

Chapter 246-903 WAC

NUCLEAR PHARMACIES AND PHARMACISTS

WAC

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WAC 246-903-001 Purpose and scope. (1) No person may lawfully provide radiopharmaceutical services unless he or she is a nuclear pharmacist, or is performing radiopharmaceutical services under the supervision of a nuclear pharmacist, and is acting in accordance with the state board of pharmacy and state radiation control agency regulations.

(2) These regulations shall not apply to anyone who is an "authorized practitioner" as that term is defined in section 2 of these regulations.

(3) The requirements imposed by these nuclear pharmacy regulations shall apply in addition to, and not in place of, any other requirements contained in regulations of the state board of pharmacy, the state radiation control agency, or any other state or federal agency.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-903-001, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-010, filed 2/1/79.]

WAC 246-903-010 Definitions. (1) A "nuclear pharmacy" is a class A pharmacy providing radiopharmaceutical services.

(2) "Nuclear pharmacist" means a licensed pharmacist who has submitted evidence to the board of pharmacy that he or she meets the requirements of WAC 246-903-030 of these regulations regarding training, education, and experience, and who has received notification by letter from the board of pharmacy that, based on the evidence submitted, he or she is recognized by the board of pharmacy as qualified to provide radiopharmaceutical services.

(3) "Radiopharmaceutical service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(4) A "radiopharmaceutical" is any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent

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kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(6) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to insure the integrity of the test.

(7) "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.

(8) "Authorized practitioner" means a practitioner duly authorized by law to possess, use, and administer radiopharmaceuticals.

(9) "Accepted professional standards" are those set forth in the *Nuclear Pharmacy Practice Standards* published by the American Pharmaceutical Association, Board of Pharmaceutical Specialties, adopted on March 18, 1986.

[Statutory Authority: RCW 18.64.005. WSR 93-04-016 (Order 329B), § 246-903-010, filed 1/25/93, effective 2/25/93; WSR 92-12-035 (Order 277B), § 246-903-010, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-903-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-020, filed 2/1/79.]

WAC 246-903-020 Nuclear pharmacies. (1) A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the supervision of a nuclear pharmacist. The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.

(2) Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. A nuclear pharmacy handling radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by

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obtaining a waiver from the state board of pharmacy. Detailed floor plans shall be submitted to the state board of pharmacy and the state radiation control agency before approval of the license.

(3) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted professional standards.

(4) The board recognizes that the preparation of nuclear pharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(5) Nuclear pharmacies shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the state board of pharmacy, the state radiation control agency and other state and federal agencies.

(6) For nuclear pharmacies handling radiopharmaceuticals exclusively, the state board of pharmacy may waive regulations pertaining to the pharmacy permits for nonradiopharmaceuticals for requirements that do not pertain to the practice of nuclear pharmacy.

(7) Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.

(8) A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.

(9) In addition to any labeling requirements of the state board of pharmacy for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (a) Standard radiation symbol; (b) the words "caution-radioactive material"; (c) the name of the radiopharmaceutical; (d) the amount of radioactive material contained, in millicuries or microcuries; (e) if a liquid, the volume in milliliters; (f) the requested calibration time for the amount of radioactivity contained; (g) expiration data, if applicable; and (h) specific concentration of radioactivity.

(10) The immediate container shall be labeled with: (a) The standard radiation symbol; (b) the words "caution-radioactive material"; (c) the name of the nuclear pharmacy; (d) the prescription number; (e) the name of the radiopharmaceutical; (f) the date; and (g) the amount of radioactive material contained in millicuries or microcuries.

(11) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

(12) Nuclear pharmacies may redistribute NDA approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.

(13) The nuclear pharmacy shall have the current revisions of state laws and regulations of the state board of pharmacy and state radiation control agency.

(14) The nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided. A detailed library listing shall be submitted to the state board of pharmacy and state radiation control agency before approval of the license.

[Statutory Authority: RCW 18.64.005. WSR 93-04-016 (Order 329B), § 246-903-020, filed 1/25/93, effective 2/25/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-903-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-030, filed 2/1/79.]

WAC 246-903-030 Nuclear pharmacists. In order for a pharmacist to qualify under these regulations as a nuclear pharmacist, he or she must:

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the state radiation control agency; and,

(2) Be a pharmacist licensed to practice in Washington; and,

(3) Submit to the board of pharmacy either:

(a) Certification that he or she has completed a minimum of 6 months on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services, or

(b) Certification that he or she has completed a nuclear pharmacy training program in an accredited college of pharmacy or

(c) That upon application to the board in affidavit form, and upon the furnishing of such other information as the board may require, the board may grant partial or equivalent credit for education and experience gained in programs not sponsored by an accredited college of pharmacy, if, in the opinion of the board, the education and experience gained by participants in these programs would provide the same level of competence as participation in a program at an accredited college of pharmacy; and

(4) Receive a letter of notification from the board of pharmacy that the evidence submitted that the pharmacist meets the requirements of subsections 1, 2, and 3 above has been accepted by the board and that, based thereon, the pharmacist is recognized by the board as a nuclear pharmacist.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-903-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-040, filed 2/1/79.]

WAC 246-903-040 Minimum equipment requirements. (1) Nuclear pharmacies shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided. A detailed list of equipment and description of use must be submitted to the state board of pharmacy and radiation control agency before approval of the license.

(2) The state board of pharmacy may, for good cause shown, waive regulations pertaining to the equipment and supplies required for nuclear pharmacies handling radiopharmaceuticals exclusively.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-903-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(9). WSR 79-02-061 (Order 145, Resolution No. 1-79), § 360-54-050, filed 2/1/79.]