*WISCONSIN LEGISLATIVE COUNCIL STAFF*

*RULES CLEARINGHOUSE*

**Ronald Sklansky**
Director
(608) 266–1946

**Richard Sweet**
Assistant Director
(608) 266–2982

**David J. Stute, Director**
Legislative Council Staff
(608) 266–1304

One E. Main St., Ste. 401
P.O. Box 2536
Madison, WI 53701–2536
FAX: (608) 266–3830

# CLEARINGHOUSE RULE 97–141

## Comments

**[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated October 1994.]**

***2. Form, Style and Placement in Administrative Code***

a. The analysis should indicate whether the provisions of s. 299.11 (2), Stats., have been met.

b. When a unit of a rule is divided into subunits and the subunits are preceded with introductory material, the introductory material always ends in a colon and leads into the subunits. Section s. NR 149.02 (3) (intro.) and 149.07 (1) (b) should be rewritten to comply with this rule. [See s. 1.03 (8), Manual.] Another method also is possible. For example, if the first sentence of s. NR 149.02 (3) is not meant to grammatically lead into the following subunits, then the sentence should be renumbered as par. (a). The remaining paragraphs should be renumbered accordingly. The entire rule should be reviewed for this structural problem.

c. It appears that the Note to s. NR 149.03 (25) contains substantive material. The information contained in that Note should be placed in the text of the rule, specifically within the definition of "reference sample" set forth in s. NR 149.03 (25). [See s. 1.09 (1), Manual.]

d. Throughout s. NR 149.04 (1) (a) to (h), the phrase "certification or registration for" should be inserted. For example, the phrase should be inserted after "include" in the first sentence of s. NR 149.04 (1) (a) and after "for" in the second sentence of that paragraph.

e. What is a "certifiable parameter" referred to in s. NR 149.04 (1) (f)? Does that term refer to an "analyte"? If so, the term "analyte," which is a defined term, should be used. If not, the rule should provide a definition of "certifiable parameter."

f. The first occurrence of "and" in the third column of test category 10 in Table 1 appears to be superfluous. Should it be deleted?

g. In Table 2, items 21. and 22. both contain a reference to footnote 1. Is this intentional?

h. Section NR 149.07 (1) (a) 1. and 2. refer to an application for transfer of ownership; s. NR 149.07 (1) (a) 2. refers to a laboratory request for acceptance under a reciprocity agreement. However, the material in sub. (1) (intro.) does not refer to those types of applications. The introductory material should be revised to correspond to the information contained in the subunits.

i. The phrase "per this section," in s. NR 149.07 (2), should be replaced with "as set forth in sub. (1)."

j. Section NR 149.07 (4) (a) should specify that a laboratory applying for reciprocal certification is not required to be evaluated by department personnel or by a department representative prior to receiving certification or registration.

k. In the title to s. NR 149.09, "CERTIFICATION" should be inserted after "RECIPROCITY." In addition, the title to sub. (1) should refer to the registration and reciprocity certification period.

l. In the title to s. NR 149.09 (3), "CERTIFICATION" should be inserted after "RECIPROCITY."

m. In s. NR 149.09 (4), the phrase "the department shall expire the certification . . ." is grammatically incorrect and should be rewritten.

n. With the creation of s. NR 149.11 (1m), should s. NR 149.11 (7) be repealed?

o. Section NR 149.13 (1) (intro.) refers to the information set forth in the paragraphs following that subsection as "criteria." It appears that the items set forth in those paragraphs are actually requirements.

p. In s. NR 149.13 (2) (intro.), the phrase "shall be" should be replaced by the word "are."

q. Section NR 149.13 (4) states that if a certified or registered laboratory does not meet the required acceptance limits, the department "may" require the laboratory to take certain actions. Should "may" be changed to "shall"? If not, the rule should specify the factors the department must consider when deciding whether to require such actions. These comments also apply to the department's decision whether to initiate an assessment of the laboratory's quality control records.

r. Section NR 149.25 (1) (c) refers to the chosen immunoassay technique "as specified by the department." Where in the rule is this technique specified?

s. In the Note following s. NR 149.25, "and" should be changed to "or."

***4. Adequacy of References to Related Statutes, Rules and Forms***

a. In the Note following s. NR 149.02 (1), the phrase "administrative codes" should be changed to "administrative rules." This comment also applies to the Note following s. NR 149.03 (8m).

b. Section NR 149.02 (3) should contain a cross-reference to the administrative rules promulgated by the Department of Agriculture, Trade and Consumer Protection (DATCP) and the Department of Health and Family Services (DHFS) which provide for the certification or approval of laboratories by DATCP and DHFS. Also, a cross-reference should be substituted for the phrase "department rules" in sub. (3) (b).

c. Section NR 149.07 (1) (c), which requires submission of reference sample analysis results, should contain a cross-reference to s. NR 149.13, which sets forth the procedure for analysis of reference samples.

d. Section NR 149.13 (3) (a) should contain a cross-reference to sub. (4) of that section, specifying that sub. (4) sets forth the procedures to be followed if the results of a reference sample analysis do not meet the criteria specified in sub. (2) and the department requires the laboratory to analyze additional reference samples.

e. In s. NR 149.43 (3), the cross-reference to "s. 255.22, Stats.," is incorrect.

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

a. The second sentence in s. NR 149.02 (1) should be rewritten as follows: "No laboratory may submit data to the department for use in a covered program unless the laboratory is registered or certified under this chapter to perform the test from which the data was gathered." The third sentence of that section should be rewritten as follows: "The department may not accept data from a laboratory which is not certified or registered as required under this chapter except as provided in s. NR 149.44."

b. Section NR 149.02 (3) (b) should be rewritten to specify the circumstances under which a laboratory must be certified or approved by the DHFS or the U.S. Environmental Protection Agency (EPA), namely when results of radiological tests are submitted to the department for use in a program which requires radiological tests to be performed by a certified or approved laboratory.

c. Section NR 149.03 (14m) refers to "target analytes." Is "target analyte" different from "analyte," which is a defined term in s. NR 149.03 (4)? If so, the rule should explain the difference. If not, the term "analyte" should be used consistently throughout the rule.

d. The phrase "certification or registration under" should be inserted at the beginning of s. NR 149.04 (1) (g).

e. In s. NR 149.04 (1) (h), it is unclear what is meant by the statement that test category 20 "includes all of the necessary wet chemistry techniques specified in the approved methods."

Does this mean that certification or registration is available for all of those techniques or does it mean that, in order to obtain certification or registration for test category 20, the laboratory must perform all of the "necessary wet chemistry techniques"? This issue should be clarified.

f. The analysis to the rule should explain why reference samples are not required for hexavalent chromium, or gold and platinum, in test categories 8 and 9 in Table 1.

g. Section NR 149.05 (5) provides that, prior to granting certification or registration, the department may adjust the base fee and category fees "on an application" to equal the current fiscal year fees. However, s. NR 149.07 (1) (b) requires the applicant to submit the appropriate fees ***with*** application. Thus, by the time the department has received an application, it has also received the fee payment from the applicant. Should s. NR 149.05 (5) be rewritten to clarify the procedure to be followed when an applicant has submitted the incorrect application fee?

h. Section NR 149.07 (1) (intro.) provides that the department "may" accept certain applications. Why is the department's acceptance of applications discretionary? Under what conditions may the department refuse to accept an application which meets the requirements of the chapter?

i. In s. NR 149.07 (1) (a) 4., it appears that the first occurrence of "test" should be changed to "analyte."

j. In s. NR 149.07 (1) (intro.), the reference to "laboratories that are not currently certified or registered" is confusing because it is not clear to what time period "currently" refers. The rule should instead refer to "laboratories which do not hold a valid certification or registration under this chapter." Likewise, in the second sentence of the introduction, "currently" should be deleted.

k. The second sentence in s. NR 149.07 (1) (a) 4. is confusing. The sentence should be rewritten as follows: "A laboratory shall use only methods which meet the requirements of s. NR 149.11."

l. In s. NR 149.07 (1) (b) (intro.), it would be more precise to substitute "submit" for "pay." This comment applies also to subds. 1., 2. and 3. of par. (b).

m. Section NR 149.07 (1) (c) requires an applicant to submit current "acceptable" reference sample results. At the time that a laboratory is submitting reference sample results, how does a laboratory know whether those results are "acceptable"? The last sentence of the paragraph is unclear and should be rewritten.

n. In the first sentence of s. NR 149.07 (1) (d), it is unclear what is meant by the phrase "other analyte specific information as required by the method." Also, the semicolon in the second sentence should be deleted.

o. In s. NR 149.07 (1) (e) (intro.), the material after the first sentence should be rewritten to read: "Intent may be manifested by any of the following factors:". Also, should sub. (1) (e) 3. require that the potential client be physically located in Wisconsin? If not, how can a letter from a potential client requesting analytical work under a covered program show intent to perform work in Wisconsin?

p. Should the first sentence of s. NR 149.07 (2) be rewritten as follows: "If the laboratory has not submitted all of the necessary materials described in sub. (1) (a) to (h) within one year from the date the application is received by the department, the application shall expire."?

q. Section NR 149.07 (4) (a) provides that laboratories ". . . shall successfully complete an on-site evaluation . . . ." However, the rules actually require that the department or a department representative conduct the on-site evaluation. In addition, in the second sentence of that paragraph, "a later date is" should be inserted after "unless."

r. Section NR 149.07 (5) (c) should be rewritten to recognize that reference sample results are not required for registration or certification for the analysis of every analyte.

s. The use of the phrase "of each year" in s. NR 149.09 (1) is confusing. That sentence should be rewritten to specify that the certification and registration period commences on September 1 and ends on August 31 of the following year.

t. The third sentence in s. NR 149.09 (1) should specify when the department must provide written requests for fee payments and other items necessary for renewal of registration, certification or reciprocity certification. In addition, that sentence requires laboratories to notify the department of any "changes in methods and personnel." Should the rule be rewritten to specify that laboratories must notify the department only of those changes in personnel who conduct analyses for which certification or registration is required? This comment applies to sub. (2) (c) as well. Also, should the rule provide a more precise description of the types of "changes in methods" of which a laboratory must notify the department? For example, should the rule instead refer to "changes in method of analysis for analytes for which registration or certification renewal is requested"?

u. In s. NR 149.09 (2) (b), "for which certification or registration renewal is requested" should be inserted after "categories."

v. In s. NR 149.09 (3) (b), it appears that the intent of the rule would be more clearly communicated if "current" were deleted and "valid for the period for which reciprocity certification renewal is requested" were inserted after "accreditation." Also, the word "of" should be inserted after the word "copy."

w. Section NR 149.09 (3) (d) requires an applicant for reciprocal certification to submit a copy of the most recent report from an on-site evaluation if the host accrediting agency has performed an evaluation in the previous certification period. If an evaluation has not been performed, how is the application affected?

x. "Given in," appearing twice in s. NR 149.09 (4), should be replaced with "Under."

y. In s. NR 149.11 (1) (intro.), the final clause should be rewritten to clarify whether all of the criteria stated in pars. (a) to (d) must be met or whether meeting any one of the criteria is sufficient.

z. Section NR 149.11 (1m) should specify ***which*** department regulations and department guidance laboratories must make available to analysts.

aa. Is it the intent of s. NR 149.11 (6) that laboratories keep the results of validation procedures on file forever? If not, the rule should specify how long these documents must be kept on file.

ab. Section NR 149.13 (3) (c) should be made a separate subsection of s. NR 149.13 if laboratories are exempt from the requirements of the entire section. If laboratories applying for recognition under a reciprocity agreement are only exempt from sub. (3), then the word "section" should be replaced by the word "subsection."

ac. In s. NR 149.13 (4) (a) 2., what does the word "qualify" mean?

ad. It is unclear why s. NR 149.13 (4) (a) 3. states that the department may "initiate enforcement action" if the results of a third reference sample do not meet acceptance criteria while par. (b) states that the department may revoke a laboratory certification if the results of a second sample did not meet the acceptance criteria. In addition, in par. (b), the only action which the department may take upon the failure of the second sample to meet acceptance criteria is to revoke a laboratory certification. What action may the department take if the failure to meet the acceptance criteria occurs when the laboratory is attempting to obtain initial certification? In addition, does par. (b) apply to registered laboratories as well as to certified laboratories?

ae. In s. NR 149.25 (1) (d), it is unclear whether a laboratory must meet all of the requirements set forth in subds. 1., 2. and 3. in order to be exempt from certification or whether compliance with one of these requirements is sufficient. This should be clarified. In addition, subd. 1. states that laboratories are exempt from certification or registration for immunoassay if "test results are not submitted to the department." However, it appears that certification and registration under ch. NR 149 is required only for laboratories which submit data to the department. This point should be clarified. Finally, in sub. (1) (d) 3., the hyphen should be replaced by the word "to."