64E-5.630 Use of Radiopharmaceuticals for Therapy.

[THIS STATE OF FLORIDA REGULATION IS EQUIVALENT TO 10 CFR 35.300]

A licensee is allowed to use any unsealed radioactive material in a radiopharmaceutical that requires a written directive as described in subsection 64E-5.607(3), F.A.C., and for a therapeutic medical use provided the following is met:

(1) For any unsealed radiopharmaceutical including parenteral use listed in subsection 64E-5.630(4), F.A.C., and sodium iodide I-131 use listed in subsections 64E-5.630(2) and (3), F.A.C., the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the applicable training and experience specified in Rule 64E-5.660 or 64E-5.657, F.A.C.

(2) Only for oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.661 or 64E-5.657, F.A.C.

(3) Only for oral administration of sodium iodide I-131 in quantities greater than 33 millicuries (1.22 gigabecquerels) the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.662 or 64E-5.657, F.A.C.

(4) Only parenteral use of radioactive materials the licensee must satisfy the following:

(a) Radioactive material is obtained from a manufacturer or pharmacy licensed as specified in subsection 64E-5.210(10), F.A.C., or in equivalent NRC or agreement state regulations; or

(b) Radioactive material is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or

(c) Radioactive material is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA; or

(d) Radioactive material is prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and meets the training requirements specified in Rule 64E-5.650 or 64E-5.660, F.A.C.; or

3. An individual under the supervision of an authorized user as specified in paragraphs 64E-5.601(3)(a) and (b), 64E-5.607(3)(e) or subsection 64E-5.608(1), F.A.C.

(e) The authorized user must satisfy the training and experience specified in Rule 64E-5.663 or 64E-5.657, F.A.C.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 8-25-91, Amended 5-12-93, Formerly 10D-91.739, Amended 8-6-01, 2-11-10.

NRC Licensing action, Mail control number 576535:

Conclusion – Ralph Tullo, M.D. can be named authorized user for 10 CFR 35.300 in NRC License Number 40-01683-01 as requested by Avera Sacred Heart Hospital since Dr. Tullo was authorized for 35.300 under equivalent State of Florida regulations in State of Florida License 2490-1 issued to Central Florida Regional Hospital.

/RA/

Roberto J. Torres
Senior Health Physicist
January 27, 2012

64E-5.660 Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C.

[THIS STATE OF FLORIDA REGULATION IS EQUIVALENT TO 10 CFR 35.390]

Except as provided in Rule 64E-5.657, F.A.C., the licensee shall require the authorized user of unsealed radioactive materials specified in Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., which require a written directive to:

(1) Be certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state and who meets the requirements in sub-subparagraphs 64E-5.660(2)(a)2.g. and paragraph 64E-5.660(2)(b), F.A.C., of this section. (Specialty boards whose certification processes have been recognized by the NRC or an agreement state will be posted on the NRC's Web page at http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in subparagraph 64E-5.660(2)(a)1. through sub-subparagraph 64E-5.660(2)(a)2.e., F.A.C., of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(b) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(2)(a) Have completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include the following:

1. Classroom and laboratory training in the following areas:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Chemistry of radioactive material for medical use; and

e. Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in Rule 64E-5.657 or 4E-5.660, F.A.C., or equivalent agreement state requirements. A supervising authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must also have experience in administering dosages in the same dosage category or categories (*i.e.*, sub-subparagraph 64E-5.660(2)(a)2.g., F.A.C.,) as the individual requesting authorized user status. The work experience must involve the following:

a. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

b. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

c. Calculating, measuring, and safely preparing patient or human research subject dosages;

d. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

e. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

f. Performing checks for proper operation of survey meters; and

g. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status as listed below:

(I) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required or sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C.;

(II) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(III) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or

(IV) Parenteral administration of any other radionuclide, for which a written directive is required; and

(b) Have obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 64E-5.660(1)(a), sub-subparagraph 64E-5.660(2)(a)2.g. or paragraph 64E-5.660(2)(a), F.A.C., of this section, and have demonstrated the ability to function independently as an authorized user to fulfill the radiation safety related duties for a medical use licensee authorized under Rule 64E-5.626, 64E-5.627 or 64E-5.630, F.A.C., that require a written directive. Have obtained written attestation, signed by a preceptor authorized user or a residency program director who represents a consensus of residency program faculties (as long as at least one member of the residency program faculty is an authorized individual in the same category designated by the applicant seeking authorized status) who meets the requirements in Rule 64E-5.657 or 64E-5.660, F.A.C., or equivalent agreement state requirements. The preceptor authorized user, who meets the requirements in subsection 64E-5.660(2), F.A.C., must have experience in administering dosages in the same dosage category or categories specified in sub-sub-subparagraph 64E-5.660(2)(a)2.g.(II), F.A.C., as the individual requesting authorized user status.

Rulemaking Authority 404.022, 404.051, 404.061, 404.071, 404.081, 404.141 FS. Law Implemented 404.022, 404.051(1), (4), (5), (6), (8), (9), (10), (11), 404.061(2), (3), 404.071(1), 404.081, 404.141 FS. History–New 2-11-10.

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