4740.2085 QUALITY ASSURANCE MANUAL.

A. A laboratory must possess and follow a written manual of quality assurance.

B. The manual may include several separate procedures or incorporate documents by reference.

C. The manual or its separate procedures must contain:

(1) identification on each page to ensure that the page is recognized as part of the manual and clear identification of the end of the manual;

(2) the laboratory's name;

(3) a revision number; and

(4) a date indicating when the revision became effective.

D. The manual must be reviewed periodically and updated when necessary. Documentation of the review process must include the scope of the review, identification of the reviewer, and the date the review was completed.

E. At the time of application, a laboratory must submit a copy of the manual, including documents incorporated by reference if these documents are not generally available to the commissioner. Each subsequent revision of the manual or any of its separate procedures must be submitted to the commissioner in its entirety no later than 30 days after the effective date of the revision.

F. Unless a laboratory justifies why an item is not applicable, the manual must incorporate the quality assurance practices described in parts 4740.2087 and 4740.2089, including but not limited to policies and procedures used to:

(1) determine continual compliance with parts 4740.2010 to 4740.2120;

(2) collect and transport samples, including containers and preservatives according to part 4740.2087, subpart 1;

(3) track samples from the time the laboratory receives them through the time the samples are disposed, including chain-of-custody procedures for samples requested to be processed for possible legal action according to parts 4740.2087, subparts 2 and 3; and 4740.2097;

(4) track the purity and acceptability of laboratory standards and reagents, including the laboratory's source of reagent grade water according to part 4740.2089;

(5) maintain functional equipment, including routine maintenance performed and scheduled according to parts 4740.2091, subpart 2; and 4740.2093, subpart 2;

(6) determine data accuracy and precision for each certified method and analyte within each test category, for example, establishing control limits, preparing control charts, and performing calculations, according to the applicable provisions of parts 4740.2100 to 4740.2120;

(7) validate data conversion, transcription, and reporting according to part 4740.2095;

(8) accept or reject samples according to part 4740.2087, subpart 3;

(9) correct unacceptable proficiency testing results according to part 4740.2070, subparts 9 and 10, or perform quality control checks according to the applicable provisions of parts 4740.2087 to 4740.2120;

(10) record changes in training and education of laboratory personnel, including on-the-job training relevant to analysis and reporting of results according to part 4740.2099;

(11) subcontract testing; and

(12) address client complaints.

G. A laboratory must routinely evaluate and document the effectiveness of its quality system to ensure that requirements for certification in parts 4740.2010 to 4740.2120 are met.

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446*

Published Electronically: *October 9, 2006*