly reviews will be reported at the quarterly meetings of the radiation safety committee for discussion and evaluation. In addition, reports of the reviews will be sent to the responsible authorized physician's department to be presented at the clinical quality assurance meetings.

The function and effectiveness of the Radiopharmaceutical Quality Management program will be reviewed annually by the Radiation Safety Officer and the radiation safety committee at the same time the committee reviews the total radiation safety program (10CFR35.22). The committee will evaluate the program for changes or additions that would make the program more effective or more efficient. Documentation of quarterly reviews and annual evaluations of the Radiopharmaceutical Quality Management Program will be retained for inspection by the NRC.

III. Responsibility to Know and Understand Policy

These policies and procedures and the noted paragraphs of 10CFR35 are to be read and understood by all persons responsible for directing and those performing the preparation and/or the administration of radiopharmaceuticals. This policy and attached sections from 10CFR35 shall be read and understood before a person administers radiopharmaceuticals.

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§ 35.2 Definitions.

"Address of use" means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

"Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken,

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

"Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

"Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

"Dental use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

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≫ *Diagnostic clinical procedures manual* means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Management" means the chief executive officer or that person's delegate or delegates.

"Medical Institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

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"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

≫ *Misadministration* means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

(i) Involving the wrong patient or wrong radiopharmaceutical, or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

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(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong patient or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;

(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(iii) When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(5) A brachytherapy radiation dose:

(i) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

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(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

(i) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(ii) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

"Mobile nuclear medicine service" means the transportation and medical use of byproduct material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

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"Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

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§ 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

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(1) That, prior to administration, a written directive [1] is prepared for:

(i) Any teletherapy radiation dose;

(ii) Any gamma stereotactic radiosurgery radiation dose;

(iii) Any brachytherapy radiation dose;

(iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or

(v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) A representative sample of patient administrations,

(ii) All recordable events, and

(iii) All misadministrations

to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph (a) of this section; and

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(c) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

(d) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modifications to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

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[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

§ 35.33 Notifications, reports, and records of misadministrations.

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center [2] no later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The licensee shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

[2] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

(b) Each licensee shall retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

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§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Part 30 and §§ 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

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(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume