

4740.2075 APPROVAL OF PROVIDERS OF PT SAMPLES.

Subpart 1. **Provider availability.** The commissioner shall make available a list of approved PT providers.

Subp. 2. **Criteria for approval.** The commissioner must approve a PT provider if the PT provider:

A. is compliant with the NELAC standards effective July 1, 2004, to June 30, 2005, or a more current revision, provided the revision is in effect, upon the date it becomes effective;

B. defines the scope of each PT study;

C. evaluates results from all proficiency testing studies using the acceptance criteria described in the NELAC standards or those specified by the commissioner;

D. scores each result as either "acceptable," "not acceptable," "no evaluation," or "not reported";

E. provides to participant laboratories reports that include:

(1) the provider name, in the header;

(2) the laboratory name, laboratory address (physical location), and EPA laboratory ID number, in the header, and the name, title, and telephone number of the laboratory point of contact in the header or cover letter;

(3) the study number and study type in the header;

(4) the shipment date and closing date of the study in the header;

(5) the date of any amended report, if applicable, in the header; and

(6) the following report information:

(a) analyte name for each analyte included in the sample;

(b) method description;

(c) laboratory value as reported;

(d) assigned values and acceptance values reported to three significant figures, with the exception of tests requiring reports of presence or absence of the analyte;

(e) the acceptable/not acceptable status;

(f) a "no evaluation" score for reported values containing alpha characters;

(g) an indication of the amended results, for amended reports, including a brief description of the reason for the amendment; and

(h) an indication of the length of the report presented by either "page X of Y" or the total number of pages with each page numbered consecutively;

F. sends reports of results no later than 21 calendar days after the study closing date. If the report and other proficiency testing sample information are available in electronic format, it must be available only to the participant laboratory and the state agencies selected by the laboratory;

G. maintains the overall effectiveness of the provider's quality system to indicate that samples provided for testing are verifiable, homogeneous, and stable;

H. makes available to the commissioner and any participating laboratory, upon request, a complete report of the provider's analytical data and documentation of the provider's quality system, which relates to the assigned values, homogeneity, and stability of a particular proficiency testing study;

I. makes available to the commissioner, upon request, a report listing the total number of participating laboratories and the number of laboratories scoring "not acceptable" for each analyte;

J. supplies reports to the commissioner in an electronic format acceptable to the commissioner; and

K. supplies the laboratory with a PT sample formulated from a lot that has not been previously sent to the laboratory. If the lot has previously been used in a proficiency testing sample or its assigned values sent to any laboratory, the original PT sample tracking ID must be obliterated and the new sample tracking ID must be unique.

Subp. 3. **Obtaining or maintaining approval status.** In order to obtain and maintain the commissioner's approval to supply PT samples for particular fields of testing, providers must establish and maintain a quality system meeting the requirements of this part.

Subp. 4. **Questionable PT samples.** Upon notice from a laboratory and verification by the approved provider that a PT sample did not meet the requirements in this part, the commissioner may:

A. determine that the affected laboratory must analyze another PT sample for that field of testing; or

B. review quality control data produced by the laboratory to determine compliance with parts 4740.2010 to 4740.2120.

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446*

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