



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 16-085

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

2. Form, Style and Placement in Administrative Code

a. The board should consider adding an “A” to the beginning of the sentence in s. Phar 15.14 (2) (L) (“Quality assurance program”) to form a complete sentence when read with the introductory material. [s. 1.03 (3), Manual.]

b. The sentence in s. Phar 15.17 (4) that begins with “There shall be a procedure” should be rewritten to ensure that it forms a complete sentence when read with the introductory material. [s. 1.03 (3), Manual.]

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In s. Phar 15.01 (4) (b), is it necessary to use the word “sterile” twice in the phrase “sterile compounded sterile preparation”?

b. The proposed rule encompasses a number of punctuation errors. The board should make the following amendments:

- (1) Section Phar 15.01 (7). The comma in the phrase “any, active pharmaceutical ingredient” should be removed.
- (2) Section Phar 15.01 (9). A comma should be added between the terms “form” and “including” in the definition of “Container-closure system”.
- (3) Section Phar 15.12 (10). A hyphen should be inserted between the words “non” and “sterile” to create the term “non-sterile”.

- (4) Section Phar 15.20 (2). The comma between the words “supplier” and “shall” should be removed.
- (5) Section Phar 15.30 (14). A hyphen should be inserted between the terms “HEPA” and “filtered” to create the term “HEPA-filtered”.
- (6) Section Phar 15.32 (2) (e). A comma should be inserted between the terms “gloves” and “hand”. Also in this section, an apostrophe should be added to the end of the term “manufacturers” to create a possessive term.
- (7) Section Phar 15.37 (3). A hyphen should be added between the terms “container” and “closure” both times the terms are used in the sentence to create the term “container-closure”. This comports with the hyphenation of this term that is used throughout the proposed rule.

c. When drafting rule text, all subunits of a rule should end with a period. [s. 1.03 (4), Manual]. The board should add a period to the end of the following sentences:

- (1) Section Phar 15.01 (11). The definition of “freezer”.
- (2) Section Phar 15.01 (13). The definition of “refrigerator”.
- (3) Section Phar 15.13 (1) (f). The sentence “Compounding records are complete”.
- (4) Section Phar 15.14 (3). A period should be added to the end of the title “Review of policies and procedures”. [s. 1.05 (c), Manual.]
- (5) Section Phar 15.20 (1) (a). The sentence “The component is stored in its original container under conditions to avoid decomposition”.

d. In s. Phar 15.01 (14), is the phrase “throughout its beyond use date” accurate, given that the beyond use date is defined as a specific date in sub. (4)? Would it be more appropriate to refer to the period prior to the beyond use date?

e. The board should also consider reorganizing the subdivisions under s. Phar 15.01 (14). Paragraphs (a) to (e) do not clearly fall under the definition of “Stability”. These subdivisions may be better characterized as subsections under s. Phar 15.01. [s. 1.03, Manual.] In addition, if the board does not use the term “Stability” as a standalone term in its proposed rule, the board should eliminate the term “Stability” from s. Phar 15.01.

f. The board could consider adding more detail to the sections of the rule that relate to records. For example, the board could consider amending the title of s. Phar 15.12 from “Records” to “Records of compounding” if that definition comports with the board’s intent. Records are referred to elsewhere in the proposed rule, such as in s. Phar 15.11 (5). It may create confusion to have the term “Records” used in the rule when the requirements of records under s. Phar 15.12 apply only to “Records of compounding”.

g. The board could consider describing what kind of final check is envisioned under s. Phar 15.13 (1). For example, it is not clear whether a final check shall be performed after all compounding, or after certain compounding procedures.

h. If acronyms are used for names of agencies or programs, they must be defined and used consistently. [s. 1.01 (8), Manual.] The board should make the following amendments to the use of acronyms:

- (1) Section Phar 15.16 (1). The term “FDA” should be spelled out the first time it is used.
- (2) Section Phar 15.16 (4). The term “United States food and drug administration” should be replaced with the acronym “FDA” if, in s. Phar 15.16 (1), the board defines and establishes the use of the term “FDA”.
- (3) Section Phar 15.35 (3) (b) 2. The term “SAL” should be defined before the acronym is used.

i. In s. Phar 15.20 (3), the board should review the provision for clarity and its relationship to other provisions in s. Phar 15.20. For example, in what circumstances may components be transferred to other containers? How does the transfer of components relate to the timeliness of usage of those components and the requirement that a component be stored in its original container under s. Phar 15.20 (1)?

j. The number “one” is spelled out, unless it is in reference to a date, percentage, or money, or in a series of numbers. [s. 1.01 (5), Manual.] The board should change the numeral “1” to “one” in the following sections:

- (1) Section Phar 15.30 (15). The term “1 unit” should be rewritten to “one unit”.
- (2) Section Phar 15.31 (2) (d). The term “1 meter” should be rewritten to “one meter”.
- (3) Section Phar 15.34 (4). The term “1 hour” should be rewritten to “one hour”.

k. The terms “class” in s. Phar 15.31 (3) (p) and (q) should be capitalized to comport with how that term is used in the definitions under s. Phar 15.30.

l. The term “Spills occur” should be changed to “A spill occurs” in s. Phar 15.33 (3) (a) because it is preferable to use the singular of a term. [s. 1.01 (9) (e), Manual.]

m. The term “Category I” in s. Phar 15.37 (1) (b) should be changed to “Category 1” to comport with how that term is used in the definitions under s. Phar 15.30.