



Wisconsin Legislative Council

RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 22-007

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

2. Form, Style and Placement in Administrative Code

a. For the definition of “High-risk level compounded sterile preparations”, consider modifying the last sentence to identify the defined term, perhaps changing the material to: ““High-risk level compounded sterile preparations” include water containing preparations that are stored for more than six hours before terminal sterilization.”

b. For the definitions of “Low-risk level compounded sterile preparations” and “Medium-risk level compounded sterile preparations”, the sentences within those definitions that begin with the material, “The compounding process ...”, appear to be substantive provisions that may not be appropriate to include within a definition. [s. 1.07 (1) (d), Manual.]

c. Is it necessary to specifically define “immediate use compounded sterile preparations”, as that term is used in s. Phar 15.34? Also, presence or absence of a hyphen between “immediate” and “use” should be consistent. Presently, the rule text of s. Phar 15.34 uses the hyphen but s. Phar 15.34 (title) does not.

d. The treatment of SECTION 4 should more accurately describe the provisions of the existing code that are amended. Section Phar 15.37 (1) (a) and (b) are included but not changed by the proposed rule, so it appears the rule should treat only s. Phar 15.37 (1) (intro.), (c), and (d). Also, in s. Phar 15.37 (1) (c) 1. (intro.), underscored material should follow stricken material at the beginning of the sentence. In s. Phar 15.37 (1) (c) 1. a., the treatment to revise the deadline to 14 days should be written “4 14”.