

3745-89-05 Requirements for maintaining laboratory certification.

- (A) The requirements for maintaining laboratory certification include each of the following:
- (1) Documentation that all analysts designated on laboratory certificates of approval have participated proportionally in drinking water analyses for which they are designated;
 - (2) Documentation that only individuals who have interim authorization or have participated acceptably in a recent on-site survey for a laboratory certification and/or are listed on a laboratory certificate of approval have performed drinking water analyses and reported results thereof for the purpose of determining compliance with plant control tests and Chapters 3745-81 and 3745-82 and rule 3745-91-06 of the Administrative Code;
 - (3) Documentation that drinking water analyses required for the purpose of determining compliance with plant control tests and Chapters 3745-81 and 3745-82 and rule 3745-91-06 of the Administrative Code are performed in accordance with the analytical methods which the laboratory has been certified to use;
 - (4) Obtaining written approval from the director prior to making any changes in the analytical methodologies or procedures which the laboratory has been certified to use;
 - (5) Documentation that the laboratory and equipment therein conform to the laboratory plan approved by the director, and that all necessary laboratory equipment is operational;
 - (6) Notification to the director in writing of any change(s) in personnel or equipment which may affect the laboratory's ability to accurately perform drinking water analyses;
 - (7) Submitting revised plans and obtaining approval from the director prior to any proposed laboratory remodeling or relocation. During any remodeling or relocation, the director may refuse to accept drinking water analytical results for the purpose of determining compliance with plant control tests and Chapters 3745-81 and 3745-82 and rule 3745-91-06 of the Administrative Code. Upon completion of said remodeling or relocation the laboratory shall notify the director in writing.
 - (8) Documentation that an acceptable quality assurance plan as described

in rule 3745-89-03 of the Administrative Code is being followed;

- (9) Maintenance of an acceptable quality assurance plan for drinking water analyses and submittal of revisions to the director prior to implementation of any revisions;
 - (10) An acceptable level of performance for the reporting of analytical data as described in rule 3745-89-08 of the Administrative Code, including an absence of any falsification in the reports, as well as reporting analytical results in accordance with the reporting limits established in appendix B of rule 3745-89-03 of the Administrative Code;
 - (11) Obtaining acceptable results within the past twelve months in at least one proficiency test;
 - (12) Satisfactory performance for analyses included in interlaboratory comparison and verification studies if such are required by the director;
 - (13) Allowing on-site surveys of the laboratory by certification personnel, including unannounced on-site surveys;
 - (14) Acceptable performance as described in paragraph (A)(5) of rule 3745-89-03 of the Administrative Code during each on-site survey (including unannounced on-site surveys); and
 - (15) Correction of deviations noted in survey reports, as set forth in paragraph (A)(6) of rule 3745-89-03 of the Administrative Code, within the time specified by the director; the corrections shall be reported to the director in writing, satisfactorily addressing each individual deviation.
- (B) The laboratory may be required to issue notification to its customers, within a specified period of time, explaining deviations noted in the survey. The laboratory may also be required to notify affected customers of unacceptable data, which may include, but not be limited to, a clear, accurate, and easily understood explanation of why the results were unacceptable.
- (C) In addition to paragraph (A) of this rule, laboratories holding a valid and unexpired laboratory certification for gross alpha particle activity, radium-226 and radium-228 radioactivity, gross beta particle activity, strontium-89 and strontium-90 radioactivity, tritium, or radioactivity from photon emitters (excluding iodine-131), shall participate in all quality control samples and proficiency test samples. Satisfactory performance in appropriate analyses as described in rule 3745-89-03 of the Administrative Code shall be obtained in at least one proficiency test study per year.

- (D) Failure to maintain certification in accordance with this rule may result in suspension or revocation of a laboratory's certification in accordance with rule 3745-89-06 of the Administrative Code.

Replaces: Former 3745-89-05

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