Sec. 20-576-60. Definitions

As used in sections 20-576-60 to 20-576-63, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Agreement state" means any state that has entered into an agreement with the United States Nuclear Regulatory Commission or the Atomic Energy Commission under 42 U.S.C. § 2021;

(2) "Commission" means the Commission of Pharmacy;

(3) "Component" means any active or non-active ingredient of a drug product;

(4) "Department" means the Department of Consumer Protection;

(5) "Nuclear pharmacist" or "authorized nuclear pharmacist" means a pharmacist who holds a current pharmacist license issued by the commission, and who meets the following standards:

(A) has a current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(B) is identified as an authorized nuclear pharmacist on a United States Nuclear Regulatory Commission or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy;

(6) "Nuclear pharmacy technician" means a person who:

(A) works under the direct supervision of a nuclear pharmacist;

(B) is currently registered as a pharmacy technician with the department; and

(C)

(i) has successfully completed a nuclear pharmacy technician training program provided by an accredited college program or an equivalent company sponsored program approved by the commission, or

(ii) is listed as an "Authorized User of Radioactive Materials" on the nuclear pharmacy's United States Nuclear Regulatory Commission or agreement state license;

(7) "Nuclear pharmacy" means a pharmacy that provides radiopharmaceutical services and holds a Connecticut pharmacy license;

(8) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs;

(9) "Quality assurance procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of the product history, internal test assessment, and maintenance of all required records;

(10) "Quality control testing" means the performance of appropriate chemical, biological and physical tests on compounded and prepared radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals;

(11) "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclides with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator or eluates derived therefrom, which is intended to be used in preparation of any such substance. The term "radiopharmaceutical" includes, but is not limited to, positron-emission tomography agents, any biological product, including, but not limited to, blood formed element, antibody or peptide, that is labeled with

a radionuclide or solely intended to be labeled with a radionuclide;

(12) "Radiopharmaceutical compounding" means the preparation, mixing, assembling, packaging, or labeling of a radiopharmaceutical that:

(A) is the result of a practitioner's drug prescription order in the course of professional practice;

(B) is for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing;

(C) includes use of reagent kits and radiopharmaceuticals in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(D) is performed in accordance with the preparation instructions contained in the approved drug product labeling or other preparation directions as provided by the manufacturer;

(E) is performed in consideration of patient safety and efficacy, with validated procedures which deviate from the preparation instructions specified in the approved drug product labeling; or

(F) may utilize professional judgment, scientific knowledge, literature evidence and other reference materials according to current standards of practice as the basis for employing any deviations from the labeled preparation instructions or modifications to a radiopharmaceutical, if the final drug product, created as a result of any such deviations or modifications, is subjected to appropriate quality control testing necessary to confirm the presence of the desired radiopharmaceutical qualities;

(13) "Radiopharmaceutical services" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping, and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for the provision of pharmaceutical care; and

(14) "Reagent kit" means a sterile and pyrogen-free reaction vial containing nonradioactive chemicals, including, but not limited to, complexing agent (ligand), reducing agent, stabilizer, or dispersing agent.

(Adopted effective November 30, 2006)