15A NCAC 11 .0318 is proposed for amendment as follows:

15A NCAC 11 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

(a) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Authorized medical physicist" means an individual who:

(1) Meets the requirements in 10 CFR 35.51(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.961(a), or (b), and 35.59;~~ or

(2) Is identified as an authorized medical physicist or teletherapy physicist on:

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

(B) A medical use permit issued by the U.S. Nuclear Regulatory Commission master material licensee;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee.

(b) For the purposes of this ~~Rule,~~ Rule and Rule .0117 (a)(2) of this Chapter, "Authorized nuclear pharmacist" means a pharmacist who:

(1) Meets the requirements in 10 CFR 35.55(a) and 35.59; ~~or, before October 24, 2005, met the requirements in 10 CFR 35.980(a) and 35.59;~~ or

(2) Is identified as an authorized nuclear pharmacist on:

(A) A specific license issued by the U.S. Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

(B) A permit issued by the U.S. Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use license that authorizes medical use or the practice of nuclear pharmacy; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; ~~or~~

(3) Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) Is designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(4).

(c) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Authorized user" means a ~~physician~~ physician, dentist, or podiatrist who:

(1) Meets the requirements in 10 CFR 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.396(a), 35.490(a), 35.590(a), or 35.690(a); ~~or on or before October 24, 2005, met the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59;~~ or

(2) Is identified as an authorized user on:

(A) A U.S. Nuclear Regulatory Commission or Agreement State license that authorizes medical use of radioactive material;

(B) A permit issued by a U.S. Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;

(C) A permit issued by a U.S. Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(D) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

(d) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal or interstitial application.

(e) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Brachytherapy source" means a radioactive source or a manufacture-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(f) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "High dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(g) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

(h) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(i) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Medium dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 200 rads (2 gray), but less than 1200 rads (12 gray) per hour at the point or surface where the dose is prescribed.

(j) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(k) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Pulsed dose-rate afterloader" means a type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

(l) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Radiation safety officer" ~~as used in this Section,~~ means an individual who:

(1) Meets the requirements in 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59; ~~or, before October 24, 2005, met the requirements of 10 CFR 35.900(a) and 35.59, as incorporated by reference in 15A NCAC 11 .0117;~~ or

(2) Is identified as a Radiation Safety Officer on:

(A) A specific medical use license issued by the U.S. Nuclear Regulatory Commission, or an Agreement State; or

(B) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(m) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a therapeutic dose to a tissue volume.

(n) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(o) For the purposes of this Rule and Rule .0117 (a)(2) of this Chapter, "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(p) License required:

(1) A person shall not manufacture, produce, acquire, receive, possess, use or transfer radioactive material for medical use except in accordance with a specific license issued by the agency or as allowed pursuant to Subparagraphs (p)(2) and (p)(3) of this Rule.

(2) An individual may receive, possess, use, or transfer radioactive material in accordance with the rules of this Section under the supervision of an authorized user as provided in this Section unless prohibited by license condition.

(3) An individual may prepare unsealed radioactive material for medical use in accordance with the rules of this Section under the supervision of a pharmacist who is an authorized user or physician who is an authorized user as provided in this Section unless prohibited by license condition.

(q) A license application for human use of radioactive material shall be approved if the agency determines that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;

(3) The issuance of the license will not be inimical to the health and safety of the public;

(4) The following training and supervisory relationship are adhered to:

(A) the user of radioisotopes applied to humans for diagnostic, therapeutic, or investigational purposes shall be a physician authorized by a condition of a specific license, including a specific license of broad scope.

(B) An authorized physician may delegate only to persons who are physicians under the supervision of the authorized physician, the following:

(i) the approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources;

(ii) the prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered;

(iii) the determination of the route of administration; and

(iv) the interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(C) The authorized physician shall review the work of the supervised individual as it pertains to the delegated work in Subparagraph (q)(4) of this Rule and the records kept reflecting that ~~work.~~ work; and

(5) the applicant satisfies any applicable requirements in Rules .0319 to .0322 of this Section.

(r) Subject to the provisions of Subparagraph (q)(4) and Paragraphs (s) to (v) of this Rule, an authorized physician may permit technicians and other paramedic personnel to perform the following activities:

(1) preparation and quality control testing of radiopharmaceuticals and sources of radiation;

(2) measurement of radiopharmaceutical doses prior to administration;

(3) use of ~~appropriate~~ instrumentation for the collection of data to be used by the physician;

(4) administration of radiopharmaceuticals and radiation from radioisotope sources to patients.

(s) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to Paragraph (r) of this Rule shall:

(1) prior to giving permission, determine that the technicians and other paramedical personnel have been properly trained to perform their duties with training in the following subjects, as applicable to the duties assigned:

(A) general characteristics of radiation and radioactive materials;

(B) physical, chemical, and pharmaceutical characteristics of each radiopharmaceutical to be used;

(C) mathematics and calculations basic to the use and measurement of radioactivity, including units of radiation dose and radiation exposure;

(D) use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments, and limitations of instruments;

(E) principles and practices of radiation protection; and

(F) additional training in the above subjects, as appropriate, when new duties are ~~added.~~ added;

(2) assure that the technicians and other paramedical personnel receive retraining in the subjects listed in Subparagraph (s)(1) of this Rule to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology;

(3) keep records showing the bases for the determinations of proper training;

(4) retain responsibility as licensee or authorized user for the satisfactory performance of the ~~activites;~~ activities; and

(5) review the work of the supervised individual and the records kept reflecting that work.

(t) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medicine technology by the Nuclear Medicine Technologist Certification Board or the Society of Nuclear Medicine shall be deemed to satisfy the training requirements in Subparagraphs (s)(1) and (2) of this Rule.

(u) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to Paragraph (r) of this Rule and, if so, shall include in his application for license, license amendment, or license renewal a statement of the activities to be so performed and a description of an adequate program for training the personnel, including retraining as required to keep abreast of developments in technology, or for otherwise determining that the personnel are properly trained to perform their duties.

(v) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician shall be ~~immediately~~ accessible, but not necessarily a physician authorized by the agency to be a user of radioisotopes.

(w) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user shall:

(1 In addition to the requirements in Rule .1003 of this Chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, this Chapter, and license conditions with respect to the use of radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user for ~~medial~~ medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules of this Chapter, and license conditions with respect to the medical use of radioactive material.

(x) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user shall:

(1) In addition to the requirements in Paragraph (s) of this Rule and Rule .1003 of this Chapter, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules of this Chapter, and license conditions.

(y) A licensee that permits supervised activities under Paragraphs (r) and (s) of this Rule is responsible for the acts and omissions of the supervised individual.

(z) A licensee's management shall appoint a Radiation Safety Officer (RSO) who agrees in writing to be responsible for implementing the radiation safety program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(aa) A licensee shall establish in writing the authority, duties and responsibilities of the Radiation Safety Officer.

(bb) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, and management prerogative to:

(1) identify radiation safety problems;

(2) investigate radiation safety problems such as overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, medical events, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(3) initiate, recommend or provide corrective actions for radiation safety problems;

(4) verify implementation of corrective actions; and

(5) retain records of items listed in Subparagraphs (1) through (4) of this Paragraph.

(cc) In addition to the requirements in Rule .1003 of this Chapter, the licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released in accordance with the requirements of Rule .0358 of this Section. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) Patient or human research subject control;

(2) Visitor control, including

(A) Routine visitation to hospitalized individuals in accordance with the provisions of Rule .1611(a)(1) of this Chapter; and

(B) Visitation authorized by Rule .1611(e) of this Chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

(dd) The licensee shall retain records of the radiation safety instructions required by Paragraphs (w), (x), and (cc) for three years. The record must include:

(1) List of topics covered;

(2) The date of the instruction;

(3) The name(s) of the attendee(s); and

(4) The name(s) of the individual(s) who provided the instruction.

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