

1
2 **TITLE 22 EXAMINING BOARDS**
3 **PART 15 TEXAS STATE BOARD OF PHARMACY**
4 **CHAPTER 291 PHARMACIES**
5 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

6
7 **§291.33 Operational Standards**

8
9 (a) Licensing requirements.

10
11 (1) – (8) (No change.)

12
13 (9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply
14 with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile
15 Preparations).

16
17 (10) **Prior to June 1, 2014, a [A]** Class A pharmacy engaged in the compounding of sterile
18 preparations shall comply with the provisions of §291.133 of this title (relating to Pharmacies
19 Compounding Sterile Preparations).

20
21 **(11) Effective June 1, 2014, a Class A pharmacy shall not compound sterile preparations**
22 **unless the pharmacy has applied and obtained a Class A-S pharmacy license.**

23
24 **(12)** ~~[(14)]~~ A Class A pharmacy engaged in the provision of remote pharmacy services,
25 including storage and dispensing of prescription drugs, shall comply with the provisions of
26 §291.121 of this title (relating to Remote Pharmacy Services).

27
28 **(13)** ~~[(12)]~~ Class A pharmacy engaged in centralized prescription dispensing and/or prescription
29 drug or medication order processing shall comply with the provisions of §291.123 of this title
30 (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of
31 this title (relating to Centralized Prescription Dispensing).

32
33 (c) – (i) (No change.)
34
35

36 **§291.36 Pharmacies Compounding Sterile Preparations (Class A-S)**

37
38 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
39 **preparations shall be designated as a Class A-S pharmacy.**

40
41 **(1) A Class A-S pharmacy shall register annually or biennially with the board on a**
42 **pharmacy license application provided by the board, following the procedures as**
43 **specified in §291.1 of this title (relating to Pharmacy License Application). A Class A-S**
44 **license may not be issued unless the pharmacy has been inspected by the board to**
45 **ensure the pharmacy meets the requirements as specified in §291.133 of this chapter**
46 **(relating to Pharmacies Compounding Sterile Preparations).**

47
48 **(2) A Class A-S pharmacy may not renew a pharmacy license unless the pharmacy has**
49 **been inspected by the board within the last renewal period.**
50

51 (3) A Class A-S pharmacy which changes ownership shall notify the board within ten
52 days of the change of ownership and apply for a new and separate license as specified in
53 §291.3 of this title (relating to Required Notifications).

54
55 (4) A Class A-S pharmacy which changes location and/or name shall notify the board
56 within ten days of the change and file for an amended license as specified in §291.3 of
57 this title.

58
59 (5) A Class A-S pharmacy owned by a partnership or corporation which changes
60 managing officers shall notify the board in writing of the names of the new managing
61 officers within ten days of the change, following the procedures as specified in §291.3 of
62 this title.

63
64 (6) A Class A-S pharmacy shall notify the board in writing within ten days of closing,
65 following the procedures as specified in §291.5 of this title (relating to Closing a
66 Pharmacy).

67
68 (7) A separate license is required for each principal place of business and only one
69 pharmacy license may be issued to a specific location.

70
71 (8) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
72 charged for the issuance and renewal of a license and the issuance of an amended
73 license.

74
75 (9) A Class A-S pharmacy which would otherwise be required to be licensed under the
76 Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply
77 with the provisions of §291.31 of this subchapter (relating to Definitions), §291.32 of this
78 subchapter (relating to Personnel), §291.33 of this subchapter (relating to Operational
79 Standards), §291.34 of this subchapter (relating to Records), §291.35 of this subchapter
80 (relating to Official Prescription Records), and §291.133 of this title (relating to
81 Pharmacies Compounding Sterile Preparations).

82
83 (10) A Class A-S pharmacy engaged in the compounding of non-sterile preparations
84 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
85 Compounding Non-Sterile Preparations).

86
87 (11) A Class A-S pharmacy engaged in the provision of remote pharmacy services,
88 including storage and dispensing of prescription drugs, shall comply with the provisions
89 of §291.121 of this title (relating to Remote Pharmacy Services).

90
91 (12) A Class A-S pharmacy engaged in centralized prescription dispensing and/or
92 prescription drug or medication order processing shall comply with the provisions of
93 §291.123 of this title (relating to Centralized Prescription Drug or Medication Order
94 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
95

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER C NUCLEAR PHARMACY (CLASS B)

5
6 **§291.54 Operational Standards**

7
8 (a) Licensing requirements.

9
10 (1) – (10) (No change.)

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

15
16 (12) **Prior to June 1, 2014, a [A]-Class B [~~nuclear~~] pharmacy engaged in the compounding of**
17 **sterile non-radioactive preparations shall comply with the provisions of §291.133 of this title**
18 **(relating to Pharmacies Compounding Sterile Preparations).**

19
20 **(13) Effective June 1, 2014, a Class B pharmacy shall not compound sterile preparations**
21 **unless the pharmacy has applied and obtained a Class B-S pharmacy license.**

22
23 (b) – (i) (No change.)

24
25
26 **§291.56 Pharmacies Compounding Sterile Preparations (Class B-S)**

27
28 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
29 **preparations shall be designated as a Class B-S pharmacy.**

30
31 **(1) It is unlawful for a person to provide radioactive drug services unless such provision**
32 **is performed by a person licensed to act as an authorized nuclear pharmacist, as defined**
33 **by the board, or is a person acting under the direct supervision of an authorized nuclear**
34 **pharmacist acting in accordance with the Act and its rules, and the regulations of the**
35 **Texas Department of State Health Services, Radiation Control Program. Subsection (a) of**
36 **this section does not apply to:**

37 **(A) a licensed practitioner or his or her designated agent for administration to his or**
38 **her patient, provided no person may receive, possess, use, transfer, own, acquire, or**
39 **dispose of radiopharmaceuticals except as authorized in a specific or a general license**
40 **as provided in accordance with the requirements of the Texas Department of State Health**
41 **Services, Radiation Control Program, Texas Administrative Code, Title 25, Part 1,**
42 **Subchapter F, §289.252 relating to Licensing of Radioactive Material, or the Act;**

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

47
48 **(2) An applicant for a Class B-S pharmacy shall provide evidence to the board of the**
49 **possession of a Texas Department of State Health Services radioactive material license**
50 **or proof of application for a radioactive material license.**

52 (3) A Class B-S pharmacy shall register annually or biennially with the board on a
53 pharmacy license application provided by the board, following the procedures as
54 specified in §291.1 of this title (relating to Pharmacy License Application). A Class B-S
55 license may not be issued unless the pharmacy has been inspected by the board to
56 ensure the pharmacy meets the requirements as specified in §291.133 of this chapter
57 (relating to Pharmacies Compounding Sterile Preparations).

58
59 (4) A Class B-S pharmacy may not renew a pharmacy license unless the pharmacy has
60 been inspected by the board within the last renewal period.

61
62 (5) A Class B-S pharmacy which changes ownership shall notify the board within ten
63 days of the change of ownership and apply for a new and separate license as specified in
64 §291.3 of this title (relating to Required Notifications).

65
66 (6) A Class B-S pharmacy which changes location and/or name shall notify the board
67 within ten days of the change and file for an amended license as specified in §291.3 of
68 this title.

69
70 (7) A Class B-S pharmacy owned by a partnership or corporation which changes
71 managing officers shall notify the board in writing of the names of the new managing
72 officers within ten days of the change, following the procedures as specified in §291.3 of
73 this title.

74
75 (8) A Class B-S pharmacy shall notify the board in writing within ten days of closing,
76 following the procedures as specified in §291.5 of this title (relating to Closing a
77 Pharmacy).

78
79 (9) A separate license is required for each principal place of business and only one
80 pharmacy license may be issued to a specific location.

81
82 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
83 charged for the issuance and renewal of a license and the issuance of an amended
84 license.

85
86 (11) A Class B-S pharmacy which would otherwise be required to be licensed under the
87 Act, §560.051(a)(1) concerning Community Pharmacy (Class A) is required to comply
88 with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title
89 (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of
90 this title (relating to Records), and §291.35 of this title (relating to Official Prescription
91 Records), and §291.133 of this title (relating to Pharmacies Compounding Sterile
92 Preparations).

93
94 (12) A Class B-S pharmacy engaged in the compounding of non-sterile preparations
95 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
96 Compounding Non-Sterile Preparations).

97
98 (13) A Class B-S pharmacy engaged in the provision of remote pharmacy services,
99 including storage and dispensing of prescription drugs, shall comply with the provisions
100 of §291.121 of this title (relating to Remote Pharmacy Services).

102 (14) A Class B-S pharmacy engaged in centralized prescription dispensing and/or
103 prescription drug or medication order processing shall comply with the provisions of
104 §291.123 of this title (relating to Centralized Prescription Drug or Medication Order
105 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).
106

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER D INSTITUTIONAL PHARMACY (CLASS C)

5
6 **§291.74 Operational Standards**
7

8 (a) Licensing requirements.

9
10 (1) – (9) (No change.)

11
12 (10) A Class C ~~[(Institutional)]~~ pharmacy engaged in the compounding of non-sterile
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-sterile Preparations).

15
16 (11) **Prior to June 1, 2014, a** [A] Class C ~~[(Institutional)]~~ pharmacy engaged in the
17 compounding of sterile preparations shall comply with the provisions of §291.133 of this title
18 (relating to Pharmacies Compounding Sterile Preparations).

19
20 **(12) Effective June 1, 2014, a Class C pharmacy shall not compound sterile preparations**
21 **unless the pharmacy has applied and obtained a Class C-S pharmacy.**

22
23 **(13)** ~~[(12)]~~ A Class C ~~[(Institutional)]~~ pharmacy engaged in the provision of remote pharmacy
24 services, including storage and dispensing of prescription drugs, shall comply with the
25 provisions of §291.121 of this title (relating to Remote Pharmacy Services).

26
27 **(14)** ~~[(13)]~~ A Class C ~~[(Institutional)]~~ pharmacy engaged in centralized prescription dispensing
28 and/or prescription drug or medication order processing shall comply with the provisions of
29 §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing)
30 and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

31
32 **(15)** ~~[(14)]~~ A Class C ~~[(Institutional)]~~ pharmacy with an ongoing clinical pharmacy program that
33 proposes to allow a pharmacy technician to verify the accuracy of work performed by another
34 pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a
35 patient admitted to the hospital if the patient's orders have previously been reviewed and
36 approved by a pharmacist shall make application to the board as follows.

37
38 (A) The pharmacist-in-charge must submit an application on a form provided by the board,
39 containing the following information:

40
41 (i) name, address, and pharmacy license number;

42
43 (ii) name and license number of the pharmacist-in-charge;

44
45 (iii) name and registration numbers of the pharmacy technicians;

46
47 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to verify
48 the accuracy of work performed by another pharmacy technician;

49
50 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and
51

52 (vi) any other information specified on the application.

53
54 (B) The pharmacy may not allow a pharmacy technician to check the work of another
55 pharmacy technician until the board has reviewed and approved the application and issued an
56 amended license to the pharmacy.

57
58 (C) Every two years, in connection with the application for renewal of the pharmacy license,
59 the pharmacy shall provide updated documentation that the pharmacy continues to have an
60 ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this paragraph.

61
62 **(16)** ~~[(15)]~~ A rural hospital that wishes to allow a pharmacy technician to perform the duties
63 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to the
64 board as follows.

65
66 ~~[(A) For an initial applications prior to September 1, 2010, the pharmacist-in-charge must~~
67 ~~submit a letter to the board containing the following information:~~

68
69 ~~—(i) name, address, and pharmacy license number;~~

70
71 ~~—(ii) name and license number of the pharmacist-in-charge;~~

72
73 ~~—(iii) name and registration number of the pharmacy technicians;~~

74
75 ~~—(iv) a statement indicating that pharmacy technicians will be performing the duties specified~~
76 ~~in §291.73(e)(2)(D) of this title; and~~

77
78 ~~—(v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural~~
79 ~~hospital is either:~~

80
81 ~~—(I) located in a county with a population of 50,000 or less as defined by the United States~~
82 ~~Census Bureau in the most recent U.S. census; or~~

83
84 ~~—(II) designated by the Centers for Medicare and Medicaid Services as a critical access~~
85 ~~hospital, rural referral center, or sole community hospital.]~~

86
87 **(A)** ~~[(B) After September 1, 2010 and prior]~~ **Prior** to allowing a pharmacy technician to perform
88 the duties specified in §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an
89 application on a form provided by the board, containing the following information:

90
91 (i) name, address, and pharmacy license number;

92
93 (ii) name and license number of the pharmacist-in-charge;

94
95 (iii) name and registration number of the pharmacy technicians;

96
97 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to perform
98 the duties specified in §291.73(e)(2)(D) of this title;

99
100 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that the rural
101 hospital is either:

103 (I) located in a county with a population of 50,000 or less as defined by the United States
104 Census Bureau in the most recent U.S. census; or

105
106 (II) designated by the Centers for Medicare and Medicaid Services as a critical access
107 hospital, rural referral center, or sole community hospital; and

108
109 (vi) any other information specified on the application.

110
111 **(B)** ~~[(C)]~~ A rural hospital ~~[that makes application after September 1, 2010]~~ may not allow a
112 pharmacy technician to perform the duties specified in §291.73(e)(2)(D) of this title until the
113 board has reviewed and approved the application and issued an amended license to the
114 pharmacy.

115
116 **(C)** ~~[(C)]~~ Every two years in conjunction with the application for renewal of the pharmacy license,
117 the pharmacist-in-charge shall update the application for pharmacy technicians to perform the
118 duties specified in §291.73(e)(2)(D) of this title.

119
120 (b) – (j) (No change.)

121
122 **§291.76 Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center**

123
124 (a) – (c) (No change.)

125
126 (d) Operational standards.

127
128 (1) Licensing requirements.

129
130 (A) – (I) (No change.)

131
132 (J) An ASC pharmacy engaged in the compounding of non-sterile preparations shall comply
133 with the provisions of §291.131 of this title.

134
135 (K) **Prior to June 1, 2014, an [An]** ASC pharmacy engaged in the compounding of sterile
136 preparations shall comply with the provisions of §291.133 of this title.

137
138 **(L) Effective June 1, 2014, an ASC pharmacy must discontinue compounding sterile**
139 **preparations and shall be licensed as a Class C-S pharmacy.**

140
141 **(M)** ~~[(L)]~~ An ASC pharmacy engaged in the provision of remote pharmacy services, including
142 storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of
143 this title (relating to Remote Pharmacy Services).

144
145 **(N)** ~~[(M)]~~ An ASC pharmacy engaged in centralized prescription dispensing and/or
146 prescription drug or medication order processing shall comply with the provisions of §291.123 of
147 this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or
148 §291.125 of this title (relating to Centralized Prescription Dispensing).

149
150 (2) – (9) (No change.)

151
152 (e) (No change.)

§291.77 Pharmacies Compounding Sterile Preparations (Class C-S)

Licensing requirements. A pharmacy engaged in the compounding of sterile preparations shall be designated as a Class C-S pharmacy.

(1) A Class C-S pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application). A Class C-S license may not be issued unless the pharmacy has been inspected by the board to ensure the pharmacy meets the requirements as specified in §291.133 of this chapter (relating to Pharmacies Compounding Sterile Preparations).

(2) A Class C-S pharmacy may not renew a pharmacy license unless the pharmacy has been inspected by the board within the last renewal period.

(3) If the Class C-S pharmacy is owned or operated by a hospital management or consulting firm, the following conditions apply.

(A) The pharmacy license application shall list the hospital management or consulting firm as the owner or operator.

(B) The hospital management or consulting firm shall obtain DEA and DPS controlled substance registrations that are issued in their name, unless the following occurs:

(i) the hospital management or consulting firm and the facility cosign a contractual pharmacy service agreement which assigns overall responsibility for controlled substances to the facility; and

(ii) such hospital pharmacy management or consulting firm maintains dual responsibility for the controlled substances.

(4) A Class C-S pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(5) A Class C-S pharmacy which changes location and/or name shall notify the board within 10 days of the change and file for an amended license as specified in §291.3 of this title.

(6) A Class C-S pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change following the procedures in §291.3 of this title.

(7) A Class C-S pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

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

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

206
207 (10) A Class C-S pharmacy, licensed under the Act, §560.051(a)(3), which also operates
208 another type of pharmacy which would otherwise be required to be licensed under the
209 Act, §560.051(a)(1) (Community Pharmacy (Class A)) or the Act, §560.051(a)(2) (Nuclear
210 Pharmacy (Class B)), is not required to secure a license for the such other type of
211 pharmacy; provided, however, such licensee is required to comply with the provisions of
212 §291.31 of this subchapter (relating to Definitions), §291.32 of this subchapter (relating to
213 Personnel), §291.33 of this subchapter (relating to Operational Standards), §291.34 of this
214 subchapter (relating to Records), and §291.35 of this subchapter (relating to Official
215 Prescription Records), contained in Community Pharmacy (Class A), or §291.51 of this
216 title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title
217 (relating to Personnel), §291.54 of this title (relating to Operational Standards), and
218 §291.55 of this title (relating to Records), contained in Nuclear Pharmacy (Class B), to the
219 extent such sections are applicable to the operation of the pharmacy.

220
221 (11) A Class C-S pharmacy engaged in the compounding of non-sterile preparations
222 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
223 Compounding Non-sterile Preparations).

224
225 (12) A Class C-S pharmacy engaged in the provision of remote pharmacy services,
226 including storage and dispensing of prescription drugs, shall comply with the provisions
227 of §291.121 of this title (relating to Remote Pharmacy Services).

228
229 (13) A Class C-S pharmacy engaged in centralized prescription dispensing and/or
230 prescription drug or medication order processing shall comply with the provisions of
231 §291.123 of this title (relating to Central Prescription Drug or Medication Order
232 Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

233
234 (14) A Class C-S pharmacy with an ongoing clinical pharmacy program that proposes to
235 allow a pharmacy technician to verify the accuracy of work performed by another
236 pharmacy technician relating to the filling of floor stock and unit dose distribution
237 systems for a patient admitted to the hospital if the patient's orders have previously been
238 reviewed and approved by a pharmacist shall make application to the board as follows.

239
240 (A) The pharmacist-in-charge must submit an application on a form provided by the
241 board, containing the following information:

242
243 (i) name, address, and pharmacy license number;

244
245 (ii) name and license number of the pharmacist-in-charge;

246
247 (iii) name and registration numbers of the pharmacy technicians;

248
249 (iv) anticipated date the pharmacy plans to begin allowing a pharmacy technician to
250 verify the accuracy of work performed by another pharmacy technician;

251
252 (v) documentation that the pharmacy has an ongoing clinical pharmacy program; and

253
254 (vi) any other information specified on the application.

255
256 (B) The pharmacy may not allow a pharmacy technician to check the work of another
257 pharmacy technician until the board has reviewed and approved the application and
258 issued an amended license to the pharmacy.

259
260 (C) Every two years, in connection with the application for renewal of the pharmacy
261 license, the pharmacy shall provide updated documentation that the pharmacy continues
262 to have an ongoing clinical pharmacy program as specified in subparagraph (A)(v) of this
263 paragraph.

264
265 (15) A rural hospital that wishes to allow a pharmacy technician to perform the duties
266 specified in §291.73(e)(2)(D) of this title (relating to Personnel), shall make application to
267 the board as follows.

268
269 (A) Prior to allowing a pharmacy technician to perform the duties specified in
270 §291.73(e)(2)(D) of this title, the pharmacist-in-charge must submit an application on a
271 form provided by the board, containing the following information:

272
273 (i) name, address, and pharmacy license number;

274
275 (ii) name and license number of the pharmacist-in-charge;

276
277 (iii) name and registration number of the pharmacy technicians;

278
279 (iv) proposed date the pharmacy wishes to start allowing pharmacy technicians to
280 perform the duties specified in §291.73(e)(2)(D) of this title;

281
282 (v) documentation that the hospital is a rural hospital with 75 or fewer beds and that
283 the rural hospital is either:

284
285 (I) located in a county with a population of 50,000 or less as defined by the United
286 States Census Bureau in the most recent U.S. census; or

287
288 (II) designated by the Centers for Medicare and Medicaid Services as a critical
289 access hospital, rural referral center, or sole community hospital; and

290
291 (vi) any other information specified on the application.

292
293 (B) A rural hospital may not allow a pharmacy technician to perform the duties
294 specified in §291.73(e)(2)(D) of this title until the board has reviewed and approved the
295 application and issued an amended license to the pharmacy.

296
297 (C) Every two years in conjunction with the application for renewal of the pharmacy
298 license, the pharmacist-in-charge shall update the application for pharmacy technicians
299 to perform the duties specified in §291.73(e)(2)(D) of this title.

1 TITLE 22 EXAMINING BOARDS
2 PART 15 TEXAS STATE BOARD OF PHARMACY
3 CHAPTER 291 PHARMACIES
4 SUBCHAPTER F NON-RESIDENT PHARMACY (CLASS E)

5
6 **§291.104 Operational Standards**

7
8 (a) Licensing requirements.

9
10 (1) – (12) (No change.)

11
12 (13) A Class E [~~Non-Resident~~] pharmacy engaged in the compounding of non-sterile
13 preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies
14 Compounding Non-Sterile Preparations).

15
16 (14) **Prior to June 1, 2014, a** [A] Class E [~~Non-Resident~~] pharmacy engaged in the
17 compounding of sterile preparations shall comply with the provisions of §291.133 of this title
18 (relating to Pharmacies Compounding Sterile Preparations).

19
20 **(15) Effective June 1, 2014, a Class E pharmacy shall not compound sterile preparations**
21 **unless the pharmacy has applied and obtained a Class E-S pharmacy.**

22
23 (b) – (f) (No change.)

24
25
26 **§291.106 Pharmacies Compounding Sterile Preparations (Class E-S)**

27
28 **Licensing requirements. A pharmacy engaged in the compounding of sterile**
29 **preparations shall be licensed as a Class E-S pharmacy.**

30
31 **(1) A Class E-S pharmacy shall register with the board on a pharmacy license application**
32 **provided by the board, following the procedures specified in §291.1 of this title (relating**
33 **to Pharmacy License Application).**

34
35 **(2) A Class E-S license may not be issued unless the pharmacy has been inspected by**
36 **the board or its designee to ensure the pharmacy meets the requirements as specified in**
37 **§291.133 of this title (relating to Pharmacies Compounding Sterile Preparations). A**
38 **Class E-S pharmacy shall reimburse the board for all expenses, including travel, related**
39 **to the inspection of the Class E-S pharmacy.**

40
41 **(3) On initial application, the pharmacy shall follow the procedures specified in §291.1 of**
42 **this title (relating to Pharmacy License Application) and then provide the following**
43 **additional information specified in §560.052(c) and (f) of the Act (relating to**
44 **Qualifications):**

45
46 **(A) evidence that the applicant holds a pharmacy license, registration, or permit issued**
47 **by the state in which the pharmacy is located;**

48
49 **(B) the name of the owner and pharmacist-in-charge of the pharmacy for service of**
50 **process;**

52 (C) evidence of the applicant's ability to provide to the board a record of a prescription
53 drug order dispensed by the applicant to a resident of this state not later than 72 hours
54 after the time the board requests the record;

55
56 (D) an affidavit by the pharmacist-in-charge which states that the pharmacist has read
57 and understands the laws and rules relating to a Class E pharmacy; and

58
59 (E) proof of creditworthiness.

60
61 (4) A Class E-S pharmacy may not renew a pharmacy license unless the pharmacy
62 has been inspected by the board or its designee within the last 2 years.

63
64 (5) A Class E-S pharmacy which changes ownership shall notify the board within ten
65 days of the change of ownership and apply for a new and separate license as specified in
66 §291.3 of this title (relating to Required Notifications).

67
68 (6) A Class E-S pharmacy which changes location and/or name shall notify the board
69 within ten days of the change and file for an amended license as specified in §291.3 of
70 this title.

71
72 (7) A Class E-S pharmacy owned by a partnership or corporation which changes
73 managing officers shall notify the board in writing of the names of the new managing
74 officers within ten days of the change, following the procedures in §291.3 of this title.

75
76 (8) A Class E-S pharmacy shall notify the board in writing within ten days of closing.

77
78 (9) A separate license is required for each principal place of business and only one
79 pharmacy license may be issued to a specific location.

80
81 (10) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be
82 charged for the issuance and renewal of a license and the issuance of an amended
83 license.

84
85 (11) The board may grant an exemption from the licensing requirements of this Act on
86 the application of a pharmacy located in a state of the United States other than this state
87 that restricts its dispensing of prescription drugs or devices to residents of this state to
88 isolated transactions.

89
90 (12) A Class E-S pharmacy engaged in the centralized dispensing of prescription drug
91 or medication orders shall comply with the provisions of §291.125 of this title (relating to
92 Centralized Prescription Dispensing).

93
94 (13) A Class E-S pharmacy engaged in central processing of prescription drug or
95 medication orders shall comply with the provisions of §291.123 of this title (relating to
96 Central Prescription or Medication Order Processing).

97
98 (14) A Class E-S pharmacy engaged in the compounding of non-sterile preparations
99 shall comply with the provisions of §291.131 of this title (relating to Pharmacies
100 Compounding Non-Sterile Preparations).

102 **(15) A Class E-S pharmacy engaged in the compounding of sterile preparations shall**
103 **comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding**
104 **Sterile Preparations).**

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:</p> <p>(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies;</p> <p>(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in a Class A (Community), Class C (Institutional), and Class E (Non-resident) pharmacies to a practitioner's office for office use by the practitioner;</p> <p>(3) compounding and distribution of compounded sterile preparations by a Class A (Community) pharmacy for a Class C (Institutional) pharmacy; and</p> <p>(4) compounding of sterile preparations by a Class C (Institutional) pharmacy and the distribution of the compounded preparations to other Class C (Institutional) pharmacies under common ownership.</p> <p>(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.</p> <p>(1) ACPE--Accreditation Council for Pharmacy Education.</p> <p>(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:</p>	<p>(a) Purpose. Pharmacies compounding sterile preparations, prepackaging pharmaceutical products, and distributing those products shall comply with all requirements for their specific license classification and this section. The purpose of this section is to provide standards for the:</p> <p>(1) compounding of sterile preparations pursuant to a prescription or medication order for a patient from a practitioner in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies;</p> <p>(2) compounding, dispensing, and delivery of a reasonable quantity of a compounded sterile preparation in Class A-S, Class B-S, Class C-S, and Class E-S pharmacies to a practitioner's office for office use by the practitioner;</p> <p>(3) compounding and distribution of compounded sterile preparations by a Class A-S pharmacy for a Class C-S pharmacy; and</p> <p>(4) compounding of sterile preparations by a Class C-S pharmacy and the distribution of the compounded preparations to other Class C or Class C-S pharmacies under common ownership.</p> <p>(b) Definitions. In addition to the definitions for specific license classifications, the following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.</p> <p>(1) ACPE--Accreditation Council for Pharmacy Education.</p> <p>(2) Airborne particulate cleanliness class--The level of cleanliness specified by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). For example:</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(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);</p> <p>(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</p> <p>(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).</p> <p>(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.</p> <p>(4) Anteroom--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:</p> <p>(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and</p> <p>(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.</p> <p>(5) Aseptic Processing--The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during preparation.</p> <p>(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of</p>	<p>(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);</p> <p>(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</p> <p>(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).</p> <p>(3) Ancillary supplies--Supplies necessary for the preparation and administration of compounded sterile preparations.</p> <p>(4) Ante-area--An ISO Class 8 or better area where personnel may perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other high-particulate generating activities. It is also a transition area that:</p> <p>(A) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and</p> <p>(B) reduces the need for the heating, ventilating and air conditioning (HVAC) control system to respond to large disturbances.</p> <p>(5) Aseptic Processing-- A mode of processing pharmaceutical and medical preparations that involves the separate sterilization of the preparation and of the package (containers–closures or packaging material for medical devices) and the transfer of the preparation into the container and its closure under at least ISO Class 5 conditions.</p> <p>(6) Automated compounding device--An automated device that compounds, measures, and/or packages a specified quantity of</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>individual components in a predetermined sequence for a designated sterile preparation.</p> <p>(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.</p> <p>(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.</p> <p>(9) Beyond-use date--The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.</p> <p>(10) 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.</p> <p>(11) Buffer Area, Buffer or Core Room, Buffer or Clean Room Areas, Buffer Room Area, Buffer or Clean Area, or Buffer Zone--An ISO Class 7 area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.</p> <p>(12) 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.</p>	<p>individual components in a predetermined sequence for a designated sterile preparation.</p> <p>(7) Batch--A specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.</p> <p>(8) Batch preparation compounding--Compounding of multiple sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period. Batch preparation/compounding does not include the preparation of multiple sterile preparation units pursuant to patient specific medication orders.</p> <p>(9) Beyond-use date--The date or time after which the compounded sterile preparation shall not be stored or transported or begin to be administered to a patient. The beyond-use date is determined from the date or time the preparation is compounded.</p> <p>(10) Biological Safety Cabinet, Class II--A ventilated cabinet for personnel, product or preparation, 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.</p> <p>(11) Buffer Area--An ISO Class 7 area where the primary engineering control area is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.</p> <p>(12) Clean room--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.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.</p> <p>(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:</p> <p>(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or</p> <p>(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.</p> <p>(15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).</p> <p>(16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing</p>	<p>(13) Component--Any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.</p> <p>(14) Compounding--The preparation, mixing, assembling, packaging, or labeling of a drug or device:</p> <p>(A) as the result of a practitioner's prescription drug or medication order based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;</p> <p>(C) in anticipation of prescription drug or medication orders based on routine, regularly observed prescribing patterns; or</p> <p>(D) for or as an incident to research, teaching, or chemical analysis and not for sale or dispensing, except as allowed under §562.154 or Chapter 563 of the Occupations Code.</p> <p>(15) Compounding Aseptic Isolator--A form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless it has first passed through a microbial retentive filter (HEPA minimum).</p> <p>(16) Compounding Aseptic Containment Isolator--A compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.</p> <p>(17) Critical Area--A critical area is an ISO Class 5 environment.</p> <p>(18) Critical Sites--Sterile ingredients of compounded sterile preparations and locations on devices and components used to prepare, package, and transfer compounded sterile preparations that provide opportunity for exposure to contamination.</p> <p>(19) Cytotoxic--A pharmaceutical that has the capability of killing living cells.</p> <p>(20) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.</p> <p>(21) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.</p> <p>(22) Disinfectant--A disinfectant is an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial spores. It refers to substances applied to inanimate objects.</p> <p>(23) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.</p>	<p>airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.</p> <p>(17) Critical Area—An ISO Class 5 environment.</p> <p>(18) Critical Sites-- A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.</p> <p>(19) Device--An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner.</p> <p>(20) Direct Compounding Area--A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.</p> <p>(21) Disinfectant—An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.</p> <p>(22) First Air--The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.</p> <p>(23) Hazardous Drugs—Drugs that, studies in animals or humans indicate exposure to the drugs, have a potential for causing cancer, development or reproductive toxicity, or harm to organs.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).</p> <p>(25) HVAC--Heating, ventilation, and air conditioning.</p> <p>(26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.</p> <p>(27) IPA--Isopropyl alcohol (2-propanol).</p> <p>(28) Media-Fill Test--A media-fill test is used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean--Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.</p> <p>(29) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.</p>	<p>(24) Hot water--The temperature of water from the pharmacy's sink maintained at a minimum of 105 degrees F (41 degrees C).</p> <p>(25) HVAC--Heating, ventilation, and air conditioning.</p> <p>(26) Immediate use--A sterile preparation that is not prepared according to USP 797 standards (i.e. outside the pharmacy and most likely not by pharmacy personnel) which shall be stored for no longer than one hour after completion of the preparation.</p> <p>(27) IPA--Isopropyl alcohol (2-propanol).</p> <p>(28) Labeling—All labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term “label” designates that part of the labeling on the immediate container.</p> <p>(29) Media-Fill Test--A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparation without microbial contamination. During this test, a microbiological growth medium such as Soybean--Casein Digest Medium is substituted for the actual drug preparation to simulate admixture compounding. The issues to consider in the development of a media-fill test are the following: media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.</p> <p>(30) Multiple-Dose Container--A multiple-unit container for articles or preparations intended for potential administration only and usually contains antimicrobial preservatives. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(30) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.</p> <p>(31) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.</p> <p>(32) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).</p> <p>(33) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.</p> <p>(34) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber.</p> <p>(35) Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when</p>	<p>(31) Negative Pressure Room--A room that is at a lower pressure compared to adjacent spaces and, therefore, the net flow of air is into the room.</p> <p>(32) Office use--The administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy in accordance with Chapter 562 of the Act, or for administration or provision by a veterinarian in accordance with §563.054 of the Act.</p> <p>(33) Pharmacy Bulk Package--A container of a sterile preparation for potential use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).</p> <p>(34) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original container into unit dose packaging or a multiple dose container for distribution within a facility licensed as a Class C pharmacy or to other pharmacies under common ownership for distribution within those facilities. The term as defined does not prohibit the prepackaging of drug products for use within other pharmacy classes.</p> <p>(35) Preparation or Compounded Sterile Preparation--A sterile admixture compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber. The components of the preparation may or may not be sterile products.</p> <p>(36) Primary Engineering Control--A device or room that provides an ISO Class 5 environment for the exposure of critical sites when</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, and compounding aseptic isolators and compounding aseptic containment isolators.</p> <p>(36) Product--A product is a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.</p> <p>(37) Positive Control--A quality assurance sample prepared to test positive for microbial growth.</p> <p>(38) Positive Pressure Room--A room that is at a higher pressure compared to adjacent spaces and, therefore, the net airflow is out of the room.</p> <p>(39) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.</p> <p>(40) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.</p> <p>(41) Reasonable quantity--An amount of a compounded drug that:</p> <p>(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;</p> <p>(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and</p> <p>(C) for any practitioner and all practitioners as a whole, is not greater</p>	<p>compounding sterile preparations. Such devices include, but may not be limited to, laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators.</p> <p>(37) Product--A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.</p> <p>(38) Positive Control--A quality assurance sample prepared to test positive for microbial growth.</p> <p>(39) Positive Pressure Room--A room that is at a higher pressure compared to adjacent spaces and, therefore, the net airflow is out of the room.</p> <p>(40) Quality assurance--The set of activities used to ensure that the process used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.</p> <p>(41) Quality control--The set of testing activities used to determine that the ingredients, components (e.g., containers), and final compounded sterile preparations prepared meet predetermined requirements with respect to identity, purity, non-pyrogenicity, and sterility.</p> <p>(42) Reasonable quantity--An amount of a compounded drug that:</p> <p>(A) does not exceed the amount a practitioner anticipates may be used in the practitioner's office or facility before the beyond use date of the drug;</p> <p>(B) is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice; and</p> <p>(C) for any practitioner and all practitioners as a whole, is not greater</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.</p> <p>(42) Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.</p> <p>(43) Single-dose container--A container intended for a single use, other than single-dose vials and single-dose large volume potential solutions. Examples of single-dose containers include pre-filled syringes, cartridges, and fusion-sealed containers without preservatives.</p> <p>(44) Single-dose vial--A vial intended for a single use. Exceptions to this definition would be single dose vials routinely used to compound total potential nutrition (TPN) preparations (e.g., sodium chloride, sodium acetate, sodium phosphate, potassium chloride, potassium acetate, potassium phosphate, calcium gluconate, magnesium sulfate, multivitamin for injection, multi-trace elements, ascorbic acid, folic acid, heparin, phytonadione, l-carnitine, cysteine, selenium, injectable zinc).</p> <p>(45) Single-dose large volume parenteral solution--Large volume parenteral solutions (i.e., containers of solution of at least 1000 mL) routinely used for compounding sterile TPN preparations or for batch compounding (e.g., sterile water for injection (SWFI); 5%, 10%, and 70% dextrose in SWFI; 0.9% sodium chloride; 0.45% sodium chloride; 5% dextrose/0.9% sodium chloride; 5% dextrose/0.45% sodium chloride).</p> <p>(46) SOPs--Standard operating procedures.</p>	<p>than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.</p> <p>(43) Segregated Compounding Area--A designated space, either a demarcated area or room, that is restricted to preparing low-risk level compounded sterile preparations with 12-hour or less beyond-use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.</p> <p>(44) Single-dose container—A single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.</p> <p>(45) SOPs--Standard operating procedures.</p> <p>(46) Sterilizing Grade Membranes— Membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(47) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10⁶, i.e., or a probability of less than one in one million of a non-sterile unit.</p> <p>(48) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.</p> <p>(49) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.</p> <p>(c) Personnel.</p> <p>(1) Pharmacist-in-charge.</p> <p>(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.</p> <p>(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:</p> <p>(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;</p>	<p>Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the manufacturer's practice.</p> <p>(47) Sterilization by Filtration— Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.</p> <p>(48) Terminal Sterilization--The application of a lethal process, e.g., steam under pressure or autoclaving, to sealed final preparation containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10⁻⁶ or a probability of less than one in one million of a non-sterile unit.</p> <p>(49) Unidirectional Flow--An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.</p> <p>(50) USP/NF--The current edition of the United States Pharmacopeia/National Formulary.</p> <p>(c) Personnel.</p> <p>(1) Pharmacist-in-charge.</p> <p>(A) General. The pharmacy shall have a pharmacist-in-charge in compliance with the specific license classification of the pharmacy.</p> <p>(B) Responsibilities. In addition to the responsibilities for the specific class of pharmacy, the pharmacist-in-charge shall have the responsibility for, at a minimum, the following concerning the compounding of sterile preparations:</p> <p>(i) developing a system to ensure that all pharmacy personnel responsible for compounding and/or supervising the compounding of sterile preparations within the pharmacy receive appropriate education and training and competency evaluation;</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;</p> <p>(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;</p> <p>(iv) ensuring that the equipment used in compounding is properly maintained;</p> <p>(v) developing a system for the disposal and distribution of drugs from the pharmacy;</p> <p>(vi) developing a system for bulk compounding or batch preparation of drugs;</p> <p>(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and</p> <p>(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.</p> <p>(2) Pharmacists. Special requirements for compounding sterile preparations.</p> <p>(A) All pharmacists engaged in compounding sterile preparations shall:</p> <p>(i) possess the education, training, and proficiency necessary to properly and safely perform compounding duties undertaken or supervised; and</p> <p>(ii) obtain continuing education appropriate for the type of</p>	<p>(ii) determining that all personnel involved in compounding sterile preparations obtain continuing education appropriate for the type of compounding done by the personnel;</p> <p>(iii) supervising a system to ensure appropriate procurement of drugs and devices and storage of all pharmaceutical materials including pharmaceuticals, components used in the compounding of sterile preparations, and drug delivery devices;</p> <p>(iv) ensuring that the equipment used in compounding is properly maintained;</p> <p>(v) developing a system for the disposal and distribution of drugs from the pharmacy;</p> <p>(vi) developing a system for bulk compounding or batch preparation of drugs;</p> <p>(vii) developing a system for the compounding, sterility assurance, quality assurance, and quality control of sterile preparations; and</p> <p>(viii) if applicable, ensuring that the pharmacy has a system to dispose of hazardous waste in a manner so as not to endanger the public health.</p> <p>(2) Pharmacists.</p> <p>(A) General.</p> <p>(i) A pharmacist is responsible for ensuring that compounded sterile preparations are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.</p> <p>(ii) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>compounding done by the pharmacist.</p> <p>(B) A pharmacist shall inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.</p> <p>(C) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.</p> <p>(D) A pharmacist is responsible for the proper maintenance, cleanliness, and use of all equipment used in the compounding process.</p> <p>(E) A pharmacist shall be accessible at all times to respond to patients' and other health professionals' questions and needs. Such access may be through a telephone or pager which is answered 24 hours a day.</p> <p>(3) Pharmacy technicians and pharmacy technician trainees. Pharmacy technicians and pharmacy technician trainees may compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees:</p> <p>(A) have completed the education and training specified in paragraph (4) of this subsection; and</p> <p>(B) are supervised by a pharmacist who has completed the training specified in paragraph (4) of this subsection, conducts in-process and final checks, and affixes his or her initials to the appropriate quality control records.</p> <p>(4) Special education, training, and evaluation requirements for pharmacy personnel compounding or responsible for the direct supervision of pharmacy personnel compounding sterile preparations.</p> <p>(A) General.</p>	<p>(iii) A pharmacist shall review all compounding records for accuracy and conduct in-process and final checks and verification of calculations to ensure that errors have not occurred in the compounding process.</p> <p>(iv) A pharmacist is responsible for ensuring the proper maintenance, cleanliness, and use of all equipment used in the compounding process.</p> <p>(v) A pharmacist shall be accessible at all times, 24 hours a day, to respond to patients' and other health professionals' questions and needs.</p> <p>(B) Initial training and continuing education.</p> <p>(i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:</p> <p>(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D);</p> <p>(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and</p> <p>(III) possess knowledge about:</p> <p>(-a-) aseptic processing;</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(i) All pharmacy personnel preparing sterile preparations shall receive didactic and experiential training and competency evaluation through demonstration, testing (written and practical) as outlined by the pharmacist-in-charge and described in the policy and procedure or training manual. Such training shall include instruction and experience in the following areas:</p> <ul style="list-style-type: none"> (I) aseptic technique; (II) critical area contamination factors; (III) environmental monitoring; (IV) structure and engineering controls related to facilities; (V) equipment and supplies; (VI) sterile preparation calculations and terminology; (VII) sterile preparation compounding documentation; (VIII) quality assurance procedures; (IX) aseptic preparation procedures including proper gowning and gloving technique; (X) handling of cytotoxic and hazardous drugs, if applicable; and (XI) general conduct in the controlled area. <p>(ii) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated as satisfactory through written and practical tests, and media-fill challenge testing, and such evaluation documented.</p> <p>(iii) Although media-fill tests may be incorporated into the</p>	<p>(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;</p> <p>(-c-) chemical, pharmaceutical, and clinical properties of drugs;</p> <p>(-d-) container, equipment, and closure system selection; and</p> <p>(-e-) sterilization techniques.</p> <p>(ii) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding and is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.</p> <p>(iii) In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:</p> <ul style="list-style-type: none"> (I) two hours of ACPE-accredited continuing education relating to the areas listed in clause (i)(II) of this subparagraph if the pharmacist is engaged in compounding low and medium risk sterile preparations; or (II) four hours of ACPE-accredited continuing education relating to the areas listed in clause (i)(II) of this subparagraph if the pharmacist is engaged in compounding high risk sterile preparations. <p>(3) Pharmacy technicians and pharmacy technician trainees.</p> <ul style="list-style-type: none"> (A) 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). (B) Initial training and continuing education. <p>(i) Pharmacy technicians and pharmacy technician trainees may</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>experiential portion of a training program, media-fill tests must be conducted at each pharmacy where an individual compounds sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist:</p> <p>(I) has completed a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in this subparagraph; and</p> <p>(II) completes the on-site media-fill tests within seven days of commencing work at the pharmacy.</p> <p>(iv) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of all types of manipulations, products, risk levels, and batch sizes that personnel preparing that type of sterile preparation are likely to encounter.</p> <p>(v) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:</p> <p>(I) during orientation and training prior to the regular performance of those tasks;</p> <p>(II) whenever the quality assurance program yields an unacceptable result;</p> <p>(III) whenever unacceptable techniques are observed; and</p> <p>(IV) at least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding.</p>	<p>compound sterile preparations provided the pharmacy technicians and/or pharmacy technician trainees are supervised by a pharmacist who has completed the training specified in paragraph (4)(D) of this subsection, conducts in-process and final checks, and affixes his or her initials to the appropriate quality control records.</p> <p>(ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall comply with the following:</p> <p>(I) complete through completion of a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection;</p> <p>(II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and</p> <p>(III) possess knowledge about:</p> <p>(-a-) aseptic processing;</p> <p>(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;</p> <p>(-c-) chemical, pharmaceutical, and clinical properties of drugs;</p> <p>(-d-) container, equipment, and closure system selection; and</p> <p>(-e-) sterilization techniques.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(B) Pharmacists.</p> <p>(i) All pharmacists who compound sterile preparations for administration to patients or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall:</p> <p>(I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained through:</p> <p>(-a-) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (1) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or</p> <p>(-b-) completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph.</p> <p>(II) possess knowledge about:</p> <p>(-a-) aseptic processing;</p> <p>(-b-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;</p> <p>(-c-) chemical, pharmaceutical, and clinical properties of drugs;</p> <p>(-d-) container, equipment, and closure system selection; and</p> <p>(-e-) sterilization techniques.</p>	<p>(iii) Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided:</p> <p>(I) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;</p> <p>(II) the individual is under the direct supervision of and responsible to a pharmacist who has completed training as specified in paragraph (2)(C) of this subsection; and</p> <p>(III) the supervising pharmacist conducts in-process and final checks.</p> <p>(iv) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who is actively engaged in performing sterile compounding, is qualified and has completed training as specified in paragraph (2) or (3) of this subsection.</p> <p>(v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:</p> <p>(I) two hours of ACPE accredited continuing education relating to the areas listed in clause (ii)(III) of this subparagraph if the pharmacy technician is engaged in compounding low and medium risk sterile preparations; or</p> <p>(II) four hours of ACPE accredited continuing education relating to the areas listed in clause (ii)(III) of this subparagraph if pharmacy technician is engaged in compounding high risk sterile preparations.</p> <p>(4) Evaluation and testing requirements.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(ii) The required experiential portion of the training programs specified in this subparagraph must be supervised by an individual who has already completed training as specified in subparagraph (B) or (C) of this paragraph.</p> <p>(C) Pharmacy technicians and pharmacy technician trainees. In addition to specific qualifications for registration, all pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:</p> <p>(i) have initial training obtained either through completion of:</p> <p>(I) a single course, a minimum of 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may be obtained through:</p> <p>(-a-) completion of a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; or</p> <p>(-b-) completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience in the areas listed in subparagraph (A) of this paragraph; or</p> <p>(II) a training program which is accredited by the American Society of Health-System Pharmacists. Individuals enrolled in training programs accredited by the American Society of Health-System Pharmacists may compound sterile preparations in a licensed pharmacy provided:</p> <p>(-a-) the compounding occurs only during times the individual is assigned to a pharmacy as a part of the experiential component of the American Society of Health-System Pharmacists training program;</p> <p>(-b-) the individual is under the direct supervision of and</p>	<p>(A) All pharmacy personnel preparing sterile preparations shall be trained conscientiously and skillfully by expert personnel through multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations, garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures before beginning to prepare compounded sterile preparations.</p> <p>(B) All pharmacy personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially followed by:</p> <p>(i) every 12 months for low- and medium-risk level compounding; and</p> <p>(ii) every six months for high-risk level compounding.</p> <p>(C) Pharmacy personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall:</p> <p>(i) be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies; and</p> <p>(ii) not be allowed to compound sterile preparations for patient use until passing results are achieved.</p> <p>(D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:</p> <p>(I) aseptic technique;</p> <p>(II) critical area contamination factors;</p> <p>(III) environmental monitoring;</p> <p>(IV) structure and engineering controls related to facilities;</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>responsible to a pharmacist who has completed training as specified in subparagraph (B) of this paragraph; and</p> <p>(-c-) the supervising pharmacist conducts in-process and final checks.</p> <p>(ii) acquire the required experiential portion of the training programs specified in this subparagraph under the supervision of an individual who has already completed training as specified in subparagraph (B) or (C) of this paragraph.</p>	<p>(V) equipment and supplies;</p> <p>(VI) sterile preparation calculations and terminology;</p> <p>(VII) sterile preparation compounding documentation;</p> <p>(VIII) quality assurance procedures;</p> <p>(IX) aseptic preparation procedures including proper gowning and gloving technique;</p> <p>(X) handling of hazardous drugs, if applicable;</p> <p>(XI) cleaning procedures; and</p> <p>(XII) general conduct in the clean room.</p> <p>(E) The aseptic technique of each person compounding or responsible for the direct supervision of personnel compounding sterile preparations shall be observed and evaluated by expert personnel as satisfactory through written and practical tests, and media-fill challenge testing, and such evaluation documented.</p> <p>(F) Media-fill tests must be conducted at each pharmacy where an individual compounds sterile preparations. No preparation intended for patient use shall be compounded by an individual until the on-site media-fill tests test indicates that the individual can competently perform aseptic procedures, except that a pharmacist may temporarily compound sterile preparations and supervise pharmacy technicians compounding sterile preparations without media-fill tests provided the pharmacist completes the on-site media-fill tests within seven days of commencing work at the pharmacy.</p> <p>(G) Media-fill tests procedures for assessing the preparation of specific types of sterile preparations shall be representative of the most challenging or stressful conditions encountered by the pharmacy personnel being evaluated for each risk level and for sterilizing high-risk</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
	<p>level compounded sterile preparations.</p> <p>(H) Media-fill challenge tests simulating high-risk level compounding shall be used to verify the capability of the compounding environment and process to produce a sterile preparation.</p> <p>(I) Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to compounding sterile preparations from the compounding personnel and environment. Media-filled vials are generally incubated at 20 to 25 or at 30 to 35 for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature. Failure is indicated by visible turbidity in the medium on or before 14 days.</p> <p>(J) The pharmacist-in-charge shall ensure continuing competency of pharmacy personnel through in-service education, training, and media-fill tests to supplement initial training. Personnel competency shall be evaluated:</p> <ul style="list-style-type: none"> (i) during orientation and training prior to the regular performance of those tasks; (ii) whenever the quality assurance program yields an unacceptable result; (iii) whenever unacceptable techniques are observed; and (iv) at least on an annual basis for low- and medium-risk level compounding, and every six months for high-risk level compounding. <p>(K) The pharmacist-in-charge shall ensure that proper hand hygiene and garbing practices of compounding personnel are evaluated prior to compounding sterile preparations intended for patient use and whenever an aseptic media fill is performed.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
	<p>(i) Sampling of compounding personnel glove fingertips shall be performed for all risk level compounding.</p> <p>(ii) All compounding personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).</p> <p>(iii) Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA).</p> <p>(iv) The visual observation shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency.</p> <p>(v) All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than three times before initially being allowed to compound sterile preparations for patient use. Immediately after the compounding personnel completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands from the compounding personnel onto agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature. Re-evaluation of all compounding personnel shall occur at least annually for compounding personnel who compound low and medium risk level preparations and every six months for compounding personnel who compound high risk level preparations.</p> <p>(L) The pharmacist-in-charge shall ensure surface sampling shall be conducted in all ISO classified areas on a periodic basis. Sampling shall be accomplished using contact plates at the conclusion of compounding. The sample area shall be gently touched with the agar surface by rolling the plate across the surface to be sampled.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(D) Documentation of Training. The pharmacy shall maintain a record on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and contain the following information:</p> <p>(i) name of the person receiving the training or completing the testing or media-fill tests;</p> <p>(ii) date(s) of the training, testing, or media-fill challenge testing;</p> <p>(iii) general description of the topics covered in the training or testing or of the process validated;</p> <p>(iv) name of the person supervising the training, testing, or media-fill challenge testing; and</p> <p>(v) signature or initials of the person receiving the training or completing the testing or media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill challenge testing of personnel.</p> <p>(d) Operational Standards.</p> <p>(1) General Requirements.</p> <p>(A) Sterile preparations may be compounded in licensed pharmacies:</p> <p>(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;</p> <p>(ii) in anticipation of future prescription drug or medication orders</p>	<p>(5) Documentation of Training. The pharmacy shall maintain a record of the training and continuing education on each person who compounds sterile preparations. The record shall contain, at a minimum, a written record of initial and in-service training, education, and the results of written and practical testing and media-fill testing of pharmacy personnel. The record shall be maintained and available for inspection by the board and contain the following information:</p> <p>(A) name of the person receiving the training or completing the testing or media-fill tests;</p> <p>(B) date(s) of the training, testing, or media-fill challenge testing;</p> <p>(C) general description of the topics covered in the training or testing or of the process validated;</p> <p>(D) name of the person supervising the training, testing, or media-fill challenge testing; and</p> <p>(E) signature or initials of the person receiving the training or completing the testing or media-fill challenge testing and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or media-fill challenge testing of personnel.</p> <p>(d) Operational Standards.</p> <p>(1) General Requirements.</p> <p>(A) Sterile preparations may be compounded:</p> <p>(i) upon presentation of a practitioner's prescription drug or medication order based on a valid pharmacist/patient/prescriber relationship;</p> <p>(ii) in anticipation of future prescription drug or medication orders</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>based on routine, regularly observed prescribing patterns; or</p> <p>(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.</p> <p>(B) Sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.</p> <p>(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (5)(G) of this subsection.</p> <p>(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.</p> <p>(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:</p> <p>(I) name and strength of the compounded preparation or list of the active ingredients and strengths;</p> <p>(II) facility's lot number;</p> <p>(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (5)(G) of this subsection;</p> <p>(IV) quantity or amount in the container;</p> <p>(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p>	<p>based on routine, regularly observed prescribing patterns; or</p> <p>(iii) in reasonable quantities for office use by a practitioner and for use by a veterinarian.</p> <p>(B) Sterile compounding in anticipation of future prescription drug or medication orders must be based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared is stable for the anticipated shelf time.</p> <p>(i) The pharmacist's professional judgment shall be based on the criteria used to determine a beyond-use date outlined in paragraph (6)(G) of this subsection.</p> <p>(ii) Documentation of the criteria used to determine the stability for the anticipated shelf time must be maintained and be available for inspection.</p> <p>(iii) Any preparation compounded in anticipation of future prescription drug or medication orders shall be labeled. Such label shall contain:</p> <p>(I) name and strength of the compounded preparation or list of the active ingredients and strengths;</p> <p>(II) facility's lot number;</p> <p>(III) beyond-use date as determined by the pharmacist using appropriate documented criteria as outlined in paragraph (6)(G) of this subsection;</p> <p>(IV) quantity or amount in the container;</p> <p>(V) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(VI) device-specific instructions, where appropriate.</p> <p>(C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:</p> <p>(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;</p> <p>(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and</p> <p>(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.</p> <p>(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.</p> <p>(E) A pharmacy may enter into an agreement to compound and</p>	<p>(VI) device-specific instructions, where appropriate.</p> <p>(C) Commercially available products may be compounded for dispensing to individual patients or for office use provided the following conditions are met:</p> <p>(i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patient's needs;</p> <p>(ii) the pharmacy maintains documentation that the product is not reasonably available due to a drug shortage or unavailability from the manufacturer; and</p> <p>(iii) the prescribing practitioner has requested that the drug be compounded as described in subparagraph (D) of this paragraph.</p> <p>(D) A pharmacy may not compound preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders the strength or dosage form and specifies why the patient needs the particular strength or dosage form of the preparation or why the preparation for office use is needed in the particular strength or dosage form of the preparation. The prescribing practitioner shall provide documentation of a patient specific medical need and the preparation produces a clinically significant therapeutic response (e.g. the physician requests an alternate preparation due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The methodology for documenting unavailability includes maintaining a copy of the wholesaler's notification showing back-ordered, discontinued, or out-of-stock items. This documentation must be available in hard-copy or electronic format for inspection by the board.</p> <p>(E) A pharmacy may enter into an agreement to compound and</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).</p> <p>(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.</p> <p>(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.</p> <p>(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed below.</p> <p>(A) Low-risk level compounded sterile preparations.</p> <p>(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions.</p> <p>(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.</p> <p>(II) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are preformed promptly and attentively.</p> <p>(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.</p>	<p>dispense prescription/medication orders for another pharmacy provided the pharmacy complies with the provisions of §291.125 of this title (relating to Centralized Prescription Dispensing).</p> <p>(F) Compounding pharmacies/pharmacists may advertise and promote the fact that they provide sterile prescription compounding services, which may include specific drug preparations and classes of drugs.</p> <p>(G) A pharmacy may not compound veterinary preparations for use in food producing animals except in accordance with federal guidelines.</p> <p>(2) Microbial Contamination Risk Levels. Risk Levels for sterile compounded preparations shall be as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF and as listed below.</p> <p>(A) Low-risk level compounded sterile preparations.</p> <p>(i) Low-Risk conditions. Low-risk level compounded sterile preparations are those compounded under all of the following conditions.</p> <p>(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.</p> <p>(II) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the compounded sterile preparation.</p> <p>(III) Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(IV) For a low-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods may not exceed the following periods: before administration, 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, 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.</p> <p>(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.</p> <p>(I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any glass particles.</p> <p>(II) Manually measuring and mixing no more than three manufactured products to compound drug admixtures.</p> <p>(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions.</p> <p>(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (5)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within an ISO Class 7 buffer area.</p>	<p>containers for storage and dispensing.</p> <p>(IV) For a low-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, the storage periods may not exceed the following periods: before administration the compounded sterile preparation is stored properly and are exposed for not more than 48 hours at controlled room temperature, for not more than 14 days if stored at a cold temperature, and for 45 days if stored in a frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius. For delayed activation device systems, the storage period begins when the device is activated.</p> <p>(ii) Examples of Low-Risk Compounding. Examples of low-risk compounding include the following.</p> <p>(I) Single volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any particles.</p> <p>(II) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.</p> <p>(B) Low-Risk Level compounded sterile preparations with 12-hour or less beyond-use date. Low-risk level compounded sterile preparations are those compounded pursuant to a physician's order for a specific patient under all of the following conditions.</p> <p>(i) The compounded sterile preparations are compounded in compounding aseptic isolator or compounding aseptic containment isolator that does not meet the requirements described in paragraph (6)(A)(ii)(II) of this subsection relating to Low and Medium Risk Preparations or the compounded sterile preparations are compounded in laminar airflow workbench or a biological safety cabinet that cannot be located within an ISO Class 7 buffer area.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(ii) The primary engineering control device is located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.</p> <p>(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, or that is adjacent to construction sites, warehouses, or food preparation.</p> <p>(iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.</p> <p>(C) Medium-risk level compounded sterile preparations.</p> <p>(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.</p> <p>(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.</p> <p>(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer.</p> <p>(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products).</p> <p>(IV) The compounded sterile preparations do not contain broad</p>	<p>(ii) The primary engineering control device shall be certified and maintain ISO Class 5 for exposure of critical sites and shall be located in a segregated compounding area restricted to sterile compounding activities that minimizes the risk of contamination of the compounded sterile preparation.</p> <p>(iii) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.</p> <p>(iv) For a low-risk preparation compounded as described in clauses (i) - (iii) of this subparagraph, administration of such compounded sterile preparations must commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less.</p> <p>(C) Medium-risk level compounded sterile preparations.</p> <p>(i) Medium-Risk Conditions. Medium-risk level compounded sterile preparations, are those compounded aseptically under low-risk conditions and one or more of the following conditions exists.</p> <p>(I) Multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions.</p> <p>(II) The compounding process includes complex aseptic manipulations other than the single-volume transfer.</p> <p>(III) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogenous mixing (e.g., reconstitution of intravenous immunoglobulin or other intravenous protein products).</p> <p>(IV) The compounded sterile preparations do not contain broad</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).</p> <p>(V) For a medium-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits the beyond use dates may not 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 temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees Celsius or colder.</p> <p>(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following.</p> <p>(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.</p> <p>(II) Filling of reservoirs of injection and infusion devices with multiple sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.</p> <p>(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).</p> <p>(IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.</p> <p>(D) High-risk level compounded sterile preparations.</p> <p>(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions.</p>	<p>spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).</p> <p>(V) For a medium-risk preparation, in the absence of direct sterility testing results the beyond use dates may not 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 temperature, for not more than 9 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.</p> <p>(ii) Examples of medium-risk compounding. Examples of medium-risk compounding include the following.</p> <p>(I) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.</p> <p>(II) Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuations of air from those reservoirs before the filled device is dispensed.</p> <p>(III) Filling of reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius (77 and 104 degrees Fahrenheit).</p> <p>(IV) Transfer of volumes from multiple ampuls or vials into a single, final sterile container or product.</p> <p>(D) High-risk level compounded sterile preparations.</p> <p>(i) High-risk Conditions. High-risk level compounded sterile preparations are those compounded under any of the following conditions.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(I) Non-sterile ingredients, including manufactured products are incorporated or a non-sterile device is employed before terminal sterilization.</p> <p>(II) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to ISO Class 5. This includes storage in environments inferior to ISO Class 5 of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.</p> <p>(III) Non-sterile preparations are exposed no more than 6 hours before being sterilized.</p> <p>(IV) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.</p> <p>(V) For a high-risk preparation, in the absence of direct sterility testing results or appropriate information sources that justify different limits, 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 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state at minus 20 degrees or colder.</p> <p>(VI) All non-sterile measuring, mixing, and purifying equipment is rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding while assuring cleanliness. All high-risk compounded sterile aqueous solutions subjected to terminal sterilization are passed through a filter with a</p>	<p>(I) Non-sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral) are incorporated or a non-sterile device is employed before terminal sterilization.</p> <p>(II) Any of the following are exposed to air quality worse than ISO Class 5 for more than 1 hour:</p> <ul style="list-style-type: none"> (-a-) sterile contents of commercially manufactured products; (-b-) CSPs that lack effective antimicrobial preservatives; and (-c-) sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs. <p>(III) Compounding personnel are improperly garbed and gloved.</p> <p>(IV) Non-sterile water-containing preparations are exposed no more than 6 hours before being sterilized.</p> <p>(V) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.</p> <p>(VI) For a sterilized high-risk level preparation, in the absence of passing a 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 24 hours at controlled room temperature, for not more than 3 days at a cold temperature, and for 45 days in solid frozen state between minus 25 degrees Celsius and minus 10 degrees Celsius.</p> <p>(VII) All non-sterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk compounded sterile solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration shall be performed entirely within an ISO Class 5 or superior air quality environment.</p> <p>(ii) Examples of high-risk compounding. Examples of high-risk compounding include the following.</p> <p>(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized.</p> <p>(II) Exposing the sterile ingredients and components used to prepare and package compounded sterile preparations to room air quality worse than ISO Class 5.</p> <p>(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.</p> <p>(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.</p> <p>(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk, medium-risk, and high-risk level compounded sterile preparations when all of the following criteria are met.</p> <p>(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile non-hazardous commercial</p>	<p>larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level compounded sterile preparations by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer nominal pore size filter entirely within an ISO Class 5 or superior air quality environment.</p> <p>(ii) Examples of high-risk compounding. Examples of high-risk compounding include the following.</p> <p>(I) Dissolving non-sterile bulk drug powders to make solutions, which will be terminally sterilized.</p> <p>(II) Exposing the sterile ingredients and components used to prepare and package compounded sterile preparations to room air quality worse than ISO Class 5 for more than one hour.</p> <p>(III) Measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed.</p> <p>(IV) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.</p> <p>(3) Immediate Use Compounded Sterile Preparations. For the purpose of emergency or immediate patient care, such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the compounded sterile preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Compounded sterile preparations are exempted from the requirements described in this paragraph for low-risk level compounded sterile preparations when all of the following criteria are met.</p> <p>(A) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile non-hazardous commercial</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution.</p> <p>(B) Unless required for the preparation, the preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.</p> <p>(C) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.</p> <p>(D) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.</p> <p>(E) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.</p> <p>(F) Cytotoxic drugs shall not be prepared as immediate use compounded sterile preparations.</p>	<p>drug and diagnostic radiopharmaceutical drug products, including an infusion or diluent solution, from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container/device.</p> <p>(B) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed 1 hour.</p> <p>(C) During preparation, aseptic technique is followed and, if not immediately administered, the finished compounded sterile preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter of biological fluids, mix-ups with other compounded sterile preparations, and direct contact of outside surfaces.</p> <p>(D) Administration begins not later than one hour following the completion of preparing the compounded sterile preparation.</p> <p>(E) When the compounded sterile preparations is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the compounded sterile preparation shall bear a label listing patient identification information such as name and identification number(s), the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact 1-hour beyond-use time and date.</p> <p>(F) If administration has not begun within one hour following the completion of preparing the compounded sterile preparation, the compounded sterile preparation is promptly and safely discarded. Immediate use compounded sterile preparations shall not be stored for later use.</p> <p>(G) Hazardous drugs shall not be prepared as immediate use compounded sterile preparations.</p> <p>(4) Single-dose and multiple dose containers. (A) Opened or needle punctured single-dose containers, such as bags</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(4) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:</p> <p>(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;</p> <p>(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and</p> <p>(C) the United States Pharmacopeia/National Formulary or the USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations.</p> <p>(5) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination of critical sites.</p>	<p>bottles, syringes, and vials of sterile products shall be used within one hour if opened in worse than ISO Class 5 air quality. Any remaining contents must be discarded.</p> <p>(B) Single-dose containers, including single-dose large volume parenteral solutions and single-dose vials, exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture.</p> <p>(C) Opened single-dose fusion sealed containers shall not be stored for any time period.</p> <p>(D) Multiple-dose containers may be used up to 28 days after initial needle puncture unless otherwise specified by the manufacturer.</p> <p>(5) Library. In addition to the library requirements of the pharmacy's specific license classification, a pharmacy shall maintain current or updated copies in hard-copy or electronic format of each of the following:</p> <p>(A) a reference text on injectable drug preparations, such as Handbook on Injectable Drug Products;</p> <p>(B) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs; and</p> <p>(C) the United States Pharmacopeia/National Formulary containing USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding—Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.</p> <p>(6) Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(A) Low and Medium Risk Preparations.</p> <p>(i) A pharmacy that prepares low- and medium-risk preparations shall have a clean room/controlled area for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room/controlled area shall:</p> <p>(I) be clean, well lit, and of sufficient size to support sterile compounding activities;</p> <p>(II) be used only for the compounding of sterile preparations;</p> <p>(III) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer room/area;</p> <p>(IV) have non-porous and washable floors or floor covering to enable regular disinfection;</p> <p>(V) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;</p> <p>(VI) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), nonshedding and resistant to damage by disinfectant agents;</p> <p>(VII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;</p> <p>(VIII) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;</p>	<p>(A) Low and Medium Risk Preparations.</p> <p>(i) A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:</p> <p>(I) be clean, well lit, and of sufficient size to support sterile compounding activities;</p> <p>(II) be maintained at a comfortable temperature (e.g., 20 degrees Celsius or cooler) allowing compounding personnel to perform flawlessly when attired in the required aseptic compounding garb;</p> <p>(III) be used only for the compounding of sterile preparations;</p> <p>(IV) be designed such that hand sanitizing and gowning occurs outside the buffer area but allows hands-free access by compounding personnel to the buffer area;</p> <p>(V) have non-porous and washable floors or floor covering to enable regular disinfection;</p> <p>(VI) be ventilated in a manner to avoid disruption from the HVAC system and room cross-drafts;</p> <p>(VII) have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices (e.g., coved), non-shedding and resistant to damage by disinfectant agents;</p> <p>(VIII) have junctures of ceilings to walls coved or caulked to avoid cracks and crevices;</p> <p>(IX) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(IX) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the controlled area;</p> <p>(X) contain an anteroom/ante-zone that provides at least an ISO class 8 air quality and may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination; and</p> <p>(XI) contain a buffer zone or buffer room designed to maintain at least ISO Class 7 conditions. The following is applicable for the buffer area.</p> <p>(-a-) There shall be some demarcation designation that delineates the anteroom or area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area.</p> <p>(-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.</p> <p>(-c-) A buffer zone that is not physically separated from the anteroom shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.</p> <p>(-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.</p> <p>(ii) The pharmacy shall prepare sterile pharmaceuticals in a primary engineering control device, such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator, compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5 conditions during normal activity.</p>	<p>(X) contain only the appropriate compounding supplies and not be used for bulk storage for supplies and materials. Objects that shed particles shall not be brought into the clean room;</p> <p>(XI) contain an ante-area that provides at least an ISO class 8 air quality and contains a sink with hot and cold running water that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination; and</p> <p>(XII) contain a buffer area designed to maintain at least ISO Class 7 conditions for 0.5-µm and larger particles under dynamic working conditions. The following is applicable for the buffer area.</p> <p>(-a-) There shall be some demarcation designation that delineates the ante-area from the buffer area. The demarcation shall be such that it does not create conditions that could adversely affect the cleanliness of the area.</p> <p>(-b-) The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation should be continuously monitored.</p> <p>(-c-) A buffer area that is not physically separated from the ante-area shall employ the principle of displacement airflow as defined in Chapter 797, Pharmaceutical Compounding--Sterile Preparations, of the USP/NF, with limited access to personnel.</p> <p>(-d-) The buffer area shall not contain sources of water (i.e., sinks) or floor drains.</p> <p>(ii) The pharmacy shall prepare sterile preparations in a primary engineering control device, such as a laminar air flow hood, biological safety cabinet, compounding aseptic isolator, compounding aseptic containment isolator which is capable of maintaining at least ISO Class 5 conditions for 0.5-µm particles while compounding sterile preparations.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(I) The primary engineering control shall:</p> <p>(-a-) be located in the buffer area or room and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system.</p> <p>(-b-) be certified by an independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and when it is relocated, in accordance with the manufacturer's specifications; and</p> <p>(-c-) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented.</p> <p>(II) The compounding aseptic isolator or compounding aseptic containment isolator must be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.</p> <p>(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.</p> <p>(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.</p> <p>(-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse</p>	<p>(I) The primary engineering control shall:</p> <p>(-a-) be located in the buffer area and placed in the buffer area in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the heating, ventilating and air condition system.</p> <p>(-b-) be certified by a qualified independent contractor according to the International Organization of Standardization (ISO) Classification of Particulate Matter in Room Air (ISO 14644-1) for operational efficiency at least every six months and whenever the device or room is relocated or altered or major service to the facility is performed, in accordance with the manufacturer's specifications;</p> <p>(-c-) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specification, and the inspection and/or replacement date documented; and</p> <p>(-d-) be located in a buffer area that has a minimum differential positive pressure of 0.02 to 0.05 inches water column.</p> <p>(II) The compounding aseptic isolator or compounding aseptic containment isolator must be placed in an ISO Class 7 buffer area unless the isolator meets all of the following conditions.</p> <p>(-a-) The isolator must provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.</p> <p>(-b-) Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site must maintain ISO Class 5 levels during compounding operations.</p> <p>(-c-) The pharmacy shall maintain documentation from the manufacturer that the isolator meets this standard when located in worse</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>than ISO Class 7 environments.</p> <p>(B) High-risk Preparations. In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer room that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.</p> <p>(C) Automated compounding device. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a routine basis, based on the manufacturer's recommendations.</p> <p>(D) Cytotoxic drugs. If the preparation is cytotoxic, the following is also applicable.</p> <p>(i) General.</p> <p>(I) All personnel involved in the compounding of cytotoxic products shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and</p>	<p>than ISO Class 7 environments.</p> <p>(B) High-risk Preparations.</p> <p>(i) In addition to the requirements in subparagraph (A) of this paragraph, when high-risk preparations are compounded, the primary engineering control shall be located in a buffer area that provides a physical separation, through the use of walls, doors and pass-throughs and has a minimum differential positive pressure of 0.02 to 0.05 inches water column.</p> <p>(ii) Presterilization procedures for high-risk level compounded sterile preparations, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.</p> <p>(C) Automated compounding device. If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing and document the calibration and verification on a daily basis, based on the manufacturer's recommendations, and review the results at least weekly.</p> <p>(D) Hazardous drugs. If the preparation is hazardous, the following is also applicable.</p> <p>(i) General.</p> <p>(I) Hazardous drugs shall be prepared only under conditions that protect personnel during preparation and storage.</p> <p>(II) Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.</p> <p>(III) All personnel involved in the compounding of hazardous drugs shall wear appropriate protective apparel, such as gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and appropriate gloving at all times when handling hazardous drugs,</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>appropriate gloving.</p> <p>(II) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.</p> <p>(III) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.</p> <p>(IV) Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with cytotoxic agents.</p> <p>(ii) Primary engineering control device. Cytotoxic drugs shall be prepared in a Class II or III vertical flow biological safety cabinet or compounding aseptic containment isolator located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:</p> <p>(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better anteroom; and</p> <p>(II) have a pressure indicator that can be readily monitored for correct room pressurization.</p> <p>(iii) Facilities that prepare a low volume of cytotoxic drugs. Pharmacies that prepare a low volume of cytotoxic drugs, are not required to comply with the provisions of clause (ii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC or CACI that is located in a non-negative pressure room).</p> <p>(E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer rooms,</p>	<p>including receiving, distribution, stocking, inventorying, preparation, for administration and disposal.</p> <p>(IV) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with aseptic techniques required for preparing sterile preparations.</p> <p>(V) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.</p> <p>(VI) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents.</p> <p>(ii) Primary engineering control device. Hazardous drugs shall be prepared in a Class II or III vertical flow biological safety cabinet or compounding aseptic containment isolator located in an ISO Class 7 area that is physically separated from other preparation areas. The area for preparation of sterile chemotherapeutic preparations shall:</p> <p>(I) have not less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better ante-area; and</p> <p>(II) have a pressure indicator that can be readily monitored for correct room pressurization.</p> <p>(iii) Facilities that prepare a low volume of hazardous drugs. Pharmacies that prepare a low volume of hazardous drugs, are not required to comply with the provisions of clause (ii) of this subparagraph if the pharmacy uses a device that provides two tiers of containment (e.g., closed-system vial transfer device within a BSC or CACI that is located in a non-negative pressure room).</p> <p>(E) Cleaning and disinfecting the sterile compounding areas. The following cleaning and disinfecting practices and frequencies apply to direct and contiguous compounding areas, which include ISO Class 5 compounding areas for exposure of critical sites as well as buffer areas,</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>anterooms, and ante-areas.</p> <p>(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.</p> <p>(ii) These procedures shall be conducted prior to and after each work shift (at a minimum of every 12 hours while the pharmacy is open) and when there are spills or environmental quality breaches.</p> <p>(iii) Before compounding is performed, all items are removed from the direct and contiguous compounding areas and all surfaces are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), that is left on for a time sufficient to exert its antimicrobial effect.</p> <p>(iv) Work surfaces near the direct and contiguous compounding areas in the buffer or clean area are cleaned of loose material and residue from spills, followed by an application of a residue-free disinfecting agent that is left on for a time sufficient to exert its antimicrobial effect.</p> <p>(v) Floors in the buffer or clean area are cleaned by mopping at least once daily when no aseptic operations are in progress preceding from the buffer or clean room area to the anteroom area.</p> <p>(vi) In the anteroom area, walls, ceilings, and shelving shall be cleaned monthly.</p>	<p>ante-areas, and segregated compounding areas.</p> <p>(i) The pharmacist-in-charge is responsible for developing written procedures for cleaning and disinfecting the direct and contiguous compounding areas and assuring the procedures are followed.</p> <p>(ii) These procedures shall be conducted at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding of individual compounded sterile preparations, when there are spills, and when surface contamination is known or suspected from procedural breaches.</p> <p>(iii) Before compounding is performed, all items shall be removed from the direct and contiguous compounding areas and all surfaces are cleaned by removing loose material and residue from spills, followed by an application of a residue-free disinfecting agent (e.g., IPA), which is allowed to dry before compounding begins.</p> <p>(iv) Work surfaces in the ISO Class 7 buffer areas and ISO Class 8 ante-areas, as well as segregated compounding areas, shall be cleaned and disinfected at least daily. Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality.</p> <p>(v) Floors in the buffer area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent at least once daily when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly.</p> <p>(vi) In the buffer area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents shall be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(vii) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as IPA. However, if supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the buffer or clean area without the need to disinfect the individual supply items. No shipping or other external cartons may be taken into the buffer or clean area.</p> <p>(viii) Storage shelving, emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.</p> <p>(F) Security requirements. The pharmacy may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the pharmacy</p>	<p>(viii) All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer area and ant-are, but only in that order. If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bio-burden of the area being cleaned.</p> <p>(ix) Supplies and equipment removed from shipping cartons must be wiped with a disinfecting agent, such as sterile IPA. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes. However, if sterile supplies are received in sealed pouches, the pouches may be removed as the supplies are introduced into the ISO Class 5 area without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer area or segregated compounding area.</p> <p>(x) Storage shelving emptied of all supplies, walls, and ceilings are cleaned and disinfected at planned intervals, monthly, if not more frequently.</p> <p>(xi) Cleaning must be done by personnel trained in appropriate cleaning techniques.</p> <p>(xii) Proper documentation and frequency of cleaning must be maintained and shall contain the following:</p> <ul style="list-style-type: none"> (I) date and time of cleaning; (II) type of cleaning performed; and (III) name of individual who performed the cleaning. <p>(F) Security requirements. The pharmacist-in-charge may authorize personnel to gain access to that area of the pharmacy containing dispensed sterile preparations, in the absence of the pharmacist, for the purpose of retrieving dispensed prescriptions to deliver to patients. If the</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>allows such after-hours access, the area containing the dispensed sterile pharmaceuticals shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.</p> <p>(G) Storage requirements and beyond-use dating.</p> <p>(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).</p> <p>(ii) Beyond-use dating.</p> <p>(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.</p> <p>(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.</p> <p>(III) Beyond-use dates for compounded sterile preparations that lack justification from either appropriate literature sources or by direct testing evidence must be assigned as described in Chapter 797, Pharmaceutical Compounding--Sterile Preparations of the USP/NF.</p>	<p>pharmacy allows such after-hours access, the area containing the dispensed sterile preparations shall be an enclosed and lockable area separate from the area containing undispensed prescription drugs. A list of the authorized personnel having such access shall be in the pharmacy's policy and procedure manual.</p> <p>(G) Storage requirements and beyond-use dating.</p> <p>(i) Storage requirements. All drugs shall be stored at the proper temperature and conditions, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).</p> <p>(ii) Beyond-use dating.</p> <p>(I) Beyond-use dates for compounded sterile preparations shall be assigned based on professional experience, which shall include careful interpretation of appropriate information sources for the same or similar formulations.</p> <p>(II) Beyond-use dates for compounded sterile preparations that are prepared strictly in accordance with manufacturers' product labeling must be those specified in that labeling, or from appropriate literature sources or direct testing.</p> <p>(III) Beyond-use dates for compounded sterile preparations that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in Chapter 795, in Stability Criteria and Beyond-Use Dating under Pharmaceutical Compounding-Nonsterile Preparations of the USP/NF.</p> <p>(IV) When assigning a beyond-use date, compounding personnel shall consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(6) Equipment and supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:</p> <p>(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile pharmaceuticals are stored in the refrigerator;</p> <p>(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;</p> <p>(C) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;</p> <p>(D) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:</p> <p>(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;</p> <p>(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;</p> <p>(iii) cleaned and sanitized immediately prior to and after each use; and</p>	<p>(V) The sterility and storage and stability beyond-use date for attached and activated container pairs of drug products for intravascular administration shall be applied as indicated by the manufacturer.</p> <p>(7) Equipment and supplies. Pharmacies compounding sterile preparations shall have the following equipment and supplies:</p> <p>(A) a calibrated system or device (i.e., thermometer) to monitor the temperature to ensure that proper storage requirements are met, if sterile preparations are stored in the refrigerator;</p> <p>(B) a calibrated system or device to monitor the temperature where bulk chemicals are stored;</p> <p>(C) a temperature-sensing mechanism suitably placed in the controlled temperature storage space to reflect accurately the true temperature;</p> <p>(D) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly maintained and subject to periodic inspection by the Texas State Board of Pharmacy;</p> <p>(E) equipment and utensils necessary for the proper compounding of sterile preparations. Such equipment and utensils used in the compounding process shall be:</p> <p>(i) of appropriate design, appropriate capacity, and be operated within designed operational limits;</p> <p>(ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug preparation beyond the desired result;</p> <p>(iii) cleaned and sanitized immediately prior to and after each use; and</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;</p> <p>(E) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;</p> <p>(F) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;</p> <p>(G) infusion devices, if applicable; and</p> <p>(H) all necessary supplies, including:</p> <p>(i) disposable needles, syringes, and other supplies for aseptic mixing;</p> <p>(ii) disinfectant cleaning solutions;</p> <p>(iii) hand washing agents with bactericidal action;</p> <p>(iv) disposable, lint free towels or wipes;</p> <p>(v) appropriate filters and filtration equipment;</p> <p>(vi) cytotoxic spill kits, if applicable; and</p> <p>(vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.</p> <p>(7) Labeling.</p> <p>(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following.</p>	<p>(iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance;</p> <p>(F) appropriate disposal containers for used needles, syringes, etc., and if applicable, hazardous waste from the preparation of hazardous drugs and/or biohazardous waste;</p> <p>(G) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;</p> <p>(H) infusion devices, if applicable; and</p> <p>(I) all necessary supplies, including:</p> <p>(i) disposable needles, syringes, and other supplies for aseptic mixing;</p> <p>(ii) disinfectant cleaning solutions;</p> <p>(iii) hand washing agents with bactericidal action;</p> <p>(iv) disposable, lint free towels or wipes;</p> <p>(v) appropriate filters and filtration equipment;</p> <p>(vi) hazardous spill kits, if applicable; and</p> <p>(vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and gloves, as applicable.</p> <p>(8) Labeling.</p> <p>(A) Prescription drug or medication orders. In addition to the labeling requirements for the pharmacy's specific license classification, the label dispensed or distributed pursuant to a prescription drug or medication order shall contain the following:</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(i) The generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation.</p> <p>(ii) For outpatient prescription orders only, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement).</p> <p>(iii) A beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (4) of this subsection.</p> <p>(B) Batch. If the sterile pharmaceutical is compounded in a batch, the following shall also be included on the batch label.</p> <p>(i) unique lot number assigned to the batch;</p> <p>(ii) quantity;</p> <p>(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(iv) device-specific instructions, where appropriate.</p> <p>(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:</p> <p>(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"</p> <p>(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and</p> <p>(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.</p>	<p>(i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the compounded sterile preparation;</p> <p>(ii) for outpatient prescription orders only, a statement that the compounded sterile preparation has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement);</p> <p>(iii) a beyond-use date. The beyond-use date shall be determined as outlined in Chapter 797, Pharmacy Compounding--Sterile Preparations of the USP/NF, and paragraph (7)(G) of this subsection;</p> <p>(B) Batch. If the sterile preparation is compounded in a batch, the following shall also be included on the batch label:</p> <p>(i) unique lot number assigned to the batch;</p> <p>(ii) quantity;</p> <p>(iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(iv) device-specific instructions, where appropriate.</p> <p>(C) Pharmacy bulk package. The label of a pharmacy bulk package shall:</p> <p>(i) state prominently "Pharmacy Bulk Package--Not for Direct Infusion;"</p> <p>(ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and</p> <p>(iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(8) Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.</p> <p>(9) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders must be met.</p> <p>(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).</p> <p>(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:</p> <ul style="list-style-type: none"> (i) appropriate disposition of hazardous solutions and ancillary supplies; (ii) proper disposition of controlled substances in the home; (iii) self-administration of drugs, where appropriate; (iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and 	<p>(9) Written drug information for prescription drug orders only. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.</p> <p>(10) Pharmaceutical Care Services. In addition to the pharmaceutical care requirements for the pharmacy's specific license classification, the following requirements for sterile preparations compounded pursuant to prescription drug orders must be met.</p> <p>(A) Primary provider. There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacy of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record (PMR).</p> <p>(B) Patient training. The pharmacist-in-charge shall develop policies to ensure that the patient and/or patient's caregiver receives information regarding drugs and their safe and appropriate use, including instruction when applicable, regarding:</p> <ul style="list-style-type: none"> (i) appropriate disposition of hazardous solutions and ancillary supplies; (ii) proper disposition of controlled substances in the home; (iii) self-administration of drugs, where appropriate; (iv) emergency procedures, including how to contact an appropriate individual in the event of problems or emergencies related to drug therapy; and

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:</p> <p>(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;</p> <p>(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;</p> <p>(III) handling and disposition of premixed and self-mixed intravenous admixtures; and</p> <p>(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.</p> <p>(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).</p> <p>(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:</p> <p>(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider; and</p> <p>(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions.</p>	<p>(v) if the patient or patient's caregiver prepares sterile preparations in the home, the following additional information shall be provided:</p> <p>(I) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives to premixed intravenous solutions;</p> <p>(II) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed solutions;</p> <p>(III) handling and disposition of premixed and self-mixed intravenous admixtures; and</p> <p>(IV) proper disposition of intravenous admixture compounding supplies such as syringes, vials, ampules, and intravenous solution containers.</p> <p>(C) Pharmacist-patient relationship. It is imperative that a pharmacist-patient relationship be established and maintained throughout the patient's course of therapy. This shall be documented in the patient's medication record (PMR).</p> <p>(D) Patient monitoring. The pharmacist-in-charge shall develop policies to ensure that:</p> <p>(i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider;</p> <p>(ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions; and</p> <p>(iii) reports of adverse events with a compounded sterile preparation are reviewed promptly and thoroughly to correct and prevent future occurrences.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(10) Drugs, components, and materials used in sterile compounding.</p> <p>(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.</p> <p>(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:</p> <ul style="list-style-type: none"> (i) Chemically Pure (CP); (ii) Analytical Reagent (AR); (iii) American Chemical Society (ACS); or (iv) Food Chemical Codex. <p>(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.</p> <p>(D) All components shall:</p> <ul style="list-style-type: none"> (i) be manufactured in an FDA-registered facility; or (ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures. <p>(E) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.</p> <p>(F) Components, drug preparation containers, and closures shall be</p>	<p>(11) Drugs, components, and materials used in sterile compounding.</p> <p>(A) Drugs used in sterile compounding shall be a USP/NF grade substances manufactured in an FDA-registered facility.</p> <p>(B) If USP/NF grade substances are not available shall be of a chemical grade in one of the following categories:</p> <ul style="list-style-type: none"> (i) Chemically Pure (CP); (ii) Analytical Reagent (AR); (iii) American Chemical Society (ACS); or (iv) Food Chemical Codex. <p>(C) If a drug, component or material is not purchased from a FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.</p> <p>(D) All components shall:</p> <ul style="list-style-type: none"> (i) be manufactured in an FDA-registered facility; or (ii) in the professional judgment of the pharmacist, be of high quality and obtained from acceptable and reliable alternative sources; and (iii) stored in properly labeled containers in a clean, dry area, under proper temperatures. <p>(E) Drug preparation containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug preparation beyond the desired result.</p> <p>(F) Components, drug preparation containers, and closures shall be</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>rotated so that the oldest stock is used first.</p> <p>(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.</p> <p>(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.</p> <p>(11) Compounding process.</p> <p>(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed for:</p> <ul style="list-style-type: none"> (i) the facility; (ii) equipment; (iii) personnel; (iv) preparation evaluation; (v) quality assurance; (vi) preparation recall; (vii) packaging; and (viii) storage of compounded sterile preparations. <p>(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.</p>	<p>rotated so that the oldest stock is used first.</p> <p>(G) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.</p> <p>(H) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.</p> <p>(12) Compounding process.</p> <p>(A) Standard operating procedures (SOPs). All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process. At a minimum, SOPs shall be developed and implemented for:</p> <ul style="list-style-type: none"> (i) the facility; (ii) equipment; (iii) personnel; (iv) preparation evaluation; (v) quality assurance; (vi) preparation recall; (vii) packaging; and (viii) storage of compounded sterile preparations. <p>(B) USP/NF. Any compounded formulation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(C) Personnel Cleansing and Garbing.</p> <p>(i) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from direct contact with components, drug preparation containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected.</p> <p>(ii) Before entering the clean area, compounding personnel must remove the following:</p> <p>(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);</p> <p>(II) all cosmetics, because they shed flakes and particles; and</p> <p>(III) all hand, wrist, and other body jewelry.</p> <p>(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment.</p> <p>(iv) Personnel must don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:</p> <p>(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents.</p>	<p>(C) Personnel Cleansing and Garbing.</p> <p>(i) Any person with an apparent illness or open lesion, including rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, that may adversely affect the safety or quality of a drug preparation being compounded shall be excluded from working in ISO Class 5 and ISO Class 7 compounding areas until the condition is remedied.</p> <p>(ii) Before entering the buffer area, compounding personnel must remove the following:</p> <p>(I) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);</p> <p>(II) all cosmetics, because they shed flakes and particles; and</p> <p>(III) all hand, wrist, and other body jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of personal protective equipment (e.g., fit of gloves and cuffs of sleeves).</p> <p>(iii) The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.</p> <p>(iv) Personnel shall don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:</p> <p>(I) Activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face mask/eye shield. Eye shields are optional unless working with irritants like germicidal disinfecting agents or when preparing hazardous drugs.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the anteroom/ante-area.</p> <p>(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists.</p> <p>(IV) Gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins.</p> <p>(V) Gloves, either those which are sterile or have been disinfected by applying 70% IPA or appropriate disinfectant to all contact surface areas and allowed to dry, that form a continuous barrier with the gown shall be the last item donned before compounding begins. Routine application of 70% IPA shall occur throughout the compounding day and whenever nonsterile surfaces are touched.</p> <p>(VI) When compounding personnel must temporarily exit the ISO Class 7 environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 anteroom/ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves</p>	<p>(II) After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, personnel shall perform a hand hygiene procedure by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Personnel shall begin washing arms at the hands and continue washing to elbows for at least 30 seconds with either a plain (non-antimicrobial) soap, or antimicrobial soap, and water while in the ante-area. Hands and forearms to the elbows shall be completely dried using lint-free disposable towels, an electronic hands-free hand dryer, or a HEPA filtered hands dryer.</p> <p>(III) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclosed at the neck.</p> <p>(IV) Once inside the buffer area or segregated compounding area, and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands shall be allowed to dry thoroughly before donning sterile gloves.</p> <p>(V) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins. Routine application of sterile 70% IPA shall occur throughout the compounding day and whenever nonsterile surfaces are touched.</p> <p>(v) When compounding personnel shall temporarily exit the ISO Class 7 environment during a work shift, the exterior gown, if not visibly soiled, may be removed and retained in the ISO Class 8 ante-area, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and gloves shall be</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>must be replaced with new ones before re-entering the ISO Class 7 clean environment along with performing proper hand hygiene.</p> <p>(D) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.</p> <p>(12) Quality Assurance.</p> <p>(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a product that is sterile and that contains the stated amount of active ingredient(s).</p> <p>(i) Low risk preparations.</p> <p>(I) Quality assurance practices include, but are not limited to the following:</p>	<p>replaced with new ones before re-entering the ISO Class 7 clean environment along with performing proper hand hygiene.</p> <p>(vi) During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonsterile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 shall re-garb personal protective equipment along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 buffer area.</p> <p>(vii) When compounding aseptic isolators or compounding aseptic containment isolators are the source of the ISO Class 5 environment, the compounding personnel should follow the requirements as specified in this subparagraph, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any components of personal protective equipment or cleansing are not required.</p> <p>(13) Quality Assurance.</p> <p>(A) Initial Formula Validation. Prior to routine compounding of a sterile preparation, a pharmacy shall conduct an evaluation that shows that the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).</p> <p>(i) Low risk preparations.</p> <p>(I) Quality assurance practices include, but are not limited to the following:</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.</p> <p>(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.</p> <p>(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.</p> <p>(-d-) Visual inspection of compounded sterile preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile produce. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean--Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(ii) Medium risk preparations.</p> <p>(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-</p>	<p>(-a-) Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.</p> <p>(-b-) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles.</p> <p>(-c-) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.</p> <p>(-d-) Visual inspection of compounded sterile preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually by each person authorized to compound in a low-risk level under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level sterile preparations. Once begun, this test is completed without interruption within an ISO Class 5 air quality environment. Three sets of four 5-milliliter aliquots of sterile Soybean--Casein Digest Medium are transferred with the same sterile 10-milliliter syringe and vented needle combination into separate sealed, empty, sterile 30-milliliter clear vials (i.e., four 5-milliliter aliquots into each of three 30-milliliter vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(ii) Medium risk preparations.</p> <p>(I) Quality assurance procedures for medium-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations, as well as a more challenging media-</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>fill test passed annually, or more frequently.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(iii) High risk preparations.</p> <p>(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.</p> <p>(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is</p>	<p>fill test passed annually, or more frequently.</p> <p>(II) Example of a Media-Fill Test Procedure. This, or an equivalent test, is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. This test is completed without interruption within an ISO Class 5 air quality environment. Six 100-milliliter aliquots of sterile Soybean--Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-milliliter syringe and 18-gauge needle combination is used to exchange two 5-milliliter aliquots of medium from one container to the other container in the pair. For example, after a 5-milliliter aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-milliliter aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-milliliter aliquot is transferred from it back to the second container in the pair. Following the two 5-milliliter aliquot exchanges in each pair of containers, a 5-milliliter aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-milliliter clear vial, using a sterile 10-milliliter syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. The vials are incubated within a range of 20 - 35 degrees Celsius for a minimum of 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days. The media-fill test must include a positive-control sample.</p> <p>(iii) High risk preparations.</p> <p>(I) Procedures for high-risk level compounded sterile preparations include all those for low-risk level compounded sterile preparations. In addition, a media-fill test that represents high-risk level compounding is performed twice a year by each person authorized to compound high-risk level compounded sterile preparations.</p> <p>(II) Example of a Media-Fill Test Procedure Compounded Sterile Preparations Sterilized by Filtration. This test, or an equivalent test, is</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:</p> <p>(-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.</p> <p>(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.</p> <p>(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.</p> <p>(B) Finished preparation release checks and tests.</p> <p>(i) High-risk level compounded sterile preparations. All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius (36 - 46 degrees Fahrenheit) and longer than six hours at warmer than 8 degrees Celsius (46 degrees Fahrenheit) before they are sterilized shall be tested to ensure they are sterile and do not contain</p>	<p>performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level compounded sterile preparations. Note: Sterility tests for autoclaved compounded sterile preparations are not required unless they are prepared in batches of more than 25 units. This test is completed without interruption in the following sequence:</p> <p>(-a-) Dissolve 3 grams of nonsterile commercially available Soybean--Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a 3% nonsterile solution.</p> <p>(-b-) Draw 25 milliliters of the medium into each of three 30-milliliter sterile syringes. Transfer 5 milliliters from each syringe into separate sterile 10-milliliter vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.</p> <p>(-c-) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next 10 milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20 to 35 degrees Celsius for a minimum of 14 days. Inspect for microbial growth over 14 days as described in Chapter 797 Pharmaceutical Compounding--Sterile Preparations, of the USP/NF.</p> <p>(B) Finished preparation release checks and tests.</p> <p>(i) All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (such as ampuls, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than 12 hours at 2 - 8 degrees Celsius and longer than six hours at warmer than 8 degrees Celsius before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>excessive bacterial endotoxins as specified in Chapter 71, Sterility Tests of the USP/NF.</p> <p>(ii) All compounded sterile preparations that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.</p> <p>(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.</p>	<p>before being dispensed or administered.</p> <p>(ii) All compounded sterile preparations that are intended to be solutions must be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed.</p> <p>(iii) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded sterile preparations at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are dispensed or administered.</p> <p>(C) Viable and nonviable environmental sampling testing. Environmental sampling shall occur, at a minimum, every six months as part of a comprehensive quality management program and under any of the following conditions:</p> <p>(i) as part of the commissioning and certification of new facilities and equipment;</p> <p>(ii) following any servicing of facilities and equipment;</p> <p>(iii) as part of the re-certification of facilities and equipment;</p> <p>(iv) in response to identified problems with end products or staff technique; or</p> <p>(v) in response to issues with compounded sterile preparations, observed compounding personnel work practices, or patient-related infections (where the compounded sterile preparation is being considered as a potential source of the infection).</p> <p>(D) Total particle counts. Certification that each ISO classified area (e.g., ISO Class 5, 7, and 8), is within established guidelines shall be</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
	<p>performed no less than every six months and whenever the equipment is relocated or the physical structure of the buffer area or ante-area has been altered. All certification records shall be maintained and reviewed to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour. Testing shall be performed by qualified operators using current, state-of-the-art equipment. with results of the following:</p> <ul style="list-style-type: none"> (i) ISO Class 5 – not more than 3520 particles 0.5 µm and larger size per cubic meter of air; (ii) ISO Class 7 – not more than 352,000 particles of 0.5 µm and larger size per cubic meter of air for any buffer area; and (iii) ISO Class 8 – not more than 3,520,000 particles of 0.5 µm and larger size per cubic meter of air for any ante-area. <p>(E) Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and the general pharmacy area shall not be less than 0.02 inch water column.</p> <p>(F) Sampling plan. An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed. Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas and in the segregated compounding areas at greatest risk of contamination. The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.</p> <p>(G) Viable air sampling. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels. For low-, medium-, and high-risk level compounding, air sampling shall</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(13) Quality control.</p>	<p>be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within the laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area. For low-risk level compounded sterile preparations within 12-hour or less beyond-use-date prepared in a primary engineering control that maintains an ISO Class 5, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO Class 5 environment during the certification of the primary engineering control.</p> <p>(H) Air sampling frequency and process. Air sampling shall be performed at least every 6 months as a part of the re-certification of facilities and equipment. A sufficient volume of air shall be sampled and the manufacturer’s guidelines for use of the electronic air sampling equipment followed. At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.</p> <p>(I) Compounding accuracy checks. Written procedures for double-checking compounding accuracy shall be followed for every compounded sterile preparation during preparation and immediately prior to release, including label accuracy and the accuracy of the addition of all drug products or ingredients used to prepare the finished preparation and their volumes or quantities. At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.</p> <p>(14) Quality control.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 797, Pharmaceutical Compounding--Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter 1160, Pharmaceutical Calculations in Prescription Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.</p> <p>(B) Verification of compounding accuracy and sterility.</p> <p>(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.</p> <p>(ii) If the correct identify, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately.</p> <p>(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.</p>	<p>(A) Quality control procedures. The pharmacy shall follow established quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, pharmacy personnel shall consider the provisions of USP Chapter 71, Sterility Tests, USP Chapter 85, Bacterial Endotoxins Test, Pharmaceutical Compounding—Nonsterile Preparations, USP Chapter 795, USP Chapter 797, Pharmaceutical Compounding--Sterile Preparations, Chapter 1075, Good Compounding Practices, and Chapter 1160, Pharmaceutical Calculations in Prescription Compounding, and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding of the current USP/NF. Such procedures shall be documented and be available for inspection.</p> <p>(B) Verification of compounding accuracy and sterility.</p> <p>(i) The accuracy of identities, concentrations, amounts, and purities of ingredients in compounded sterile preparations shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers.</p> <p>(ii) If the correct identity, purity, strength, and sterility of ingredients and components of compounded sterile preparations cannot be confirmed such ingredients and components shall be discarded immediately.</p> <p>(iii) If individual ingredients, such as bulk drug substances, are not labeled with expiration dates, when the drug substances are stable indefinitely in their commercial packages under labeled storage conditions, such ingredients may gain or lose moisture during storage and use and shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in compounded sterile preparations.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(e) Records.</p> <p>(1) Maintenance of records. Every record required under this section must be:</p> <p>(A) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and</p> <p>(B) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.</p> <p>(2) Compounding records.</p> <p>(A) Compounding pursuant to patient specific prescription drug orders. Compounding records for all compounded pharmaceuticals shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:</p> <p>(i) the date of preparation;</p> <p>(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;</p> <p>(iii) signature or initials of the pharmacist or pharmacy technician or</p>	<p>(e) Records. Any testing, cleaning, procedures, or other activities required in this subsection shall be documented and such documentation shall be maintained by the pharmacy.</p> <p>(1) Maintenance of records. Every record required under this section must be:</p> <p>(A) kept by the pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and</p> <p>(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.</p> <p>(2) Compounding records.</p> <p>(A) Compounding pursuant to patient specific prescription drug orders. Compounding records for all compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:</p> <p>(i) the date of preparation;</p> <p>(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;</p> <p>(iii) signature or initials of the pharmacist or pharmacy technician or</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>pharmacy technician trainee performing the compounding;</p> <p>(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;</p> <p>(v) the quantity in units of finished products or amount of raw materials;</p> <p>(vi) the container used and the number of units prepared; and</p> <p>(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:</p> <p>(I) the criteria used to determine the beyond-use date; and</p> <p>(II) documentation of performance of quality control procedures.</p> <p>(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.</p> <p>(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:</p> <p>(I) the formula;</p> <p>(II) the components;</p> <p>(III) the compounding directions;</p> <p>(IV) a sample label;</p>	<p>pharmacy technician trainee performing the compounding;</p> <p>(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;</p> <p>(v) the quantity in units of finished preparation or amount of raw materials;</p> <p>(vi) the container used and the number of units prepared; and</p> <p>(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:</p> <p>(I) the criteria used to determine the beyond-use date; and</p> <p>(II) documentation of performance of quality control procedures.</p> <p>(B) Compounding records when batch compounding or compounding in anticipation of future prescription drug or medication orders.</p> <p>(i) Master work sheet. A master work sheet shall be developed and approved by a pharmacist for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:</p> <p>(I) the formula;</p> <p>(II) the components;</p> <p>(III) the compounding directions;</p> <p>(IV) a sample label;</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(V) evaluation and testing requirements;</p> <p>(VI) specific equipment used during preparation; and</p> <p>(VII) storage requirements.</p> <p>(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:</p> <p>(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;</p> <p>(II) lot number for each component;</p> <p>(III) component manufacturer/distributor or suitable identifying number;</p> <p>(IV) container specifications (e.g., syringe, pump cassette);</p> <p>(V) unique lot or control number assigned to batch;</p> <p>(VI) expiration date of batch-prepared preparations;</p> <p>(VII) date of preparation;</p> <p>(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;</p> <p>(IX) name, initials, or electronic signature of the responsible pharmacist;</p> <p>(X) finished preparation evaluation and testing specifications, if applicable; and</p> <p>(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.</p>	<p>(V) evaluation and testing requirements;</p> <p>(VI) specific equipment used during preparation; and</p> <p>(VII) storage requirements.</p> <p>(ii) Preparation work sheet. The preparation work sheet for each batch of preparations shall document the following:</p> <p>(I) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;</p> <p>(II) lot number for each component;</p> <p>(III) component manufacturer/distributor or suitable identifying number;</p> <p>(IV) container specifications (e.g., syringe, pump cassette);</p> <p>(V) unique lot or control number assigned to batch;</p> <p>(VI) expiration date of batch-prepared preparations;</p> <p>(VII) date of preparation;</p> <p>(VIII) name, initials, or electronic signature of the person(s) involved in the preparation;</p> <p>(IX) name, initials, or electronic signature of the responsible pharmacist;</p> <p>(X) finished preparation evaluation and testing specifications, if applicable; and</p> <p>(XI) comparison of actual yield to anticipated or theoretical yield, when appropriate.</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(f) Office Use Compounding and Distribution of Compounded Preparations to Class C Pharmacies or Veterinarians in Accordance with §563.054 of the Act.</p> <p>(1) General.</p> <p>(A) A pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner in accordance with this subsection.</p> <p>(B) A Class A (Community) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C (Institutional) pharmacy.</p> <p>(C) A Class C (Institutional) pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C pharmacy has compounded for other Class C pharmacies under common ownership.</p> <p>(D) To dispense and deliver a compounded preparation under this subsection, a pharmacy must:</p> <p>(i) verify the source of the raw materials to be used in a compounded drug;</p> <p>(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);</p> <p>(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;</p> <p>(iv) comply with all applicable competency and accrediting standards as determined by the board; and</p>	<p>(f) Office Use Compounding and Distribution of Sterile Compounded Preparations</p> <p>(1) General.</p> <p>(A) A pharmacy may compound, dispense, deliver, and distribute a compounded sterile preparation as specified in subchapter D, Texas Pharmacy Act Chapter 562.</p> <p>(B) A Class A-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations to a Class C or Class C-S pharmacy.</p> <p>(C) A Class C-S pharmacy is not required to register or be licensed under Chapter 431, Health and Safety Code, to distribute sterile compounded preparations that the Class C-S pharmacy has compounded for other Class C or Class C-S pharmacies under common ownership.</p> <p>(D) To compound and deliver a compounded preparation under this subsection, a pharmacy must:</p> <p>(i) verify the source of the raw materials to be used in a compounded drug;</p> <p>(ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements, and the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191);</p> <p>(iii) enter into a written agreement with a practitioner for the practitioner's office use of a compounded preparation;</p> <p>(iv) comply with all applicable competency and accrediting standards as determined by the board; and</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(v) comply with the provisions of this subsection.</p> <p>(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:</p> <p>(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except as authorized by §563.054 of the Act;</p> <p>(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;</p> <p>(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:</p> <p>(i) a patient to report an adverse reaction or submit a complaint; and</p> <p>(ii) the pharmacy to recall batches of compounded preparations.</p> <p>(3) Recordkeeping.</p> <p>(A) Maintenance of Records.</p> <p>(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to a Class C pharmacy for administration to a patient shall:</p> <p>(l) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or</p>	<p>(v) comply with the provisions of this subsection.</p> <p>(2) Written Agreement. A pharmacy that provides sterile compounded preparations to practitioners for office use or to another pharmacy shall enter into a written agreement with the practitioner or pharmacy. The written agreement shall:</p> <p>(A) address acceptable standards of practice for a compounding pharmacy and a practitioner and receiving pharmacy that enter into the agreement including a statement that the compounded drugs may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity except to a veterinarian as authorized by §563.054 of the Act;</p> <p>(B) require the practitioner or receiving pharmacy to include on a patient's chart, medication order or medication administration record the lot number and beyond-use date of a compounded preparation administered to a patient;</p> <p>(C) describe the scope of services to be performed by the pharmacy and practitioner or receiving pharmacy, including a statement of the process for:</p> <p>(i) a patient to report an adverse reaction or submit a complaint; and</p> <p>(ii) the pharmacy to recall batches of compounded preparations.</p> <p>(3) Recordkeeping.</p> <p>(A) Maintenance of Records.</p> <p>(i) Records of orders and distribution of sterile compounded preparations to a practitioner for office use or to an institutional pharmacy for administration to a patient shall:</p> <p>(l) be kept by the pharmacy and be available, for at least two years from the date of the record, for inspecting and copying by the board or</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>its representative and to other authorized local, state, or federal law enforcement agencies;</p> <p>(II) maintained separately from the records of products dispensed pursuant to a prescription or medication order; and</p> <p>(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.</p> <p>(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.</p> <p>(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:</p> <p>(i) date of the order;</p> <p>(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the Class C Pharmacy ordering the preparation; and</p> <p>(iii) name, strength, and quantity of the preparation ordered.</p> <p>(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a</p>	<p>its representative and to other authorized local, state, or federal law enforcement agencies;</p> <p>(II) maintained separately from the records of preparations dispensed pursuant to a prescription or medication order; and</p> <p>(III) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy or its representative. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format. Failure to provide the records set out in this subsection, either on site or within 72 hours for whatever reason, constitutes prima facie evidence of failure to keep and maintain records.</p> <p>(ii) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided the data processing system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.</p> <p>(B) Orders. The pharmacy shall maintain a record of all sterile compounded preparations ordered by a practitioner for office use or by an institutional pharmacy for administration to a patient. The record shall include the following information:</p> <p>(i) date of the order;</p> <p>(ii) name, address, and phone number of the practitioner who ordered the preparation and if applicable, the name, address and phone number of the institutional pharmacy ordering the preparation; and</p> <p>(iii) name, strength, and quantity of the preparation ordered.</p> <p>(C) Distributions. The pharmacy shall maintain a record of all sterile compounded preparations distributed pursuant to an order to a practitioner for office use or by an institutional pharmacy for</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>practitioner for office use or by a Class C pharmacy for administration to a patient. The record shall include the following information:</p> <ul style="list-style-type: none"> (i) date the preparation was compounded; (ii) date the preparation was distributed; (iii) name, strength and quantity in each container of the preparation; (iv) pharmacy's lot number; (v) quantity of containers shipped; and (vi) name, address, and phone number of the practitioner or Class C Pharmacy to whom the preparation is distributed. <p>(D) Audit Trail.</p> <p>(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class C pharmacy for administration to a patient in such a manner as to be able to provide a audit trail for all orders and distributions of any of the following during a specified time period.</p> <ul style="list-style-type: none"> (I) any strength and dosage form of a preparation (by either brand or generic name or both); (II) any ingredient; (III) any lot number; (IV) any practitioner; (V) any facility; and (VI) any pharmacy, if applicable. 	<p>administration to a patient. The record shall include the following information:</p> <ul style="list-style-type: none"> (i) date the preparation was compounded; (ii) date the preparation was distributed; (iii) name, strength and quantity in each container of the preparation; (iv) pharmacy's lot number; (v) quantity of containers shipped; and (vi) name, address, and phone number of the practitioner or institutional pharmacy to whom the preparation is distributed. <p>(D) Audit Trail.</p> <p>(i) The pharmacy shall store the order and distribution records of preparations for all sterile compounded preparations ordered by and or distributed to a practitioner for office use or by a Class S pharmacy for administration to a patient in such a manner as to be able to provide an audit trail for all orders and distributions of any of the following during a specified time period.</p> <ul style="list-style-type: none"> (I) any strength and dosage form of a preparation (by either brand or generic name or both); (II) any ingredient; (III) any lot number; (IV) any practitioner; (V) any facility; and (VI) any pharmacy, if applicable.

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(ii) The audit trail shall contain the following information:</p> <p>(I) date of order and date of the distribution;</p> <p>(II) practitioner's name, address, and name of the Class C pharmacy, if applicable;</p> <p>(III) name, strength and quantity of the preparation in each container of the preparation;</p> <p>(IV) name and quantity of each active ingredient;</p> <p>(V) quantity of containers distributed; and</p> <p>(VI) pharmacy's lot number;</p> <p>(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:</p> <p>(A) name, address, and phone number of the compounding pharmacy;</p> <p>(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";</p> <p>(C) name and strength of the preparation or list of the active ingredients and strengths;</p> <p>(D) pharmacy's lot number;</p> <p>(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;</p> <p>(F) quantity or amount in the container;</p>	<p>(ii) The audit trail shall contain the following information:</p> <p>(I) date of order and date of the distribution;</p> <p>(II) practitioner's name, address, and name of the institutional pharmacy, if applicable;</p> <p>(III) name, strength and quantity of the preparation in each container of the preparation;</p> <p>(IV) name and quantity of each active ingredient;</p> <p>(V) quantity of containers distributed; and</p> <p>(VI) pharmacy's lot number;</p> <p>(4) Labeling. The pharmacy shall affix a label to the preparation containing the following information:</p> <p>(A) name, address, and phone number of the compounding pharmacy;</p> <p>(B) the statement: "For Institutional or Office Use Only--Not for Resale"; or if the preparation is distributed to a veterinarian the statement: "Compounded Preparation";</p> <p>(C) name and strength of the preparation or list of the active ingredients and strengths;</p> <p>(D) pharmacy's lot number;</p> <p>(E) beyond-use date as determined by the pharmacist using appropriate documented criteria;</p> <p>(F) quantity or amount in the container;</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(H) device-specific instructions, where appropriate.</p> <p>(g) Recall Procedures.</p> <p>(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.</p> <p>(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.</p> <p>(3) In the event of a recall, the pharmacist-in-charge shall ensure that:</p> <p>(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;</p> <p>(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;</p> <p>(C) if the preparation is prepared as a batch, the board is notified of the recall, in writing;</p> <p>(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;</p> <p>(E) the preparation is quarantined; and</p> <p>(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective</p>	<p>(G) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and</p> <p>(H) device-specific instructions, where appropriate.</p> <p>(g) Recall Procedures.</p> <p>(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.</p> <p>(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.</p> <p>(3) In the event of a recall, the pharmacist-in-charge shall ensure that:</p> <p>(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;</p> <p>(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;</p> <p>(C) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;</p> <p>(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;</p> <p>(E) the preparation is quarantined; and</p> <p>(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective</p>

<p align="center">§291.133 Pharmacies Compounding Sterile Preparations – CURRENT</p>	<p align="center">§291.133 Pharmacies Compounding Sterile Preparations - RECOMMENDATION</p>
<p>measures.</p> <p>(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.</p>	<p>measures.</p> <p>(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.</p> <p>(5) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.</p>