

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS A PROPOSED RULE

Short Title: Nuclear Pharmacy

Rule Numbers: §§291.52, 291.53, 291.54

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, updated the definitions; require nuclear pharmacies to be inspected prior to renewal; and clarify the requirements for compounding non-sterile radiopharmaceuticals.

1 CHAPTER 291 PHARMACIES
2 SUBCHAPTER C NUCLEAR PHARMACY (CLASS B)

3
4
5 **§291.52 Definitions**

6
7 The following words and terms, when used in this subchapter, shall have the following
8 meanings, unless the context clearly indicates otherwise. Any term not defined in this section
9 shall have the definition set forth in the Act, §551.003.

10
11 (1) – (6) (No change.)

12
13 (7) Aseptic processing-- **A mode of processing pharmaceutical and medical products that**
14 **involves the separate sterilization of the product and of the package (containers–**
15 **closures or packaging material for medical devices) and the transfer of the product into**
16 **the container and its closure under at least ISO Class 5 conditions.** [~~The technique~~
17 ~~involving procedures designed to preclude contamination of drugs, packaging, equipment, or~~
18 ~~supplies by microorganisms during processing.~~]

19
20 (8) – (13) (No change.)

21
22 (14) Clean room [~~or controlled area~~]-A room in which the concentration of airborne particles is
23 controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the
24 environment are monitored so that a microbial level for air, surface, and personnel gear are not
25 exceeded for a specified cleanliness class.

26
27 (15) – (17) (No change.)

28
29 (18) Critical site-- **A location that includes any component or fluid pathway surfaces (e.g.,**
30 **vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs)**
31 **exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered),**
32 **moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial**
33 **particulate contamination of the critical site increases with the size of the openings and**
34 **exposure time.** [~~Sterile ingredients of compounded sterile preparations and locations on~~
35 ~~devices and components used to prepare, package, and transfer compounded sterile~~
36 ~~preparations that provide opportunity for exposure to contamination.~~]

37
38 (19) – (43) (No change.)

39
40 **§291.53 Personnel**

41
42 (a) – (b) (No change.)

43
44 (c) Authorized nuclear pharmacists.

45
46 (1) (No change.)

47
48 (2) Special requirements for compounding **of non-radiopharmaceuticals preparations.**

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

53
54 (B) Sterile Preparations. All pharmacists engaged in compounding sterile **non-**
55 radiopharmaceuticals shall meet the training requirements specified in §291.133 of this title
56 (relating to Pharmacies Compounding Sterile Preparations).

57
58 (3) (No change.)

59
60 (d) Pharmacy Technicians and Pharmacy Technician Trainees.

61
62 (1) (No change.)

63
64 (2) Special requirements for compounding **of non-radiopharmaceuticals preparations.**

65
66 (A) Non-sterile preparations. All pharmacy technicians and pharmacy technician trainees
67 engaged in compounding non-sterile **non-**radiopharmaceuticals shall meet the training
68 requirements specified in §291.131 of this title.

69
70 (B) Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged
71 in compounding sterile **non-**radiopharmaceuticals shall meet the training requirements specified
72 in §291.133 of this title.

73
74 (3) – (4) (No change.)

75
76 ~~[(e) Special education, training, and evaluation requirements for pharmacy personnel
77 compounding or responsible for the direct supervision of pharmacy personnel compounding
78 sterile radiopharmaceuticals. All pharmacy personnel preparing sterile radiopharmaceuticals
79 shall meet the training requirements specified in §291.133 of this title.]~~

80 81 **§291.54 Operational Standards**

82
83 (a) Licensing requirements.

84
85 (1) – (3) (No change.)

86
87 **(4) A Class B pharmacy may not renew a pharmacy license unless the pharmacy has**
88 **been inspected by the board within the last renewal period.**

89
90 **(5)** ~~[(4)]~~ A Class B pharmacy which changes ownership shall notify the board within ten days of
91 the change of ownership and apply for a new and separate license as specified in §291.3 of this
92 title (relating to Required Notifications).

93
94 **(6)** ~~[(5)]~~ A Class B pharmacy which changes location and/or name shall notify the board within
95 ten days of the change and file for an amended license as specified in §291.3 of this title.

96
97 **(7)** ~~[(6)]~~ A Class B pharmacy owned by a partnership or corporation which changes managing
98 officers shall notify the board in writing of the names of the new managing officers within ten
99 days of the change, following the procedures in §291.3 of this title.

100

101 **(8)** ~~[(7)]~~ A Class B pharmacy shall notify the board in writing within ten days of closing, following
102 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

103
104 **(9)** ~~[(8)]~~ A separate license is required for each principal place of business and only one
105 pharmacy license may be issued to a specific location.

106
107 **(10)** ~~[(9)]~~ A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
108 charged for the issuance and renewal of a license and the issuance of an amended license.

109
110 **(11)** ~~[(10)]~~ A Class B pharmacy, licensed under the provisions of the Act, §560.051(a)(2), which
111 also operates another type of pharmacy which would otherwise be required to be licensed under
112 the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a
113 license for such other type of pharmacy; provided, however, such licensee is required to comply
114 with the provisions of §291.31 of this title (relating to Definitions); §291.32 of this title (relating to
115 Personnel); §291.33 of this title (relating to Operational Standards); §291.34 of this title (relating
116 to Records); and §291.35 of this title (relating to Official Prescription Requirements), to the
117 extent such rules are applicable to the operation of the pharmacy.

118
119 **(12)** ~~[(11)]~~ A Class B (nuclear) pharmacy engaged in the compounding of non-sterile non-
120 radioactive preparations shall comply with the provisions of §291.131 of this title (relating to
121 Pharmacies Compounding Non-Sterile Preparations).

122
123 **(13)** ~~[(12)]~~ A Class B (nuclear) pharmacy engaged in the compounding of sterile non-
124 radioactive preparations shall comply with the provisions of §291.133 of this title (relating to
125 Pharmacies Compounding Sterile Preparations).

126
127 (b) Risk levels for compounded sterile radiopharmaceuticals. Risk Levels for sterile
128 compounded radiopharmaceuticals shall be as listed below.

129
130 (1) Low-risk level compounded sterile radiopharmaceuticals.

131
132 (A) Low-risk level compounded sterile radiopharmaceuticals are those compounded under all
133 of the following conditions.

134
135 (i) The compounded sterile preparations are compounded with aseptic manipulations
136 entirely within ISO Class 5 or better air quality using only sterile ingredients, products,
137 components, and devices.

138
139 (ii) The compounding involves only transfer, measuring, and mixing manipulations with
140 closed or sealed packaging systems that are performed promptly and attentively.

141
142 (iii) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on
143 vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile
144 administration devices and packages of other sterile products.

145
146 ~~[(iv) For a low-risk preparation, in the absence of passing a sterility test, the storage periods
147 cannot exceed the following periods: before administration, 48 hours at controlled room
148 temperature, for not more than 14 days if stored in cold temperatures, and for 45 days if stored
149 in a frozen state at minus 20 degrees Celsius or colder. For delayed activation device systems,
150 the storage period begins when the device is activated.]~~

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

155
156 (2) Medium-risk level compounded sterile radiopharmaceuticals.

157
158 (A) Medium-risk level compounded sterile radiopharmaceuticals are those compounded
159 aseptically under low-risk conditions and one or more of the of the following conditions exists.

160
161 (i) Multiple individual or small doses of sterile products are combined or pooled to prepare a
162 compounded sterile radiopharmaceuticals that will be administered either to multiple patients or
163 to one patient on multiple occasions.

164
165 (ii) The compounding process includes complex aseptic manipulations other than the single-
166 volume transfer.

167
168 (iii) The compounding process requires unusually long duration, such as that required to
169 complete the dissolution or homogenous mixing.

170
171 (iv) The sterile compounded radiopharmaceuticals do not contain broad-spectrum
172 bacteriostatic substances, and they are administered over several days.

173
174 ~~[(v) For a medium-risk preparation, in the absence of passing sterility test, the storage
175 periods cannot exceed the following time periods: before administration, the compounded sterile
176 preparations are properly stored and are exposed for not more than 30 hours at controlled room
177 temperature for not more than 7 days at a cold temperature, and for 45 days in solid frozen
178 state at minus 20 degrees or colder.]~~

179
180 (B) Examples of medium-risk compounding include the following.

181
182 (i) Compounding of total parenteral nutrition fluids using a manual or automated device
183 during which there are multiple injections, detachments, and attachments of nutrient source
184 products to the device or machine to deliver all nutritional components to a final sterile
185 container.

186
187 (ii) Filling of reservoirs of injection and infusion devices with multiple sterile drug products
188 and evacuations of air from those reservoirs before the filled device is dispensed.

189
190 (iii) Filling of reservoirs of injection and infusion devices with volumes of sterile drug
191 solutions that will be administered over several days at ambient temperatures between 25 and
192 40 degrees Celsius (77 and 104 degrees Fahrenheit).

193
194 (iv) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or
195 product.

196
197 (3) High-risk level compounded sterile radiopharmaceuticals.

198
199 (A) High-risk level compounded sterile radiopharmaceuticals are those compounded under
200 any of the following conditions.

201

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

204
205 (ii) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior
206 to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or
207 partially used packages of manufactured sterile products that lack antimicrobial preservatives.

208
209 (iii) Non-sterile preparations are exposed no more than 6 hours before being sterilized.

210
211 (iv) It is assumed, and not verified by examination of labeling and documentation from
212 suppliers or by direct determination, that the chemical purity and content strength of ingredients
213 meet their original or compendial specifications in unopened or in opened packages of bulk
214 ingredients.

215
216 ~~[(v) For a high-risk preparation, in the absence of passing sterility test, the storage periods
217 cannot exceed the following time periods: before administration, the compounded sterile
218 preparations are properly stored and are exposed for not more than 24 hours at controlled room
219 temperature for not more than 3 days at a cold temperature, and for 45 days in solid frozen
220 state at minus 20 degrees or colder.]~~

221
222 (B) Examples of high-risk compounding include the following.

223
224 (i) Dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be
225 terminally sterilized.

226
227 (ii) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior
228 to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or
229 partially used packages of manufactured sterile products that lack antimicrobial preservatives.

230
231 (iii) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is
232 performed.

233
234 (iv) Assuming, without appropriate evidence or direct determination, that packages of bulk
235 ingredients contain at least 95% by weight of their active chemical moiety and have not been
236 contaminated or adulterated between uses.

237
238 (c) – (f) (No change.)

239
240 (g) Radiopharmaceuticals and/or radioactive materials.

241
242 (1) General requirements.

243
244 (A) – (B) (No change.)

245
246 (C) An authorized nuclear pharmacist may transfer to authorized users radioactive materials
247 not intended for drug use in accordance with the requirements of the Texas Department of State
248 Health Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1,
249 Subchapter F, §289.252 relating to Licensing of Radioactive Material^[7].

250
251 (D) (No change.)

252

253 (2) – (No change.)
254
255 (h) – (i) (No change.)
256