

1 **PART 15 TEXAS STATE BOARD OF PHARMACY**
2 **CHAPTER 291 PHARMACIES**
3 **SUBCHAPTER C NUCLEAR PHARMACY (CLASS B)**
4

5
6 **§291.51 Purpose**
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8 The purpose of this subchapter is to provide standards for the preparation, labeling, and
9 distribution of compounded radiopharmaceuticals by licensed nuclear pharmacies, pursuant to a
10 radioactive prescription drug order. The intent of this subchapter is to establish a minimum
11 acceptable level of pharmaceutical care to the patient so that the patient's health is protected
12 while contributing to positive patient outcomes. The board has determined that this subchapter
13 is necessary to protect the health and welfare of the citizens of this state.
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16 **§291.52 Definitions**
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18 The following words and terms, when used in this subchapter, shall have the following
19 meanings, unless the context clearly indicates otherwise. Any term not defined in this section
20 shall have the definition set forth in the Act, §551.003.
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22 (1) Act--The Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Occupations Code, as
23 amended.
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25 (2) Accurately as prescribed--Dispensing, delivering, and/or distributing a prescription drug
26 order or radioactive prescription drug order:
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28 (A) to the correct patient (or agent of the patient) for whom the drug or device was prescribed;
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30 (B) with the correct drug in the correct strength, quantity, and dosage form ordered by the
31 practitioner; and
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33 (C) with correct labeling (including directions for use) as ordered by the practitioner. Provided,
34 however, that nothing herein shall prohibit pharmacist substitution if substitution is conducted in
35 strict accordance with applicable laws and rules, including Subchapter A, Chapter 562 of the
36 Act.
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38 (3) ACPE--Accreditation Council for Pharmacy Education.
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40 (4) Administer--The direct application of a prescription drug and/or radiopharmaceutical, by
41 injection, inhalation, ingestion, or any other means to the body of a patient by:
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43 (A) a practitioner, an authorized agent under his supervision, or other person authorized by
44 law; or
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46 (B) the patient at the direction of a practitioner.
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48 (5) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum
49 allowable number of particles per cubic meter of air as specified in the International
50 Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For
51 example:

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(A) ISO Class 5 (formerly Class 100) is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100 particles 0.5 microns in diameter per cubic foot of air);

(B) ISO Class 7 (formerly Class 10,000) is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 10,000 particles 0.5 microns in diameter per cubic foot of air); and

(C) ISO Class 8 (formerly Class 100,000) is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air (formerly stated as 100,000 particles 0.5 microns in diameter per cubic foot of air).

(6) Ancillary supplies--Supplies necessary for the administration of compounded sterile radiopharmaceuticals.

(7) Aseptic processing--The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(8) Authentication of product history--Identifying the purchasing source, the intermediate handling, and the ultimate disposition of any component of a radioactive drug.

(9) Authorized nuclear pharmacist--A pharmacist who:

(A) has completed the specialized training requirements specified by this subchapter for the preparation and distribution of radiopharmaceuticals; and

(B) is named on a Texas radioactive material license, issued by the Texas Department of State Health Services, Radiation Control Program.

(10) Authorized user--Any individual named on a Texas radioactive material license, issued by the Texas Department of State Health Services, Radiation Control Program.

(11) Automated compounding or drug dispensing device--An automated device that compounds, measures, counts, packages, and/or labels a specified quantity of dosage units for a designated drug product.

(12) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protection, and HEPA filtered exhausted air for environmental protection.

(13) Board--The Texas State Board of Pharmacy.

(14) Clean room or controlled area--A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

102 (15) Component--Any ingredient intended for use in the compounding of a drug preparation,
103 including those that may not appear in such preparation.

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105 (16) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or
106 device:

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108 (A) as the result of a practitioner's prescription drug or medication order based on the
109 practitioner-patient-pharmacist relationship in the course of professional practice;

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111 (B) for administration to a patient by a practitioner as the result of a practitioner's initiative
112 based on the practitioner-patient-pharmacist relationship in the course of professional practice;

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114 (C) in anticipation of prescription drug or medication orders based on routine, regularly
115 observed prescribing patterns; or

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117 (D) for or as an incident to research, teaching, or chemical analysis and not for sale or
118 dispensing, except as allowed under §562.154 or Chapter 563 of the Act.

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120 (17) Controlled substance--A drug, immediate precursor, or other substance listed in
121 Schedules I - V or Penalty Groups 1-4 of the Texas Controlled Substances Act, as amended, or
122 a drug, immediate precursor, or other substance included in Schedule I, II, III, IV, or V of the
123 Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public
124 Law 91-513).

125
126 (18) Critical site--Sterile ingredients of compounded sterile preparations and locations on
127 devices and components used to prepare, package, and transfer compounded sterile
128 preparations that provide opportunity for exposure to contamination.

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130 (19) Dangerous drug--A drug or device that:

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132 (A) is not included in Penalty Group 1, 2, 3, or 4, Chapter 481, Health and Safety Code, and
133 is unsafe for self-medication; or

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135 (B) bears or is required to bear the legend:

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137 (i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another
138 legend that complies with federal law; or

139
140 (ii) "Caution: federal law restricts this drug to use by or on the order of a licensed
141 veterinarian."

142
143 (20) Data communication device--An electronic device that receives electronic information from
144 one source and transmits or routes it to another (e.g., bridge, router, switch, or gateway).

145
146 (21) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or
147 device, radiopharmaceutical, or controlled substance from one person to another, whether or
148 not for a consideration.

149
150 (22) Designated agent--

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152 (A) an individual, including a licensed nurse, physician assistant, or pharmacist:

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154 (i) who is designated by a practitioner and authorized to communicate a prescription drug
155 order to a pharmacist; and
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157 (ii) for whom the practitioner assumes legal responsibility;
158
159 (B) a licensed nurse, physician assistant, or pharmacist employed in a health care facility to
160 whom a practitioner communicates a prescription drug order; or
161
162 (C) a registered nurse or physician assistant authorized by a practitioner to administer a
163 prescription drug order for a dangerous drug under Subchapter B, Chapter 157 (Occupations
164 Code).
165
166 (23) Device--An instrument, apparatus, implement, machine, contrivance, implant, in vitro
167 reagent, or other similar or related articles, including any component parts or accessory that is
168 required under federal or state law to be ordered or prescribed by a practitioner.
169
170 (24) Diagnostic prescription drug order--A radioactive prescription drug order issued for a
171 diagnostic purpose.
172
173 (25) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug
174 or device, or a radiopharmaceutical in the course of professional practice to an ultimate user or
175 his agent by or pursuant to the lawful order of a practitioner.
176
177 (26) Dispensing pharmacist--The authorized nuclear pharmacist responsible for the final check
178 of the dispensed prescription before delivery to the patient.
179
180 (27) Distribute--The delivering of a prescription drug or device, or a radiopharmaceutical other
181 than by administering or dispensing.
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183 (28) Electronic radioactive prescription drug order--A radioactive prescription drug order which
184 is transmitted by an electronic device to the receiver (pharmacy).
185
186 (29) Internal test assessment--Validation of tests for quality control necessary to insure the
187 integrity of the test.
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189 (30) Nuclear pharmacy technique--The mechanical ability required to perform the
190 nonjudgmental, technical aspects of preparing and dispensing radiopharmaceuticals.
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192 (31) Original prescription--The:
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194 (A) original written radioactive prescription drug orders; or
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196 (B) original verbal or electronic radioactive prescription drug orders maintained either
197 manually or electronically by the pharmacist.
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199 (32) Pharmacist-in-charge--The pharmacist designated on a pharmacy license as the
200 pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and
201 rules pertaining to the practice of pharmacy.
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203 (33) Pharmacy technician--An individual whose responsibility in a pharmacy is to provide
204 technical services that do not require professional judgment regarding preparing and distributing
205 drugs and who works under the direct supervision of and is responsible to a pharmacist.
206

207 (34) Pharmacy technician trainee--An individual who is registered with the board as a
208 pharmacy technician trainee and is authorized to participate in a pharmacy's technician training
209 program.
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211 (35) Process validation--Documented evidence providing a high degree of assurance that a
212 specific process will consistently produce a product meeting its predetermined specifications
213 and quality attributes.
214

215 (36) Quality assurance--The set of activities used to ensure that the process used in the
216 preparation of sterile radiopharmaceuticals lead to preparations that meet predetermined
217 standards of quality.
218

219 (37) Radiopharmaceutical--A prescription drug or device that exhibits spontaneous
220 disintegration of unstable nuclei with the emission of a nuclear particle(s) or photon(s), including
221 any nonradioactive reagent kit or nuclide generator that is intended to be used in preparation of
222 any such substance.
223

224 (38) Radioactive drug quality control--The set of testing activities used to determine that the
225 ingredients, components (e.g., containers), and final radiopharmaceutical prepared meets
226 predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility and
227 the interpretation of the resulting data in order to determine the feasibility for use in humans and
228 animals including internal test assessment, authentication of product history, and the keeping of
229 mandatory records.
230

231 (39) Radioactive drug service--The act of distributing radiopharmaceuticals; the participation in
232 radiopharmaceutical selection and the performance of radiopharmaceutical drug reviews.
233

234 (40) Radioactive prescription drug order--An order from a practitioner or a practitioner's
235 designated agent for a radiopharmaceutical to be dispensed.
236

237 (41) Sterile radiopharmaceutical--A dosage form of a radiopharmaceutical free from living
238 micro-organisms.
239

240 (42) Therapeutic prescription drug order--A radioactive prescription drug order issued for a
241 specific patient for a therapeutic purpose.
242

243 (43) Ultimate user--A person who has obtained and possesses a prescription drug or
244 radiopharmaceutical for administration to a patient by a practitioner.
245

246 **§291.53 Personnel**
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248
249 (a) Pharmacists-in-Charge.
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251 (1) General.
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253 (A) Every nuclear pharmacy shall have an authorized nuclear pharmacist designated on the
254 nuclear pharmacy license as the pharmacist-in-charge who shall be responsible for a nuclear
255 pharmacy's compliance with laws and regulations, both state and federal, pertaining to the
256 practice of nuclear pharmacy.

257
258 (B) The nuclear pharmacy pharmacist-in-charge shall see that directives from the board are
259 communicated to the owner(s), management, other pharmacists, and interns of the nuclear
260 pharmacy.

261
262 (C) Each Class B pharmacy shall have one pharmacist-in-charge who is employed on a full-
263 time basis, who may be the pharmacist-in-charge for only one such pharmacy; provided,
264 however, such pharmacist-in-charge may be the pharmacist-in-charge of:

265
266 (i) more than one Class B pharmacy, if the additional Class B pharmacies are not open to
267 provide pharmacy services simultaneously; or

268
269 (ii) up to two Class B pharmacies open simultaneously if the pharmacist-in-charge works at
270 least 10 hours per week in each pharmacy.

271
272 (2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,
273 the following:

274
275 (A) ensuring that radiopharmaceuticals are dispensed and delivered safely and accurately as
276 prescribed;

277
278 (B) developing a system to assure that all pharmacy personnel responsible for compounding
279 and/or supervising the compounding of radiopharmaceuticals within the pharmacy receive
280 appropriate education and training and competency evaluation;

281
282 (C) determining that all pharmacists involved in compounding sterile radiopharmaceuticals
283 obtain continuing education appropriate for the type of compounding done by the pharmacist;

284
285 (D) supervising a system to assure appropriate procurement of drugs and devices and
286 storage of all pharmaceutical materials including radiopharmaceuticals, components used in the
287 compounding of radiopharmaceuticals, and drug delivery devices;

288
289 (E) assuring that the equipment used in compounding is properly maintained;

290
291 (F) developing a system for the disposal and distribution of drugs from the Class B pharmacy;

292
293 (G) developing a system for bulk compounding or batch preparation of radiopharmaceuticals;

294
295 (H) developing a system for the compounding, sterility assurance, and quality control of
296 sterile radiopharmaceuticals;

297
298 (I) maintaining records of all transactions of the Class B pharmacy necessary to maintain
299 accurate control over and accountability for all pharmaceutical materials including
300 radiopharmaceuticals, required by applicable state and federal laws and rules;

301
302 (J) developing a system to assure the maintenance of effective controls against the theft or
303 diversion of prescription drugs, and records for such drugs;

304
305 (K) assuring that the pharmacy has a system to dispose of radioactive and cytotoxic waste in
306 a manner so as not to endanger the public health; and
307

308 (L) legal operation of the pharmacy, including meeting all inspection and other requirements
309 of all state and federal laws or rules governing the practice of pharmacy.
310

311 (b) Owner. The owner of a Class B pharmacy shall have responsibility for all administrative and
312 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
313 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
314 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
315 the pharmacist-in-charge or another Texas licensed pharmacist:

316 (1) establishment of policies for procurement of prescription drugs and devices and other
317 products dispensed from the Class B pharmacy;
318

319 (2) establishment of policies and procedures for the security of the prescription department
320 including the maintenance of effective controls against the theft or diversion of prescription
321 drugs;
322

323 (3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving
324 all policies and procedures for system operation, safety, security, accuracy and access, patient
325 confidentiality, prevention of unauthorized access, and malfunction;
326

327 (4) providing the pharmacy with the necessary equipment and resources commensurate with
328 its level and type of practice; and
329

330 (5) establishment of policies and procedures regarding maintenance, storage, and retrieval of
331 records in a data processing system such that the system is in compliance with state and
332 federal requirements.
333

334 (c) Authorized nuclear pharmacists.
335

336 (1) General.
337

338 (A) The pharmacist-in-charge shall be assisted by a sufficient number of additional authorized
339 nuclear pharmacists as may be required to operate the pharmacy competently, safely, and
340 adequately to meet the needs of the patients of the pharmacy.
341

342 (B) All personnel performing tasks in the preparation and distribution of radiopharmaceuticals
343 shall be under the direct supervision of an authorized nuclear pharmacist. General qualifications
344 for an authorized nuclear pharmacist are the following. A pharmacist shall:
345

346 (i) meet minimal standards of training and experience in the handling of radioactive
347 materials in accordance with the requirements of the Texas Regulations for Control of Radiation
348 of the Radiation Control Program, Texas Department of State Health Services;
349

350 (ii) be a pharmacist licensed by the board to practice pharmacy in Texas; and
351

352 (iii) submit to the board either:
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354

355 (I) written certification that he or she has current board certification as a nuclear pharmacist
356 by the Board of Pharmaceutical Specialties; or

357
358 (II) written certification signed by a preceptor authorized nuclear pharmacist that he or she
359 has achieved a level of competency sufficient to independently operate as an authorized
360 nuclear pharmacist and has satisfactorily completed 700 hours in a structured educational
361 program consisting of both:

362
363 (-a-) 200 hours of didactic training in a program accepted by the Radiation Control
364 Program, Texas Department of State Health Services in the following areas:

- 365 (-1-) radiation physics and instrumentation;
366
367 (-2-) radiation protection;
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369 (-3-) mathematics pertaining to the use and measurement of radioactivity;
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371 (-4-) radiation biology; and
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373 (-5-) chemistry of radioactive material for medical use; and
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375
376 (-b-) 500 hours of supervised practical experience in a nuclear pharmacy involving the
377 following:

- 378 (-1-) shipping, receiving, and performing related radiation surveys;
379
380 (-2-) using and performing checks for proper operation of instruments used to determine
381 the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-
382 or beta-emitting radionuclides;
383
384 (-3-) calculating, assaying, and safely preparing dosages for patients or human research
385 subjects;
386
387 (-4-) using administrative controls to avoid adverse medical events in the administration
388 of radioactive material; and
389
390 (-5-) using procedures to prevent or minimize contamination and using proper
391 decontamination procedures.
392

393
394 (C) The board may issue a letter of notification that the evidence submitted by the pharmacist
395 meets the requirements of subparagraph (B)(i) - (iii) of this paragraph and has been accepted
396 by the board and that, based thereon, the pharmacist is recognized as an authorized nuclear
397 pharmacist.
398

399 (D) Authorized nuclear pharmacists are solely responsible for the direct supervision of
400 pharmacy technicians and pharmacy technician trainees and for delegating nuclear pharmacy
401 techniques and additional duties, other than those listed in paragraph (2) of this subsection, to
402 pharmacy technicians and pharmacy technician trainees. Each authorized nuclear pharmacist:
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404 (i) shall verify the accuracy of all acts, tasks, or functions performed by pharmacy
405 technicians and pharmacy technician trainees; and

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(ii) shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(E) All authorized nuclear pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(F) The dispensing pharmacist shall ensure that the drug is dispensed and delivered safely and accurately as prescribed.

(2) Special requirements for compounding.

(A) Non-sterile preparations. All pharmacists engaged in compounding non-sterile radiopharmaceuticals shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(B) Sterile Preparations. All pharmacists engaged in compounding sterile radiopharmaceuticals shall meet the training requirements specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(3) Duties. Duties which may only be performed by an authorized nuclear pharmacist are as follows:

(A) receiving verbal therapeutic prescription drug orders and reducing these orders to writing, either manually or electronically;

(B) receiving verbal, diagnostic prescription drug orders in instances where patient specificity is required for patient safety (e.g., radiolabeled blood products, radiolabeled antibodies) and reducing these orders to writing, either manually or electronically;

(C) interpreting and evaluating radioactive prescription drug orders;

(D) selection of drug products; and

(E) performing the final check of the dispensed prescription before delivery to the patient to ensure that the radioactive prescription drug order has been dispensed accurately as prescribed.

(d) Pharmacy Technicians and Pharmacy Technician Trainees.

(1) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(2) Special requirements for compounding.

(A) Non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile radiopharmaceuticals shall meet the training requirements specified in §291.131 of this title.

456 (B) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged
457 in compounding sterile radiopharmaceuticals shall meet the training requirements specified in
458 §291.133 of this title.

459
460 (3) Duties.

461
462 (A) Pharmacy technicians and pharmacy technician trainees may not perform any of the
463 duties listed in subsection (c)(3) of this section.

464
465 (B) An authorized nuclear pharmacist may delegate to pharmacy technicians and pharmacy
466 technician trainees any nuclear pharmacy technique which is associated with the preparation
467 and distribution of radiopharmaceuticals provided:

468
469 (i) an authorized nuclear pharmacist verifies the accuracy of all acts, tasks, and functions
470 performed by pharmacy technicians and pharmacy technician trainees; and

471
472 (ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision
473 of and responsible to a pharmacist.

474
475 (4) Ratio of authorized nuclear pharmacist to pharmacy technicians and pharmacy technician
476 trainees.

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478 (A) The ratio of authorized nuclear pharmacists to pharmacy technicians and pharmacy
479 technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and
480 is trained in the handling of radioactive materials.

481
482 (B) The ratio of authorized nuclear pharmacists to pharmacy technician trainees may not
483 exceed 1:2.

484
485 (e) Special education, training, and evaluation requirements for pharmacy personnel
486 compounding or responsible for the direct supervision of pharmacy personnel compounding
487 sterile radiopharmaceuticals. All pharmacy personnel preparing sterile radiopharmaceuticals
488 shall meet the training requirements specified in §291.133 of this title.

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491 **§291.54 Operational Standards**

492
493 (a) Licensing requirements.

494
495 (1) It is unlawful for a person to provide radioactive drug services unless such provision is
496 performed by a person licensed to act as an authorized nuclear pharmacist, as defined by the
497 board, or is a person acting under the direct supervision of an authorized nuclear pharmacist
498 acting in accordance with the Act and its rules, and the regulations of the Texas Department of
499 State Health Services, Radiation Control Program. Subsection (a) of this section does not apply
500 to:

501
502 (A) a licensed practitioner or his or her designated agent for administration to his or her
503 patient, provided no person may receive, possess, use, transfer, own, acquire, or dispose of
504 radiopharmaceuticals except as authorized in a specific or a general license as provided in
505 accordance with the requirements of the Texas Department of State Health Services, Radiation

506 Control Program, Texas Administrative Code, Title 25, Part 1, Subchapter F, §289.252 relating
507 to Licensing of Radioactive Material, or the Act;

508

509 (B) institutions and/or facilities with nuclear medicine services operated by practitioners and
510 who are licensed by the Texas Department of State Health Services, Radiation Control
511 Program, to prescribe, administer, and dispense radioactive materials (drugs and/or devices).

512

513 (2) An applicant for a Class B pharmacy shall provide evidence to the board of the possession
514 of a Texas Department of State Health Services radioactive material license or proof of
515 application for a radioactive material license.

516

517 (3) A Class B pharmacy shall register with the board on a pharmacy license application
518 provided by the board, following the procedures specified in §291.1 of this title (relating to
519 Pharmacy License Application).

520

521 (4) A Class B pharmacy which changes ownership shall notify the board within ten days of the
522 change of ownership and apply for a new and separate license as specified in §291.3 of this title
523 (relating to Required Notifications).

524

525 (5) A Class B pharmacy which changes location and/or name shall notify the board within ten
526 days of the change and file for an amended license as specified in §291.3 of this title.

527

528 (6) A Class B pharmacy owned by a partnership or corporation which changes managing
529 officers shall notify the board in writing of the names of the new managing officers within ten
530 days of the change, following the procedures in §291.3 of this title.

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532 (7) A Class B pharmacy shall notify the board in writing within ten days of closing, following the
533 procedures in §291.5 of this title (relating to Closing a Pharmacy).

534

535 (8) A separate license is required for each principal place of business and only one pharmacy
536 license may be issued to a specific location.

537

538 (9) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged
539 for the issuance and renewal of a license and the issuance of an amended license.

540

541 (10) A Class B pharmacy, licensed under the provisions of the Act, §560.051(a)(2), which also
542 operates another type of pharmacy which would otherwise be required to be licensed under the
543 Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a
544 license for such other type of pharmacy; provided, however, such licensee is required to comply
545 with the provisions of §291.31 of this title (relating to Definitions); §291.32 of this title (relating to
546 Personnel); §291.33 of this title (relating to Operational Standards); §291.34 of this title (relating
547 to Records); and §291.35 of this title (relating to Official Prescription Requirements), to the
548 extent such rules are applicable to the operation of the pharmacy.

549

550 (11) A Class B (nuclear) pharmacy engaged in the compounding of non-sterile non-radioactive
551 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
552 Compounding Non-Sterile Preparations).

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554 (12) A Class B (nuclear) pharmacy engaged in the compounding of sterile non-radioactive
555 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
556 Compounding Sterile Preparations).

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(b) Risk levels for compounded sterile radiopharmaceuticals. Risk Levels for sterile compounded radiopharmaceuticals shall be as listed below.

(1) Low-risk level compounded sterile radiopharmaceuticals.

(A) Low-risk level compounded sterile radiopharmaceuticals are those compounded under all of the following conditions.

(i) The compounded sterile preparations are compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices.

(ii) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are performed promptly and attentively.

(iii) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.

(iv) For a low-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following periods: before administration, 48 hours at controlled room temperature, for not more than 14 days if stored in cold temperatures, and for 45 days if stored in a frozen state at minus 20 degrees Celsius or colder). For delayed activation device systems, the storage period begins when the device is activated.

(B) Examples of low-risk compounding include radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multidose container.

(2) Medium-risk level compounded sterile radiopharmaceuticals.

(A) Medium-risk level compounded sterile radiopharmaceuticals are those compounded aseptically under low-risk conditions and one or more of the of the following conditions exists.

(i) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile radiopharmaceuticals that will be administered either to multiple patients or to one patient on multiple occasions.

(ii) The compounding process includes complex aseptic manipulations other than the single-volume transfer.

(iii) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing.

(iv) The sterile compounded radiopharmaceuticals do not contain broad-spectrum bacteriostatic substances, and they are administered over several days.

(v) For a medium-risk preparation, in the absence of passing sterility test, the storage periods cannot exceed the following time periods: before administration, the compounded sterile preparations are properly stored and are exposed for not more than 30 hours at controlled room

608 temperature for not more than 7 days at a cold temperature, and for 45 days in solid frozen
609 state at minus 20 degrees or colder.

610
611 (B) Examples of medium-risk compounding include the following.

612
613 (i) Compounding of total parenteral nutrition fluids using a manual or automated device
614 during which there are multiple injections, detachments, and attachments of nutrient source
615 products to the device or machine to deliver all nutritional components to a final sterile
616 container.

617
618 (ii) Filling of reservoirs of injection and infusion devices with multiple sterile drug products
619 and evacuations of air from those reservoirs before the filled device is dispensed.

620
621 (iii) Filling of reservoirs of injection and infusion devices with volumes of sterile drug
622 solutions that will be administered over several days at ambient temperatures between 25 and
623 40 degrees Celsius (77 and 104 degrees Fahrenheit).

624
625 (iv) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or
626 product.

627
628 (3) High-risk level compounded sterile radiopharmaceuticals.

629
630 (A) High-risk level compounded sterile radiopharmaceuticals are those compounded under
631 any of the following conditions.

632
633 (i) Non-sterile ingredients, including manufactured products are incorporated, or a non-
634 sterile device is employed before terminal sterilization.

635
636 (ii) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior
637 to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or
638 partially used packages of manufactured sterile products that lack antimicrobial preservatives.

639
640 (iii) Non-sterile preparations are exposed no more than 6 hours before being sterilized.

641
642 (iv) It is assumed, and not verified by examination of labeling and documentation from
643 suppliers or by direct determination, that the chemical purity and content strength of ingredients
644 meet their original or compendial specifications in unopened or in opened packages of bulk
645 ingredients.

646
647 (v) For a high-risk preparation, in the absence of passing sterility test, the storage periods
648 cannot exceed the following time periods: before administration, the compounded sterile
649 preparations are properly stored and are exposed for not more than 24 hours at controlled room
650 temperature for not more than 3 days at a cold temperature, and for 45 days in solid frozen
651 state at minus 20 degrees or colder.

652
653 (B) Examples of high-risk compounding include the following.

654
655 (i) Dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be
656 terminally sterilized.

657

658 (ii) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior
659 to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or
660 partially used packages of manufactured sterile products that lack antimicrobial preservatives.
661

662 (iii) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is
663 performed.
664

665 (iv) Assuming, without appropriate evidence or direct determination, that packages of bulk
666 ingredients contain at least 95% by weight of their active chemical moiety and have not been
667 contaminated or adulterated between uses.
668

669 (c) Environment.

670
671 (1) Special requirements for the compounding of sterile radiopharmaceuticals. When the
672 pharmacy compounds sterile radiopharmaceuticals, the following is applicable.
673

674 (A) Low and Medium Risk Preparations.

675
676 (i) The pharmacy shall have a designated controlled area for the compounding of sterile
677 radiopharmaceuticals that is functionally separate from areas for the preparation of non-sterile
678 radiopharmaceuticals and is constructed to minimize the opportunities for particulate and
679 microbial contamination. This controlled area for the preparation of sterile radiopharmaceuticals
680 shall:

681
682 (I) have a controlled environment that is aseptic or contains an aseptic environmental
683 control device(s). If the aseptic environmental control device is located within the controlled
684 area, the controlled area must extend a minimum of six feet from the device and clearly marked
685 to identify the separation between the controlled and non-controlled area;
686

687 (II) be clean, well lighted, and of sufficient size to support sterile compounding activities;
688

689 (III) be used only for the compounding of sterile radiopharmaceuticals;
690

691 (IV) be designed to avoid outside traffic and airflow;
692

693 (V) be designed such that hand sanitizing and gowning occurs outside the controlled area
694 but accessible without use of the hands of the compounding personnel;
695

696 (VI) have non-porous and washable floors or floor covering to enable regular disinfection;
697

698 (VII) be ventilated in a manner not interfering with aseptic environmental control conditions;
699

700 (VIII) have walls, ceilings, and fixtures, shelving, counters, and cabinets that are smooth,
701 impervious, free from cracks and crevices, and nonshedding (acoustical ceiling tiles that are
702 coated with an acrylic paint are acceptable);
703

704 (IX) have drugs and supplies stored on shelving areas above the floor to permit adequate
705 floor cleaning; and
706

707 (X) contain only the appropriate compounding supplies and not be used for bulk storage for
708 supplies and materials. Objects that shed particles may not be brought into the controlled area.

709
710 (ii) The pharmacy shall prepare sterile radiopharmaceuticals in a primary engineering control
711 device, such as a vertical air flow hood, which is capable of maintaining at least ISO Class 5
712 conditions during normal activity.

713
714 (I) The primary engineering control shall:

715
716 (-a-) be located in the buffer area or room and placed in the buffer area in a manner as to
717 avoid conditions that could adversely affect its operation such as strong air currents from
718 opened doors, personnel traffic, or air streams from the heating, ventilating and air condition
719 system;

720
721 (-b-) be certified by an independent contractor according to the International Organization
722 of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for
723 operational efficiency at least every six months and when it is relocated, in accordance with the
724 manufacturer's specifications; and

725
726 (-c-) have pre-filters inspected periodically and replaced as needed, in accordance with
727 written policies and procedures and the manufacturer's specification, and the inspection and/or
728 replacement date documented.

729
730 (II) The compounding aseptic isolator or compounding aseptic containment isolator must
731 be placed in an ISO Class 8 buffer area unless the isolator meets all of the following conditions.

732
733 (-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during
734 dynamic operating conditions including transferring ingredients, components, and devices into
735 and out of the isolator and during preparation of compounded sterile preparations.

736
737 (-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical
738 exposure site must maintain ISO Class 5 levels during compounding operations.

739
740 (-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator
741 meets this standard when located in worse than ISO Class 7 environments.

742
743 (B) High-risk Preparations. In addition to the requirements in subparagraph (A)(i)(I) of this
744 paragraph, when high-risk preparations are compounded, the aseptic environment control
745 device(s) shall be located in a controlled area that maintains at least an ISO Class 7
746 environment.

747
748 (C) Automated compounding device(s). If automated compounding device(s) are used, the
749 pharmacy shall have a method to calibrate and verify the accuracy of automated compounding
750 devices used in aseptic processing and document the calibration and verification on a routine
751 basis.

752
753 (2) Security requirements.

754
755 (A) All areas occupied by a pharmacy shall be capable of being locked by key, combination or
756 other mechanical or electronic means to prohibit unauthorized access, when a pharmacist is not
757 on-site except as provided in subparagraph (B) of this paragraph.

758

759 (B) The pharmacy may authorize personnel to gain access to that area of the pharmacy
760 containing dispensed sterile radiopharmaceuticals, in the absence of the pharmacist, for the
761 purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy allows such
762 after-hours access, the area containing the dispensed sterile radiopharmaceuticals shall be an
763 enclosed and lockable area separate from the area containing undispensed prescription drugs.
764 A list of the authorized personnel having such access shall be in the pharmacy's policy and
765 procedure manual.

766
767 (C) Each pharmacist while on duty shall be responsible for the security of the prescription
768 department, including provisions for effective control against theft or diversion of prescription
769 drugs, and records for such drugs

770
771 (d) Prescription dispensing and delivery.

772
773 (1) Generic Substitution. A pharmacist may substitute on a prescription drug order issued for a
774 brand name product provided the substitution is authorized and performed in compliance with
775 Chapter 309 of this title (relating to Substitution of Drug Products).

776
777 (2) Prescription containers (immediate inner containers).

778
779 (A) A drug dispensed pursuant to a radioactive prescription drug order shall be dispensed in
780 an appropriate immediate inner container as follows.

781
782 (i) If a drug is susceptible to light, the drug shall be dispensed in a light-resistant container.

783
784 (ii) If a drug is susceptible to moisture, the drug shall be dispensed in a tight container.

785
786 (iii) The container should not interact physically or chemically with the drug product placed in
787 it so as to alter the strength, quality, or purity of the drug beyond the official requirements.

788
789 (B) Immediate inner prescription containers or closures shall not be re-used.

790
791 (3) Delivery containers (outer containers).

792
793 (A) Prescription containers may be placed in suitable containers for delivery which will
794 transport the radiopharmaceutical safely in compliance with all applicable laws and regulations.

795
796 (B) Delivery containers may be re-used provided they are maintained in a manner to prevent
797 cross contamination.

798
799 (4) Labeling.

800
801 (A) The immediate inner container of a radiopharmaceutical shall be labeled with:

802
803 (i) standard radiation symbol;

804
805 (ii) the words "caution-radioactive material" or "danger, radioactive material";

806
807 (iii) the name of the radiopharmaceutical or its abbreviation; and

808
809 (iv) the unique identification number of the prescription.

810
811 (B) The outer container of a radiopharmaceutical shall be labeled with:
812
813 (i) the name, address, and phone number of the pharmacy;
814
815 (ii) the date dispensed;
816
817 (iii) the directions for use, if applicable;
818
819 (iv) the unique identification number of the prescription;
820
821 (v) the name of the patient if known, or the statement, "for physician use" if the patient is
822 unknown;
823
824 (vi) the standard radiation symbol;
825
826 (vii) the words "caution-radioactive material" or "danger, radioactive material";
827
828 (viii) the name of the radiopharmaceutical or its abbreviation;
829
830 (ix) the amount of radioactive material contained in millicuries (mCi), microcuries (uCi), or
831 bequerels (Bq) and the corresponding time that applies to this activity, if different from the
832 requested calibration date and time;
833
834 (x) the initials or identification codes of the person preparing the product and the authorized
835 nuclear pharmacist who checked and released the final product unless recorded in the
836 pharmacy's data processing system. The record of the identity of these individuals shall not be
837 altered in the pharmacy's data processing system.
838
839 (xi) if a liquid, the volume in milliliters;
840
841 (xii) the requested calibration date and time; and
842
843 (xiii) the expiration date and/or time.
844
845 (C) The amount of radioactivity shall be determined by radiometric methods for each
846 individual preparation immediately at the time of dispensing and calculations shall be made to
847 determine the amount of activity that will be present at the requested calibration date and time,
848 due to radioactive decay in the intervening period, and this activity and time shall be placed on
849 the label per requirements set out in paragraph (4) of this subsection.
850
851 (e) Equipment. The following minimum equipment is required in a nuclear pharmacy:
852
853 (1) vertical laminar flow hood;
854
855 (2) dose calibrator;
856
857 (3) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that
858 proper storage requirements are met, if sterile preparations are stored in the refrigerator;
859

- 860 (4) if applicable, a Class A prescription balance, or analytical balance and weights. Such
861 balance shall be properly maintained and subject to periodic inspection by the board.
862
- 863 (5) scintillation analyzer;
864
- 865 (6) microscope and hemocytometer;
866
- 867 (7) equipment and utensils necessary for the proper compounding of prescription drug or
868 medication orders. Such equipment and utensils used in the compounding process shall be:
869
- 870 (A) of appropriate design, appropriate capacity, and be operated within designed operational
871 limits;
872
- 873 (B) of suitable composition so that surfaces that contact components, in-process material, or
874 drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity,
875 strength, quality, or purity of the drug product beyond acceptable standards;
876
- 877 (C) cleaned and sanitized immediately prior to each use; and
878
- 879 (D) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;
880
- 881 (8) appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic
882 waste from the preparation of chemotherapeutic agents, and/or biohazardous waste;
883
- 884 (9) all necessary supplies, including:
885
- 886 (A) disposable needles, syringes, and other aseptic mixing;
887
- 888 (B) disinfectant cleaning solutions;
889
- 890 (C) hand washing agents with bactericidal action;
891
- 892 (D) disposable, lint free towels or wipes;
893
- 894 (E) appropriate filters and filtration equipment;
895
- 896 (F) cytotoxic spill kits, if applicable; and
897
- 898 (G) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.
899
- 900 (10) adequate glassware, utensils, gloves, syringe shields and remote handling devices, and
901 adequate equipment for product quality control;
902
- 903 (11) adequate shielding material;
904
- 905 (12) data processing system including a printer or comparable equipment;
906
- 907 (13) radiation dosimeters for visitors and personnel and log entry book;
908

909 (14) exhaust/fume hood with monitor, for storage and handling of all volatile radioactive drugs
910 if applicable, to be determined by the Texas Department of State Health Services, Radiation
911 Control Program; and

912
913 (15) adequate radiation monitor(s).

914
915 (f) Library. A nuclear pharmacy shall maintain a reference library which shall include the
916 following in hard copy or electronic format:

917
918 (1) current copies of the following:

919 (A) Texas Pharmacy Act and rules;

920 (B) Texas Dangerous Drug Act and rules;

921 (C) Texas Controlled Substances Act and rules; and

922 (D) Federal Controlled Substances Act and rules (or official publication describing the
923 requirements of the Federal Controlled Substances Act and rules);

924 (2) a current or updated version of Chapter 797 of the USP/NF concerning Pharmacy
925 Compounding Sterile Preparations and other USP chapters applicable to the practice (e.g., USP
926 Chapter 823 Radiopharmaceuticals for Positron Emission Tomography - Compounding); and

927 (3) a minimum of one current or updated text dealing with nuclear medicine science.

928
929 (g) Radiopharmaceuticals and/or radioactive materials.

930 (1) General requirements.

931 (A) Radiopharmaceuticals may only be dispensed pursuant to a radioactive prescription drug
932 order.

933 (B) An authorized nuclear pharmacist may distribute radiopharmaceuticals to authorized
934 users for patient use. A nuclear pharmacy may also furnish radiopharmaceuticals for
935 departmental or physicians' use if such authorized users maintain a Texas radioactive materials
936 license, and the radiopharmaceutical is labeled "for physician use," provided such distribution is
937 documented in the control system.

938 (C) An authorized nuclear pharmacist may transfer to authorized users radioactive materials
939 not intended for drug use in accordance with the requirements of the Texas Department of State
940 Health Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1,
941 Subchapter F, §289.252 relating to Licensing of Radioactive Material,.

942 (D) The transportation of radioactive materials from the nuclear pharmacy must be in
943 accordance with current state and federal transportation regulations.

944 (2) Procurement and storage.

945 (A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of
946 drugs, but may receive input from other appropriate staff relative to such responsibility.

960
961 (B) Prescription drugs and devices shall be stored within the prescription department or a
962 locked storage area.

963
964 (C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and
965 §291.15 of this title (relating to Storage of Drugs).

966
967 (3) Out-of-date and other unusable drugs or devices.

968
969 (A) Any drug or device bearing an expiration date shall not be dispensed beyond the
970 expiration date of the drug or device.

971
972 (B) Outdated and other unusable drugs or devices shall be removed from dispensing stock
973 and shall be quarantined together until such drugs or devices are disposed of properly.

974
975 (h) Loading bulk drugs into automated compounding devices.

976
977 (1) Automated compounding device may be loaded with bulk drugs only by an authorized
978 nuclear pharmacist or by supportive personnel under the direction and direct supervision of an
979 authorized pharmacist.

980
981 (2) The label of an automated compounding device container shall indicate the brand name
982 and strength of the drug; or if no brand name, then the generic name, strength, and name of the
983 manufacturer or distributor.

984
985 (3) Records of loading bulk drugs into an automated compounding device shall be maintained
986 to show:

987
988 (A) name of the drug, strength, and dosage form;

989
990 (B) manufacturer or distributor;

991
992 (C) manufacturer's lot number;

993
994 (D) expiration date;

995
996 (E) quantity added to the automated compounding device;

997
998 (F) date of loading;

999
1000 (G) name, initials, or electronic signature of the person loading the automated compounding
1001 device; and

1002
1003 (H) name, initials, or electronic signature of the responsible authorized nuclear pharmacist.

1004
1005 (4) The automated compounding device shall not be used until an authorized nuclear
1006 pharmacist verifies that the system is properly loaded and affixes his or her signature or
1007 electronic signature to the record specified in paragraph (3) of this subsection.

1008
1009 (i) Sterile radiopharmaceuticals.

1010

- 1011 (1) Beyond-use date.
1012
1013 (A) The beyond-use date assigned shall be based on:
1014
1015 (i) established manufacturer's guidelines;
1016
1017 (ii) published literature; or
1018
1019 (iii) in-house or contracted stability studies.
1020
1021 (B) The method for establishing beyond-use dates shall be documented.
1022
1023 (2) Radioactive Drug Quality control. There shall be a documented, ongoing quality control
1024 program that monitors and evaluates personnel performance, equipment and facilities.
1025 Procedures shall be in place to assure that the pharmacy is capable of consistently preparing
1026 radiopharmaceuticals which are sterile and stable. Quality control procedures shall include, but
1027 are not limited to, the following:
1028
1029 (A) recall procedures;
1030
1031 (B) storage and dating;
1032
1033 (C) documentation of appropriate functioning of refrigerator, freezer, and other equipment;
1034
1035 (D) documentation of aseptic environmental control device(s) certification at least every year
1036 and the regular replacement of pre-filters as necessary;
1037
1038 (E) a process to evaluate and confirm the quality of the prepared radiopharmaceutical; and
1039
1040 (F) documentation of facility maintenance such as cleaning and environmental testing.
1041
1042
1043 **§291.55 Records**
1044
1045 (a) Maintenance of records.
1046
1047 (1) Every inventory or other record required to be kept under this section shall be:
1048
1049 (A) kept by the pharmacy and be available, for at least two years from the date of such
1050 inventory or record, for inspecting and copying by the board or its representative, and other
1051 authorized local, state, or federal law enforcement agencies; and
1052
1053 (B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the
1054 Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format,
1055 the requested records must be provided in a mutually agreeable electronic format it specifically
1056 requested by the board or its representative. Failure to provide the records set out in this
1057 subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep
1058 and maintain records in violation of the Act.
1059
1060 (2) Records of controlled substances listed in Schedules I and II shall be maintained
1061 separately from all other records of the pharmacy.

1062
1063 (3) Records of controlled substances, other than original prescription drug orders, listed in
1064 Schedules III - V shall be maintained separately or readily retrievable from all other records of
1065 the pharmacy. For purposes of this subsection, "readily retrievable" means that the controlled
1066 substances shall be asterisked, red-lined, or in some other manner readily identifiable apart
1067 from all other items appearing on the record.

1068
1069 (4) Records, except when specifically required to be maintained in original or hard-copy form,
1070 may be maintained in an alternative data retention system, such as a data processing system or
1071 direct imaging system provided:

1072
1073 (A) the records maintained in the alternative system contain all of the information required on
1074 the manual record; and

1075
1076 (B) the data processing system is capable of producing a hard copy of the record upon the
1077 request of the board, its representative, or other authorized local, state, or federal law
1078 enforcement or regulatory agencies.

1079
1080 (b) Prescriptions.

1081
1082 (1) Professional responsibility. Pharmacists shall exercise sound professional judgment with
1083 respect to the accuracy and authenticity of any radioactive prescription drug order they
1084 dispense. If the pharmacist questions the accuracy or authenticity of a radioactive prescription
1085 drug order, he/she shall verify the order with the practitioner prior to dispensing.

1086
1087 (2) Verbal radioactive prescription drug orders.

1088
1089 (A) Only an authorized nuclear pharmacist or a pharmacist-intern under the direct supervision
1090 of an authorized nuclear pharmacist may receive from a practitioner or a practitioner's
1091 designated agent:

1092
1093 (i) a verbal therapeutic prescription drug order; or

1094
1095 (ii) a verbal diagnostic prescription drug order in instances where patient specificity is
1096 required for patient safety (e.g., radiolabeled blood products, radiolabeled antibodies).

1097
1098 (B) A practitioner shall designate in writing the name of each agent authorized by the
1099 practitioner to communicate prescriptions verbally for the practitioner. The practitioner shall
1100 maintain at the practitioner's usual place of business a list of the designated agents. The
1101 practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a
1102 specific agent on the pharmacist's request.

1103
1104 (C) A pharmacist may not dispense a verbal radioactive prescription drug order for a
1105 dangerous drug or a controlled substance issued by a practitioner licensed in the Dominion of
1106 Canada or the United Mexican States unless the practitioner is also licensed in Texas.

1107
1108 (3) Radioactive prescription drug orders issued by practitioners in another state.

1109
1110 (A) Dangerous drug prescription orders. A pharmacist may dispense a radioactive
1111 prescription drug order for dangerous drugs issued by practitioners in a state other than Texas

1112 in the same manner as radioactive prescription drug orders for dangerous drugs issued by
1113 practitioners in Texas are dispensed.

1114
1115 (B) Controlled substance prescription drug orders. A pharmacist may dispense radioactive
1116 prescription drug orders for controlled substances in Schedule III, IV, or V issued by a
1117 practitioner in another state provided:

1118
1119 (i) the radioactive prescription drug order is written, oral, or telephonically or electronically
1120 communicated prescription as allowed by the DEA issued by a person practicing in another
1121 state and licensed by another state as a physician, dentist, veterinarian, or podiatrist, who has a
1122 current federal Drug Enforcement Administration registration number, and who may legally
1123 prescribe Schedule III, IV, or V controlled substances in such other state;

1124
1125 (ii) the radioactive prescription drug order is not dispensed more than six months from the
1126 initial date of issuance.

1127
1128 (4) Radioactive prescription drug orders issued by practitioners in the United Mexican States or
1129 the Dominion of Canada.

1130
1131 (A) Controlled substance prescription drug orders. A pharmacist may not dispense a
1132 radioactive prescription drug order for a Schedule II, III, IV, or V controlled substance issued by
1133 a practitioner licensed in the Dominion of Canada or the United Mexican States.

1134
1135 (B) Dangerous drug prescription drug orders. A pharmacist may dispense a radioactive
1136 prescription drug order for a dangerous drug issued by a person licensed in the Dominion of
1137 Canada or the United Mexican States as a physician, dentist, veterinarian, or podiatrist provided
1138 the radioactive prescription drug order is an original written prescription.

1139
1140 (C) Prescription drug orders for Schedule II controlled substances. No Schedule II controlled
1141 substance may be dispensed without a written prescription drug order of a practitioner on a
1142 official prescription form as required by the Texas Controlled Substances Act, §481.075.

1143
1144 (5) Electronic radioactive prescription drug orders. For the purpose of this paragraph,
1145 electronic radioactive prescription drug orders shall be considered the same as verbal
1146 radioactive prescription drug orders.

1147
1148 (A) An electronic radioactive prescription drug order may be transmitted by a practitioner or a
1149 practitioner's designated agent:

1150
1151 (i) directly to a pharmacy; or

1152
1153 (ii) through the use of a data communication device provided:

1154
1155 (I) the confidential prescription information is not altered during transmission; and

1156
1157 (II) confidential patient information is not accessed or maintained by the operator of the
1158 data communication device other than for legal purposes under federal and state law.

1159
1160 (B) A practitioner shall designate in writing the name of each agent authorized by the
1161 practitioner to electronically transmit prescriptions for the practitioner. The practitioner shall
1162 maintain at the practitioner's usual place of business a list of the designated agents. The

1163 practitioner shall provide a pharmacist with a copy of the practitioner's written authorization for a
1164 specific agent on the pharmacist's request.

1165
1166 (C) A pharmacist may not dispense an electronic radioactive prescription drug order for a:
1167

1168 (i) Schedule II controlled substance except as authorized for faxed prescriptions in
1169 §481.074, Health and Safety Code; or

1170
1171 (ii) dangerous drug or controlled substance issued by a practitioner licensed in the Dominion
1172 of Canada or the United Mexican States unless the practitioner is also licensed in Texas.
1173

1174 (6) Original prescription drug order records.

1175
1176 (A) Original prescriptions shall be maintained and readily retrievable by the pharmacy and
1177 remain accessible for a period of two years from the date of filling.
1178

1179 (B) If an original prescription drug order is changed, such prescription order shall be invalid
1180 and of no further force and effect; if additional drugs are to be dispensed, a new prescription
1181 drug order with a new and separate number is required.
1182

1183 (C) Original prescriptions shall be maintained in one of the following formats:
1184

1185 (i) in three separate files as follows:
1186

1187 (I) prescriptions for controlled substances listed in Schedule II;

1188 (II) prescriptions for controlled substances listed in Schedule III - V; and
1189

1190 (III) prescriptions for dangerous drugs and nonprescription drugs; or
1191

1192
1193 (ii) within a patient medication record system provided that original prescriptions for
1194 controlled substances are maintained separate from original prescriptions for noncontrolled
1195 substances and prescriptions for Schedule II controlled substances are maintained separate
1196 from all other original prescriptions.
1197

1198 (D) Original prescription records other than prescriptions for Schedule II controlled
1199 substances may be stored on microfilm, microfiche, or other system which is capable of
1200 producing a direct image of the original prescription record, e.g., digitalized imaging system. If
1201 original prescription records are stored in a direct imaging system, the following is applicable.
1202

1203 (i) The original prescription records must be maintained and readily retrievable as specified
1204 in subparagraph (C) of this paragraph.
1205

1206 (ii) The pharmacy must provide immediate access to equipment necessary to render the
1207 records easily readable.
1208

1209 (7) Prescription drug order information.

1210
1211 (A) All original radioactive prescription drug orders shall bear:

1212 (i) name of the patient, if applicable at the time of the order;
1213

1214
1215 (ii) name of the institution;
1216
1217 (iii) name, and if for a controlled substance, the address and DEA registration number of the
1218 practitioner;
1219
1220 (iv) name of the radiopharmaceutical;
1221
1222 (v) amount of radioactive material contained in millicuries (mCi), microcuries (uCi), or
1223 becquerels (Bq) and the corresponding time that applies to this activity, if different than the
1224 requested calibration date and time;
1225
1226 (vi) date and time of calibration; and
1227
1228 (vii) date of issuance.
1229
1230 (B) At the time of dispensing, a pharmacist is responsible for the addition of the following
1231 information to the original prescription:
1232
1233 (i) unique identification number of the prescription drug order;
1234
1235 (ii) initials or identification code of the person who compounded the sterile
1236 radiopharmaceutical and the pharmacist who checked and released the product unless
1237 maintained in a readily retrievable format;
1238
1239 (iii) name, quantity, lot number, and expiration date of each product used in compounding
1240 the sterile radiopharmaceutical; and
1241
1242 (iv) date of dispensing, if different from the date of issuance.
1243
1244 (8) Refills. A radioactive prescription drug order must be filled from an original prescription
1245 which may not be refilled.
1246
1247 (c) Policy and procedure manual.
1248
1249 (1) All nuclear pharmacies shall maintain a policy and procedure manual. The nuclear
1250 pharmacy policy and procedure manual is a compilation of written policy and procedure
1251 statements.
1252
1253 (2) A technical operations manual governing all nuclear pharmacy functions shall be prepared.
1254 It shall be continually revised to reflect changes in techniques, organizations, etc. All pharmacy
1255 personnel shall be familiar with the contents of the manual.
1256
1257 (3) The nuclear pharmacy policies and procedures manual shall be prepared by the
1258 pharmacist-in-charge with input from the affected personnel and from other involved staff and
1259 committees to govern procurement, preparation, distribution, storage, disposal, and control of all
1260 drugs used and the need for policies and procedures relative to procurement of multisource
1261 items, inventory, investigational drugs, and new drug applications.
1262
1263 (d) Other records. Other records to be maintained by a pharmacy:
1264

1265 (1) a permanent log of the initials or identification codes which will identify each dispensing
1266 pharmacist by name (the initials or identification code shall be unique to ensure that each
1267 pharmacist can be identified, i.e., identical initials or identification codes shall not be used);
1268
1269 (2) copy 3 of DEA order form (DEA 222) which has been properly dated, initialed, and filed,
1270 and all copies of each unaccepted or defective order form and any attached statements or other
1271 documents;
1272
1273 (3) a hard copy of the power of attorney to sign DEA 222 order forms (if applicable);
1274
1275 (4) suppliers' invoices of controlled substances; a pharmacist shall verify that the controlled
1276 drugs listed on the invoices were actually received by clearly recording his/her initials and the
1277 actual date of receipt of the controlled substances;
1278
1279 (5) suppliers' credit memos for controlled substances and dangerous drugs;
1280
1281 (6) a hard copy of inventories required by §291.17 of this title (relating to Inventory
1282 Requirements);
1283
1284 (7) hard-copy reports of surrender or destruction of controlled substances and/or dangerous
1285 drugs to an appropriate state or federal agency;
1286
1287 (8) records of distribution of controlled substances and/or dangerous drugs to other
1288 pharmacies, practitioners, or registrants; and
1289
1290 (9) a hard copy of any notification required by the Texas Pharmacy Act or these sections,
1291 including, but not limited to, the following:
1292
1293 (A) reports of theft or significant loss of controlled substances to DEA, DPS, and the board;
1294
1295 (B) notifications of a change in pharmacist-in-charge of a pharmacy; and
1296
1297 (C) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs,
1298 medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and
1299 disease.
1300
1301 (e) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping
1302 system for invoices and financial data shall comply with the following procedures.
1303
1304 (1) Controlled substance records. Invoices and financial data for controlled substances may be
1305 maintained at a central location provided the following conditions are met.
1306
1307 (A) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by
1308 registered or certified mail to the divisional director of the Drug Enforcement Administration as
1309 required by the Code of Federal Regulations, Title 21, §1304.04(a), and submits a copy of this
1310 written notification to the Texas State Board of Pharmacy. Unless the registrant is informed by
1311 the divisional director of the Drug Enforcement Administration that permission to keep central
1312 records is denied, the pharmacy may maintain central records commencing 14 days after
1313 receipt of notification by the divisional director.
1314

1315 (B) The pharmacy maintains a copy of the notification required in subparagraph (A) of this
1316 paragraph.

1317
1318 (C) The records to be maintained at the central record location shall not include executed
1319 DEA order forms, prescription drug orders, or controlled substance inventories, which shall be
1320 maintained at the pharmacy.

1321
1322 (2) Dangerous drug records. Invoices and financial data for dangerous drugs may be
1323 maintained at a central location.

1324
1325 (3) Access to records. If the records are kept on microfilm, computer media, or in any form
1326 requiring special equipment to render the records easily readable, the pharmacy shall provide
1327 access to such equipment with the records.

1328
1329 (4) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the
1330 pharmacy location within two business days of written request of a board agent or any other
1331 authorized official.

1332
1333 (5) Ownership of pharmacy records. For purposes of these sections, a pharmacy licensed
1334 under the Act is the only entity which may legally own and maintain prescription drug records.